FIRST HUMAN SURGERY USING A SURGICAL ASSISTANCE ROBOTICS DEVICE FOR LAPAROSCOPIC CHOLECYSTECTOMIES

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Abstract

Over the past 20 years, surgeons involved in soft tissue minimally invasive surgery have experienced the pros and cons of both conventional and tele-robotic laparoscopic approaches.
The Maestro System, developed by Moon Surgical (Paris, France) aims to overcome the challenges inherent to both approaches with a new concept that augments the surgeon's performance at the bedside during a laparoscopic procedure. This study aims to present the first human experience with laparoscopic cholecystectomy with the Maestro system on 10 patients. All 10 procedures were completed successfully without significant complications related to the use of the Maestro system.

Key Words

Laparoscopic Robotics; Robotic-assisted cholecystectomy; First in Human; Clinical trial; Minimally invasive surgical procedure; Robotic surgical procedures.

Introduction

Laparoscopic cholecystectomy (LCCE) is considered the gold standard for the surgical treatment of symptomatic gallstone disease [1][2]. Cholecystectomy is one of the most commonly performed surgical procedures in the world. In the US approximately 700,000 LCCE surgeries are performed every year [3]. A major drawback lies in the fact that essential components of the surgical procedure must be delegated to surgical assistant(s) to manage vision (scope positioning) as well as access (tissue exposure). This distribution of roles and responsibilities creates limitations, as surgeons may encounter issues in controlling critical elements required for safety and efficiency throughout the procedure.

Mechanical support arms that hold the scope or laparoscopic instruments instead of handing them over to an assistant have been in use for some time. Such a technique ensures the stability of the scope image and allow appropriate exposure of the operative field. Unfortunately, manual locking and unlocking of scope holders represents cumbersome workflow interruption for the surgeon. In addition, mechanical retracting of fragile organs such as the liver may lead to injury and other complications.

Tele-robotic systems specifically address the challenges created by the need to delegate essential parts of the laparoscopic procedure. Thus, control of the instruments and vision have been given back to the surgeon. For instance, with the da Vinci™ surgical system (Intuitive Surgical Inc., Mountain View, CA, USA), the surgeon has full control of the endoscope and three ancillary instruments with a foot pedal.
The use of robots has proven to be very beneficial in laparoscopic prostatectomy, allowing identical or even better outcomes than conventional laparoscopy [4], hence, up to 85% of prostatectomies are now performed robotically [4]. However, the use of robotic technology brings about new limitations, including adaptability and situational awareness, linked with the fact that the surgeon is confined in a console[5]. The physical isolation of the surgeon, who is no longer scrubbed and gowned, prevents direct

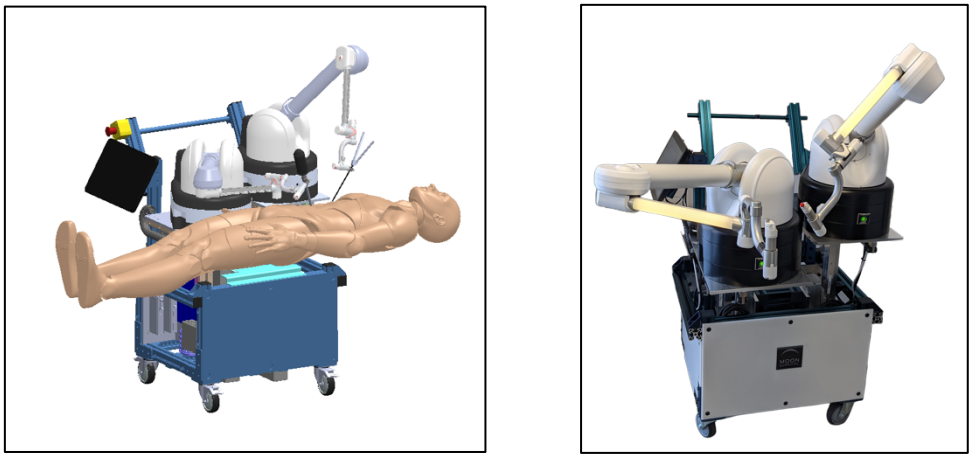
control and an accurate understanding between robot, patient, and operating room team. These limitations required improved communication between the operating room team and the surgeon.
To address the specific situational awareness and adaptability in conventional laparoscopy, significant design efforts have been integrated in the more recent tele-robotic systems. As a consequence, however, the complexity of setup and positioning significantly increased without solving the issue of disassociation between surgeon and patient. In order to deal with this unwanted situation a new platform has been elaborated by Moon Surgical (Paris, France).

