Fine tilt tuning of a laparoscopic camera by local magnetic actuation:

Two-Port Nephrectomy Experience on Human Cadavers

Massimiliano Simi [1,2,4], Ryan Pickens, M.D.[4,5], Arianna Menciassi[1], S. Duke Herrell, M.D [3,4,5], PietroValdastri[1,2,4]

[1]The Biorobotics Institute of Scuola Superiore Sant'Anna;

[2]Vanderbilt University, School of Engineering, Departments of Mechanical Engineering and [3]Biomedical Engineering;

[4]Vanderbilt initiative in Surgical Engineering (ViSE);

[5]Vanderbilt University Medical Center, Department of Urologic Surgery;

ABSTRACT

Background: Magnetic surgical camera is an emerging technology having the potential to improve visualization without taking up port site space. However, tilting downward/upward the point of view can be obtained only by constantly applying a pressure on the abdomen. This study aims to test the hypothesis that the novel concept of Local Magnetic Actuation (LMA) is able to increase the tilt range available for a magnetic camera without the need for deforming the abdominal wall. The hypothesis that two-port laparoscopic nephrectomy in fresh tissue human cadavers could be performed by using the LMA camera is also tested.

Methods: Firstly, the two cameras were separately inserted, anchored, and moved inside the inflated abdomen. Tilting angles were quantified by image analysis, while intra-abdominal

pressure changes were monitored. Then, 5 two-port nephrectomies were performed by using the LMA camera while collecting quantitative outcomes.

Results: The magnetic camera required a constant pressure on the magnetic handle to achieve an average of ±20° tilt from the horizontal position with an average of 7 mmHg loss of intra-abdominal pressure. The LMA camera allowed for 75° of tilt from the horizontal position with a resolution of ±1°, without any need to deform the abdomen. All the nephrectomies were completed successfully within an average time of 11 minutes.

Conclusion: LMA is an effective strategy to provide magnetic cameras with wide-range and high-resolution vertical motion without the need of deforming the abdominal wall.

INTRODUCTION

Magnetic coupling is one of the few physical phenomena capable of transmitting forces across a physical barrier. This ability enables an entirely new paradigm for surgical instruments: they can be mobile (working reconfigurably far from their body entry point), and a separate incision is no longer needed for each surgical tool or camera. Magnetic Anchoring and Guidance Systems (MAGS) -- introduced in 2007 by UT Southwestern Medical Center [1] -- harness magnetic forces to steer and operate completely insertable intracorporeal tools via externally handheld magnets. MAGS developed to date include cameras, retractors, dissectors, and cautery devices [1-5]. By moving the external handheld magnet around the patient's abdominal wall, the internal device can be steered to the task-appropriate location. Its position can then be manually adjusted as needed, such as to alter the view if using a MAGS camera, to lift the liver edge in the case of a MAGS retractor, or even continuously as when using a MAGS cautery device. In particular, the MAGS camera is able to provide effective triangulation through off-

axis views, thus allowing for less camera and instrument clashing in Laparoendoscopic Single-Site (LESS) procedures. Due to its ability to embrace the abdominal wall and being unconstrained by the entry incision, a MAGS camera can increase surgical visualization and provide panoramic and unconventional views of the surgical field from multiple angles [6]. Despite these clear advantages, current magnetic devices present some drawbacks mainly related to the limited motion range that can be achieved by manual control of the handle. Motion along the inflated abdomen, guaranteed by the coupling between the external and the internal magnets, can result in rough and jerked movements of the camera due to dynamic/static friction at the interface with the abdominal wall. Moreover, tilting downward/upward the point of view can be obtained only by constantly applying pressure to deform the abdomen [6, 7], resulting in a relevant workload for the operator, potential vibrations, and the risk of losing the desired view of the target. To overcome these problems and achieve a precise and expanded tilt motion, the concept of Local Magnetic Actuation (LMA) can be applied [8]. LMA -- achieved by a mix of anchoring and local actuation couples of permanent magnets linked across the abdominal wall -- consists in changing the orientation and/or the position of one magnet of the actuation pair, causing the magnetically coupled surgical camera to locally move on the inside. Building on the LMA concept, we developed a softly-tethered miniature magnetic camera that does not require manual motion of the external handle to achieve tilting of view in the vertical plane [9, 10, 11]. Although in vivo animal two-port and LESS procedures have demonstrated the benefits of LMA to provide a wide range view to a magnetic camera [12], these models had thinner abdominal walls and slightly different anatomy than human patients.

