

A magnetic levitation robotic camera for minimally invasive surgery: Useful for NOTES?

Nicola Di Lorenzo¹ · Livia Cenci¹ · Massimiliano Simi² · Claudio Arcudi¹ · Valeria Tognoni¹ · Achille Lucio Gaspari¹ · Pietro Valdastrì³

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Abstract

Background Minimally invasive surgery (MIS) is rising in popularity generating a revolution in operative medicine during the past few decades. Although laparoscopic techniques have not significantly changed in the last 10 years, several advances have been made in visualization devices and instrumentation.

Methods Our team, composed of surgeons and biomedical engineers, developed a magnetic levitation camera (MLC) with a magnetic internal mechanism dedicated to MIS. Three animal trials were performed. Porcine acute model has been chosen after animal ethical committee approval, and laparoscopic cholecystectomy, nephrectomy and hernioplasty repair have been performed.

Results MLC permits to complete efficiently several two-port laparoscopy surgeries reducing patients' invasiveness and at the same time saving surgeon's dexterity.

Conclusions We strongly believe that insertable and softly tethered devices like MLC camera will be an integral part of future surgical systems, thus improving procedures efficiency, minimizing invasiveness and enhancing surgeon dexterity and versatility of vision angles.

Keywords Robotic surgery · Magnetic levitation camera · NOTES · Minimally invasive surgery · Single-access surgery · Magnetic internal mechanism

Minimally invasive surgery (MIS) is rising in popularity generating a revolution in operative medicine during the past few decades. Thanks to minimization of surgical trauma, it offers the benefits of less postoperative pain, early ambulation and shorter hospital stay as well as better cosmetic results [1]. Since the first cholecystectomy performed by Philippe Mouret in 1987 in Lyons, the list of procedures performed endoscopically has been continuously expanding [2]. Thanks to the works of Buess [3], as well as that of others across the world, transanal micro-surgery has provided an incentive for the so-called natural orifice transluminal endoscopic surgery (NOTES). NOTES and single-incision laparoscopic surgery (SILS) may be considered further steps toward minimization of surgical trauma, although these methods have not yet been standardized [4]. Arezzo et al. [5] show as in selected patients who underwent cholecystectomy single-incision laparoscopic cholecystectomy (SILC) has similar overall morbidity compared with multiple-incision laparoscopic cholecystectomy (MILC); further, it results in better cosmetic satisfaction and reduced postoperative pain despite longer operative time. During the last 25 years, principles of minimally invasive surgery changed radically the way to perform most of abdominal operations like cholecystectomy, gastric bypass and colon resection. Although laparoscopic techniques have not significantly changed in the last 10 years, several advances have been made in visualization devices and instrumentation [6].

Clear vision and good instrument triangulation are anyway a central prerogative, which is hard sometimes to

In the era of laparoscopy, magnetic levitation camera permits to perform efficiently several two-port laparoscopy surgeries reducing patient's invasiveness.

✉ Livia Cenci
liviacenci@yahoo.it

¹ Dept. of Experimental Medicine and Surgery, University of Roma Tor Vergata, Via Montpellier 1, 00133 Rome, Italy

² The BioRobotics Institute, Scuola Superiore Sant'Anna, Piazza Martiri della Libertà, 33, 56127 Pisa, Italy

³ STORM Lab UK, School of Electronic and Electrical Engineering, University of Leeds, Leeds LS2 9JT, UK

get. Specifically, coaxiality of camera light source and instruments are the main limits of NOTES, together with distance of target organs from NOTES access point that jeopardize instruments stiffness and consequently forces transmission.

An effective solution for addressing these issues is potentially represented by softly tethered miniaturized intra-abdominal camera. This type of device is anchored, guided and actuated by external units, with power and torque transmitted across the abdominal wall through magnetic linkage [7].

Research about applications of magnetic fields in laparoscopy performed by Cadeddu et al. [8, 9] demonstrated the feasibility of a magnetic camera to be inserted into the abdominal cavity and to be moved and controlled by external magnets placed on the abdominal wall. Similarly, Swain et al. [10, 11] developed a magnetic camera prototype that could be inserted through a common laparoscopic trocar and manually moved with an external handheld magnet. These devices, based on the principle of magnetic anchoring and guidance systems (MAGS), represent the first attempt to replace the laparoscope in minimally invasive surgery in order to improve the angle view of the camera, to facilitate instruments triangulation replacing a bulky instrument like the laparoscope inside the abdomen, and to reduce the number of ports required for surgery. These cameras are not constrained by the entry incision and provide additional camera angles that increase surgical visualization and improve orientation. However, these magnetic prototypes present drawbacks mainly related to scarce precision and maneuvering or poor motion range. In order to guarantee a finer control, a robotic camera system with active internal degrees of freedom has been proposed by Allen et al. [12]; however, it results too large for passing through a traditional trocar and due to his complex system it requires care during insertion and shielding from physiological environment. Furthermore, this device does not include an anchoring system, and it is sutured on the abdominal wall during experimental validation.

