

# Magnetic Surgery

## Results From First Prospective Clinical Trial in 50 Patients

Homero Rivas, MD, MBA, FACS, FASMBS,\* Ignacio Robles, MD,† Francisco Riquelme, MD,‡  
Marcelo Vivanco, MD,§ Julio Jiménez, MD,‡ Boris Marinkovic, MD,† and Mario Uribe, MD†

**Objective:** To evaluate a new magnetic surgical system during reduced-port laparoscopic cholecystectomy in a prospective, multicenter clinical trial.

**Background:** Laparoscopic instrumentation coupled by magnetic fields may enhance surgeon performance by allowing for shaft-less retraction and mobilization. The movements can be performed under direct visualization, generating different angles of traction and reducing the number of trocars to perform the procedure. This may reduce well-known associated complications of trocars, including incisional pain, scarring, infection, bowel, and vascular injuries, among others.

**Methods:** A prospective, multicenter, single-arm, open-label study was performed to assess the safety and performance of a magnetic surgical system (Levita Magnetics' Surgical System). The investigational device was used during a 3-port laparoscopic technique. The primary endpoints evaluated were safety and feasibility of the device to adequately mobilize the gallbladder to achieve effective exposure of the targeted surgical site. Patients were followed for 30 days postprocedure.

**Results:** Between January 2014 and March 2015, 50 patients presenting with benign gallbladder disease were recruited. Forty-five women and 5 men with an average age of 39 years (18–59), average body mass index of 27 kg/m<sup>2</sup> (20.4–34.1) and an average abdominal wall thickness of 2.6 cm (1.8–4.6). The procedures were successfully performed in all 50 patients. No device-related serious adverse events were reported. Surgeons rated as “excellent” (90%) or “sufficient” (10%) the exposure of the surgical site.

**Conclusions:** This clinical trial shows that this new magnetic surgical system is safe and effective in reduced-port laparoscopic cholecystectomy.

**Keywords:** clinical trial, innovation, magnetic surgery, new technology

(*Ann Surg* 2018;267:88–93)

Open cholecystectomy was the standard treatment for symptomatic cholelithiasis until the early 1990s, when 4-port laparoscopic cholecystectomy began its rapid adoption.<sup>1,2</sup> Laparoscopic

cholecystectomy resulted in a significant decrease in surgical trauma and improvement of patient outcomes, including less pain, an overall decrease in rate of complications, shorter hospitalizations, improved cosmetic results, better patient acceptance, and faster recovery periods.<sup>2,3</sup> Perhaps more importantly, this has resulted in a better quality of life for patients and also in substantial savings for health care systems, with added benefits to society.<sup>4,5</sup>

Even after the wide adoption of laparoscopic surgery and its benefits, access techniques continued to evolve in the search for technologies that allow us to perform even less invasive procedures, and thus minimizing surgical damage to the patient.<sup>6,7</sup> Efforts have taken place to reduce the size and number of all surgical instruments required for a given operation to reduce the number and size of incisions (broadly described as *reduced-port techniques*). Although reducing the number of ports might seem very appealing, this can represent demanding technical challenges, as this increases the difficulty of performing any surgery.<sup>6,7</sup> The capability of triangulation is usually compromised; especially on reduced-port techniques and internal and external instrument clashing impairs the technical capability of any surgeon.<sup>8</sup> In general, limited instrumentation may lead to inadequate visualization and poor organ mobilization, which may increase the risk for iatrogenic injury, the difficulty of the procedure, and prolong operating times, among other problems that result in poor outcomes.<sup>9,10</sup>

There have been significant efforts to solve such challenges, such as needle-sized instruments, percutaneous sutures, and even internal retractors.<sup>11–14</sup> Most of these solutions are, however, cumbersome, fragile and are static solutions in a dynamic environment that requires simple and reliable mobility. Moreover, such instrumentation may lead to organ perforation, with another subset of potential and severe complications.<sup>15</sup> This combination of factors results in important constraints and limitations for reduced-port surgery.