In this paper, we first test the hypothesis that LMA actuation is able to increase the tilt range available for a magnetic camera without the need for deforming the abdominal wall. Then, we

test the hypothesis that two-port laparoscopic nephrectomy in fresh tissue human cadavers could be performed by using the LMA camera.

MATERIALS AND METHODS

The LMA camera used in this study consists of two main parts, a head (local actuation module) and a tail (anchoring module) -- linked by a flexible joint -- resulting in a 95 mm long and 12.7 mm wide cylindrical device, with a weight of 20 g. The tail module embeds two magnets for anchoring, stabilization, and manual rough positioning. The head module incorporates a couple of donut-shaped magnets (diametrical magnetization) that can be rotated by an internal miniature motor to achieve local actuation when coupled with an external static magnetic field. A self-contained vision system -- composed by a VGA medical camera (Karl Storz GmbH, Tuttlingen, Germany) and a crown of 6 white light-emitting diodes (LEDs) for a 36 lumen illumination -- is integrated on board. The vision module, comprising both camera and illumination, was mounted with a 10° base inclination (Fig. 1.A). Two thin flexible cables (1.2 mm in diameter each) provide powering, image transmission, and an effective means of retrieval in case of failure.

As described in **[10, 11],** the LMA camera can be intra-abdominally anchored. Rough positioning and pan can be achieved by moving a magnetic external handle placed on the abdominal skin, similarly to a standard magnetic camera. However, the main benefit stems from the innovative embedded LMA mechanism that exploits the static external magnetic field generated by the handle and the motorized rotation of the internal donut-shaped magnets, activated by a push button interface available to the surgeon. The rotation of internal magnets about their own axis provides either attraction or repulsion to the camera (Fig. 1.B), achieving a

very precise and wide-span tilt motion of the point of view without requiring any movement of the external handle. The proper dimensioning of the mechanism also involves the elasticity of the joint connecting the tail to the head module and the gravity force acting on the head module, as detailed in [11]. The monolithic nature of the compliant joint embedded in the proposed mechanism has the advantage of no wear debris, no pinch points, and no need for lubrication, which are critical issues for robotic devices that have to be used inside the human body. Moreover, the robotic camera (Fig. 2.A) does not present any protruding part, nor cavity, thus facilitating the sterilization process. Zooming is achieved by moving the magnetic camera closer to the site and tilting the head module or by digitally enlarging the picture, at the price of reduced image resolution.

The external magnetic handle, which guarantees camera anchoring, rough positioning, and LMA operation, is composed of three N42 NdFeB cubic magnets (19 mm each side) embedded in a plastic case. Due to the LMA principle of operation and in order to maximize tilt span, a screw system allows adjustment of the static magnetic field surrounding the camera by moving the external magnet coupled with the head module (on the far right in Fig. 1.A). This allows for compensating variations in abdominal wall thickness from 1 cm to 5 cm. The handle weighs 180 g and measures 92-107 mm (length) by 25 mm (height) by 35 mm (width).

In order to provide a direct comparison with LMA camera tilting performance, a magnetic camera based on the prototype described in [6] was fabricated. This mock-up embedded a 3 mm fixed-focus medical imaging element (Medigus Ltd, Omer, Israel) placed with a 30° downward-looking orientation, two LEDs with 40 lumens of brightness each, and two diametrically magnetized N42 NdFeB cylindrical permanent magnets (9.5 mm in diameter and 9.5 mm in length), housed in a rapid prototyping cylindrical plastic case (15 mm in diameter and 80 mm in

length; 40 g in weight) (Fig. 2.B). Two wires (1.2 mm in diameter each) were used for signal and energy transmission. The same handle described for the LMA camera (without the adjustable magnet) was used to control the device during trials.
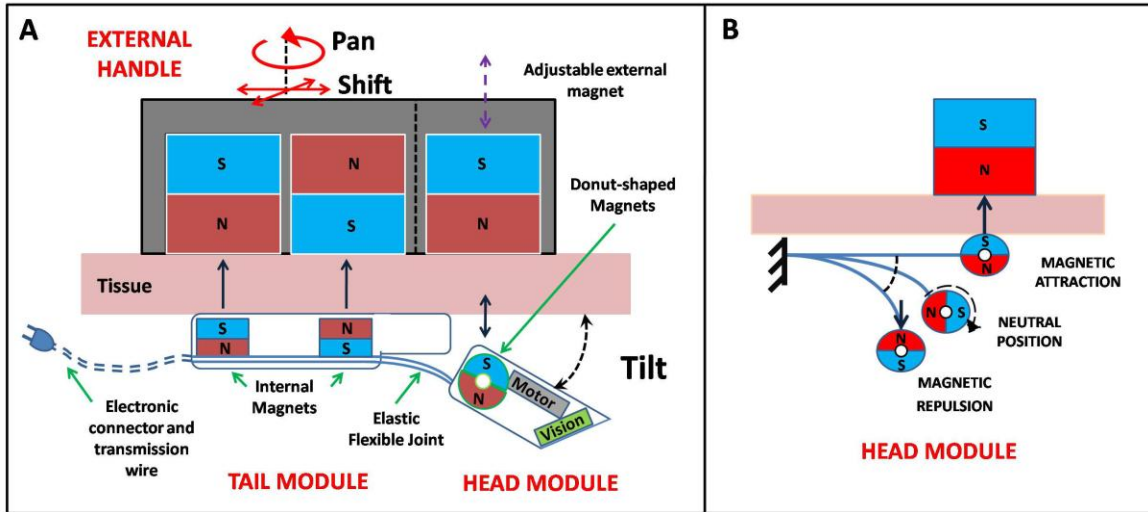

