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First in-human experience with a novel robotic platform and Magnetic Surgery System

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Abstract

Background: Magnetic technologies have been introduced to reduce invasiveness of surgical procedures. This study was aimed to analyse the performance of a novel combined magnetic-robotic controller as an enhanced accessory to the Magnetic Surgical System in laparoscopic cholecystectomy (LC).

Methods: This was a prospective study of 10 consecutive patients undergoing LC with this novel surgical system.

Results: Ten patients were included, nine were female. The mean age was 30.3 ± 9 years. All patients had chronic cholecystitis. Procedures were completed successfully. The median operative time was 50 ± 11 min. The system performed effectively in all cases with no need of additional interventions. There were no device-related complications or side effects. All patients were discharged the same day. Recovery was uneventful during follow-up.

Conclusions: This study demonstrates the first in-human successful performance of surgeries utilizing a novel combination of magnetic and robotic technologies in one integrated system.

KEYWORDS
cholecystectomy, magnetic surgery, minimally invasive surgery, robotic surgery

1 | INTRODUCTION

Magnetic technologies are now applied to surgical instruments, designed to work in tandem with minimally invasive surgery (MIS) to further reduce the invasiveness of procedures.[1–3] The development of new surgical techniques and novel technologies has resulted in lessened surgical trauma and improvement of patient outcomes including; reduced pain, less complications, less scars, shorter length of hospital stay, faster recovery period and better rate of patient acceptance.[4] Recently, device development and technique modification have focused to reduce the number and size of surgical instruments required to perform common procedures. Collectively, these efforts are often referred to as 'reduced-port techniques'. However, these modifications and the required instrumentation can represent demanding technical challenges, with increased difficulty and lengthier procedures.[5]

Technical limitations may include compromised capability of triangulation for; tissue manipulation, external and internal instrument clashing, inadequate visualization and less adequate organ mobilization.[1,6–9] When implementing new technologies, safe conduct of the intended procedure is paramount and surgeons must be aware of performing proper technique to avoid; prolonged surgical times, iatrogenic injuries and other unintended consequences.[10]

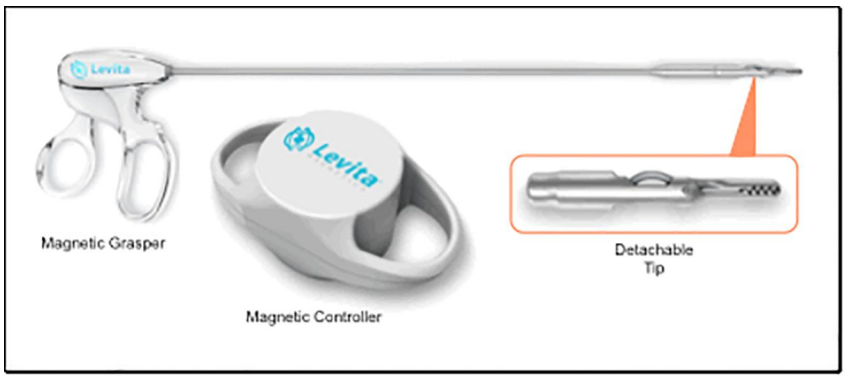

FIGURE 1 Magnetic Surgical System, including laparoscopic grasper, externally manipulated controller used by robotic arm and detachable tip for tissue grasping and manoeuvring

The concept of magnetic surgery (MS) has been developed to increase the benefits of MIS, as this technology reduces the invasiveness of procedures by decreasing the number of trocar access sites needed.[11] Additionally, robotic surgery (RS) enhances; flexibility, precision, and control during delicate and complex procedures. Furthermore, the system improves the ergonomics for the surgeon and provides a high-definition, magnified, 3-D view of the surgical site.[12]