The present study evaluates an innovative solution to this challenge through the use of magnetic devices that are coupled and mobilized by external magnetic fields through the abdominal wall. Previously, the potential of magnetic instrumentation was proposed in preliminary studies using different types of prototypes.<sup>16–19</sup> In general, this type of technology might offer great advantages including restoring of triangulation, improved tissue and organ mobilization, and a decreased need for trocars due to the nature of the magnetic coupling across the abdominal wall. Although performing a conventional laparoscopy using a reduced number of trocars would face important constraints, the use of magnetically coupled instrumentation can elegantly overcome these challenges. The Magnetic Surgical System is intended to facilitate tissue grasping, retraction, and mobilization during laparoscopic surgery.

The purpose of the present study was to evaluate the safety and feasibility of this novel Magnetic Surgical System within a prospective clinical trial using reduced-port laparoscopic cholecystectomy procedures.

From the \*Stanford University School of Medicine, Stanford, CA; †Hospital Salvador, Santiago, Chile; ‡Hospital Luis Tisne, Santiago, Chile; and §Hospital Padre Hurtado, Santiago, Chile.

www.clinicaltrials.gov (registration number: NCT02049983).

This study was supported by CORFO grant 13IEAT-20911 and sponsored by Levita Magnetics Corp.

Disclaimer: The authors report no conflicts of interest.

This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.annalsofsurgery.com).

Reprints: Homero Rivas, MD, MBA, FACS, FASMBS, Stanford University School of Medicine, 300 Pasteur Dr, H3680H, Stanford, CA 94305.

E-mail: hrivas@stanford.edu.

Copyright © 2016 The Author(s). Published by Wolters Kluwer Health, Inc.

ISSN: 0003-4932/16/26701-0088

DOI: 10.1097/SLA.0000000000002045



**FIGURE 1.** Magnetic Surgical System compose by the detachable magnetic grasper and the external magnet. Copyright Levita Magnetics.

## METHODS

From January 2014 until March 2015, a prospective, multi-center, single-arm, open-label study was conducted to assess the safety and feasibility of the Magnetic Surgical System during laparoscopic cholecystectomies. The Magnetic Surgical System developed by Levita Magnetics Corp. (San Mateo, CA) has received the CE Mark and has been cleared for commercialization by the Food and Drug Administration.

The system comprises an external magnet and a grasper with a detachable grasper tip and handle (Fig. 1). The external magnet is a cylinder that has a diameter of 8 cm and the detachable grasper tip is 6.5 cm long with a diameter of 1 cm. The Magnetic Grasper Device is compatible with a  $\geq 10$  mm laparoscopic port. The magnetic grasper assembly delivers and applies the detachable grasper tip to the gallbladder. Gently squeezing the handle, the internal mechanism releases the detachable tip. The handle is then removed, leaving the introduction port available for use by another procedural instrument. With the detachable grasper tip secured to the organ, the external magnet is placed over the abdominal wall and a magnetic attraction is achieved with the detachable tip (Fig. 2). The external magnet can then be freely moved, facilitating unconstrained shaftless tissue retraction and mobilization. Under direct visualization, the desired retraction of the gallbladder can be obtained by mobilizing the external magnet. The usual position of the external magnet is on top of the right upper quadrant. At the end of the procedure, the detachable grasper tip is decoupled from the external magnet, reconnected to the handle and removed from the patient.

Patients presenting with benign gallbladder disease and who were eligible for laparoscopic cholecystectomy were potential candidates for the present study. The exclusion criteria can be summarized in: presence of metallic implants, biliary diseases other than gallstones or polyps, severe comorbid diseases, and contraindication to laparoscopic surgery. (Detailed table of inclusion and exclusion criteria in Appendix 1, <http://links.lww.com/SLA/B125>). Three



**FIGURE 2.** Representation of the system use during surgery. Left: External magnet on the patient right hypocomdrium. Right: Internal grasper attached to gallbladder and coupled with external magnet performing retraction. Copyright Levita Magnetics.

different hospitals in Santiago, Chile, were part of the present study. Principles of Good Clinical Practice and the International Ethical Guidelines for Biomedical Research Involving Human Subjects were strictly followed. The present study was registered on [clinicaltrials.gov](http://clinicaltrials.gov) in January 2014, before the enrollment of patients (NCT02049983). The study was approved by the associated local Ethics Committees and written informed consent was obtained from all participants before enrollment. All participants were expected to undergo postoperative pain evaluation and rate their overall satisfaction with the procedure. The magnetic surgical system was used on study patients during a laparoscopic cholecystectomy procedure with a 3-port laparoscopic technique. The primary endpoints evaluated were safety and feasibility outcomes.

