



Robotic cholecystectomy: first experience with the new Senhance robotic system

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Abstract

This retrospective study was performed to evaluate the safety and feasibility of the new Senhance robotic system (Transenterix) for robotic cholecystectomy. Our series is the first experience with cholecystectomies utilizing this new platform. From May 2017 to August 2017, 20 robotic cholecystectomies were performed using the Senhance robotic system. Patients were between 23 years and 78 years of age, eligible for a laparoscopic procedure with general anesthesia, with no life-threatening co-morbidities that limited the subjects' life-expectancy to fewer than 12 months. A retrospective chart review was performed for a variety of pre-, peri- and postoperative data including, but not limited to patient demographics, intraoperative complications and postoperative complications. 9 male and 11 female patients were included in this study. Median age was 39.5 years (range 23–78); median BMI was 27.35 kg/m² (range 22.8–48.3). Median docking time was 10 min (range 2–26), and median operative time was 71.5 min (range 34–197). Conversion to standard laparoscopy occurred in one case for lysis of extensive adhesions. There were no conversions to open technique. There were no intra- or post-operative complications noted. We report the first series of robotic cholecystectomies using the new Senhance system. Docking time and total operative time decreased significantly over the course of this series and did not plateau; console time did not change significantly. This study demonstrates the feasibility of utilizing this platform in performing minimally invasive cholecystectomies.

Keywords Robotic cholecystectomy · Robotic surgery · Senhance robotic system

Introduction

Cholecystectomy has become one of the most common operations performed in the Western world. Initially a major operation with a large incision and lengthy recovery time, the surgery transitioned to a minimally invasive approach in the 1990s [1]. Today, nearly 90% of cholecystectomies

are performed laparoscopically [2, 3]. Multiple studies have demonstrated reduced post-operative pain, shorter hospital stays, and improved cosmetic results for minimally invasive surgery, and overall hospital costs are lower [4]. Limitations of laparoscopy include reduced haptics, impaired ergonomics, and limited degrees of instrument motion. Early robotic platforms promised to ameliorate these deficiencies. A recent retrospective study found robotic cholecystectomies in the United States had increased from 0.2% of cases to 1.8% of cases between 2008 and 2015 [5]. Prospective studies have demonstrated the safety of earlier robotic platforms (da Vinci© by Intuitive) in performing laparoscopic cholecystectomies, but they have not identified significant benefit to the patient. Instead studies revealed increased operative times and have documented significantly increased costs [6–9].

The Senhance surgical system is a new robotic platform that consists of a cockpit, manipulator arms and a connection node (Fig. 1). This new system provides robotic surgery with numerous advantages including eye-tracking camera

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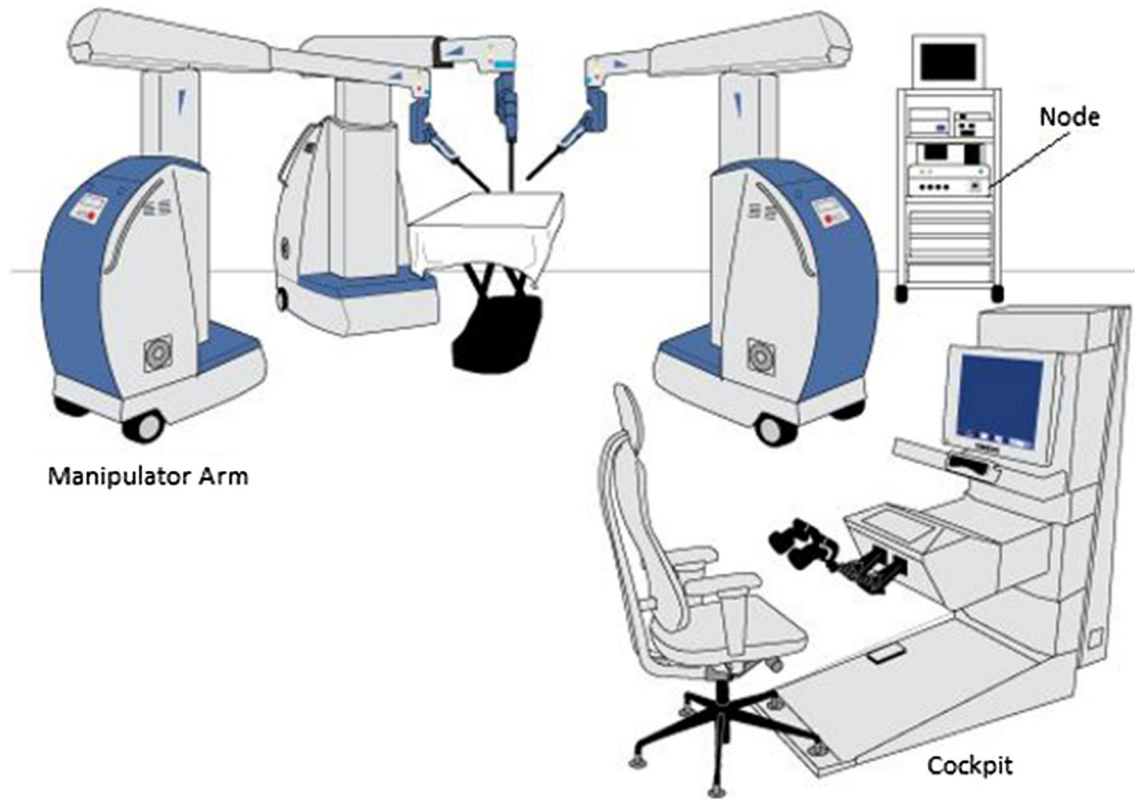


