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The first experience of robot-assisted vental mesh rectopexy using the Senhance® system in the treatment of patients with obstructive defecation syndrome

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ABSTRACT AIM: to assess primary results of robot-assisted ventral mesh procedure using the new Senhance® robotic system for obstructive defecation syndrome.

> PATIENTS AND METHODS: the prospective cohort study included patients who underwent robot-assisted ventral mesh rectopexy with the Senhance® system for obstructive defecation syndrome caused by rectocele and/or rectal prolapse and/or internal intussusception. The optimal trocar sites, the location of robotic arms, operation time and intraoperative blood loss were evaluated, as well as post-op morbidity rate (Clavien-Dindo scale), pain intensity (VAS scale) and recurrence rate.

> RESULTS: the study included 22 patients. Operation time was 87.1 ± 24.3 minutes. The intraoperative blood loss was 19.8 ± 9.6 ml. No conversion to open or laparoscopic approach occurred, no morbidity occurred. Pain intensity on day 1 was 0.255 mm according to VAS. No anatomical recurrence was revealed. The median follow-up period was 20.4 months (7-22 months).

> CONCLUSIONS: robotic-assisted ventral rectopexy using the Senhance® system is effective and safe. The results are similar to laparoscopic ones. However, the use of the Senhance® system is cost effective compared to other robotic

KEYWORDS: obstructive defecation, rectocele, rectal prolapse, robotic surgery, Senhance robot, rectopexy

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INTRODUCTION

Laparoscopic ventral rectopexy with a mesh implant (LVR) was first described by D'Hoore and Penninckx [1], and since its implementation into routine clinical practice has become widespread as a method of choice for obstructive defecation, prolapse and internal intussusceptions of the rectum, rectocele, enterocele [2-5]. With the advent of robotic surgery, a new approach to rectopexy was gradually became popular, and by 2015,

robotic procedures in the United States were 27% [6]. According to a significant number of studies, robot-assisted ventral mesh rectopexy (RVR) is a safe and effective alternative to the traditional laparoscopic technique and demonstrates similar anatomical and functional results [7–10]. For most of the parameters studied, there were no statistically significant differences between robotic and laparoscopic approaches [11], but several articles reported better clinical outcomes after robotic surgery in terms of obstructive ОРИГИНАЛЬНЫЕ CTATЬИ
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defecation, fecal incontinence and sexual function [12–14].

It should be noted that robotic technologies have brought a number of technical advantages to prolapse surgery, such as three-dimensional image of the surgical field, multiple magnification, higher precision of manipulation due to instruments with several degrees of freedom, reduced hand tremors and improved ergonomics for the operator [10,15-17]. These possibilities turned out to be most significant when performing dissection of the rectovaginal septum to the level of the pelvis diaphragm in a limited space of the small pelvis, when isolating and preserving vessels and autonomic nerves, as well as the deepest possible fixation of the distal end of the mesh [9,17,18]. Due to these advantages, a number of studies have noted a trend to reduce intraoperative blood loss and the morbidity and conversion rates due to robotic approach [8,19-21]. However, the higher cost and longer operative time compared to the laparoscopic approach have markedly dampened the initial enthusiasm and slowed the spread of RVR worldwide [8,21-24].

For a long time, robotic surgery was associated with the use of the only available system — DaVinci® (Intuitive Surgical, Sunnyvale, California, USA). As one of the alternative technical solutions, the robotic surgical system The Senhance® Surgical System ® Asensus Surgical US, Inc (Durham, North Carolina, USA) appeared in 2016. Its main differences can be considered improved ergonomics for the operator, the presence of technology for intelligent camera guidance "Eye-Sensing Control" and tactile feedback, reusable instruments that significantly reduce the cost of surgical treatment, developed artificial intelligence that allows for realtime tissue recognition and marking on monitor. In addition, the system allows the use of a wide range of video systems from various manufacturers and the same access and tools as for manual laparoscopy. It also allows the use of laparoscopic instruments and trocars with a diameter of 3 mm and 5 mm, which reduces the invasiveness of the operation. All these aspects make it possible to

quickly integrate the system into the daily work of the operating room.