Following more than 30 feasibility studies on cadaveric models, and after formal approval of the local IRB, the first human cases with the Maestro Platform were performed. The current study was designed and executed to demonstrate the feasibility and safety in elective laparoscopic cholecystectomy performed with the help of the Maestro device.

Materials and Methods

Study Device

The Maestro System (Moon Surgical SAS., Paris, France) is a two-arm platform device *(Fig 1)* that holds and assists in the positioning of off-the-shelf laparoscopes and retractors during a laparoscopic intervention. Both arms of the Maestro platform have been designed to minimize mechanical friction when moving the arm. They constantly compensate for the mass of the tool attached thanks to a proprietary software system.



(Fig 1) Schematic illustration of the Maestro Platform and its key touchpoint, and picture of the system in cholecystectomy position

The device allows for the instruments to be held statically or, alternatively, to be instantly repositioned by the surgeon. The instrument is automatically kept in place by the system whenever the surgeon releases the instrument. Repositioning the instrument is performed in complete mechanical transparency.

Each arm is mounted on a motorized independent platform which enables to position the system as required by the operative field and the patient configuration. Platforms can translate both on the vertical and horizontal axis. Color LED feedback indicators located on the arms at all times provide the surgeon with information about the state of each arm: idle, manipulating an instrument, or static holding.

Study Design and Method

The First-in-Human study was designed as a single arm, prospective, single center, single operator feasibility trial. Ethics Committee and Competent Authority approvals for the clinical investigation were obtained from the FAMHP and an Ethics Committee designated by the College in accordance with the regulation (EU) 2017/745 on medical devices and in line with the law of December 22, 2020. The study was registered under: CIV-22-01-038769 (Eudamed), and NCT05243433 (clinicaltrials.gov ID) as per applicable regulations.

Adult patients scheduled for elective laparoscopic cholecystectomy were offered to participate freely. Patient screening and enrolment started in March 2022. Participants were provided with both oral and written information about the instrument and the current study and signed the consent form if willing to participate.

The primary objective of the study was to provide evidence for the safety and effectiveness of the Maestro Platform for surgical assistance in laparoscopic cholecystectomy.

The primary safety endpoint was the safety of the procedure using the Maestro Platform without device-related serious adverse events at the time of procedure and within 30 days. Adverse events were to be categorized as device or procedure related.

The primary effectiveness endpoint was the successful completion of the procedure using the Maestro Platform without conversion to a manual minimally invasive or open surgical procedure specifically due to a device failure or malfunction.

The demographic data included: age of the patient, gender, BMI, previous abdominal surgery. Perioperative data included atypical anatomy, technical ease of the procedure independently from the system, surgeon's comfort and satisfaction using the system, duration of the procedure and duration of the hospitalization.

When imaging data and laparoscopically observed data did not match, the patient was noted as having an atypical anatomy, with a precise description of the anatomy.

The surgeon's comfort, satisfaction, and appreciation of the technical ease of the procedure were evaluated by the surgeon immediately after the procedure. They were scored on a five-point scale.

The procedure duration time was calculated between the insertion of the scope and the time of placing the gallbladder in the extraction bag (Bagging).