Our team, composed of surgeons and biomedical engineers, developed a magnetic levitation camera (MLC) with a magnetic internal mechanism (MIM) dedicated to minimally invasive surgery. The robot is composed of two main parts, head and tail, linked by a flexible joint. The tail module embeds two magnets for anchoring and manual rough translation. The head module incorporates two motorized donut-shaped magnets and a miniaturized vision system at the tip composed by a STORZ commercial camera and a crown of six white high-efficiency light-emitting diodes (LEDs) for illumination. As described extensively by Simi et al. [13], the small robotic MLS camera can be intra-abdominally anchored and moved by

external permanent magnets (EPM) placed on the external abdominal wall. Furthermore, the main benefit stems from the robotized innovative embedded mechanism that exploits the static external magnetic field to induce a precise smooth bending of the robotic head, activated by a push button interface, guaranteeing a wide span (0° – 80°) tilt motion of the point of view. The monolithic nature of compliant mechanisms has the advantage of no wear debris, no pinch points and no need for lubrication, which are critical in the sensitive internal body environment; furthermore, it also simplifies the sterilization processes [14]. A thin flexible cable guarantees robot powering, real-time signal transmission and an effective retrieval of the device in case of failure. Thanks to its compact size, the camera is compatible with standard 12-mm trocar; thus, the access port can be used both for inserting the robot and a different instrument afterward, avoiding a dedicated port for a video endoscope.

Materials and methods

Three animal trials were performed. Porcine acute model was chosen after animal ethical committee approval. The experiments were carried out in an authorized laboratory with the assistance of a specially trained medical team. Following induction of general anesthesia with orotracheal intubation, a 12-mm trocar was placed near the umbilicus and carbon dioxide was introduced in the peritoneal cavity.

The robot includes a VGA vision system composed of a thin endoscopic camera (STORZ, CCD 500×582 , 30 fps, 85° FOV) and set of six high-efficiency white LEDs (NESW007BT, Nichia Corp., Tokushima, Japan) for illumination. The vision system is embedded in the robot head with a fixed viewing angle of 20° .

As a standard monitoring procedure, only for experimental purpose, a 30° laparoscope was inserted through an additional port to get a whole examination of the abdominal cavity and to record the procedure from an external point of view. MLC devices were inserted from the first 12-mm standard trocar.

Anchoring of the device to the external permanent magnet was obtained just after the insertion of the magnetic camera through the trocar.

Three off-the-shelf (KJ Magnetics, Jamison US) cubic ($25.5 \text{ mm} \times 25.5 \text{ mm} \times 25.5 \text{ mm}$) magnets (NdFeB, N52), embedded in a plastic case, were selected as best compromise between high magnetic field and size, to generate the external magnetic field. They produce an intense magnetic field (1.42 T) that quickly decays with distance. The magnetic force (ranging from 1 N to 3 N) exerted on the MLC tail is able to hold it lifted on the abdomen wall also providing a stable and precise external

translation motion. Moreover, a magnetic force of 200 mN acting on the MLC head enables the camera controlled levitation.

Gross movement of the capsule was obtained just moving the external permanent magnets with one hand by an assistant on the abdomen, while fine movement and tilting of the head were achieved with the internal motor connected with a remote controller. The angle sight can be modified from 0° to 80° with a precision of about 2° , until the desired position. Multiple devices, inserted at the same time from the same trocar, were pointed to the same operative field. In order to improve image quality, two tethered magnetic light sources were developed and introduced inside porcine model through trocars. Both a permanent magnet and two high-efficiency LEDs were assembled in a cylindrical (11 mm in diameter) plastic case. They can be moved and fixed thanks to other external permanent magnets.

Before camera robots insertion, ethylene oxide sterilization of the device was performed and a hydrophobic coating was sprayed on the camera lenses to prevent moisture accumulation. Then, about 500 mm of cable was left inside the inflated abdomen to provide freedom of movement to the cameras.

