



Early experience with the Senhance®-laparoscopic/robotic platform in the US

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Abstract

The introduction of new robotic platforms will grow considerably in the near future as several manufacturers are in the developing stages of different innovative systems. One of the newest systems, the Senhance® platform (TransEnterix Surgical Inc., Morrisville, NC, USA) has been utilized in a variety of cases in Europe but only recently approved for limited clinical use in the United States. Here, we present our initial experience with this state-of-the-art system in patients requiring a variety of procedures.

Keywords Laparoscopy · Robotic · Senhance · Mini-laparoscopy · Minimally invasive · TransEnterix

Brief communication

The field of robotic surgery continues to expand as several companies are in the developing stages of manufacturing different platforms. An area that has been dominated over the last two decades by a single corporation will soon see a flood of robotic platforms that will provide distinct features with benefits to both patients and surgeons [1, 2]. Although reliable rates on the usage of robotic surgery worldwide are unavailable, some procedures have experienced dramatic increases in robotic approaches in recent years despite the lack of available data proving significant clinical advantage over other minimally invasive techniques [3].

One of the newest systems is the Senhance® laparoscopic/robotic platform (TransEnterix Surgical Inc., Morrisville, NC, USA) recently introduced in the United States. The Senhance® robot (previously known as ALF-X) was originally commercialized in the European marketplace after receiving CE mark approval by European regulators in 2014. The system was first designed by the Italian company SOFAR S.P.A. and originally advertised as a platform for laparoscopic abdominal and pelvic surgery, as well as

limited thoracic procedures excluding cardiac surgery. After the first clinical cases were completed successfully in 2015 in Europe [4, 5], the robotic division of SOFAR S.P.A was acquired by TransEnterix Surgical Inc. based in Morrisville, North Carolina, USA. This was followed by clearance by the Food and Drug Administration (FDA) in October 2017 through the 510(k) pathway after the company provided data demonstrating substantial equivalence of the Senhance® system to the daVinci Si IS3000 device on 150 patients that had undergone various gynecological operations and 45 patients that had colorectal procedures in Europe (<https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm580452.htm>). Further expansion of FDA approved procedures in May 2018 included cholecystectomies and inguinal hernia repairs.

The Senhance® system consists of a console that contains a screen, a keyboard, and two laparoscopic-type handles from which the surgeon controls the two working arms. The surgeon sits comfortably in an upright position as opposed to leaning on the console as with other platforms. The console also has an eye-tracking feature that provides the possibility of maneuvering the laparoscope with the movement of the surgeon's eyes. Visualization of the surgical field can be delivered in 2D or 3D modes depending on the surgeon's preference. The working instruments are introduced into the abdominal cavity using commercially available laparoscopic trocars, and instruments can be re-sterilized for reuse.

A unique feature of the device is the capability of having haptic feedback that allows the operator to perceive a sense

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of force when the tip of the instrument comes in contact with tissues. Currently, the instrumental armamentarium available includes graspers, scissors, and a hook electrocautery. Bipolar energy can be utilized by incorporating energy to any of these instruments. Three individual arm booms are used to operate the working instruments allowing quick access to the patient bedside should the need for conversion to a pure laparoscopic or open approach arises.

The Senhance® platform has been used widely in Europe where the availability of other robotic systems is somewhat limited compared to the US. Following testing using dry lab trainers and animal models [6–8], the first clinical cases centered around the usage in gynecologic surgery [5, 9, 10]. More recently, Stefan et al. published the largest series of patients undergoing general surgery procedures including unilateral and bilateral herniorrhaphies, ventral hernia repairs, anti-reflux procedures, cholecystectomies and colonic resections [11]. In their experience, considerable proficiency is obtained after 30 cases and the learning curve is reduced in surgeons with prior laparoscopic experience.

Our experience

The first Senhance® surgeries performed in the United States were done at Florida Hospital (Advent Health) in Orlando, Florida in April and June 2018. These included a variety of FDA-approved colorectal and general surgery cases synthesized in Table 1. Prior to using the platform

on our patients, our institution established a credentialing process that included a combination of live animal laboratories, and proctoring by European surgeons brought to our institution to assist during these first cases. All three authors were required to complete at least three animal studies that included cholecystectomies, enteric anastomoses and nephrectomies. Although these procedures were not meant to be replicated in humans, they allowed us to become familiar with the instrumentation and the technology. Following the animal studies, the surgeons were proctored and evaluated by experienced European surgeons that submitted competency forms to our medical staff committee for credentialing approval. All three surgeons have years of experience in all aspects of surgery, including laparoscopy, robotic and open procedures. Except for patients that underwent herniorrhaphy, all others required placement of accessory ports for laparoscopic assistance. Currently, the platform is only approved to use three working arms. All cases were completed with the platform as planned.

