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First Experiences with the New Senhance® Telerobotic System in Visceral Surgery

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Minimally invasive surgery · Robotic surgery · Senhance® robotic system

Summary
Until recently, robotic-assisted surgery has exclusively been connected to the name DaVinci®. In 2016, a second robotic system, the Senhance®, became available. To introduce the new robotic system into clinical routine, detailed team training and an integration program were useful. Within the first 6 months, 116 cases were performed with this system. 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. Initial experience with the Senhance system as the first installation in Germany shows that it is suitable for surgery in general and for visceral surgery in particular. 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. After the establishment of this second robotic system, future studies will have to specifically look at differences in surgical results and basic conditions of different robotic-assisted systems. This paper documents the decision-making process of a hospital towards the integration of a robotic system and the selection criteria used while also demonstrating the planning and execution process during the introduction of the system into clinical routine.

Introduction

Since the 1980s, minimally invasive techniques have been used in visceral surgery in order to reduce the procedural trauma to a minimum. The first laparoscopic appendectomy was performed in 1983 by Kurt Semm, a gynecologist from Kiel, Germany. In 1987, the French surgeon Philippe Mouret performed the first cholecystectomy [1]. Since then, a huge number of indications and very different techniques have been added to the portfolio of minimally invasive surgery. Today, about 6 million laparoscopic procedures are performed per year. By now, the procedural experience in the area of laparoscopy is vast.

Robotic-assisted surgery is among the innovations in minimally invasive surgery that have emerged in the last 2 decades. In 1997, a cholecystectomy was the first robotic-assisted surgery performed in Belgium. Robotic-assisted surgery was shaped by the then only system available – the DaVinci® surgical system (Intuitive Surgical, Sunnyvale, CA, USA) [2]. Because of the high and unreimbursed costs and the comparably long process times, robotic-assisted operations have only become established in urological surgery. In general and visceral surgery, robotic-assisted surgery has so far only been used in selected complex cases. Regardless, the worldwide number of robotic-assisted surgeries is growing, and in the recent past, growing interest in robotic surgery has been recorded. The introduction of another robotic system and the anticipation of a further system have created new excitement in the field of 'robotic surgery'. Since laparoscopic surgery has been fully established in all areas of general and visceral surgery, it appears that now, with the second available system and in anticipation of the market maturity of other systems, the next step towards a wider spread of robotic surgery has been made.

So far, patient benefits of robotic-assisted (DaVinci) surgery have been shown in urology, especially for prostatectomy [3]. Benefits for surgeons in the area of ergonomic operations have recently been more and more the focus of interest. In traditional laparoscopy, the operating surgeon is dependent on the experience of the assistant and his/her camera steering. Non-physiological movements of the arms while maneuvering the instruments through the angle of the trocars with arms wide spread will tire out the operator. In this con-

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Fig. 1. Position of the robotic arms and distance to the console.

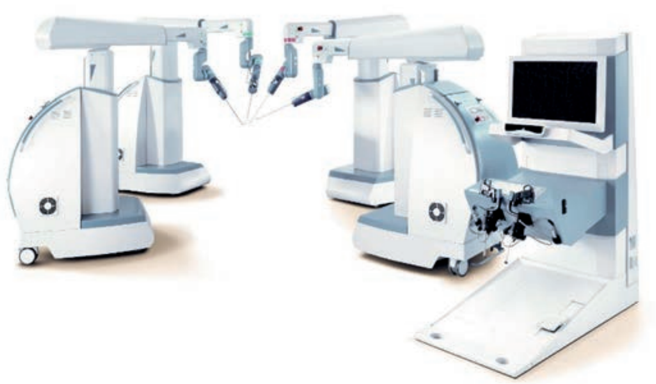

Fig. 2. Senhance® system with 4 robotic arms and console (© TransEnterix Inc.).

text, a special advantage of robotic-assisted surgery may be comfortable ergonomics including a comfortable and relaxed seating position, a 3-dimensional (3D) view of the operating field, up to 16-fold magnification, and stable camera positioning which automatically compensates for unwanted camera movements. In addition, a laparoscopy-based system like the new robotic system could be more quickly and successfully integrated into visceral surgery and gain more acceptance as a system which in its application is more related to open surgery. The benefits of laparoscopy could thus be linked to the benefits of precision, vision, and ergonomics for the surgeon.