Surgical technique

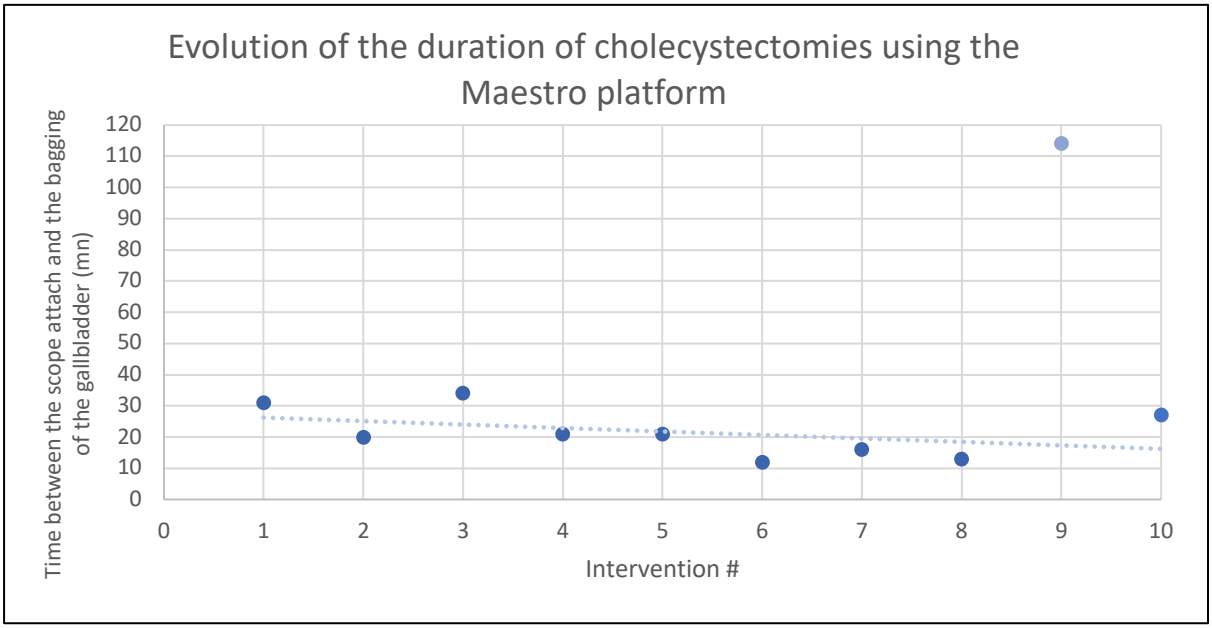
The system was provided to the surgeon already draped and brought to the bedside after trocar placement. With our standard technique, cholecystectomy procedures were performed with the surgeon on the left side of the patient. (Fig2)

Four trocars were used. A 5 mm epigastric port allowed the introduction of a grasping forceps held by the Maestro system. It maintained constant traction on the liver unless adjustments were required for changes in visualization and exposure of the hepatocystic triangle. A 10 mm trocar was inserted at the umbilicus for the 30-degree optical system held by the Maestro system. As per routine, the working trocars that are used by the surgeon are two 5 mm ports, one placed in the right lateral subcostal position and one in the white line. After dissection of the hepatocystic triangle, the cystic artery and cystic duct were clipped and divided without operative cholangiography. Dissection of the gallbladder from the liver bed was performed by retrograde technique. The gallbladder was then placed in a collecting bag and removed at the 10 mm umbilicus port site.

(Fig 2) Disposition of the patient, the surgeon, the trocars, and the Maestro platform

Results

Of the ten participants who gave consent to participate in the study, all underwent the laparoscopic cholecystectomy using the Maestro Platform between April 13th and June 7th 2022. All 10 surgeries were successfully completed without added trocar, conversion to a conventional minimally invasive, or open surgical procedure. No intraoperative complications occurred. No external arm clashes were noted during any procedure. In 6 cases, the surgeon felt very satisfied. The surgeon felt satisfied in 3 procedures and mixed satisfied in 1 case. In the seven last cases, the surgeon felt very comfortable. The surgeon felt comfortable in 2 procedures and mixed in 1 case. In 6 cases, the technical ease of the procedure was very easy, 1 was easy, 2 procedures were considered moderate, and 1 was seen as difficult. The anatomy was considered as atypical in 1 case. The median duration of the surgeries was 21 minutes (*Graph 1)*. The procedural time showed a decrease (x=k(T10-T1)), NS.



Graph 1. Duration of cholecystectomies using the Maestro platform

One retroperitoneal bleeding caused by a Veress needle puncture at initiation of the pneumoperitoneum resulted in a control laparoscopic re-intervention the following day, and the patient stayed under surveillance for 10 days. This was not related to the use of the Maestro system.

