

Novel magnetically guided intra-abdominal camera to facilitate laparoendoscopic single-site surgery: initial human experience

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Abstract

Background Magnetic anchoring guidance systems (MAGS) are composed of an internal surgical instrument controlled by an external handheld magnet and do not require a dedicated surgical port. Therefore, this system may help to reduce internal and external collision of instruments associated with laparoendoscopic single-site (LESS) surgery. Herein, we describe the initial clinical experience with a magnetically anchored camera system

used during laparoscopic nephrectomy and appendectomy in two human patients.

Methods Two separate cases were performed using a single-incision working port with the addition of a magnetically anchored camera that was controlled externally with a magnet.

Results Surgery was successful in both cases. Nephrectomy was completed in 120 min with 150 ml estimated blood loss (EBL) and the patient was discharged home on postoperative day 2. Appendectomy was successfully completed in 55 min with EBL of 10 ml and the patient was discharged home the following morning.

Conclusions Use of a MAGS camera results in fewer instrument collisions, improves surgical working space, and provides an image comparable to that in standard laparoscopy.

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A new alternative to conventional laparoscopy is laparoendoscopic single-site (LESS) surgery. LESS procedures utilize conventional as well as angled and articulating instrumentation introduced through either adjacent conventional trocars or a specialized multilumen port. In addition to clear benefits in terms of cosmesis, other possible advantages of LESS surgery compared with conventional laparoscopy include less postoperative pain, faster recovery, less adhesion formation, and improvements in short-term measures of convalescence. Early clinical series have demonstrated the feasibility, as well as the safe and successful completion, of several LESS procedures [1–8].

However, LESS procedures are significantly challenged by limited instrument triangulation capabilities, narrow visual field through conventional laparoscopes or endoscopes, and both internal and external instrument collisions that can considerably limit surgeon performance and possibly procedure safety.

To overcome the limitations imposed by fixed trocar technology, LESS procedures, and natural orifice transluminal surgery (NOTES), we have developed, in prototype, a novel adjunct laparoscopic concept known as the magnetic anchoring and guidance system (MAGS). This consists of a moveable magnet- or needle-lockable platform that is positioned intra-abdominally and stabilized by an external magnetic element placed on the abdominal skin [9–11]. The platform is introduced via a single access port and allows unrestricted intra-abdominal movement and spacing of surgical instruments. Accordingly, MAGS has the potential to realize the benefits of LESS or NOTES surgery by restoring triangulation for the surgeon, reducing instrument collision, and overcoming cumbersome hurdles associated with flexible endoscopic platforms. We have previously demonstrated in an animal model that the MAGS platform can be used to actively control an intra-abdominal deployable camera and multiple working instruments introduced through a transabdominal, transvaginal, transgastric or transcolonic access route [9–13]. Herein we present the first clinical report of LESS procedures performed utilizing a novel MAGS camera in place of a conventional laparoscope or endoscope.

Methods

MAGS camera

The design and development of MAGS tools have been previously described [9–12, 14]. Briefly, magnetic

anchoring technology involves an internal component consisting of a surgical instrument attached to housing fitted with permanent magnets or ferromagnetic targets and an external handheld component carrying a complementary set of permanent or electromagnet stacks (Fig. 1A). The two components are held together via magnetic coupling such that the internal component may be directly manipulated by moving the external unit. In the permanent-magnet embodiment, the stacks use high-energy neodymium–iron–boron (NdFeB) magnets and are engineered to generate coupling forces well in excess of those required to suspend 25–45 g surgical instruments over a distance of 3.0 cm. Manipulation of the internal MAGS camera is accomplished by movement of the external magnet and variable abdominal wall compression (e.g., pushing the front of the external magnet down causes the internal platform to deflect downwards) (Fig. 1B).