Specifications of the System – Why Did We Decide for the SENHANCE®?

The Department of Minimally Invasive and Robotic Surgery is integrated in the Clinic for General, Visceral, and Vascular Surgery.

Annually, more than 1,200 minimally invasive operations are performed, including about 500 inguinal hernia repairs (transabdominal preperitoneal (TAPP)/intraperitoneal onlay mesh (IPOM)), 350 cholecystectomies, 100 procedures in the upper gastrointestinal (GI) area (fundoplication, anti-reflux surgery, bariatric surgery), and more than 100 colorectal procedures. Additionally, there are a high number of appendectomies, adhesiolysis procedures, splenectomies, and adrenalectomies.

For several years, we have researched the area of robotics with specific focus on systems with close orientation towards the techniques of laparoscopic surgery. We were looking for a system that could be used specifically in general and visceral surgery as well as in gynecology at reasonable cost.

Seamless integration of such a system into our operating room (OR) routine, foreseeable costs per case, and a rather short learning curve for our experienced laparoscopic surgeons were important cornerstones of our decision-making process.

In November 2016, we identified the Senhance system (TransEnterix, Inc., Morrisville, NC, USA) which fulfills our main requirements:

(1) Patient safety: At any given time, a fast changeover to traditional laparoscopic surgery can be performed since the system uses standard trocars and the robotic arms can be removed from the operating bed within seconds.

(2) Follow-on cost: Compared to the already existing robotic system, per-case follow-on costs are reduced. Especially with a high case load, this reduction is significant. Hence, especially during the learning curve, it was feasible to perform smaller routine interventions.

(3) Laparoscopic surgery as a base: The system is based on laparoscopic surgery. Standard trocars are used, so at any given time the surgical assistant at the table can intervene laparoscopically or can use additional laparoscopic instruments through additional trocars.

(4) Vision and camera work: An integrated 3D camera with 16-fold magnification offers a very high-quality visible field and precise assessment of thinnest tissue structures. With 'Eye-Sensing Control', the camera can be maneuvered precisely by the eye movements of the surgeon after the initial calibration ('third hand').

(5) Haptic feedback: Pressure on or pull from tissue or, for example, the pull of a suture are fed back to the surgeon through built-in sensors. Hence, one does not have to rely on visual control of the operating field alone.

(6) Direct visual contact: The operator, sitting during the procedure at an open console, has direct visual contact with the assistant and the instrumentation nurse at the operating table. There is no limitation to communication (fig. 1).

(7) Comfort for the operator: From the console, the operation can be performed in a comfortable seating position without neck strain.

(8) Functionality: The optimal turning point of the trocar in the abdominal wall is calculated by each robotic arm. This avoids manipulation or bruising of the tissue.

The first preclinical and clinical studies with the new mechatronic support were performed in Rome, Italy in gynecology and in Milano with colorectal cases [4–8]. When working with the new robotic system, 3 or 4 (colorectal surgery) independently usable robotic arms are used (fig. 2). These are individually linked to a switchboard ('Node'). Within this Node, all information regarding positioning of the arms, freedom of movement, instruments connected, and mode of operation are gathered in a computer and transmitted to the console. Additionally, a monitor is integrated in this Node allowing the team at the patient side to share a view of the operating field. The console is located about 2 m away from the patient; from here, the

Fig. 3. Haptic handpiece at the console of the Senhance® system (© TransEnterix Inc.).

Fig. 4. Instruments with adapter for connection to the robotic arm.

surgeon operates 2 haptic handlebars and the eye-sensing camera (fig. 3). Through eye motion control, the instruments used can be assigned to the robotic arm desired or to the left or right steering handle. Communication with the team at the patient side is easy and unproblematic at all times.

Pushing down of a foot switch activates the handle bar functions, thereby enabling the arms of the robotic system. Releasing the foot switch immediately freezes all instrument and optics positions in the abdominal cavity. This allows the operator to regain a comfortable seating position at any time without risking losing the positioning of the instruments in the situs.

Currently, 22 different instruments, 5 or 10 mm in diameter, are available; individual procedure trays can be assembled from that choice. All instruments are resterilizable. Both a 0-degree and a 30-degree optical system are available. Both instruments and optics are connected to re-sterilizable adapters which connect to the robotic arms through magnets (fig. 4). Fast interchange of the instruments performed by the assistant is possible without having to change the trocars.