Fig. 1 Schematic cross-section of the LMA camera and external handle (A) and LMA principle of operation (B).
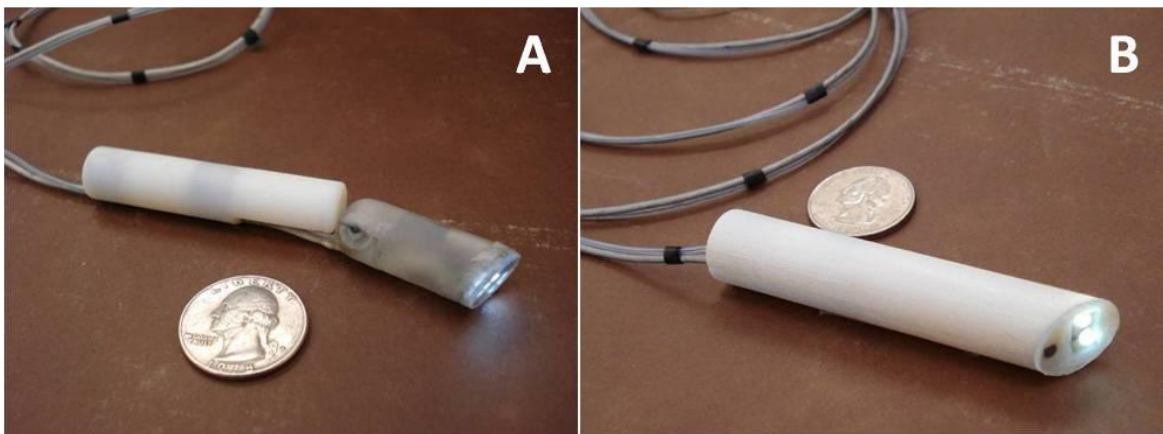

Fig.2 The two fabricated prototypes: the LMA camera (A) and the magnetic camera (B).

The operations were carried out in the Vanderbilt Cadaver Laboratory in accordance with all ethical considerations and regulations related to cadaveric experiments. Four different fresh tissue cadavers (3 males and 1 female) were used for this study. The models were all placed in a

lateral decubitus position and secured to the table at the beginning of the procedure. Two 15 mm incisions were made in the abdomen, one just inferior to the subcostal margin and one placed in the lower quadrant along the anterior axillary line. The abdominal thickness was measured at the insertion point, then a 12 mm laparoscopic port was placed in the upper incision, and a pneumoperitoneum was achieved with carbon dioxide gas.

The first portion of this study consisted in a test to compare both the magnetic camera and the LMA camera tilt motion performance. Primary endpoint was the full range of tilt. Secondary endpoint was the pressure variation within the intra-abdominal compartment while tilting each magnetic camera. We performed this trial in each of the 4 cadavers. The magnetic camera was firstly introduced through the inferior incision along with 20 mm of cable and anchored to the intra-abdominal wall using the external handle placed on the skin. Once anchored, the second 12 mm laparoscopic port was easily placed alongside the cable into the abdomen and the pneumoperitoneum was re-established. Finally, the camera was shifted along the abdomen and placed to focus first on the kidney area, then on the liver. We evaluated its full range of tilt by applying an external pushing force to the handle. We performed 5 tilting motions for each area. A standard laparoscopic camera (frame rate 30fps, field of view 85°), introduced through the same port, was used to visualize the magnetic camera while tilting and to record the image stream. Tilting angle was quantified by post-processing, taking advantage of a dedicated software (ImageJ v1.46). In particular, the images taken at the starting and ending position for each tilt (e.g. Fig. 4.A and 4.B) were overlaid. Then, a first line was drawn at the lower edge of the camera in the starting position, and a second line was drawn along the same feature with the camera in the maximum tilt position. The software provided the angle in between the two lines. Due to the manual handling of the laparoscope, this method may be affected by parallax error

(i.e., the laparoscope and the magnetic camera are not laying on the same horizontal plane), thus limiting the accuracy to 1°. This error is mitigated by averaging the results of the different trials. Pressure changes within the intra-abdominal compartment while tilting the magnetic camera were monitored on the laparoscopic insufflator.