The deployable camera was designed by packaging a commercially available miniature imager within a custom-designed, biocompatible polymer enclosure, itself attached to a MAGS-compatible platform with an overall 20 × 60 mm profile. The imaging system is based on a commercially available charge-coupled device (CCD) imager, which produces a color image at over 400,000 active pixels and 470 lines of resolution (similar to a standard laparoscopic camera). This version uses two high-intensity light-emitting diodes (LEDs) to provide onboard illumination, with the power supply and signal transmission provided by way of external wires (Fig. 2A, B). The LED illumination sources deliver full brightness with a maximum steady-state instrument surface temperature of approximately 30°C (measured in still air). In practice LED brightness is typically throttled down by means of a pulse-width modulation control unit to avoid image overexposure, resulting in lower surface temperatures of the light source. Manipulating the external magnet enables horizontal camera orientation (yaw) and vertical deflection (pitch) of the 0°

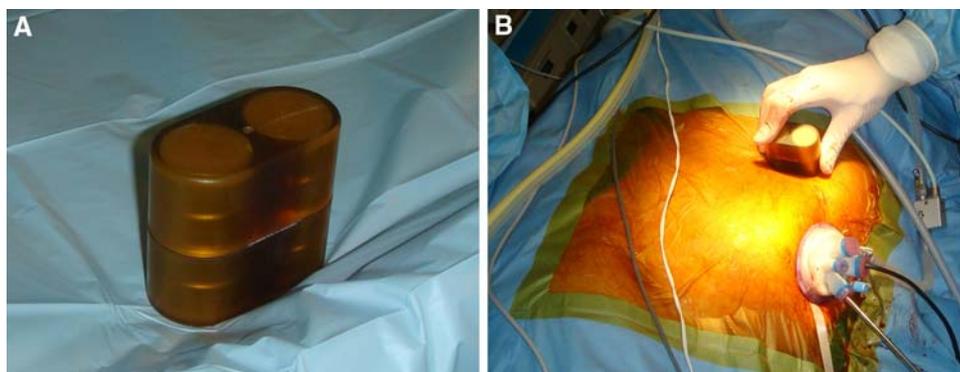
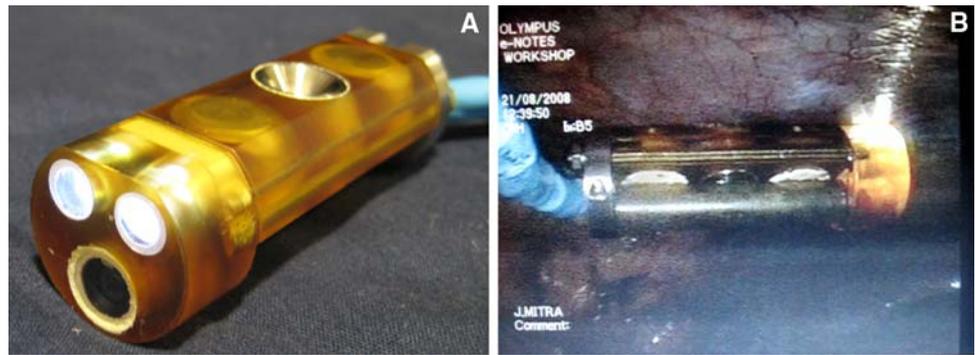


Fig. 1 **A** Handheld external MAGS component. Housing is fitted with permanent magnets separated by central depression through which percutaneous needle (18 gauge) can be inserted, allowing the MAGS camera to be locked in position and external component to be

removed. **B** Deployment of magnet on anterior abdominal wall during nephrectomy. Note that camera wires exit the abdomen through one of the Quadport cannulae, which proved effective in maintaining a seal

Fig. 2 View of internal component of MAGS camera. **A** Two LED lights provide onboard illumination for the gas-sealed camera lens. **B** Internal view of the MAGS camera on the anterior abdominal wall taken with standard endoscope inserted through the umbilical port



lens contained within the MAGS platform. The instruments can be sterilized by a low-temperature method such as hydrogen peroxide gas plasma.

Once the internal component is positioned to an optimal location using magnetic guidance, the surgeon has the option to replace the external MAGS component with a 1.3-mm-diameter (14-gauge) metal stem introduced percutaneously through an 18-gauge needle which is guided through the external platform. The stem (“needle anchor”) is captured within the internal MAGS platform midway between the magnet stacks (Fig. 3) through a self-guiding compliant receptacle and subsequently secured in place. While the needle anchoring system is not required for use of the MAGS camera, the ability to move the camera from the abdominal wall considerably expands the capability of the MAGS platform at the chosen site by allowing it to be positioned at varying angles and at varying distances from the target area. In addition, removing the magnet from the external abdominal wall reduces the external instrument footprint on the abdomen, precluding collisions and unintended magnetic attraction, increasing the force reaction capability of the internal instrument, and providing for hands-free or fine manual control of the camera position.