Levita® Magnetics (San Mateo) developed a Magnetic Surgical System (MSS). This was the first system to receive Food and Drug Administration (FDA) clearance. This innovative technological platform uses magnetic fields to enhance mobilization and degrees of movement during surgery. Simultaneously, reduces invasiveness by decreasing the number of trocar access sites. The system allows for un-constrained, shaft-less magnetic retraction and mobilization of organs, which may be an advantage over conventional surgical instruments.[3]

A first generation, Magnetic-Robotic Controller (MRC) has been developed as a means to optimize the platform. The role of the MRC is to enhance the flexibility, precision and control of 'the magnetic system' during delicate and complex procedures. The surgeon controls the arms of the robot while seated at the console near the operating table. This will improve the ergonomics and allows for positioning and re-positioning as needed. Additionally, this could be performed by an assistant or held in place with a static device, but the robotic arm (RA) can be adjustable by the surgeon throughout the surgery.

This is the first reported use of this technology in human. The objective of this study was to describe the initial clinical performance; including safety and peri-operative outcomes of the MRC as an enhanced accessory to the MSS in reduced-port LC procedures.

2 | MATERIALS AND METHODS

2.1 | Study design and ethical approvals

This prospective cohort study was conducted between August 2018 and May 2019 with the approval of the Institutional Review Board (IRB) # 16082018 at two public teaching hospitals in Santiago de Chile, Chile. This study was evaluated by the IRB boards and was considered to involve no greater than minimal risks to all the patients included.

2.2 | Consenting process

Patients who were scheduled to undergo LC for standard indications and met the inclusion criteria were offered to participate in the study. Informed consent was obtained after explaining risks and benefits to the patients.

2.3 | Criteria for study participation

Inclusion criteria included; age greater than 18 years, scheduled for elective, non-urgent cholecystectomy and consent to participate in the study protocol. Exclusion criteria included; patients with pacemakers, defibrillators or electromedical implants. Patients were also excluded if they had non-medical ferromagnetic implants, to avoid interference with the magnetic field generated during the surgery. Patients were evaluated for overall fitness for general anaesthesia and surgical intervention including coagulation panel analysis.

2.4 | Pre-operative assessment

The work-up included evaluation by the surgical team for patients presenting with chronic cholecystitis or symptomatic cholelithiasis. Pre-operative investigations comprised of blood chemistry panels as well as abdominal ultrasounds. Computerized tomography scans were obtained at the discretion of the treating surgeon for diagnostic reasons. After appropriate selection for LC, patients were then enrolled and consented for the procedure.

2.5 | Description of the robotic platform and MSS

The MSS is comprised of a laparoscopic magnetic grasper with a detachable tip and an external robotically controlled manipulator (Figure 1). The 10-mm grasper includes; a delivery/retrieval shaft

FIGURE 2 Model with free-standing robotic platform and intra-cavitary deployed magnetic grasper simulating tissue manipulation

that allows the insertion and then deployment of the detachable tip on the target tissue. With the detachable grasper tip secured to the organ, the external MRC is positioned over the abdominal wall (Figure 2). Using the RA, the external controller is coupled to the internal magnetic tip. Once connected, the surgeon operating the MRC manoeuvres the device in real-time to obtain the desired visualization and retraction to successfully perform the procedure. Using the RA, the grasper is adjusted as many times throughout the procedure as needed. The RA is controlled and manipulated by the surgeon, but it can also be manoeuvrer by a sterile or non-sterile assistant.

2.6 | Surgical technique

LC was performed in a typical manner and standardized in this study. The patient was placed supine in the French position and general anaesthesia induced. Appropriate pre-operative antibiotics were administered. Initial access was obtained with a 5-mm optical trocar. Once safe-entrance to the peritoneal cavity was obtained, a diagnostic laparoscopy was performed to evaluate for additional pathology and ensure no injury was made during initial access. Two additional ports were then placed. A 10-mm port at the umbilicus and another 5-mm trocar in the right lower abdomen. After placement of the trocars, the magnetic grasper was placed through the 10-mm trocar and deployed onto either the gallbladder fundus or body (Figure 3).