At the time of publication of this article, the available scientific literature when searching the databases PubMed, MEDLINE, EMBASE, Scopus, Cochrane library, CENTRAL, ISI Web of Science and eLibrary in the period until August 2023 did not provide experience in performing ventral rectopexy with a mesh implant using The Senhance® Surgical System ® Asensus Surgical US, Inc.

AIM

The purpose of this study was to assess initial results of robot-assisted ventral mesh rectopexy using the new Senhance system for obstructive defecation syndrome due to the presence of rectocele, internal intussusception or rectal prolapse.

PATIENTS AND METHODS

The prospective cohort study included 22 patients undergoing surgery for obstructive defecation syndrome due to rectocele and/or rectal prolapse and/or internal intussusception using robot-assisted ventral rectopexy with a mesh implant using the Senhance surgical-based digital laparoscopy system January 2022 to June 2023. In total. The mean follow-up was 20.4 months (7–22 months).

While working with Senhance Surgical System®, we noted its key features:

- The system is based on laparoscopic surgery. Standard laparoscopic instruments are used, which allows the assistant to use additional trocars and instruments, as well as make a quick transition to manual laparoscopy and return to robotic surgery if necessary (Fig. 1).
- Cost and expenses. The Senhance system can be integrated into an existing hospital operating room, with its endoscopic video system and power equipment, without the need to renovate or create a new operating room. What sets it apart from other robotic devices is the system's compatibility with conventional 3 mm, 5 mm and

10 mm laparoscopic instruments. All parts of the Senhance robot can be sterilized and are designed for repeated use. These factors together significantly reduce the cost of implementation and use of the system, in comparison with other available robotic installations.

- Visualization and camera operation. Many HD, UHD or 3D video systems can be used, including NBI and ICG, and standard laparoscopes. Thanks to the Eye-Sensing Control feature, the camera can be maneuvered parallel to the surgeon's eye movement after initial calibration (Fig. 2).
- Haptic feedback. The system has special sensors that transmit to the surgeon the force of pressure on the tissue or the tension of the suture, thereby increasing the accuracy of the operation.
- Direct visual contact with the team and observation of the operating table. The operator, the console operator, the assistant and the operating room nurse can easily communicate with each other and are within sight. The surgeon's face is not hidden by the eyepiece.
- Comfortable conditions for the operator. Working in the console does not cause inconvenience, allowing the operator to sit in an ergonomic chair with neck and back support.
- Manipulation functionality. For each robotic arm, the system calculates the optimal lever point for the trocar fulcrum point thanks to which unwanted movements and damage to soft tissues can be avoided, and changing instruments takes less than a minute (Fig. 3).

Our experience in clinical use has confirmed the stated advantages of the Senhance Surgical System® robotic system, in particular, the convenience and ergonomics of use, realized through the guidance of the surgeon's field of view and the presence of tactile feedback, as well as the possibility of laparoscopically-assisted use of the system.

Robot-assisted ventral rectopexy was performed in patients with obstructive defecation syndrome, which was expressed in the need for manual assistance during defecation, which was caused by the presence of rectocele stage 3 according to the Russian classification [25] and stages 3–4 according to POP-Q [26] and/or external prolapse rectum and/or internal invagination of the rectum according to defecography, aged from 18 to 80 years without decompensated comorbidities, as well as oncological, hematological diseases, inflammatory diseases of the colon and pelvic organs. All interventions were performed by two surgeons who were trained and proficient in using this robotic



Figure 1. Image of the main elements of the Senhance surgical system



Figure 2. Cockpit with the technology of intelligent guidance of the video camera «Eye-Sensing Control» and tactile feedback



Figure 3. Compatibility with standard laparoscopic instruments, speed and convenience of switching

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system and had significant experience in performing colorectal surgeries.

Preoperative checkup included a standard clinical examination, examination in a gynecological chair, as well as functional Valsalva tests, cough, examination in the squatting position, staging of pelvic prolapse using the POP-Q system, colonoscopy, barium enema with defecography, as well as transperineal, transvaginal and transrectal ultrasound to check defects in the pelvic floor muscles and anal sphincter. The severity of clinical symptoms was assessed using questionnaires for assessing constipation (Clevel and Clinic Constipation Scoring System) and Wexner anal incontinence scale [27].