Upon initial examination of the insufflated abdomen, one of the patients (Patient 9) presented atypical anatomy: extensive adhesions in the abdominal cavity and a diseased gallbladder. The cystic duct could not be clipped and needed micro-suturing of the insertion site in the common bile duct with a 4.0 material resorbable suture. The intervention lasted 114 minutes. The technical use of the procedure was scored as “difficult” (4/5) by the surgeon, the comfort and the satisfaction levels were maximal.

Discussion

The rationale for the proposed Maestro LIFT-OFF study was that in conventional laparoscopic procedures the surgeon is highly dependent on his/her assistant, for scope manipulation as well as operating field exposure through retraction. By overcoming this limitation, the Maestro Platform would allow surgeons to optimize their time and efficiency, without the limitations encountered with tele-robotic systems.

The surgeon was satisfied to very satisfied with the assistance provided in 9 cases out of 10. Critical point is probably that each arm of the Maestro Platform provides the surgeon a unique feeling of mechanical transparency. Even when a heavy laparoscope is attached, Maestro creates a sense of weightlessness, which benefits to positioning and creates haptic feedback. Although a recurrent issue with robotic assisted surgery[6], no arm clashes were observed during the procedures and the surgeon could manipulate the instruments without resistance, without feeling their mass, or the arm offering resistance. In the first case only did the surgeon not feel satisfied or very satisfied, which shows a steep adaptation curve.

Furthermore, the surgeon felt comfortable to very comfortable in 9 cases out of 10: the superior image stability gives the surgeon the possibility to look away from the screen and come back with the exact same image. This vision stability also allows for an increased accuracy in delicate tasks such as micro-suturing as experienced in patient #9, where the surgeon scored the comfort as maximal, although the patient had an atypical anatomy, the technical ease was considered as difficult. and the intervention was lengthy compared to the other cases.
Unlike the other robotic techniques, the Maestro device allows the surgeon to stay at the patient's bedside without the need to constantly verbalize his/her orders as required by the distance to the patient. In this case, the Maestro System showed adaptability to an unplanned anatomy. In the first case only, the surgeon did not feel comfortable or very comfortable, which again shows a steep adaptation curve.

Time was measured between the scope attachment and the bagging of the gallbladder to avoid the variation in extraction time linked to the state of the gallbladder (depending on the size and number of stones the extraction of the bag containing the gall bladder can be significantly more or less time consuming). The graph #1 suggests a swift learning curve, without reaching statistical significance.

After only 1 case, the surgeon felt comfortable and satisfied with the assistance provided. Same as with the technique, instruments and the surgeon's disposition are kept unchanged compared to traditional laparoscopy. The system simply has to be approached to the bedside once the patient is in the correct position, and the trocars have been positioned.
Given the objective of the system (i.e., providing the surgeon with the best assistant, whilst keeping the same surgical practice), the learning curve was very steep, requiring only in vitro training on a synthetic model, in which LED feedback, instrument coupling and arm positioning were incorporated.

Our results on this new approach did not demonstrate an increase in postoperative complications compared to conventional laparoscopic cholecystectomy. Moreover, the system's integration within existing and experienced laparoscopic techniques and operating room routine allowed for surgeon proficiency with minimal training.

The primary safety and effectiveness endpoints were met in this series of 10 cholecystectomy patients, demonstrating the safety and feasibility of laparoscopic assistance using the Maestro Platform.

Additional data on more patients and diverse clinical indications, such as hernias, and large operative fields like colectomies and bariatric procedures will be needed to confirm the value of this approach. The financial aspect will be an important factor towards the spread of the system.

The Maestro platform provides the surgeon a stable vision and resistance free manipulation of all the surgical tools. Moreover, the surgeon can remain at the bedside, in direct communication with the

surgical team. In conclusion, thanks to the new platform the surgeon can be completely and at all times devoted to the intervention.

Disclosure

Guy Bernard Cadière and Benjamin Cadière serve as consultants for Moon Surgical, Paris, France. Jacques Himpens, Luca Pau and Nicolas Boyer have no conflicts of interest or financial ties to disclose.

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