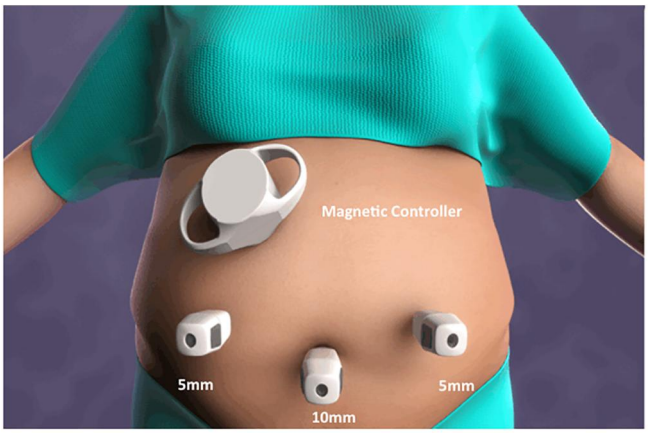

FIGURE 3 External view of trocars and magnetic controller placement

The external magnet was draped with a sterile bag and placed onto the lower chest wall or right upper quadrant and manipulated until adequate cephalad retraction of the gallbladder up over the dome of the liver by the magnetic grasper was achieved. Once coupled, movements were accomplished by use of the RA. Intra-operatively the device was manipulated for proper exposure multiple times by the operating surgeon to facilitate dissection and complete the operation (Figure 4). This largely consisted of cephalad retraction, lateral retraction for identification of critical structures, retraction for removal off of the gallbladder fossa and retrieve once the gallbladder was dissected freely. Cholecystectomy was performed in the standard manner, with a critical view of safety obtained prior to transection of any structures. Selective cholangiography was performed on two patients who presented with pre-operative elevated liver function tests.

At the end of the procedure, the external MRC is moved away from the patient, releasing the magnetic attraction. The detachable grasper tip is reconnected to the magnetic grasper shaft and removed from the patient. The gallbladder was retrieved and trocars removed, with suture closure of the 10-mm site.

2.7 | Post-operative care

Patients were admitted to the surgical ward under a standardized recovery protocol consisting of early ambulation, multimodal analgesia and initiation of diet on the same day of the surgery. After monitoring for potential peri-operative complications, patients were discharged to home when able to tolerate adequate oral intake and appropriate pain management. Patients follow-up with evaluation in the outpatient clinic at intervals of 1 week and 1 month.

2.8 | Management of adverse events

Potential adverse events were planned to be managed as per any other surgical complication following surgeon preference and intuitional guidelines.

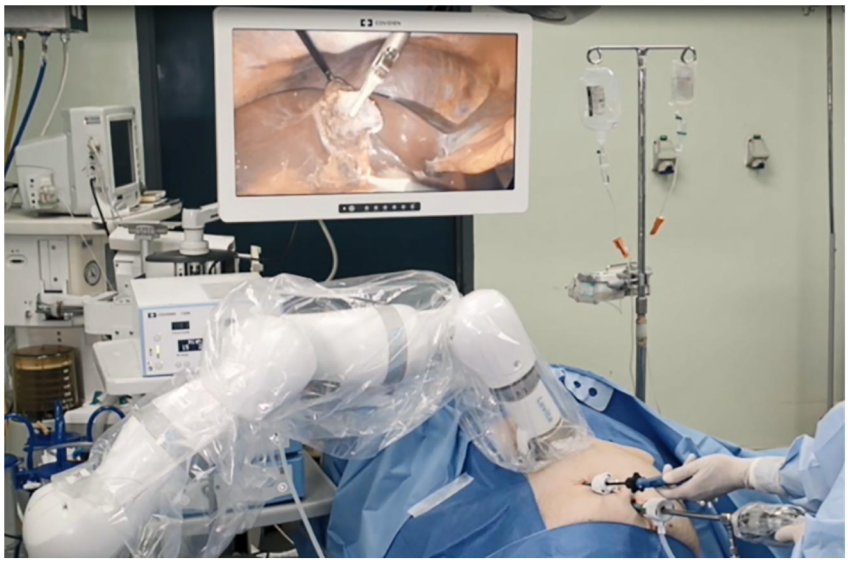

FIGURE 4 External view of the magnetic controller and internal view of the magnetic grasper