After removing the magnetic camera, the LMA camera was inserted through the same incision with 20 mm of cable and then anchored with the magnetic handle, preventively adjusted for the measured abdominal thickness. Although the LMA camera has a layout suitable with 12 mm trocars, we placed the trocar next to the cable instead of placing the camera through the trocar. This allowed us to prevent any loss of intra-abdominal pressure that had been noted on earlier experiments on pigs [12]. Also in this case, the tilt mechanism was operated 5 times per location, covering the full range of motion, and pressure changes within the intra-abdominal compartment were monitored.

A second portion of this study consisted in assessing the feasibility of performing nephrectomies in a fresh tissue human cadaver model by using the LMA camera in a two-port laparoscopic procedure. Primary endpoint was procedure completion rate. Secondary endpoints were the time required to perform the procedure, the number of times that the LMA tilt mechanism was activated, and the time that the camera point of view was tilted more than 30° downward. This last parameter quantifies the reduction in workload with respect to a state of the art magnetic camera (i.e., the camera described in [6] has a 30° downward-looking angulated lens, thus focusing on a target at an angle larger than 30° requires the operator to apply a pressure on the patient's abdomen). A total of 5 nephrectomies (1 left and 4 right) were performed on 4 different cadavers. The image from the robotic camera was displayed on a standard laparoscopic monitor. The external handle was used to adjust the LMA camera into

place between the two ports so that the instruments would be triangulated to the target organ (Fig. 3). The push button interface -- which was placed at the bedside table to be controlled by the assistant -- was used to precisely reach the desired tilt angle. We used standard laparoscopic 10 mm instruments through the two 12 mm laparoscopic ports. We reflected the colon medially by freeing it off its lateral wall attachments at the White Line of Todlt. We dissected out the ureter off the psoas muscle and lifted it medially. We dissected the medial attachments off the kidney until we reached the renal hilum, which was cut with scissors. The upper attachments were then dissected off with blunt and sharp dissection. The lateral and inferior attachments were then dissected off the kidney in a similar fashion. The ureter was then cut to completely free the kidney from all its attachments. This was considered the end of the procedure.

In order to provide further comparison with state of the art magnetic cameras [6], we also recorded the time needed to introduce and anchor the camera, the time to reach and establish a correct view of the surgical target area, the number of times we moved the LMA camera using the external handle, the number of times we had to clean the camera, the prevalence of camera clashing with any instruments, and the thickness of the abdominal wall at the incision point.
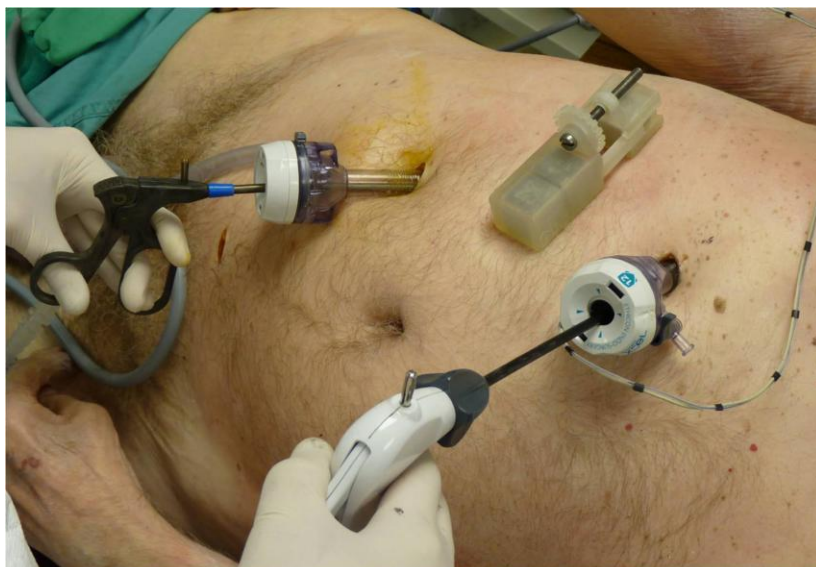
Fig. 3 The experimental set up. The device cable runs parallel to the right trocar, while the magnetic handle is coupled with the LMA camera across the abdominal wall.