Safety was defined as (1) there is no evidence of a Device Failure defined as device breakage or other malfunction requiring additional surgical intervention, including reoperation and/or device removal and (2) there is no serious adverse event probably or definitely related to the device resulting in: (a) revision/removal of the device, (b) permanent damage to the organ (ie, perforation of the surrounding organs), and/or (c) death of the study subject. Feasibility was defined as the ability of the device to adequately mobilize the gallbladder to achieve effective exposure of the targeted surgical site. The ability to adequately mobilize the gallbladder was defined as the retraction needed to achieve an effective exposure of the cystohepatic triangle (triangle of Calot). In addition, feasibility would be considered a “failure” if during the procedure it was necessary to use another trocar to insert another instrument to mobilize the gallbladder. Patients were followed for 30 days post-procedure, with follow-up visits at hospital discharge and at 7 and 30 days postprocedure.

All adverse events were reported and the principal investigator determined the adverse event severity and the relation of each adverse event to the device. An independent and external Medical Monitor reviewed all adverse events. All surgeries were digitally recorded for postprocedure analysis if needed.

Other measured variables were abdominal wall thickness using ultrasound; preoperative body mass index; operation time (time from the first incision to the last suture’s placement); device use times (time between grasper introduction and correct position and release, time between correct position and coupling with the external magnet, and total time of coupling between the internal grasper and the external magnet); damage or breakage of the detachable grasper; inner evaluation of the abdominal wall observed at 15-minute intervals throughout the procedure; time spent in the postanesthesia care unit; length of stay (time from postanesthesia care unit admission until discharge); perioperative pain as measured on a scale of 0 to 10 (preoperative baseline), 3, 6, and 24 hours postoperatively and at 7 and 30 days postoperatively; pain medication until hospital discharge; need of additional port (3-port to 4-port); operative blood loss; umbilical incisional length; rate of port site hernia; patient satisfaction (evaluated with a patient survey at the 30-day follow-up visit); and time to return to work. Lastly, ease of device use was measured by a surgeon’s assessment during the immediate postoperative period. All data were analyzed on a per the protocol basis.

## RESULTS

Fifty patients with benign gallbladder disease (cholelithiasis or gallbladder polyps) were recruited to be part of the present study. Twenty-five subjects were enrolled at Hospital Del Salvador, twenty one subjects at Hospital Tisne, and four subjects at Hospital Padre Hurtado. All subjects provided written informed consent before their study enrollment.

**TABLE 1.** Baseline Patient Characteristics

Attribute	Result
Sex	
Female	45
Male	5
Age (years)	
Average (SD)	39 (12.4)
Minimum	18
Maximum	59
BMI (kg/m <sup>2</sup> )	
Average (SD)	27.0 (3.6)
Minimum	20.4
Maximum	34.1
Indication for surgery	
Gallbladder Stones	43
Gallbladder Polyps	7
Ultrasound assessments	
Gallbladder thickness (mm)—average, SD	1.8 (0.5)
Abdominal wall thickness (cm)	
Average (SD)	2.6 (0.6)
Minimum	1.8
Maximum	4.6

BMI indicates body mass index; SD, standard deviation.

Forty-five patients were women and the average body mass index was 27.0 kg/m<sup>2</sup>, with a range of 20.4 to 34.1 kg/m<sup>2</sup>. Forty-three subjects had a cholecystectomy procedure due to the presence of gallbladder stones and 7 subjects were indicated for surgery due to gallbladder polyps. Preprocedure ultrasound assessments showed an average gallbladder thickness of 1.8 mm and an average abdominal wall thickness of 2.6 cm, with a range of 1.8 to 4.6 cm. (Table 1) Average preprocedure pain was 0.2 on a scale of 0 to 10, where 0 = “no pain.” Three subjects required prescription medication for pain control before the procedure.