We collected data on the operation time, docking time, the placement of trocars and robotic manipulators and the need to move them during the intervention, the incidence of intraoperative complications and the need for conversion, as well as the volume of intraoperative blood loss and early postoperative complications, the severity of pain on the 1st day after surgery according to VAS. To record data, we used the TRUST Registry protocol (ClinicalTrials.gov Identifier: NCT03385109). All data were summarized and structured into one database using MS Excel 12 (MicroSoft, USA). The conduct of this study was approved by the local ethics committee. All patients provided written voluntary informed consent to participate in the study.

Statistical data analysis

Descriptive statistical analysis was carried out using SPSSStatistic 26.0 (IBM, USA) and Statistica 10.0 (StatSoft, USA) programs. At the first stage, all quantitative data were checked for compliance with the normal distribution law (NDL) using the Shapiro-Wilk test, since the sample size was less than 50. In cases where the sample was subject to the NLD law, the description was planned to be carried out in the form of the mean and standard deviation (M \pm SD). In cases where the sample did not comply with the NZR (significance level p < 0.05), then the description was planned to be carried out in the form of the median, 25% and

75% quartiles (Me [Q1;Q2]). Absolute (quantity) and relative (percentage) data were used to describe categorical (nominal) data.

The average age of the patients was 58 years (32–77 years, [50;63]), the average number of births was 3 (0–4 births, [2;4]), the average BMI was 30.2 kg/m² (18.1–36 kg/m², [25.1;32.2]). Among previously performed operations on the pelvic organs, patients indicated 2 hysterectomy with appendages, 1 supravaginal amputation of the uterus, and 4 patients had previously undergone a cesarean section. The average duration of existing symptoms of pelvic prolapse was 8.16 ± 4 years (2–20 years, 8 [5;10]). The average score on the Clevel and Clinic Constipation scale among patients was 13.8 ± 5.7 (6–28, 12 [10;19]), stress urinary incontinence was observed in a third of patients (36.4%).

Surgical details

All operations were performed under general anesthesia in the Trendelenburg position with an inclination of 35° and the table turned to the left side by about 15 degrees. The height of the operating table before docking was 115 ± 7 cm, and varied depending on the anatomical features of the patient and the thickness of the anterior abdominal wall. The working angle of the tool was also further optimized by its length: standard (30 cm) and extended tools (45 cm) are available for the system.

In the technique of performing ventral rectopexy with a mesh implant, the following stages can be roughly distinguished:

1. Insertion of ports and tools

As a standard, 5 ports were used: 1×12 mm, 1×10 mm and 3×5 mm, and were positioned as shown in Figure 4.

A 10 mm optical trocar was placed at the paraumbilical point, a 12 mm robotic trocar for the working instrument — in the right lateral area, and a 5 mm robotic trocar controlled by the operator's left hand — in the left lateral area. Two 5 mm trocars were additionally inserted in the left lateral and left iliac region for the assistant's auxiliary instruments.

The following tools were used:

- 3D camera with an angle of 30° Olympus VISERAELITEII (Olympus Corporation, Japan);
- Robotic atraumatic grabber, needle holder, scissors, monopolar hook, bipolar dissector;
- Laparoscopic atraumatic Babcock clamp, herniostapler, bipolar dissector, grabber, monopolar hook.

2. Rectal mobilization

Using an atraumatic Babcock clamp through the left lateral port of 5 mm, the assistant retracted the sigmoid colon to the left and, using monopolar coagulation, the operator dissected the peritoneum from the area of the sacral promontory to the deepest point of the Douglaspouch, isolating and preserving the hypogastric nerve. Dissection was performed along the anterior surface of the rectum in the plane between the rectovaginal fascia and Denonvilliers' fascia to the level of the pelvic floor with visualization of the levator ani muscles on both sides (Fig. 5).