RESULTS

Concerning the comparison between magnetic and LMA camera tilting, the magnetic camera required a constant pressure on the magnetic handle from an assistant to achieve an average of ±20° tilt from the horizontal position. In particular, an average of 18° (range of 14°-23°) and 22° (range of 18°-25°) were measured at the kidney and liver areas, respectively. Since the optics is mounted at 30°, this provides a full range of the view of 10°-50° on the vertical axis. Motion from the horizontal plane to the 20° tilted position is shown in Fig. 4.A and 4.B, respectively. The need to apply a constant pressure on the handle -- thus on the abdominal wall -- to achieve 20° tilt of the magnetic camera resulted in an average of 7 mmHg (range of 5-10 mmHg) loss of pressure inside the abdominal cavity.

The LMA camera allowed for an average full range of motion of 75° on the vertical axis, with an average of 76° (range of 74°-79°) and 74° (range of 72°-76°) at the kidney and liver areas, respectively, and with a step resolution of 1° in both directions (upward/downward) (Fig. 4.C, D). Therefore, camera view can be tilted from 10° to 85° (Fig. 5) without any manual interaction with the external handle, except for the initial adjustment of the magnetic field to the specific tissue thickness (performed just one time per cadaver, at the beginning of the trial). No significant image vibration and no loss of pressure were observed during the operation of the LMA tilt mechanism.
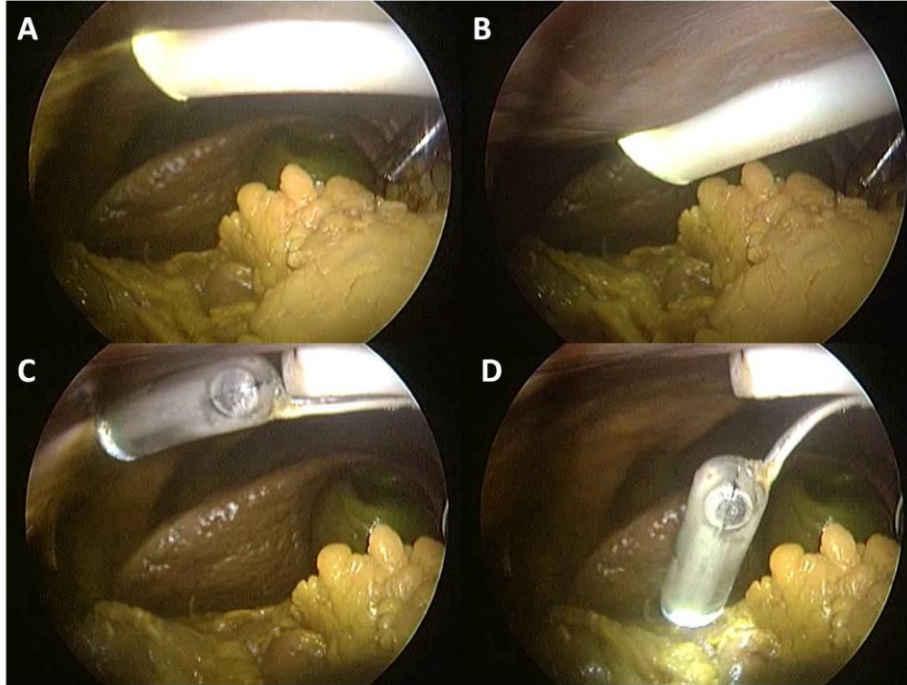
Fig 4. Magnetic camera in horizontal position (A) and maximum tilt (B).

LMA camera in horizontal position (C) and maximum tilt (D).

The difference in maximum range of motion is evident by comparing (B) to (D).

All the 5 nephrectomies were performed using only the LMA camera without any complication. Average completion time was 11 minutes (range of 7-18). The 4 cadavers presented an average abdominal thickness of 2 cm. Magnetic coupling was always effective, and the camera was never dropped in the abdominal cavity. All the procedures were executed with a standard laparoscopic small bowel grasper and scissor without having to take time to exchange instruments (Fig. 6). None of the procedures required conversion to standard conventional laparoscopy, and all the data collected during surgeries are reported in Table 1.