The intraoperative and immediate postoperative results are summarized in Table 2. All 3 trocars were placed at the start of the procedure in the usual position, omitting the right upper quadrant lateral port. The magnetic grasper was introduced through the 10 mm trocar port pursuant to the device instructions and always under direct visualization. In all 50 cases, the cholecystectomy procedure was performed using 3 ports instead of the conventional 4-port technique. In 1 procedure, an additional trocar was placed at the end of the procedure after successful use and final retrieval of the magnetic grasper device. In this patient, extraction of the gallbladder through the umbilical port resulted in internal spilling of gallstones into the abdominal cavity, requiring this additional 10 mm trocar port to assist in retrieval of the stones. This trocar was placed after use of the Magnetic Surgical System was complete and was removed from the abdomen. No procedures required conversion to an open surgical approach.

The total procedure time averaged 63 minutes. The total time that the detachable grasper tip was in the abdomen averaged 36 minutes. The total time that the grasper tip was coupled with the external magnet averaged 34 minutes. No damage or breakage of the detachable grasper was observed in any of the 50 cases. No device malfunctions were reported. The surgeons reported that the device was easy to use in all cases and rated the quality of exposure as “excellent” in 45 cases and “sufficient” in 5 cases. Figure 3 shows a typical exposure obtained with the device. Estimated blood loss was reported in 32 cases with an average estimated blood loss of 11 mL. Bile spillage was reported in 6 cases with an average estimated volume of 39 mL, none of the cases related to the device. Subjects remained in the hospital postprocedure for an average of 22 hours.

**TABLE 2.** Intraoperative and Immediate Postoperative Results

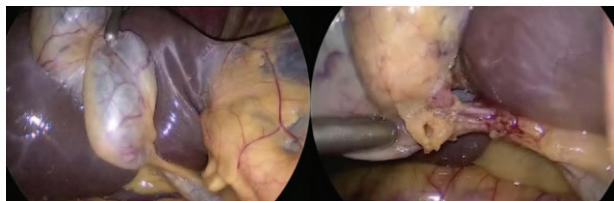
Attribute	Outcome
Umbilical incision size (mm)—average	10.1
Grasper application times (sec)	
Time between grasper introduction and correct position and release—average (SD)	23 (19)
Time between correct position and coupling with external magnet—average (SD)	50 (60)
Procedure times (min)	
Overall procedure time—average (SD)	63 (19)
Grasper times (min)	
Time magnetic grasper in abdomen—average (SD)	36 (0:12)
Time magnetic grasper coupled with magnetic controller—average (SD)	34 (0:12)
Device ease of use	
Yes	50
No	0
Quality of exposure	
Excellent	45
Sufficient	5
Insufficient	0
Device malfunctions	
Yes	0
No	50
Conversions (%)	
Open surgery	0
Four (4)-port surgery	1*
Estimated blood loss (mL)	
Number of subjects with blood loss	32
Average within all subjects (SD), n = 50	7 (11)
Average within subjects with blood loss (SD), n = 32	11 (11)
Estimated bile spilled (mL)	
Number of subjects with bile spilled	6
Average within all subjects (SD), n = 50	5 (18)
Average within subjects with bile spilled (SD), n = 6	39 (41)
PACU Time (min)—average (SD)	137 (58)
Pain scores	
0 Hours postprocedure—average (min, max), n = 48	1.0 (0, 6)
3 Hours postprocedure—average (min, max), n = 50	1.8 (0, 8)
6 Hours postprocedure—average (min, max), n = 50	1.5 (0, 6)
At discharge—average (min, max), n = 50	1.3 (0, 4)
External abdominal wall evaluation (at 6 hours postop)	
Normal	50
Redness	0
Bruising	0
Other	0

\*Converted after the use of device was complete.

PACU indicates postanesthesia care unit; SD, standard deviation.

The average pain score decreased as the postprocedure time increased from 3 hours to discharge. The abdominal wall was qualitatively evaluated before discharge. A qualitatively “normal” appearance of the abdominal wall directly in contact with the external magnet was reported in all cases at 6 hours after the surgery.