Fig. 1 Senhance surgical system with cockpit, manipulator arms and a connection node

control system, haptic feedback, reusable endoscopic instruments without limited lives, possibility of utilizing 5 mm cameras, and a high configuration versatility due to total independency of the manipulator arms [10]. This system has proven its safety and feasibility in a variety of gynecologic procedures [11–14].

We established a robotic surgery program with the Senhance system in our hospital in May 2017. We started the program with a well-defined, standardized procedure, the laparoscopic cholecystectomy. Here we present the first clinical experience of this new robotic system with this operation. The primary goal of this study is to verify the safety and feasibility of the Senhance system.

Materials and methods

A retrospective chart review was performed of all patients who underwent robotic cholecystectomy with the Senhance robotic system (Transenterix) from May to August 2017 at the University Medical Center Hamburg-Eppendorf (Germany). All surgeons had previous experience with standard laparoscopic cholecystectomy and also had previous experience with the da Vinci system. All surgeons and scrub nurses underwent a 3-day training course on the robotic system that

included simulator sessions and pig lab cases. The team of surgeons and scrub nurses was always the same to insure the level of expertise. The console provides the surgeon with an eye-tracking system that allows to assign instruments to different handles and to move the camera while simultaneously moving instruments. Furthermore, haptic feedback via the handles gives the surgeon a certain amount of feeling for traction and tissue resistance. Included in the study were patients between 23 years and 78 years of age who were eligible for a laparoscopic procedure under general anesthesia, who had no life-threatening disease with a life-expectancy of fewer than 12 months, and who provided informed written consent prior to surgery specifying use of the robot system. The Institutional Review Board approved the study (Hmb-KHG, § 12,1, Ethics commission Hamburg). All patient information remained confidential and was managed following the requirements of the Health Insurance Portability and Accountability Act of 1996.

Patients

There were 11 females and 9 males with a median age of 39.5 years (range 23–78) and a median BMI of 27.35 kg/m² (range 22.8–48.3). Symptomatic cholelithiasis was the indication for 15 procedures; cholelithiasis with chronic

cholecystitis for 3; cholelithiasis with chronic cholecystitis and biliary pancreatitis for 1 and acute cholecystitis for 1. A wide range of pre-, peri- and postoperative variables were collected; detailed patient characteristics may be found in Table 1.