Trials	MIN	MAX	AVERAGE
Time to Insert and Anchor [sec]	25	82	56

Time to Establish Correct View [sec]	15	60	35
Time to Perform Procedure [min]	7	18	11
Time that the camera point of view was tilted more than 30° downward [min]	5	12	6
Number of External Magnet Motions	3	7	4.8
Number of uses of LMA Mechanism	2	5	3
Number of times Camera Cleaned	0	2	0.6
Number of Camera and Instrument Clashing	0	3	1.8
Abdominal Wall Thickness [mm]	15	30	20

Table 1. *Data collected during 5 nephrectomies under LMA camera sight.*

It is worth mentioning that camera introduction and anchoring sometimes were unsuccessful at the first try due to the loss of pneumoperitoneum caused by removing the trocar. In these cases, the LMA head hit the internal organs and bent backwards, thus magnetically coupling to the tail module. Whenever this happened, the LMA camera was removed and the insertion procedure was repeated. The time data reported in Table 1 are the sum of all the endeavors made until the camera was anchored safely and reliably across the abdomen.

During the surgical procedures, the LMA camera had to be moved with the external handle to adjust panning (right/left) an average of 4.8 times (range of 3-7), whereas 3 tilt (up/down) adjustments were required with a range of 2-5. In particular, once the correct view of the surgical target was established, we used a significant tilt angle to aid in the dissection of the

inferior and medial attachments along with dividing the ureter and renal vessels (Fig. 6.A). Pan adjustment was used to help visualize the dissection of the upper pole attachments as well as dissecting the entire kidney off the lateral abdominal wall (Fig. 6.B). The average time that the camera point of view was tilted more than 30° downward was 6 minutes (range of 5-12).

Finally, an average number of 1.8 clashes (range of 0-3) between the instruments and the camera, and no external collisions were recorded, whereas camera cleaning was required less than one time per procedure (average of 0.6 times per case with a range of 0-3). The camera was cleaned intracorporally by a small piece of wet gauze introduced through one port and held by the grasper.

From a qualitative standpoint, we have to note that the external manual motion for pan adjustment was clearly jerked and rough due to manual control and internal tissue friction.
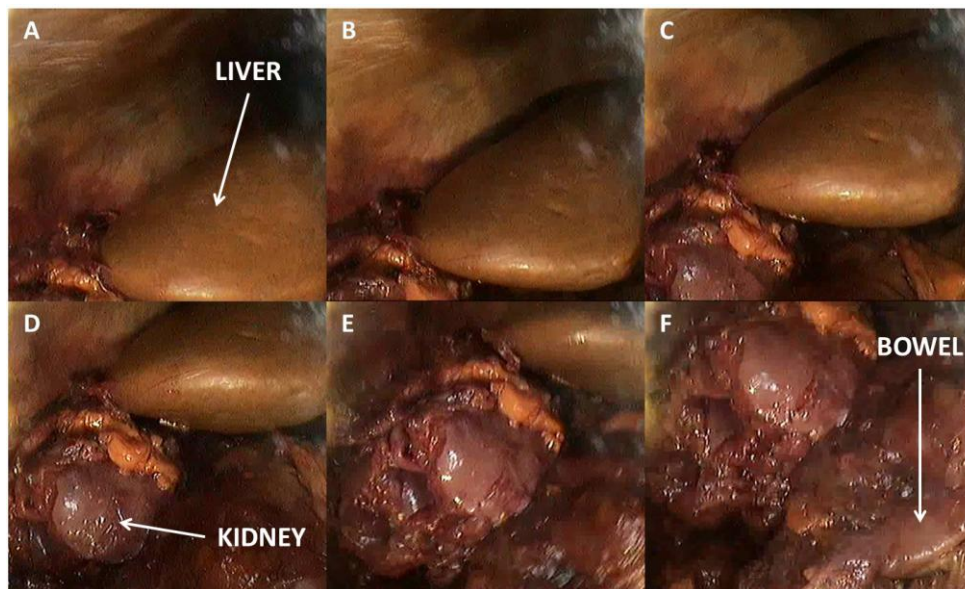