TABLE 1 Demographics and pre-operative information

Age (mean ± SD)	30.3 ± 9 years
BMI (median, kg/m^2) (IQR)	27 (20–34)
Female gender (*N*, %)	9 (90%)
Ethnicity: Hispanic (*N*, %)	10 (100%)
Previous abdominal surgery	
Caesarean section	2 (20%)
Inguinal hernia	1 (10%)
Indications for surgery	
Chronic cholecystitis	10 (100%)

Abbreviations: BMI, body mass index; IQR, interquartile range; N, Number; SD, standard deviation.

TABLE 2 Procedural details and outcomes

Successful laparoscopic approach (*N*, %)	10 (100%)
Operative time, minutes (median ± SD)	50 ± 11.8
Estimated blood loss (≤25 ml) (*N*, %)	10 (100%)
Average number of incisions (*N*)	3.0
Conversion (*N*, %)	0 (0%)
Length of stay (≤1 day) (*N*, %)	10 (100%)
Complications within 30 days (*N*, %)	0 (0%)

Abbreviations: N, number; SD, standard deviation.

2.9 | Data collection and statistical analysis

Data were collected prospectively including but not limited by; patient demographics, indications for surgery, operative times and post-operative recovery parameters such as; length of hospitalization, reoperation, operative complications and mortality. Continuous variables were presented as medians and range. Categorical data were presented as totals and percentages.

3 | RESULTS

Ten patients were included in this pilot study, nine were female. Patient's mean age was 30.3 ± 9 years and mean body mass index (BMI) was 27 (20–34 kg/m^2). Three patients had previous abdominal surgery including; two patients with previous caesarean section and one patient with prior inguinal hernia repair. All patients had a pre-operative diagnosis of chronic cholecystitis (Table 1).

All procedures were successfully completed using the laparoscopic approach and performed by a reduced-port technique with the robotically controlled magnetic grasper (three ports instead of four; one umbilical 10 mm and two 5 mm in each flank). The MSS enabled effective and efficient exposure of the gallbladder and critical structures as determined by the operating surgeons. No additional trocars were placed during the procedures to facilitate performance of the operation. No inadvertent metallic attractions occurred between the external magnet and unintended target devices or instruments. The median operative time was 50 ± 11 min and the estimated blood loss was (≤25 ml) in all cases (Table 2).

There were no complications or side effects related to the device. There was no interference with any other operating room (OR) equipment. All 10 patients were discharged the same day of the procedure. There were no readmissions or reoperations during the follow-up. Recovery was uneventful with follow-up visits at 7 and 30 days in all cases.

The learning curve for set-up and deployment by the operating room nursing team was short. After pre-operative teaching, preparation of the equipment and set-up was perceived to be simple and straight-forward. The mean time from start to introduction of Magnetic Gasper Device (MGD) was 10 minutes,[7–24] and the mean

TABLE 3 Devices performance

Magnetic grasper introduced time, min (mean, IQR)	10 (7–24)
Magnetic grasper position and release time, min (mean, IQR)	1 (1–2)
Magnetic grasper first coupled time, min (mean, IQR)	9 (1–65)
Magnetic grasper removed time, min (mean, IQR)	39 (21–57)
Number of locations on gallbladder for retraction/case (mean, %)	4 (100%)
Separate robotic arm move magnetic grasper times/case (mean, IQ)	8 (3–12)
Robotic arm—magnetic coupler decoupled successfully (*N*, %)	10 (100%)
No additional tools (*N*, %)	10 (100%)
Overall device malfunction (*N*, %)	0 (0%)

Abbreviations: IQR, interquartile range; N, number.