Integration Program

After concluding our research into robotic surgery, in November 2016, we participated in an internship program involving a gynecologic procedure at the Gemelli University Hospital in Rome followed by a colorectal procedure at the Humanitas Hospital in Milan.

The hospital chief executive officer and the executive board of our institution took the decision to purchase the new robotic system in January 2017. Right afterwards, a team consisting of 3 surgeons and 2 OR nurses was put together. This team underwent a 4-day intensive training program at the European training center of TransEnterix Inc. in Milan. The main focus of this training was the initiation and handling of the system with theoretical and practical courses. All participants were able to use the robot in a dummy setup over several hours. The training was concluded with procedural performances in an animal model, a test, and a certificate being awarded.

Since then, other surgeons as well as gynecologists and additional OR staff from our center have completed the training in Milan. In the middle of March 2017, the system was installed in our institution. This represented the first installation of such a robotic system in Germany.

Prior to the installation, a detailed plan of the integration of robotic-assisted surgery in the clinical routine was established. The cornerstones of this integration process have been:

(1) Start ideally with high-frequency procedures immediately after the team training.
(2) All procedures should be performed by a predefined team (surgeon, assistant, nurse). Start with the establishment of robotic surgery in only 1 OR entity. Inguinal hernia repair using the TAPP technique is selected first as a simple and highly standardized procedure.
(3) Step-by-step widening of the indications spectrum.

It has been a huge advantage to use the new mechatronic system immediately after the installation so that the team could immediately use the knowledge gained during the training in Milan. As part of our integration program, we had scheduled a total of 12 patients to undergo a robotic-assisted inguinal hernia repair using the TAPP technique for the week after the installation. During the first cases, in the first week, 1 clinical specialist and 1 technical specialist from TransEnterix were present and supported the team. After the first week, the clinical specialist gave support over a further 4 weeks. Thereafter, the clinical specialist was present whenever a new procedure was established. Meanwhile, the gynecologists at our institution have also started to use the robotic system. The general and visceral surgical department is now using the robot for 2 full operating days per week. On each of the operating days, 3–4 operations are performed, and a total of 116 patients were successfully operated on with robotic assistance in the last 6 months. After the inguinal hernia procedures, upper GI cases and cholecystectomies were established. Starting with sigmoid resections in diverticulitis patients, we initiated the colorectal surgery program at the beginning of October 2017 (fig. 5).

Selection of Inguinal Hernia Repair using the TAPP Technique as First Procedure

Inguinal hernia repair using the TAPP technique is the most frequently performed laparoscopic procedure in our institution with more than 400 patients treated annually, establishing a high level of surgical expertise. We selected this standardized procedure as the first procedure to be performed using the robotic system.

This procedure requires limited procedural time and the surgical field is relatively clear. Nevertheless, the procedure requires signifi-

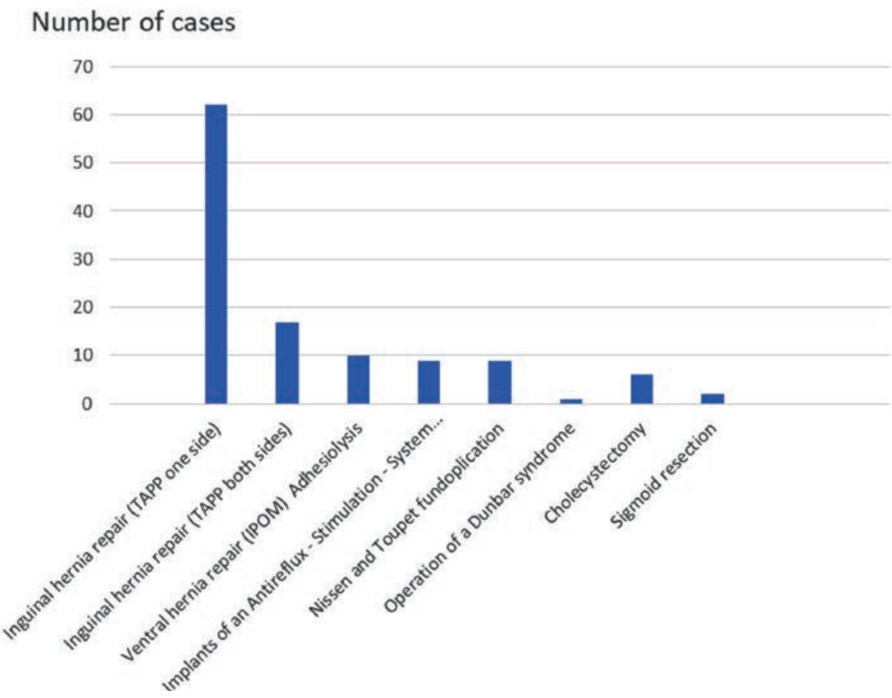

Fig. 5. Robotic-assisted operations (March 2017–October 2017).