3. Mesh fixation

A trapezoidal prolene mesh 20 cm long, 5 cm wide along the distal edge, and 2.5 cm along the proximal edge was inserted into the abdominal cavity. The mesh implant was fixed from the deepest point of dissection to the levator ani muscles on both sides with separate interrupted sutures and along the anterior the surface of the rectum to the mesorectal fascia with a PDS 2.0 (Fig. 6). The proximal end of the implant was fixed to the presacral fascia with 1–2 interrupted sutures using Ethibond 2/0 thread (Fig. 7).

4. Closure

After hemostasis control and making sure that the mesh position was adequate, the peritoneum was sutured with a continuous suture and the instruments were removed. Pelvic drainage was not used as standard.

The robotic arms were placed at the operating table, as shown in Figure 8, after which they were not required to move during surgery. According to our own previous experience of working with the new robotic system Senhance, as well as literature data, the system allows you to ergonomically

perform certain stages of surgery with robotic assistance, and others — laparoscopically, depending on the convenience and preferences of the surgeon. Thus, during the surgical intervention, a planned transition to laparoscopic access was carried out to perform individual stages, and vice versa, without wasting time and the need to change instruments.

The switching of robotic tools on the robot's "arms" is carried out by an assistant if necessary, and the switching process takes no more than a minute. The surgical control unit of the robotic system is located within the operating room, which allows the surgeon, by controlling the manipulators and camera, to direct the actions of the team at the table under direct visual control.

It seems to us that the special advantages of robotic support are most important when performing dissection in narrow anatomical spaces of the small pelvis, applying manual intracorporeal suture, as well as working within one anatomical region. Data on the method of using the Senhance

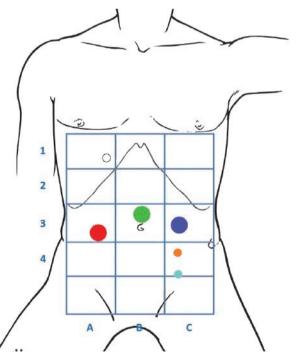


Figure 4. Green — the first arm of the robot, 10 mm, camera port; Red — the second arm of the robot, 12 mm port; Blue — the third arm of the robot, 5 mm; Orange, blue — 5 mm ports for auxiliary laparoscopic instruments for the assistant at the table

Table 1. Robot-assisted and laparoscopic stages of performing ventral rectopexy with a mesh implant

Procedure	Robot-assisted stages	laparoscopic stages п
Ventral mesh rectopexy	 3 — dissection on anterior rectal surface in recto vaginal space with preservation of vascular nervous structures; 6 — hand-sewn endocorporeal suturing for mesh fixation to mesorectum on anretior side and to longitudinal ligament at sacrum; 7 — peritonization. 	 1 — trocars insertion; 2 — dissection of adhesions; 4 — mesh insertion and positioning; 5 — insertion of sutures to peritoneal cavity.

system when performing robot-assisted stages of surgical intervention are presented in Table 1.

RESULTS

The operation time was 87.1 ± 24.3 minutes. We separately recorded the time required for docking and other stages of robot-assisted operations. Time of each stage of work are presented in Table 2

The intraoperative blood loss was 19.8 ± 9.6 ml. There were no complications requiring re-operation, or anatomical relapses during the follow-up. The median follow-up period was 20.4 months (7-22 months).

The immediate results of surgery are summarized in Table 3.

In the early postoperative period, patients were kept in the ICU until their vital functions were completely stabilized for 2 hours, after which they were transferred to the ward of the specialized department. Oral fluid intake began on the first day, food intake on the second day. On the first day after surgery, the severity of pain was assessed using a visual analogue scale: 22.5 (8–31) mm. The hospital stay after robot-assisted ventral rectopexy with a mesh implant was 3.7 (2–5) days. During the work with the system, there were no unexpected conversions from robot-assisted to manual laparoscopic surgery or transition to open access.