No major complications related to the device were reported. In 19 patients (38%), very mild internal petechiae, presumed to be related to the device, was observed during the procedure. In only 1 patient a mild external petechiae presumed related to the device at the end of the procedure was observed. In all cases, the petechiae appeared to resolve, because there was a normal external appearance



**FIGURE 3.** Typical exposure obtained using the Magnetic Surgical System. Copyright Levita Magnetics.

of the abdominal wall and lack of pain present at those affected sites during follow-up physical examination. Three serious adverse events were reported in 2 subjects. None were deemed to be device-related by the Principal Investigator or the independent external Medical Monitor who reviewed the cases. These events included a subcapsular hematoma, subcutaneous emphysema, and an extrahepatic biloma (these 2 last events in the same patient). The subject with the subcapsular hematoma received medical treatment, required no further intervention, and was discharged in good condition. The subject with the biloma required external drainage under ultrasound guidance with subsequent endoscopic retrograde cholangiopancreatography. The subcutaneous emphysema resolved spontaneously. Both subjects did well without further problems at follow-up.

The results from the follow-up visits are summarized in Table 3. During the first follow-up visit at 7 days postprocedure, subjects reported negligible pain with an average pain score of 0.6. When asked whether the patient would have the same treatment for the same outcome, 48 subjects noted that they definitely would, 1 subject definitely would not, and 1 subject stated that they were not sure. Only 2 subjects noted the current use of pain medication during the first follow-up visit.

During the second follow-up visit at 30 days postoperatively, subjects reported an average pain score of 0. When asked if the patient would have the same treatment for the same outcome, 47 subjects noted that they definitely would, 1 noted that they probably would, 1 noted that they were not sure, and 1 noted that they definitely would not. No port-site hernias were reported in any subject at either follow-up period. No subjects reported the current use of pain medication at the 30-day follow-up visit. Of the 33 patients who were working at the time of the study, the average time to return to work was 5.0 days.

The results met the prospectively outlined criteria for the primary safety endpoint for the present study. Specifically, there was no evidence of device failure at all, including device failure requiring additional surgical intervention, including reoperation and/or device removal, and there were no serious adverse events related to the device.

The device performance results met the prospectively outlined criteria for the primary performance endpoint for the present study. Specifically, this endpoint was met as in all cases the device was able to adequately mobilize the gallbladder to achieve an effective exposure of the target tissue. In addition, no additional trocars were placed to insert another instrument to mobilize the gallbladder.

It is important to describe that the device was used in a standard operating room with conventional electrosurgical equipment and no device malfunctions or equipment interference were reported.

## DISCUSSION

The results of this prospective clinical trial describe the safety and effectiveness of the Levita Magnetic Surgical System. The

**TABLE 3.** Follow-up Results

Attribute	7 Days Postop	30 Days Postop
Pain scores		
Average (Min, Max)	0.6 (0, 5)	0.0 (0, 2)
Incisional hernia		
Absent	50	50
Subject satisfaction		
Definitely Yes	48 (96%)	47 (94%)
Probably Yes	0	1 (2%)
Not Sure	1 (2%)	1 (2%)
Probably Not	0	0
Definitely Not	1 (2%)	1 (2%)
Pain medications		
Yes	2	0
No	48	50

results show that this new system can be used in laparoscopic cholecystectomy procedures in a safe and effective manner. The system can be used to facilitate reduced-port cholecystectomy procedures in an approach that provides adequate exposure and mobilization of the target tissue.

The results of the present work showed that magnetic surgery is potentially a solution to a central challenge that prevents the advance of modern endoscopic surgery: maintaining effective triangulation while reducing the number of ports. The objective is to improve patient outcomes, reduce complications, speed recovery, increase quality of life, and use resources efficiently. In this context, it is accepted that the incisions in the abdominal wall for the entry ports are a major factor in the patient's injury from the surgical procedure and the direct cause of multiple potential complications. Incisions and port placements are the source of vascular punctures, organ perforation, pain, inflammation, infections, hernias, and inadequate cosmetic results (scars) among other undesired results.<sup>3,20</sup>

Trocar-related injuries are the most common source of malpractice injury claims associated with laparoscopic procedures. Those associated with mortality are usually the result of puncturing of major vascular structures or organ perforation.<sup>20</sup> More frequently, and with much less morbidity, are punctures of the abdominal wall that result in trocar-related unintentional small vessel bleeding. Although the latter infrequently represent a cause of major complication, they usually become a cause of unintended interruptions during surgery, resulting in prolonged operating times and increased postoperative pain.