Surgical technique

Following the administration of perioperative antibiotics, general anesthesia was induced. The abdomen was entered via an umbilical mini-laparotomy and a 12 mm port was placed for the 10 mm, 0° camera. Two 5 mm ports were placed under direct vision in the left and right mid-abdomen with another 12 mm port placed sub-xiphoid (Fig. 2). The location of the ports did not differ from our standard port positioning for laparoscopic cholecystectomies, although the right-handed 5 and sub-xiphoid 12 mm ports were switched to enable clipping without changing the instrument on the right arm. In some patients with dense intra-abdominal adhesions, surgeons performed a laparoscopic adhesiolysis. The robot was then docked. Manipulator arms were at 1:00, 4:30, and 10:00, with the camera controlled at the 4:30 position. The surgeon operating the robot controlled the camera and two instruments from the console. A scrubbed bedside surgeon provided cranial retraction of the gallbladder with a laparoscopic instrument through the sub-xiphoid 12 mm port. The dissection proceeded in the standard fashion for minimally invasive cholecystectomies. After identification

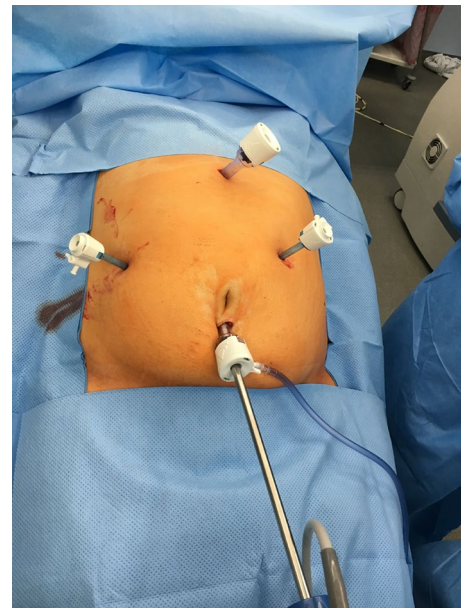


Fig. 2 Port positioning

of the critical view of safety, the scrubbed assistant applied 10 mm clips to the cystic artery and cystic duct, which were then divided. The gallbladder was then separated from the liver and extracted with a retrieval bag. After examining the surgical field and ensuring hemostasis, the robot was undocked. The 12 mm fascial defects were closed with vicryl sutures; skin for all ports was closed with resorbable sutures.

Docking time is defined as the time needed to attach all manipulator arms to the instruments after trocar placement. Operative time was defined as time from skin incision until skin closure and included docking time, while console time was defined as the time spent on the console from end of docking to undocking.

The patients were routinely hospitalized for two nights, which is standard practice in German healthcare system. On the morning of the first postoperative day, laboratory tests were routinely performed including complete blood counts, complete metabolic panels, and serum bilirubin level. Giving uneventful recovery and normal examination results, the patients were discharged. No routine outpatient follow-up with the operating surgeon was scheduled for uneventful cases.

Statistical analysis

All statistical analyses were performed using GraphPad Prism 7 (GraphPad Software, Inc., La Jolla, CA) and Microsoft Excel (Microsoft Cooperation, Redmond, WA). Categorical data are presented as the number of patients and relative percentage. The median and range were used for skewed data. For characterization of variables, mean values

Table 1 Patient characteristics

	<i>n</i> (%) or median
Gender	9 (45%) male
Age	39.5 (23–78)
BMI	27.35 (22.8–48.3)
Diagnosis	
Symptomatic cholelithiasis	15 (75%)
Cholelithiasis with chronic cholecystitis	3 (15%)
Cholelithiasis with chronic cholecystitis and biliary pancreatitis	1 (5%)
Acute cholecystitis	1 (5%)
Extent of adhesiolysis	
None/minimal	16 (80%)
Extensive	4 (20%)
Past abdominal surgical history	3 (15%) positive
Past medical history	
None	7 (35%)
Diabetes	2 (10%)
Liver disease	5 (25%)
Cardiac disease	6 (30%)
Obesity	3 (15%)
Other	13 (65%)

and standard deviations were calculated. Trend in operative and docking time between singular cases was calculated with linear regression. All p values are considered significant if p value < 0.05 .