cant preparation and an intra-abdominal continuous suture. Due to our vast experience with this indication, we were able to concentrate on the particulars and special requirements of the robotic procedure while performing the operation. No specific inclusion and exclusion criteria have been defined for the use of robotic-assisted surgery. All patients who decide to undergo inguinal hernia repair using the TAPP technique after having received appropriate information are given the option of robotic assistance.

The assistant at the operating table is responsible for positioning the patient, implementing the trocars, adjusting the operating table, and positioning the robotic arms.

The positioning of the 5-mm or 10-mm working trocars is almost identical with their positioning during the traditional TAPP procedure [9]. Leaving enough space in between the trocars has proven to be advantageous in order to optimally use all degrees of freedom of the robotic arms.

Adjustment of the height and angulation of the operating table is crucial during robotic-assisted operations, since this can optimize the degree of freedom in the motion of the robotic arms, in particular for upward and downward movement. The positioning of the single robot arms around the OR table is of equal importance. This positioning and the distance to the patient are crucial for a seamless operational process.

Settings and set-ups are the result of a learning process with growing experience, with small changes and optimizations having been implemented. The time needed to implement all settings before starting the procedure itself is rather short (docking time). The flexible and quick handling of the robotic arms is one of the most important features of the functionality of the system (fig. 6). The docking time for all procedures with finding the optimal robotic arm position was brought down to less than 10 min after only a few operations.

Standard procedure during TAPP with the new robotic system is to use 3 robotic arms. To prepare, we regularly use a monopolar hook (right hand/right robotic arm) and a bipolar grasper (left hand/left robotic arm). The robotic-assisted procedure is concluded with replacing the instruments by 2 needle holders to close the peritoneum (after implantation of the net and fixation with a special PDS (polydioxanone) stapler).

The assistant at the table exchanges the instruments connected to the robotic arms during the procedure and introduces the net, which is used to close the hernia, through the 10-mm trocar in the right middle abdominal space. The assistant fixes the net to the abdominal wall with staples.

The entire workflow and the duration and success of the procedure are not only dependent on the experience of the console operator but also on the experience of the assistant at the table. The operator should also have detailed knowledge of the settings on and around the patient. In our practice, we perform the procedures with experienced surgeons both at the console and at the table. We regularly interchange these functions to ensure that all team members are fully capable of performing all tasks during the procedure.

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 (fig. 7). After about 30 operations, the console time of an inguinal hernia repair corresponded approximately to the incision-to-suture time of a normal laparoscopy.

Patient-Informed Consent

In the early phase of the program, we were uncertain about patients' acceptance of the new robotic-assisted system. We have been

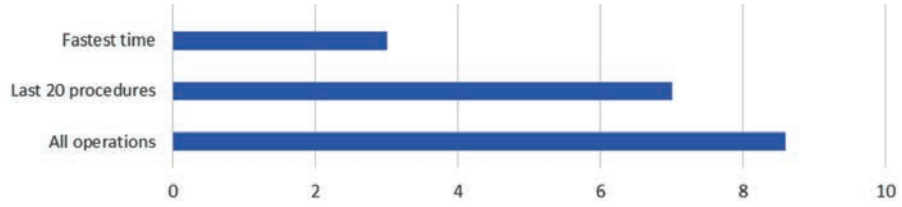

Fig. 6. Average docking time of the system in min (March–July 2017).