The only device-related complication identified in the present study was that 38% of patients had mild internal petechiae present at the coupling site. Moreover, in preliminary preclinical studies, we have searched for any microscopic tissue changes at the same coupling areas along the abdominal wall and found the changes were almost nil, especially when compared with the macroscopic and microscopic tissue changes at the abdominal wall trocar entry site, which mainly include extensive necrosis, inflammation, and fibrosis.<sup>21</sup>

It is well accepted that postoperative pain is mainly generated in the surgical incisional site where there is an activation of peripheral neuroreceptors and liberation of pain mediators.<sup>3,22</sup> Incisional pain is also associated with the need for analgesic drugs and all the complications associated with the use of these compounds. Pain is a determining factor in the time that a patient would resume normal activities after surgery; therefore, less incisional trauma results in less pain, better quality of life, and a faster recovery.<sup>3</sup> In the present study, the use of this new technology resulted in low postoperative pain

scores, high patient satisfaction (94%–96%), which aligned well with a short period of time to return to work.<sup>22,23</sup> Further clinical trials are warranted to evaluate these parameters in more detail.

Finally, scarring has been shown to have a direct link to the patient's physical and emotional health as related to their quality of life.<sup>24,25</sup> Patients prefer surgical techniques that leave less visible scarring.<sup>26,27</sup> For many, the final appearance of the resulting scar represents a very important determinant factor that correlates with their overall satisfaction of the surgical experience.<sup>28</sup> Even more, there are studies that show that patients are willing to change hospitals to receive the treatment and pay a higher financial contribution to have a less scarring procedure.<sup>29</sup> This issue continues to take more relevance as increasing attention to a satisfactory surgical patient experience is being considered as centerpiece of an optimal outcome.<sup>24,30</sup>

With all the complications and benefits described above, why are reduced-port techniques not massively adopted? Because of a reduction in the number of entry ports, the reduced-port technique poses several major technical challenges even in the hands of very experienced surgeons. Namely, triangulation is reduced, range of motion becomes restricted, there is a contraction in the surgical work space, effective retraction and exposure are diminished, and the lack of depth perception leads to instrument crowding, which is described as the “chopstick effect.” Transparietal sutures and other external retractions to suspend the gallbladder in an effort to improve exposure have been tried. This contradicts the very idea of “mobile” exposure, not to mention that the anchoring of the gallbladder onto the abdominal wall may prevent the surgeon from moving the Hartmann's pouch when attempting to expose the targeted tissue, inadvertently increasing postoperative complications. In recent years, robotic technology has been proposed in reduced-port techniques; however, this has not lead to improved results for the patients. In addition, robotic platforms have economical constraints that are evident with the limited presence of units worldwide, preventing universal adoption of these techniques.

Magnetic surgery technologies might overcome some of the challenges inherent in reducing the number of ports while avoiding the problems that current attempts might impose on the surgeons. The Levita Magnetic Surgical System assessed in this work was able to reduce the number of ports needed to adequately perform retraction, conserve triangulation, and generate an adequate surgical area in a safe and efficient way. The system was evaluated as easy to use and the time to grasp the organ and connect with the external magnet was, on average, less than 30 and 60 seconds, respectively. These features might affect in its clinical adoption, as easy-to-use devices with a clear clinical benefit have a higher adoption rate.<sup>31</sup> The average overall procedure time was 63 minutes and the coupling time between the magnetic controller and the detachable grasper was 34 minutes. These times are reasonable in comparison with described times for conventional 4-port gallbladder removal. Future studies should focus on evaluating the effect of magnetic technologies in overall procedure time.