DISCUSSION

The Senhance digital laparoscopy robotic system has a number of technical advantages, such as haptic feedback, camera guidance system with the operator's gaze, ergonomic manipulations for the surgeon, and reusable instruments compatible with conventional laparoscopic instruments, which significantly reduces the cost of treatment



Figure 5. Performing a monopolar dissection in the rectovaginal fascia: the rectum is withdrawn by an atraumatic clamp caudally



Figure 6. Insertion of a mesh implant into the abdominal cavity and fixation of its distal end with separate nodular sutures



Figure 7. Fixation of the proximal end of the mesh implant to the anterior longitudinal ligament of the spine in the area of the sacrum

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Table 2. Duration of robot-assisted ventral rectopexy with a mesh implant using the Senhance system

Total operation time, min (min-max)	87,1 (65–100)
Docking time, min.(min-max)	9 (8–10)
Console time, min.(min-max)	56,5 (51–68)
Closure step, min (min-max)	11,4 (10–16)

Table 3. Generalized results of robot-assisted ventral rectopexy with a mesh implant using the Senhance system

Intraoperative bloodloss, ml	19,8 ± 9,6
Intraoperative complications	0
Unexpected conversion,%	0
ICU time, hours	2
Post-op complications (Clavien-Dindo)	0
Post-op mortality,%	0
Post-op pain (VAS), mm	22,5 (8-31)
Recurrence,%	0

and simplifies the process of integrating the system into work. operating unit, the ability to use trocars with a diameter of 3 mm and 5 mm, which reduces the invasiveness of the intervention, and the time for changing instruments or converting to laparoscopic access is less than a minute.

At the time of publication of this article, the available literature when searching the PubMed, MEDLINE, EMBASE, Scopus, Cochrane library, CENTRAL, ISI Web of Science and eLibrary databases for the period up to August 2023 did not

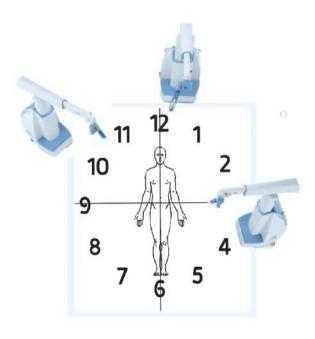


Figure 8. Location of robotic arm manipulators: Arm 1 (optical system) for 12h; Arm 2 (operator's right hand) 10 h; Hand 3 (operator's left hand) 4 h

provide experience with anterior rectopexy with a mesh implant using Senhance systems. A number of researchers report the use of this robotic system in colorectal surgery, mainly for colorectal cancer. Thus, Spinelli et al. first reported successful single-center experience with the Senhance system, safety and effectiveness of various types of operations, including colorectal [28]. Samalavicius et al. reported on 13 cases of colon cancer surgery using the new robot-assisted laparoscopy, and concluded that the system was convenient and comparable in results to traditional laparoscopy [29]. We published our first own experience of using the system, including in colorectal surgery [30]. Sasaki et al. in 2022 published the results of surgical treatment of 55 cases of colorectal cancer and noted excellent results from the use of the system [31]. A group of scientists from Belarus led by Slobodin Yu.V. report that working with the Senhance, Trans Enterix robotic system when performing colorectal surgery is convenient, safe and effective [32]. Linet al. shared successful treatment results in 46 patients [33], and Darwich et al. published a detailed technique for the surgical treatment of diverticular disease of the colon in 12 patients [34].

In this study, our own experience shows the practical possibility of performing ventral rectopexy with a mesh implant using the Senhance robotic system, as well as applying an intracorporeal suture and precision dissection in narrow spaces of the small pelvis.

The study has a number of limitations, in particular the small number of cases, as well as the lack of first-hand experience with other robotic systems to make a direct comparison between them and comparison with traditional laparoscopy. However, the use of reusable instruments and the possibility of integration into an existing operating room reduce the economic costs of performing RVR using the Senhance system, which makes this access feasible.

CONCLUSIONS

Robot-assisted ventral rectopexy with 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 economically feasible for performing ventral rectopexy with a mesh implant in terms of cost reduction compared to other robotic systems.

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Concept and design of the study: Alexander G. Khitaryan, Anastasiya A. Golovina Collection and processing of material: Anastasiya A. Golovina, Kamil S. Veliev, Arut V. Mezhunts, Albert Ζ. Alibekov, Alexev Α. Orekhov. Vera Khitaryan, Kseniya S. Oplimah

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