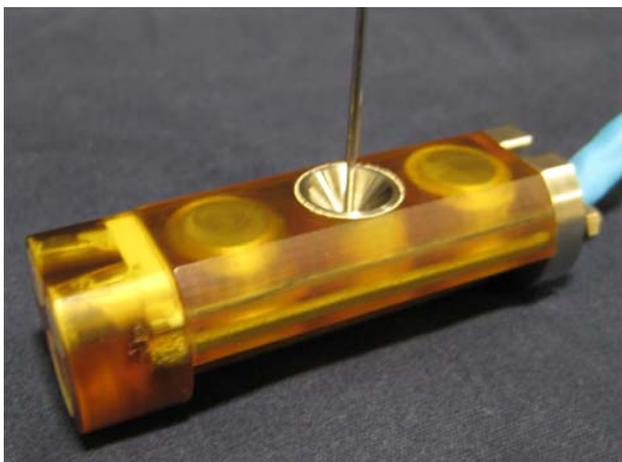


Fig. 3 The depression in the center of the camera allows for optional placement of the 18-gauge external guide needle

Description of operative techniques

Institutional Review Board approval was obtained for two human procedures, LESS nephrectomy and LESS appendectomy, at the host institution, Muljibhai Patel Urological Hospital (Nadiad Kidney Hospital).

Nephrectomy

The patient was a 50 year-old female with a nonfunctioning right kidney secondary to chronic ureteropelvic junction obstruction and recurrent infection. A 2.5-cm umbilical incision was made and the MAGS camera was advanced into the abdomen with sufficient slack in the power and signal transmission wires. A novel four-channel single-access port (Quadport, QuSurgical Concepts, Dublin, Ireland) was then deployed through the incision and the abdomen insufflated. The camera wires exited the abdomen through one of the four cannulae of the Quadport. A conventional laparoscope was introduced to visualize the MAGS camera as it was coupled to the external MAGS platform manually. When necessary, smudging of the camera lens from peritoneal contents was cleared by irrigation and a small gauze swab introduced through one of the Quadport cannulae. The MAGS camera was initially positioned below the xyphoid for bowel mobilization and ureter identification (Fig. 1B) and subsequently guided magnetically into the right lower quadrant for hilar dissection. The entire dissection was performed using the image obtained from the MAGS camera held by an assistant. When in the lower quadrant, the external MAGS component was successfully exchanged for the needle anchor in order to enhance the manipulation of the internal camera system and increase the visual field. Use of a 5-mm conventional laparoscope was necessary only for cleaning the MAGS camera lens or for coupling the MAGS camera to the external magnet. Conventional rigid laparoscopic graspers, scissor, ultrasonic shears, and clips were employed using only two cannulae of the Quadport. The kidney had two renal arteries and veins, which were transected using a conventional vascular stapler. At no time

were three tools (including laparoscope) deployed through the port. The kidney and the MAGS camera were extracted through the umbilical incision. An additional 2-mm subxyphoid trocar and instrument was used for liver retraction.

Appendectomy

The patient was a 12-year-old male with acute appendicitis. A 2.5-cm umbilical incision was made and the MAGS camera was deployed followed by placement of three-channel version of the single access device (Triport,

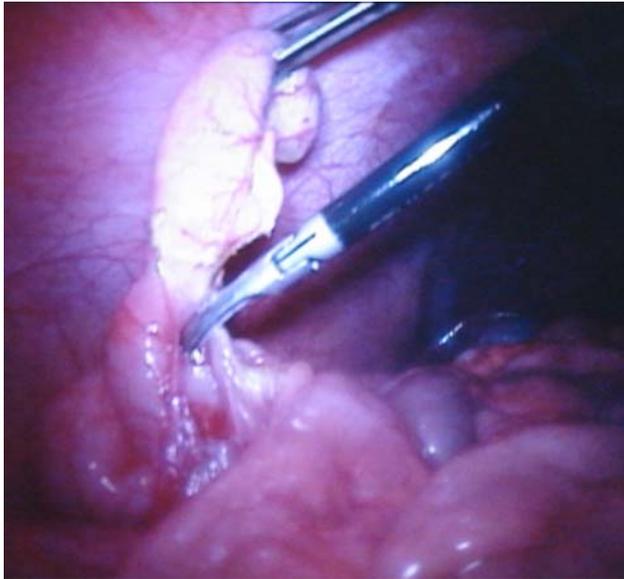


Fig. 4 Internal MAGS camera view of appendix with internal LED illumination and ultrasonic shears dividing the appendiceal mesentery. Image was captured as a digital picture from the surgical monitor