Fig.5 Full range of view (from 10° to 85°) for the LMA camera focusing on the liver during tilt span evaluation.
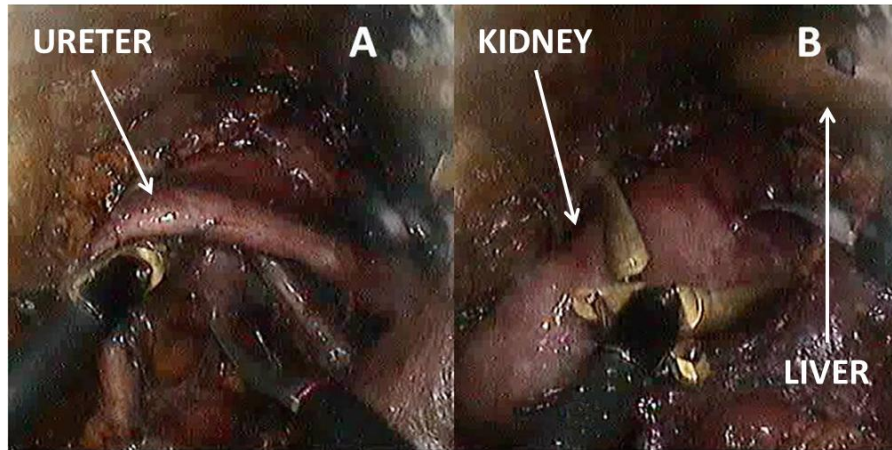
Fig.6 LMA camera sight during right nephrectomy. (A) Dissection of ureter [tilt angle about 70°]. (B) Exposure of the upper pole of the kidney [tilt angle about 40°, right pan adjustment of 20° from the previous position].

DISCUSSION

In order to enhance surgeon dexterity while reducing access trauma, a number of robotic laparoscopes have been developed [**13, 14**]. In particular, fully insertable magnetic instruments that do not take up port site space during the operation have the potential to concretely enable single or two-port surgery [**1, 15, 16**]. One of the most promising magnetic devices is the MAGS camera developed by UT Southwestern Medical Center, obviating the need for a port dedicated to the laparoscope, thus requiring one less incision [**2, 6, 7**]. Thanks to the freedom in positioning provided by magnetic coupling, this device is not constrained to the access point, thus enhancing triangulation and providing new and multiple camera viewpoints and paths to the surgical target. However, low dexterity and poor motion accuracy due to manual operation of the external handle are barriers that jeopardize an effective clinical translation of this

technology. This is particularly relevant whenever the camera view has to be moved downward or upward on the vertical plane. With a standard magnetic camera this can only be achieved by fighting against abdominal tissue elasticity through the application of a constant force on the handle (Fig. 4.A, B). This limits the vertical range of motion, requires a dedicated operator to apply the force, and may induce fatigue and vibrations, thus increasing the risk of losing the appropriate view of the target during critical steps of the surgical procedure.

Thanks to the approach proposed in this study, magnetic coupling can be varied locally on the head module of the camera in order to achieve a wide tilt range with a high resolution and stability for both upward and downward movements and without the need for a dedicated assistant maneuvering the external handle (Fig. 4.C, D). The quantitative comparison in tilting performance between magnetic camera and LMA camera was performed at the kidney and liver areas. In the case of the magnetic camera, the tilt range is dependent on the camera location. While focusing on the liver, the magnetic camera is located in the middle of the abdomen, thus the tissue offers little resistance to deformations. The tilt range gets smaller when focusing on the kidney, since the abdominal wall is constrained on the flank. This variability was not observed for the LMA camera, thanks to its principle of operation that does not require tissue deformation. While a relevant loss of pressure was observed during the operation of the magnetic camera, the LMA mechanism prevented any need for fighting against the abdominal tissue to maintain a tilted view.

The feasibility of a LMA camera was proven successfully in 5 two-port nephrectomies on a fresh tissue cadaver model, with results straightforwardly applicable to LESS procedures. The reported completion time was in line with standard laparoscopy procedures [17] and LESS nephrectomy performed by using a MAGS camera [7]. The tilt control was always precise and

reliable. Once the LMA camera was placed in position, the tilt was operated by the push button interface without the need for the assistant to manipulate the external handle, as shown in Fig. 3, thus also preventing undesired collisions with the surgeon operating the laparoscopic instruments. This resulted in an overall reduction of the workload for both the surgeon and the assistant.

In the course of this study, LMA tilt was used an average of 3 times per nephrectomy and the point of view was at a downward inclination larger than 30° for more than half of the time. This ability to tilt the camera allowed us to see important structures such as the ureter and renal vessels from a very close distance (Fig. 6.A), while keeping the camera between two triangulated instruments and not having to apply an external force that may change the intra-abdominal pressure or field of view.

Pan (right/left) adjustment was used an average of 4.8 times per procedure with a range of about 20°. This was obtained by the assistant operating the external handle and was required to focus on upper pole dissection and then aiding in freeing the kidney from its lateral attachments -- from superior to inferior -- along its border (Fig. 6.B). Extending the LMA concept to achieve panning with high motion resolution and without the need for a dedicated assistant -- as for tilting -- is the next technical challenge for LMA. Another further improvement will consist in replacing the push button interface with a different user interface that can enable the surgeon to control camera orientation while operating. Examples are foot pedal control, voice activation [18], eye tracking [19], or even full automation of the tilt motion, by implementing image segmentation and feature tracking [20]. Concerning image quality, the LMA camera provided adequate visualization to perform all the procedures without the use of a standard laparoscope,

although a stronger illumination may be desirable. Neither surgical instruments motion nor abdominal pressure regulation caused relevant vibrations in the image during the procedure.