Results

A total of 20 cholecystectomies were performed using the Senhance robotic system. The median age was 39.5 years (range 23–78) and the median BMI of 27.35 kg/m² (range 22.8–48.3). Three patients had BMI > 35 , which exceeds current recommendations for using the robot. The median docking time for all cases was 10 min (range 2–26). There was a significant learning curve identified in the docking process with a p value < 0.0001 (Fig. 3a). The median operative time for all cases, independent of the indication and intraoperative findings, was 71.5 min (range 34–197). The procedure which took 197 min was influenced by marked inflammatory changes in the tissue due to acute cholecystitis and prolonged duration till identification of cystic artery and duct. The median console time was 50 min (range

19–176). There was a significant decline in operative time over the case series, but no significant decline in console time (Fig. 3b, c). Differences become most apparent when comparing the first 10 cases against the second 10 cases, where median docking time decreased from 17 to 6 min; median OR time decreased from 110 to 68 min; and median console time from 80.5 to 45 min.

During the 20 cases, there were no significant intraoperative complications. One case, for chronic cholecystitis, was converted to standard laparoscopy given the density of adhesions and surgeon comfort with familiar technology in a forbidding operative field. No conversions to open technique were necessary. There were no post-operative complications such as surgical-site infections, urinary tract infections or hematomas.

Discussion

Minimal invasive surgery is well established in the field of general surgery and considered the gold standard for cholecystectomy. We performed a study designed to evaluate