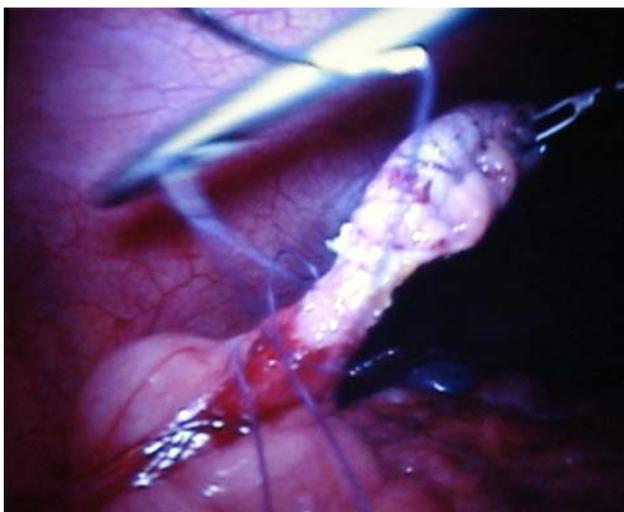


Fig. 5 Internal MAGS camera view of suture placement at base of appendix. Image was captured as a digital picture from the surgical monitor

Advanced Surgical Concepts, Wicklow, Ireland). In this case, the camera wires were externalized between the Triport and the abdominal wall, i.e., not passing through the port itself. Following abdominal insufflation, the MAGS camera was positioned in the lower left abdomen to view the appendix in the right lower quadrant. The entire dissection was performed using the MAGS camera held by an assistant. At no time was the conventional laparoscope employed. Conventional rigid laparoscopic graspers, scissors, ultrasonic shears, and needle driver were employed (Figs. 4 and 5). The appendiceal stump was secured with a free-hand suture and then divided with ultrasonic shears. The abdomen was irrigated and the appendix and MAGS camera were extracted through the umbilical incision.

Results

Nephrectomy

LESS nephrectomy with MAGS camera visualization was successfully completed with an operative time of 120 min. The MAGS camera successfully coupled across the abdominal wall (BMI 24.9 kg/m²; 2.5 cm abdominal wall thickness), uncoupling only once when inadvertently struck by a laparoscopic instrument. Exchange of the external MAGS platform for a needle anchor was also successful. The MAGS camera did require forceful downward deflection to allow visualization of the retroperitoneum with its 0° lens. The entire dissection was performed with a pair of laparoscopic instruments through the Quadport. Since a laparoscope was not used for dissection, both internal and external collision of the two instruments was minimized significantly. Rigid straight instruments were used in all instances, improving the ergonomics of the procedure over the use of bent or articulating instruments that are often used in complex LESS procedures. In addition, image quality was comparable to that of a conventional 5-mm laparoscope. Two episodes of MAGS camera smudging/fogging were successfully cleared with irrigation and a small gauze swab. There were no intraoperative complications and estimated blood loss was 150 cc. The patient was discharged on postoperative day 2 in stable condition.

Appendectomy

LESS appendectomy with MAGS camera visualization was successfully completed with operative time of 55 min. The MAGS camera successfully coupled across the abdominal wall (1.2 cm abdominal wall thickness). Needle anchoring was not performed in this case. The MAGS camera required minimal downward deflection to allow visualization of the

appendix. Image quality was comparable to that of a conventional 5-mm laparoscope and there were no episodes of MAGS camera smudging or fogging. The entire dissection was performed with a pair of conventional laparoscopic instruments through the Triport. For suture ligation of the appendiceal stump, two graspers (one to suspend the appendix) and one needle driver were placed through the Triport. A conventional laparoscope was not used for dissection or suturing, leading to a significant increase in working space, and a resultant decrease in both internal and external collision of instruments. There were no intraoperative complications and estimated blood loss was less than 10 cc. The patient was discharged on postoperative day 1 in stable condition.