We performed the kidney dissections bluntly and sharply, however, no bleeding could be visible on cadaver model in case of arteries cut. Anyway, previous animal studies support the effectiveness of the LMA camera also in vivo [12].

Regarding safety of trans-abdominal magnetic coupling, two empirical studies by UT Southwestern Medical Center support the hypothesis that this approach does not cause tissue damage or adverse clinical outcomes [21, 22]. These studies show that porcine abdominal wall tolerated a maximum pressure of 6.78 psi even when compressed across the shortest distance of 0.9 cm. Because the distance across the abdominal wall is generally greater in adult human beings (up to 4 cm upon insufflation [23]), these findings support the further clinical development of magnetic instruments. In particular, the proposed LMA camera design exerts a pressure of 0.85 psi when operated across 1.5 cm of abdominal tissue, thus being far below the above mentioned safety threshold.

Despite quantitative data about surgical procedures performed laparoscopically [17] or under MAGS camera guidance [7] are available in literature for a direct comparison, a purposely designed comparative study must be performed to assess and quantify the advantages of the proposed technique with respect to the state of the art. This will be the subject of future studies.

Although the LMA camera has an outer diameter compatible with off-the-shelf 12 mm trocars, we placed the camera along side of the port to avoid low -- but constant -- air leakage during the entire procedure caused by the thin cables running through the valve. A dedicated trocar should be designed where the camera cable can be moved in a dedicated lateral space, where it

would not interfere with surgical instruments or cause air leakage. Such a trocar would allow introduction and removal of the camera without the need for taking out the access port, thus losing the pneumoperitoneum.

No laparoscope was used to visualize the initial procedure of coupling the camera to the handle across the abdominal tissue. From a technical standpoint, this resulted in the most complex phase of the procedure, with an average completion time of 56 seconds. Indeed, placing the LMA camera through the incision without using a trocar caused a quick loss of pneumoperitoneum, thus reducing the space available between the internal organs and the anterior abdominal wall. This in turn caused the LMA camera head to hit the tissues during introduction, bending back on itself with the head module magnetically coupling to the tail module. We solved this issue by using the external handle to link the camera head as soon as it was introduced through the incision.

In addition to extending LMA to achieve panning, roll camera adjustment can be particularly significant if the camera is positioned on the sides of the abdominal cavity. In the case of a monocamera, roll can simply be obtained by means of image post-processing, while if a stereocamera -- increasingly common in surgical practice -- is used, a dedicated mechanism must be developed [24]. Also, sufficient space is available on board of the LMA camera head module to allow replacing the current vision sensor with a high definition image chip.

As for any other magnetic device, the LMA camera is incompatible both with patients having implants and pacemakers and ferromagnetic objects (scalpels, needles, etc.) in the operating room.

The use of multiple magnetic instruments, all entering through the same access port as envisaged by UT Southwestern Medical Center work in 2007 [1], is still an appealing solution to minimize access trauma. In case multiple cameras are used, unprecedented views of the procedure would be available to the surgeon. However, cross coupling of magnetic instruments inside the abdomen -- always resulting in a conversion to open surgery -- is such a high risk to prevent this scenario to come true, unless appropriate technical efforts are focused towards shielding and fail safe operation. A complete multi-physics modeling framework, together with real-time magnetic field sensors embedded onboard each single device, may play a fundamental role in enabling multiple magnetic instruments to share the same confined space, in predicting the distance at which available instrument prototypes can be used, and also in developing ones that can work in overweight patients.

CONCLUSION

Cadaver trials described in this work let us conclude that LMA is able to increase the tilt range for a magnetic camera without the need for deforming the abdominal wall. The reported results also support the conclusion that two-port laparoscopic nephrectomy in fresh tissue human cadavers can be performed by using the LMA camera. This represents a concrete step forward for magnetic surgical instrumentations, since a constant pressure on the external handle is not required anymore to tilt the view. Also, zoom of the surgical target is now easier to achieve thanks to a combination of dragging and tilting and to the extended range of vertical motion achievable with the LMA mechanism. While room for improvements is still large, we believe

that fully insertable and softly tethered magnetic devices are a promising approach to improving procedures efficacy, minimizing access trauma, and enhancing surgeon dexterity.

AKNOLEDGMENTS

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