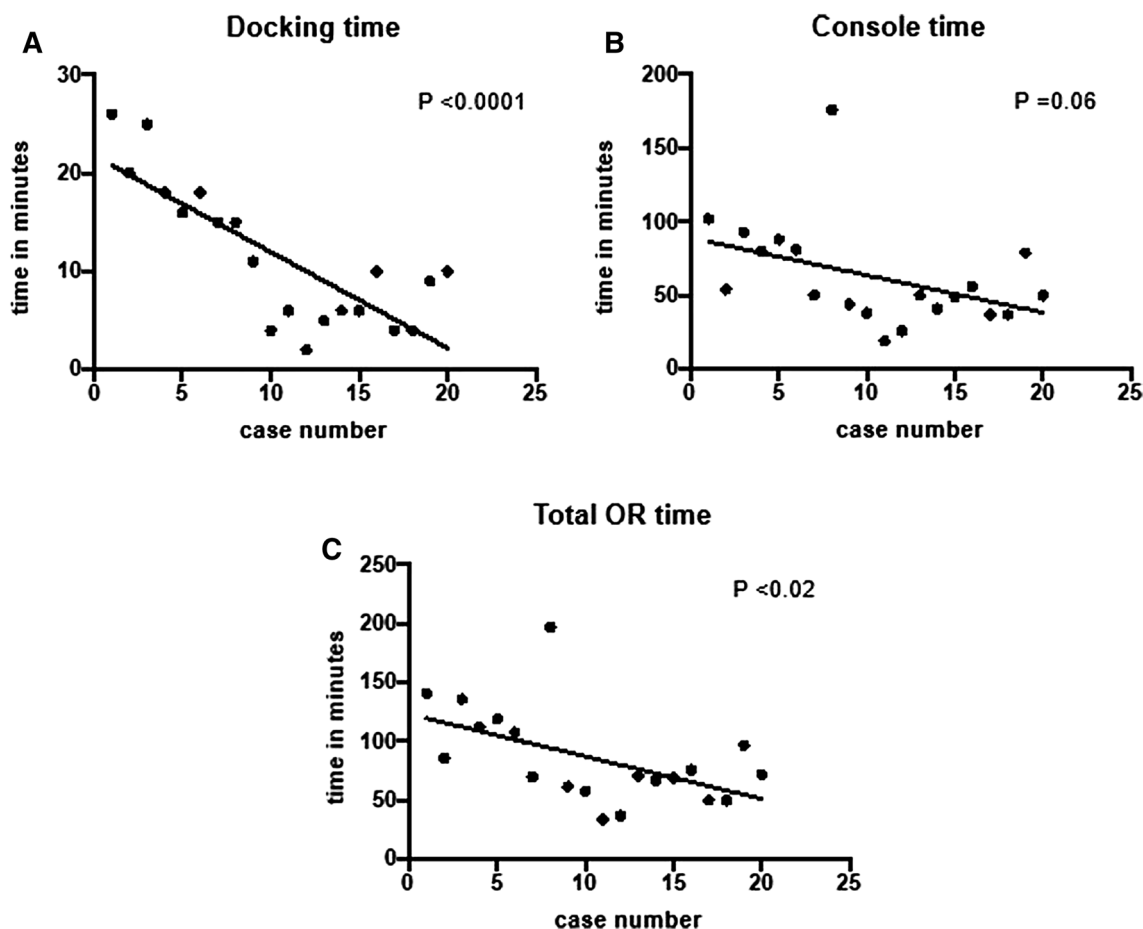


Fig. 3 a Docking time. b Console time. c Total operative time

the feasibility and safety of the Senhance Surgical System in a heterogeneous group of patients requiring cholecystectomy; this is the first reported case series using this robot for this operation. The Senhance surgical system is an innovative robotic system that is already established in a variety of gynecologic procedures [11–14]. It has a few unique advantages compared to standard laparoscopic techniques as well as robotic systems including eye tracking control over camera movement, haptic feedback, and independent manipulator arms that allow standard port placement as in laparoscopy which facilitates conversion to standard laparoscopy when indicated. Additionally, the instruments fit through standard laparoscopic 5 mm ports and are reusable without limited lives, creating a portended financial advantage compared to other robotic systems. The system ergonomically benefits the operating surgeon, which is of increasing importance given recent literature demonstrating a 74% prevalence of musculoskeletal complaints among laparoscopic surgeons, with the neck, back, and shoulders affected most commonly [15]. The similarity of the controls to laparoscopic instruments facilitates easy transition to robotic operation.

In this study we demonstrate the ability to perform a robotic cholecystectomy with the new Senhance surgical system safely. We show that even with training prior to clinical utilization, docking time still decreased significantly. This was mainly due to growing experience with the system, the instruments and their connections to the arms and also table settings. Moreover, times did not level off after twenty cases, suggesting they may decline further with additional experience. They also compared favorably with prospective trials documenting a median docking time of 10 min with the da Vinci system [16]. Median operative time was 71.5 min, which exceeded normal operative times for laparoscopic and other robotic series, previously reported at 50 min and 55 min, respectively [6]. However, recently published da Vinci and laparoscopic times reflect years of experience with those platforms, complicating comparison with the first ever cases using a new technology. The mean operative time in this series (85.6 min) does compare favorably to the mean times of centers first deploying the da Vinci machine for cholecystectomy, where means ranged from 57 to 167 min in multiple series from different institutions [17]. A mean of 82.3 min was obtained in the first series of robotic cholecystectomies at one institution deploying the Zeus Robotic Surgical System [18].

Limitations

Given the relative rarity of intra- and post-operative complications following minimally invasive cholecystectomy, our series of 20 patients lacks sufficient power to detect

differences in complications between robotic cholecystectomy using the Senhance system, robotic cholecystectomy using the da Vinci system, and standard laparoscopic cholecystectomy. Moreover, given the success of laparoscopic cholecystectomy and the inherent added expenses of robotic surgery (viz., equipment, longer operating time), it seems unlikely that robotic approaches will supplant standard laparoscopy for this particular operation. However, our aim was to show feasibility and safety and thus, the comparative simplicity of the procedure may contribute to its use as an opportunity to train surgeons and operating room staff on the successful integration of a new robotic platform.

Conclusion

Our experience in a heterogenous group of patients shows that minimally invasive cholecystectomy with the Senhance robotic system is a feasible and, within the confines of limited data, safe operation. The study demonstrates the ease of laparoscopic trained surgeons using this system. It also reveals marked improvements in docking time and console time over relatively few operations without evidence of plateau. Further comparative trials are indicated in more advanced gastrointestinal surgery.

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Compliance with ethical standards

Conflict of interest Dr. Melling received an institutional research grant from Transenterix to carry out this study. Dr. Barr received an institutional research grant from Transenterix to carry out this study. Dr. Schmitz received an institutional research grant from Transenterix to carry out this study. Dr. Polonski received an institutional research grant from Transenterix to carry out this study. Dr. Miro received an institutional research grant from Transenterix to carry out this study. Dr. Ghadban received an institutional research grant from Transenterix to carry out this study. Dr. Izbicki received an institutional research grant from Transenterix to carry out this study. Dr. Zani received an institutional research grant from Transenterix to carry out this study. Dr. Perez received an institutional research grant from Transenterix to carry out this study.

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