We performed laparoscopic cholecystectomy in two 60-kg female pigs totally under MLC vision. Only two ports were used to perform the operations. Once having fixed the cameras to the abdominal wall by moving the external magnets, visual adjustment under request of the surgeon was easily achieved by tilting the head of the system with the internal motor. Grasping and pushing up toward to the diaphragm the end of the gallbladder, a clear view of the cystic duct and cystic artery site was obtained with the camera placed just up to the liver bed and with the head tilted to 45° . In the same way, a second robotic camera was advanced to the left of the gallbladder giving an additional point of view of the surgical site. Dissection was carried out using a bougie and a laparoscopic dissector introduced from the right port, while the left hand of the surgeon suspended the gallbladder to the abdominal wall. Once cystic duct and artery were exposed, a medium-size clip was used for ligation and they were divided using laparoscopic forceps.

Right after cholecystectomy, a urologist performed a left nephrectomy on the same animal. Similarly, only two ports (5 and 12 mm) were used to insert both surgical instruments and MLCs, while one additional incision was performed to achieve the correct triangulation of the surgical instrument. After placing the camera under xiphoid process, gut was mobilized and ureter was identified. Robotic camera was moved to the lower inferior quadrant in order to identify renal ileus. Dissection was carried out using the bougie and the Radius Surgical

System. It consists of a hand-guided surgical manipulator and provides a deflectable and rotatable tip allowing 6° of freedom. Renal arteries and vein were identified and clipped. After nephrectomy, a simulation of laparoscopic abdominal hernia repair was performed anchoring a polyethylene mesh with metal anchors, in order to demonstrate the versatility of the camera. It was able to give a perfect view of the surgical site, while rigid laparoscope could not without an additional port site.

Results

All procedures were performed without any intra-operative complication. Optical position was modified just using the remote control to change the angle view of the camera or simply moving the external magnetic device on the external abdominal wall. Clear advantages in triangulation and reduction in instrument collision were demonstrated. Not more than two trocars have been contemporaneously used thanks to the MLC, which can be inserted together with an operative instrument through the same trocar. Magnetic anchoring guarantees the possibility to move the camera in every direction providing a wider view of the abdominal cavity than the standard laparoscope, which is limited from the insertion point. In every session, a second robotic camera was inserted at the same time. Surgeon could observe for the first time the surgical site from a complementary point of view. These experimental procedures had a primary importance in order to understand which are the main practical problems of our prototypes and how we can ameliorate them.

Discussion

Transabdominal magnetic anchoring and guidance systems (MAGS) for minimally invasive surgery were first described in a laparoscopic setting by Cadeddu et al., as the more recent application to NOTES. The use of magnetic fields was tested under NOTES conditions by other groups to enable liver retraction during cholecystectomy as well as to stabilize a mesh for implantation during abdominal hernia repair. Cuschieri's team [15] used a ferromagnetic glue for gastric mucosa retraction in endoscopic surgery. From the technical standpoint, the most advanced system to exploit magnetic fixation and positioning for laparoscopic and NOTES procedures is the peritoneum-mounted imaging robot as reported by Oleynikov's group [16, 17]. This wired device contains a camera, an illumination system, an electromagnetic motor and two permanent magnets located in fixed positions at the two ends of the device. A magnetic handle on the patient's abdomen is used to attract the

magnets embedded in the robot. The handle can be moved across the exterior of the abdomen in order to position and pan the imaging device. The embedded motor is used to remotely tilt the camera at arbitrary angles. A similar solution is reported by Allen's group, consisting of an 11-mm monoscopic insertable panning/tilting endoscopic imaging device. A magnetically guided intra-abdominal camera for SILS was demonstrated in humans by Cadeddu et al. [18, 19].

The current trend in diagnostic and surgical procedures is to minimize the patient's operative trauma by decreasing as far as possible the number of external incisions while increasing the technical capabilities of endoluminal and transluminal instrumentation. Therefore, given the poor controllability of magnetic fields, the development of miniaturized mechanisms that allow precise positioning and steering of the single device would improve the outcomes of both standard and innovative procedures, such as laparoscopy, NOTES and SILS. We envisaged that magnetic properties could be used not only for retraction and for fixation of the intra-abdominal tools, but also for precise steering and rotation. The novel feature of our prototype is the adjustable internal magnetic mechanism that allows fine control of steering and rotation. Compared with the steering achieved by moving the external magnetic field source, the mechanism presented here provides higher precision because the distance between the external and internal magnets is kept constant during the operation. As demonstrated by our findings, the best results with the MLS camera are obtained in large cavities, such as the stomach or the abdomen, where luminal walls do not hamper movement of the device. Nevertheless, even in a constrained environment, the MLS steering capabilities might be beneficial in enhancing diagnostic outcomes. The MLS camera design assumes a 15-cm distance between the external and internal magnets. With morbidly obese patients, such a value can easily be exceeded, and in such cases, a stronger external magnet can be used, by applying the selection criteria previously reported by our group.