This technology represents a “shaft-less” device; therefore, any potential clashing of instrument shafts would be less likely. This could also improve visualization in procedures in which the long shaft of instruments might interfere with the visual field of the surgeon. Another potential benefit, besides the reduction of invasiveness for the reduction of ports, is the potential increase in mobility that this new technology can bring. Throughout the years, either based on an anatomical location or based on a trial-and-error experience in laparoscopic surgery, surgeons have learned where to optimally place trocars for a given surgical procedure. Some variations of trocar placement are prevalent, yet many of them have standardized placements. Limited by its entry point, a

poorly placed trocar may, however, have many inherent limitations of access and ergonomics, even requiring a new placement. These challenges are greatly avoided by this novel technology, as it is not constrained by the fixed entry location. Furthermore, being able to generate different and easily changeable angles of traction can be very valuable in some clinical conditions. Nevertheless, all the potential benefits mentioned would require future studies of the cost/benefit ratio, to confirm that the adoption of this new technology is justified.

In summary, for the first time, in a prospective clinical trial, the feasibility and safety of a magnetic surgical system has been demonstrated. The potential benefits are a reduction in the invasiveness of the procedure, with a better capability of the surgeon to achieve desired movements during the procedure. These expanded surgical capabilities could result in better procedures with better patient outcomes. This pivotal study opens the potential for the development of a magnetic platform and a wide range of clinical applications of this new technology. The present study provides a foundation for the clinical beginning of Magnetic Surgery.

## ACKNOWLEDGMENTS

*The authors thank all those who contributed in this clinical trial, without their help and commitment it could not have been completed: Alex Escalona, MD and all the personnel of the Surgical Departments in Hospital Salvador, Tisne and Padre Hurtado. Special thank to Tamara de la Barra as the main research nurse.*

## REFERENCES

- Allori AC, Leitman IM, Heitman E. Delayed assessment and eager adoption of laparoscopic cholecystectomy: implications for developing surgical technologies. *World J Gastroenterol.* 2010;16:4115–4122.
- Keus F, De Jong J, Gooszen H, et al. Laparoscopic versus open cholecystectomy for patients with symptomatic cholelithiasis. *Cochrane Database Syst Rev.* 2006;4:1–81.
- Bisgaard T, Kehlet H, Rosenberg J. Pain and convalescence after laparoscopic cholecystectomy. *Eur J Surg.* 2001;167:84–96.
- Lengyel BI, Panizales MT, Steinberg J, et al. Laparoscopic cholecystectomy: what is the price of conversion? *Surg (United States).* 2012;152:173–178.
- Fullarton GM, Darling K, Williams J, et al. Evaluation of the cost of laparoscopic and open cholecystectomy. *Br J Surg.* 1994;81:124–126.
- Shussman N, Schlager A, Elazary R, et al. Single-incision laparoscopic cholecystectomy: lessons learned for success. *Surg Endosc.* 2011;25:404–407.
- Ross S, Rosemurgy A, Albrink M, et al. Consensus statement of the consortium for LESS cholecystectomy. *Surg Endosc.* 2012;26:2711–2716.
- Eisenberg D, Vidovszky TJ, Lau J, et al. Comparison of robotic and laparoendoscopic single-site surgery systems in a suturing and knot tying task. *Surg Endosc.* 2013;27:3182–3186.
- Carter JT, Kaplan JA, Nguyen JN, et al. A prospective, randomized controlled trial of single-incision laparoscopic vs conventional 3-port laparoscopic appendectomy for treatment of acute appendicitis. *J Am Coll Surg.* 2014;218:950–959.
- Ahmed I, Burr J, Castillo M, et al. Single port/incision laparoscopic surgery compared with standard three-port laparoscopic surgery for appendectomy: a randomized controlled trial. *Surg Endosc Other Interv Tech.* 2015;29:77–85.
- Steinemann DC, Limani P, Clavien P-A, et al. Internal retraction in single-port laparoscopic cholecystectomy: initial experience and learning curve. *Minim Invasive Ther Allied Technol.* 2013;22:171–176.
- Kotzampassakis N, Machairas N, Clanet M, et al. Initial experience of single-port surgery assisted by percutaneous instruments for gastric bypass: a combination of safety and minimally invasive surgery. *Obes Surg.* 2013;23:267–271.
- Tian M, Zhang P, Yang Y, et al. Two-port laparoscopic cholecystectomy with modifieduture retraction of the fundus: a practical approach. *J Minim Access Surg.* 2013;9:122–125.
- Chang J, Boules M, Rodriguez J, et al. Minilaparoscopy with interchangeable, full 5-mm end effectors: first human use of a new minimally invasive operating platform. *J Laparoendosc Adv Surg Tech.* 2016;26:1–5.