MGD position and release time was 1 (1–2 min). The mean MGD first coupled time was 9 (1–65 min), and the mean MGD removed time was 39 (21–57 min). The magnetic controller (MC) was mounted on the RA in all cases and controlled robotically. No unintentionally decoupling of the MGD to the RA-MC was reported during the study and no technical problems were observed with the MSS and RA as well (Table 3).

4 | DISCUSSION

LC is one of the most common operations performed worldwide and was the major procedure to usher in the laparoscopic era of the 1990s for general surgery. Recent studies have reported that 300 000 LC are performed annually in the United States.[13] The laparoscopic approach has resulted in significant improvements in post-operative outcomes in terms of less pain, reduction of complication rates, shorter hospital stays, faster recovery periods, improved cosmetic results as well as better patient acceptance.[14,15]

With improved outcomes after laparoscopic surgery and the improvement of instruments and technology, efforts have been focused on reducing the size and the number of instruments required to perform MIS procedures. This concept has been widely described as a 'reduced-port' or 'single-port' techniques.[16] Though logically this may be deemed beneficial, widespread adoption has been limited. This evolving process has been reported by different names including; single incision laparoscopic surgery, natural orifice transluminal endoscopic surgery [18,19] and more recently, RS applications.[6,7] RS has increased in multi-port and reduced-port MIS procedures in clinical practice; however, surgical limitations comprising internal and external instrument collision, limited working space suboptimal tissue retraction and prolonged operative times have been described.[20]

Despite that three-port LC and robotic single-port cholecystectomy are commonly performed worldwide, new technologies are underdevelopment to improve surgical outcomes. In our routine practice, we performed a four-port cholecystectomy and this modification presented in the manuscript resulted in a reduction in the invasiveness of our technique. Other surgeons could implement this technology in different ways to reduce the invasiveness of their specific approaches.

An innovative solution to the previous limitations has been proposed through the use of magnetic devices.[21,22] The implementation of this MSS with the external robotic arm allowed us to avoid additional trocar incisions during the surgical procedure, representing invasiveness. Port placements are potential causes of vascular injuries, organ perforation, post-operative pain, hernias and infections among other complications.

The concept of magnetic-assisted surgery was introduced and established to be safe, feasible and beneficial in abdominal procedures such as foregut surgery, prostate, weight loss surgery and colorectal surgery.[3,23–25]

In July 2017, Haskins et al. published their experience with 10 patients who underwent LC with the Levita™ MSS. The objective of this study was to detail the first United States experience with this FDA-approved surgical system. The mean age at the time of the study was 49 years and the average BMI was 27.6 kg/m^2. The average operative time reported was 64.4 min with no peri-operative complications. Seventy percent of the patients were discharged to home on the day of the surgery. Authors reported that the system was easy to use and provided adequate tissue retraction and exposure. Findings suggested the MSS was safe and feasible to use in patients undergoing LC.[3]

The largest known series of patients undergoing LC with the MSS had 50 cases; this prospective, multi-centre, open-label study was conducted to assess the safety and performance of the Levita™ MSS in LC. Results published by Rivas et al. in January 2018, showed that 45 women and 5 men were included in the study with an average age of 39 years and an average BMI of 27 kg/m^2. The procedures were successfully performed in all patients. Additionally, no device-related serious adverse events were reported. Participant surgeons rated as excellent (90%), on the exposure of the surgical site. This clinical trial presented this novel surgical system as a safe and effective alternative in reduced-port LC.[2]

Recently, Davalos et al. published their experience using a magnetic retractor (Levita™ MSS) in 10 patients undergoing laparoscopic colorectal procedures. The cases included four single-port right colectomies, one sigmoidectomy and five rectopexies. 90% of

the procedures were completed laparoscopically. Indications in this series included; adenocarcinoma, diverticular disease and rectal prolapse. The device was used for uterus, colon and colonic pedicle retraction with no difficulties. No intraoperative or 30-day complications were observed. Clinical outcomes advised magnetic surgical retractor is a safe, dynamic and incision-less option for surgical procedures in the field of colorectal surgery.[26]