As with any other innovative technology, there is a learning process associated with the use of this device. The eye-tracking feature requires preoperative calibration adapted to the surgeon's eyes. In our experience, becoming familiar with this feature entails approximately 45–60 min of preoperative training to become sufficiently proficient but ultimately facilitates the flow of the procedure by giving back control of the surgical field to the operating surgeon. The presence of the haptic feedback feature is beneficial for the gentle handling of tissues but comparable to that of

Table 1 Patient characteristics and procedures performed using Senhance

	Patient characteristics	Indication for surgery	Procedure	# of trocars	Length of stay
Case #1	71-Year-old female BMI 30.3 kg/m ²	Recurrent cecal adenoma	Right hemicolectomy	12-mm trocar (C) 5-mm trocars × 2 (R) 5-mm trocars × 2 (A)	2 days
Case #2	74-Year-old male BMI 28.6 kg/m ²	Bleeding cecal ulcers	Ileocectomy	12-mm trocar (C) 5-mm trocars × 2 (R) 5-mm trocars × 1 (A) 8-mm trocar x1 (A)	2 days
Case #3	54-Year-old male BMI 32.1 kg/m ²	Bilateral symptomatic inguinal hernias	Bilateral inguinal hernia repair with mesh	12-mm trocar (C) 5-mm trocars × 2 (R)	Ambulatory
Case #5	54-Year-old male BMI 28.2 kg/m ²	Incarcerated right inguinal hernia	Right inguinal hernia repair with mesh	12-mm trocar (C) 5-mm trocars × 2 (R)	Ambulatory
Case #6	61-Year-old male BMI 22.1 kg/m ²	Gallstone pancreatitis	Cholecystectomy	12-mm trocar (C) 5-mm trocars × 2 (R) 5-mm trocar (A)	Ambulatory
Case #7	67-Year-old female BMI 34.7 kg/m ²	Cholelithiasis, chronic cholecystitis	Cholecystectomy	12-mm trocar (C) 5-mm trocars × 2 (R) 5-mm trocar (A)	Ambulatory
Case #8	32-Year-old female BMI 37.8 kg/m ²	Cholelithiasis, cholecystitis	Cholecystectomy	12-mm trocar (C) 5-mm trocars × 2 (R) 5-mm trocar (A)	Ambulatory

Procedures performed using Senhance System

BMI Body Mass Index, C camera trocar, R robotic trocar, A assistant trocar

laparoscopic surgery. The revised ergonomic posture of the surgeon during the procedure is enhanced by sitting comfortably in an upright chair at approximately 50–60 cm from the monitor. Additionally, the cost reduction associated with the use of reusable instrumentation is certainly an appealing advantage compared to other robotic systems.

Some of the disadvantages of the current version of the Senhance® platform include the lack of articulating robotic instrumentation, a relatively restricted variety of instruments that does not include advanced energy and stapling devices, and large arm booms connected to a separate console that consume considerable real estate both in the operating room and for storage. In addition, eye-tracking calibration must be repeated prior to initiating each session. Restriction from the haptic feedback was also encountered when attempting to retract heavy mesentery during the colorectal procedures. These limitations will likely improve with future versions of the system.

Conclusion

To conclude, with more robotic systems becoming available, competition will undoubtedly have favorable effects on reducing costs, and surgeons will likely be more inclined to perform robotic surgery as hospitals facilitate access to new technology. The steep learning curve associated with the use of these newest robotic platforms can be alleviated with prior laparoscopic experience and dedicated proctoring as shown by others. Although the introduction of new robotic platforms will have a significant impact in the way we practice surgery and train the next generation of surgeons, it is of paramount importance that rigorous unbiased research is done before exposing patients to novel machineries.

Compliance with ethical standards

Conflict of interest Teresa Debeche-Adams has received consultation honoraria from TransEnterix. Steve Eubanks has received consulta-

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