While feasibility for abdominal surgery was demonstrated, limitations to the development so far require comment. First, further reduction in size is desirable and this can be achieved by decreasing the size of the actuation unit. Further work on the visualization system is also needed to improve image quality. This is substandard in the current prototype. Another crucial issue is the remote control by magnetic fields for navigation and coarse positioning. This problem may be addressed by adopting a robotic solution.

Image quality and illumination were more than adequate for simple surgical procedures. MLS camera robot introduction, magnetic coupling and motion control were trivial

and intuitive. The device provided adequate illumination and image quality that was comparable to a traditional video laparoscope. Moreover, the magnetic anchoring and motion provided a larger viewing volume than a traditional laparoscope, which is restricted by the fulcrum point of insertion. The MLS enhanced image stability and motion resolution still guaranteeing a tilt wide span ranges. The *in vivo* tests demonstrated that tools motion (in particular, insertion and retrieval), exerting sometimes relevant forces, can cause abdominal wall deformation, generating head vibration. Deflections and other vibrations occurred especially when the robot was not anchored parallel to the floor. In this case, a gravity force component deflected the camera head out of the plane. Concerning patient's breathing, no vibration was observed. Abdomen wall upon insufflations results stiff and not deformable reducing markedly breathing motions. In multiport laparoscopic procedures, use of this innovative approach would reduce the number of external incisions, since a devoted access for the camera would no longer be required, without affecting surgeon dexterity. The two *in vivo* tests suggest that safe procedures can be performed with MLS cameras. Multiple-camera robots, providing the surgeon with multiple points of view of the surgical arena, represent a great improvement in terms of visual information. By inserting more than a MLS camera at the same time, we obtained a view of the operative field from different points of sight. According to the opinion of the surgeon, the position of the camera placed so near to the surgical site can represent a real advantage for surgical outcome. We strongly believe that insertable and softly tethered devices like MLS camera will be an integral part of future surgical systems, thus improving procedures efficiency, minimizing invasiveness and enhancing surgeon dexterity. Several advances in visualization and instrumentation make it reasonable to think about SILS and NOTES as the future of minimally invasive surgery. This system could potentially solve classic problems like instruments triangulation, which is a critical component of successful surgical technique in SILS, and "tunnel vision," which is associated both with endoscopes used in NOTES and laparoscope used in laparoscopic single-site surgery. Considering an SPL scenario, all the ports can be used to insert instruments, thus facilitating the tasks for the surgeon and eliminating the potential conflict with the endoscopist.

Magnetic camera robot introduction, magnetic coupling and motion control were trivial and intuitive. The device provides adequate illumination and image quality that was comparable to a traditional video laparoscope. Moreover, the magnetic anchoring and motion provided unconventional views of the surgical field from multiple angles and a larger viewing volume than a traditional laparoscope which is restricted by the fulcrum point of insertion, together with

a high span (80°) and precise ($\pm 2^\circ$) robotic tilt motion provided by the MIM levitation system.

Although the use of N52 NdFeB permanent magnets, the magnetic field decays quickly around them thus providing magnetic coupling and exerting forces strictly between external magnets and internal magnets embedded in the robotic system. The magnetic field around MLC does not affect the motion of ferromagnetic laparoscopic instruments inside the abdomen, and the MLC efficacy is not limited by ferromagnetic material inside the abdomen. Only in the case of contact between instruments and MLC, the camera could stick to the instruments and temporarily change its point of view. However, the external magnets are always able to strongly hold or drag the MLC away, thus enabling separation from the attached instruments.

In fact, the potentiality of using multiple vision modules and to position multiple lightening bodies (and even more when the wireless supply will be reliable) will expand the indication for reduced port, single port and NOTES procedures.

Consequently, meaningful applications could include the surgical procedures for functional surgery (hiatal, bariatrics, pelvic functional surgery), those not requiring bulk specimens retrieval and procedures in abdominal recesses (liver segments, pelvic transvaginal surgery) where angled vision is critical to achieve.

Future developments will unveil if this scenario will become a clinical reality!

Compliance with ethical standards

Disclosures Drs. Nicola Di Lorenzo, Livia Cenci, Massimiliano Simi, Claudio Arcudi, Valeria Tognoni, Achille Lucio Gaspari and Pietro Valdastrri have no conflicts of interest or financial ties to disclose.

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