Previous studies have shown that incisions and port placement are potential causes of vascular injuries, organ perforation, pain, inflammation, hernias, poor cosmetic results and infections among other post-operative complications.[27,28] In general, MS was designed to provide other advantages in comparison with other surgical platforms, based on reduced number of incisions and trocar placements. This technology might offer restoration of triangulation, improved tissue and organ mobilization outside of the rotatability of a fixed trocar, and a reduced number of incisions and trocars as a result of the nature of the magnetic coupling across the surgical filed.

The present study reports on the first human experience using the MSS simultaneously with a device-specific surgical robot. The MRC was developed to optimize the previous platform and increase the surgeon control by combining magnetic and robotic technologies. This series is the first experience that evaluates the combination of magnetic and robotic technologies in one integrated system used for patients undergoing LC. This series demonstrates that this new concept is feasible in select patients, without complication or side effects. Importantly, no MMS and RA malfunctions were reported.

It is important to note that unique and specific preparations need to be made in anticipation of performing MS. The operating surgeon and OR staff need to be trained in specific handling of the magnet, including avoiding other metallic objects that could inadvertently be attracted to the magnet. This includes objects in the sterile field, such as instruments, or other equipment in the operating room during set-up. Also, coupling of the intra-abdominal grasper to the external magnet does require some experience, and can be more challenging in patients with thick abdominal or chest walls. In our experience, the skill of coupling was quickly learned and patient positioning or angle of retraction can overcome challenges associated with larger physical body habitus.

Future directives in larger studies will focus on generalizability to surgeons who have not previously used magnetic surgical technologies, with focus on possible outcomes such as; reduced complication rates, less pain post-operative, faster recovery and improved patient satisfaction while maintaining efficient use of healthcare resources.

As any prospective study evaluating new surgical devices and applying new technologies, this study has limitations. The trial is uncontrolled, authors were subject to selection bias and the surgeons have had previous MS experience, potentially limiting generalizability to their general surgeons. No objective measure of pain in terms of quantified analgesic use or visual-analogue scale were used and patients were not surveyed afterwards about their perception of the technique.

Our data suggest that the system is safe with patients with BMI below 35, though further data will be needed to validate these findings in patients with BMI over 35. No contact or direct pressure injuries at the device contact point with the peritoneum occurred. In this series, we had no skin injuries during the procedures, however, further studies are needed to validate our initial observations. Careful examination of the peritoneal surface during these procedures, as well as with other procedures, including bariatric surgery, with magnetic and without robotic control have not shown any injury.

In our initial experience, there were no bile leaks during the laparoscopic cholecystectomies using this novel surgical system. We might anticipate similar rates in comparison with the standard technique.

This early work may lay the groundwork for future studies of this new combined platform (MS and RS) and a range of clinical application of this new concept. Nonetheless, potential benefits should be evaluated in further studies for validation as well as cost/benefit analysis, to verify that the adoption of this new concept is warranted.

The robotic platform and MS system are commercially available at limited centres in the United States of America and Chile. Due to the relatively small production and high variability in production costs, as well as, contract negotiations varying from institution to institution, a standard cost for the device has not yet been established.

In conclusion, this first in-human study demonstrates the feasibility of combining magnetic and robotic technologies into one integrated system. Potential benefits of this system may include reduced invasiveness and increased surgeon control. This proof-of-concept human study opens new opportunities in the evolution of surgical technique with new applications of magnetics and robotics.

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CONFLICT OF INTEREST

Drs. Barajas-Gamboa, Huidoro, Jensen, Luengas, Rodriguez, Abril and Corcelles have no conflict of interests or financial ties to disclose. Dr. Kroh reported participation in those grants during the conduct of the study.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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