Discussion

The widespread adoption of laparoscopy has ushered in a new era in the surgical treatment of human diseases. Recently there has been an impetus in the surgical community to further reduce the invasiveness of laparoscopic surgery. To achieve this goal, surgeons have proposed limiting the number of abdominal incisions (LESS) or eliminating them completely (NOTES) [15]. While preclinical animal models have demonstrated the potential applications of NOTES [16], human experience with this technique is still largely limited. Conversely, laboratory and clinical work with LESS procedures has shown a remarkable explosion over the past few years. LESS has been reported in the literature for appendectomy [17] and cholecystectomy [18, 19] since 1997, although the approach failed to gain momentum for years due to technical limitations with conventional instrumentation. Innovations such as articulating instrumentation and novel multilumen ports, as well as the realization that NOTES approaches may be quite difficult, have fostered a renaissance for LESS with several recent clinical series reporting successful completion of a range of procedures [1–7]. By reducing the number of trocars/incisions, the potential advantages of LESS procedures include: (1) improved cosmesis, (2) reduced pain from injury to cutaneous nerves, (3) reduced bleeding risk from abdominal wall vasculature (i.e., epigastric vessels), and (4) reduced risk of port-site hernia or adhesion formation.

Despite the increasing experience with LESS procedures, a recent multidisciplinary consortium of laparoscopic experts (LESSCAR: Laparo-Endoscopic Single-Site Surgery Consortium for Assessment and Research) (Cleveland, OH, July 2008) called for the development of new technologies and instruments designed primarily for LESS procedures. The experts acknowledged that current laparoscopes/endoscopes and instruments (rigid, bent, and articulating) introduced together at a single site impose severe technical

restrictions (limited triangulation, poor ergonomics, and limited visual axis and field) and can limit the type of procedures performed safely [20]. To this end, the consortium identified optics and instrumentation as two of the categories requiring the most development to meet future needs. Specifically for optics, the experts stated that “high-fidelity vision is necessary to visualize anatomic regions and structures from differing perspectives, preferably off-line from the axis of the instruments.”

To overcome these challenges and improve the efficiency of LESS (as well as NOTES) procedures, we have developed a magnetic anchoring and guidance system (MAGS) for novel surgical instruments that reintroduce triangulation and improve visualization [9, 10, 12, 21]. This system translates LESS and NOTES procedures into conventional laparoscopy or even open laparotomy in terms of multi-axis visualization and manipulation. To date, our experience has been limited to animal studies. This report reflects the initial clinical experience using a MAGS camera to successfully perform two LESS procedures. In both cases, the procedures were performed successfully with comparable (if not better) operative times to conventional LESS procedures (e.g., 120 min for MAGS camera-assisted LESS nephrectomy versus 133 min for conventional LESS nephrectomy as reported by Raman et al. [22]). In both cases, the MAGS camera provided adequate illumination and image quality that was subjectively comparable to a 5-mm video laparoscope. Most importantly, the MAGS camera allowed the surgeon to continuously slide and adjust the camera position using the external magnet platform without interfering with the surgeon working through the umbilical port. The result was improved triangulation and ergonomics as one instrument (conventional laparoscope) was omitted from the umbilical port. In fact, the operative surgeon (never having used the MAGS technology) made several unsolicited comments regarding the ease of instrument manipulation without the conventional laparoscope shaft in the umbilical port.

While this initial work is promising, future MAGS technology must address current limitations. The coupling strength of magnets decreases exponentially with respect to the distance between the source magnet and its target. As such, clinical utilization of MAGS technology is presently restricted to nonobese or small (i.e., pediatric) patients, as was the case for these two patients. Current work is being directed towards development of magnet designs capable of generating stronger magnetic fields, as well as ancillary techniques similar to needle anchoring which further increase MAGS platform stability. In its present form, the camera system requires a dedicated site (either a dedicated trocar or adjacent to an access port such as the R-port used in this series) for exit of wires required for image transmission and power. Future MAGS platforms may be further

optimized by incorporating a local power source and wireless operating controls, enabling instruments to be completely independent of the deployment site. Such an advance would address the inherent limitations of current equipment that uses wire tethers. Finally, upcoming improvements include further instrument articulation capability (e.g., controllable down-angle/tilt camera motion), continued enhancement of light delivery with alternative LED configurations, and an increased range of MAGS compatible instruments.

Conclusions

Laparoendoscopic single-site surgical procedures using a magnetically anchored and guided camera system are technically feasible. The initial clinical experience with MAGS camera technology seems to improve upon three fundamental limitations of LESS: triangulation, limited visual axis and field, and ergonomics. The development of clinically useful MAGS instruments (i.e., hook cautery) and retractors [9, 12] should further improve the triangulation and ergonomics of current-day fixed-port LESS and NOTES procedures.

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