15. Allemann P, Schafer M, Demartines N. Critical appraisal of single port access cholecystectomy. *Br J Surg*. 2010;97:1476–1480.
16. Park S, Bergs RA, Eberhart R, et al. Trocar-less instrumentation for laparoscopy: magnetic positioning of intra-abdominal camera and retractor. *Ann Surg*. 2007;245:379–384.
17. Cadeddu J, Fernandez R, Desai M, et al. Novel magnetically guided intra-abdominal camera to facilitate laparoendoscopic single-site surgery: initial human experience. *Surg Endosc*. 2009;23:1894–1899.
18. Morgan M, Olweny EO, Cadeddu JA. LESS and NOTES instrumentation: future. *Curr Opin Urol*. 2014;24:58–65.
19. Dominguez G, Durand L, De Rosa J, et al. Retraction and triangulation with neodymium magnetic forceps for single-port laparoscopic cholecystectomy. *Surg Endosc*. 2009;23:1660–1666.
20. Fuller J, Ashar BS, Carey-Corrado J. Trocar-associated injuries and fatalities: an analysis of 1399 reports to the FDA. *J Minim Invasive Gynecol*. 2005;12:302–307.
21. Rodríguez-Navarro AJ, Rivas H, Robles I, et al. Novel magnetic device that enables and facilitates reduced-port surgery. [SAGES 2014 abstract archive web site]. Available at: <http://www.sages.org/meetings/annual-meeting/abstracts-archive/new-magnetic-device-that-enables-and-facilitates-reduced-port-surgery/>. Published 2014. Accessed May 16, 2016.
22. Rodríguez-Navarro AJ, Berde CB, Wiedmaier G, et al. Comparison of neosaxitoxin versus bupivacaine via port infiltration for postoperative analgesia following laparoscopic cholecystectomy. *Reg Anesth Pain Med*. 2011;36:103–109.
23. Bulian DR, Knuth J, Cerasani N, et al. Transvaginal/transumbilical hybrid—NOTES—versus 3-trocar needlescopic cholecystectomy. *Ann Surg*. 2015;261:451–458.
24. Lurje G, Raptis DA, Steinemann DC, et al. Cosmesis and body image in patients undergoing single-port versus conventional laparoscopic cholecystectomy: a multicenter double-blinded randomized controlled trial (SPOCC-trial). *Ann Surg*. 2015;262:728–735.
25. Brown BC, McKenna SP, Siddhi K, et al. The hidden cost of skin scars: quality of life after skin scarring. *J Plast Reconstr Aesthet Surg*. 2008;61:1049–1058.
26. Golkar FC, Ross SB, Sperry S, et al. Patients' perceptions of laparoendoscopic single-site surgery: the cosmetic effect. *Am J Surg*. 2012;204:751–761.
27. Lee DH, Nam SH, Song T, et al. Public perception of “scarless” laparoendoscopic single-site surgery in gynecology. *Obstet Gynecol Sci*. 2015;58:289–293.
28. Park SK, Olweny EO, Best SL, et al. Patient-reported body image and cosmesis outcomes following kidney surgery: comparison of laparoendoscopic single-site, laparoscopic, and open surgery. *Eur Urol*. 2011;60:1097–1104.
29. Fransen SA, Broeders E, Stassen L, et al. The voice of Holland: Dutch public and patient's opinion favours single-port laparoscopy. *J Minim Access Surg*. 2014;10:119–125.
30. Hartzband P, Groopman J. Untangling the web—patients, doctors and the Internet. *N Engl J Med*. 2010;362:1063–1066.
31. Wilson CB. Adoption of new surgical technology. *BMJ*. 2006;332:112–114.