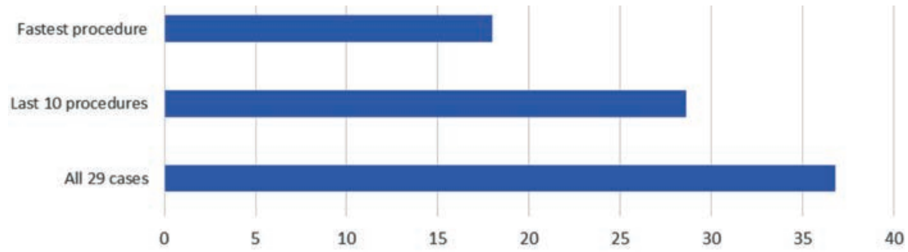

Fig. 7. Inguinal hernia repair – average personal console time (min), Dr. D. Stephan (March–July 2017).

positively surprised by the fact that only very few patients declined robotic assistance during their surgery.

On the contrary, most patients have been very open towards the innovation and insisted on being operated on with assistance from the robot.

We regarded it as very important to specifically inform the patients about the robotic-assisted treatment aspect in addition to the routine information about the laparoscopic surgery. We have developed an informed consent form in which all surgeons are named who are certified to perform operations with the system. Additionally, we have listed all procedures that are currently performed using robotic assistance.

We inform our patients in detail about the advantages and potential risks of robotic-assisted surgery. In particular, we also inform them of the fact that any technical device has a potential failure mode. This includes potential problems with mechanic functions (camera, robotic arm, console) as well as within the complex software package.

Additionally, the patient can consent to data collection and pseudomized data storage in a central data base in the context of a registry study by signing a specific consent. Thus, the patient agrees that medical records and personal information are stored in his/her personal file. He/she can also consent to relevant data being used by other researchers for scientific purposes.

Conclusion

Until now, clinical studies about robotic-assisted surgery have been almost exclusively DaVinci-related. With the introduction of an additional CE-certified and Food and Drug Administration(FDA)- approved robotic-assisted system, 'robotic surgery' can no longer be equated to 'DaVinci surgery'. With increasing market presence of alternative robots, it will become feasible to undergo studies and to research potential differences between the robotic-assisted systems with respect to process times, safety, patient benefits, and comfort for the surgeon. Starting March 14, 2017 through October 19, 2017, we performed a total of 116 robotic-assisted surgeries. Following our integration program, we started with robotic-assisted TAPP inguinal hernia repairs. In a second step, we additionally performed upper GI procedures as well as cholecystectomies assisted by the robot. During the 4th quarter of 2017, after the experience of almost 100 procedures within 6 months, we started with colorectal procedures, earlier than expected. As the starting procedure in this field, we selected sigmoid resections in diverticulitis patients. All robotic-assisted procedures are video-recorded and scientifically documented in an international registry. At this time, we only survey intraoperative and early postoperative complications. In 1 case of an inguinal hernia repair, bleeding from the musculature of the ventral abdominal wall occurred. We were able to immediately stop the bleeding laparoscopically and proceed with the robotic-assisted surgery. In 1 case of thoracic stomach surgery, we decided to switch to normal laparoscopy due to the presence of strong adhesions.

Our initial experience confirms that the Senhance system is suitable and safe for procedures in general and visceral surgery. Particularly the non-troublesome and fast interchange to a normal laparoscopic procedure makes the handling of the system fast and flexible. We were able to document fast system integration times, and our fast-growing experience with the system is reflected by shortened docking and console times. Since the system is based on laparoscopy, experienced laparoscopic surgeons will be able to quickly turn to complex surgeries. To enter into robotic-assisted surgery, demands systematic preparation. Our experience supports the development of an integration program in order to embark on the new technology in a fast and safe way. One of the most important aspects to incorporate into an integration program is a responsible economic view, and in this regard, starting with simple and highly standardized procedures is more feasible. Only an improved economic situation allows a step-by-step and safe introduction of the system in the context of an integration program, given the current nonexistence of any special reimbursement. Robotic-assisted surgery at this early stage allows us, by permanent improvement and further development of the modern techniques, to create a basis for more effective and precise surgical treatment and continuous improvement of minimally invasive 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. Manual tremor does not impair the work. Further studies need to be performed to verify these anticipated advantages for patients and surgeons. Detailed clinical case results and potential advantages and disadvantages of the system compared to laparoscopic surgery are the subject of ongoing research and will be published in due course.

Disclosure Statement

The Department of Robotic Surgery of the St. Marien Hospital, Siegen, is an internship center for TransEnterix, Inc.; D.S. is working as a proctor for TransEnterix, Inc..

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