Title: AUGMENTED REALITY IN A TUMOR RESECTION MODEL

Short running head: Augmented reality in partial nephrectomy

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Abstract

Background: Augmented Reality (AR) guidance is a technology that allows a surgeon to see sub-surface structures, by overlaying preoperative imaging data on a live laparoscopic video. Our objectives were to evaluate a state-of-the-art AR guidance system in a tumor surgical resection model, comparing the accuracy of the resection with and without the system. Our system has three phases. Phase 1: using the MRI images, the kidney's and pseudotumor's surfaces are segmented to construct a 3D model. Phase 2: the intra-operative 3D model of the kidney is computed. Phase 3: the pre-operative and intra-operative models are registered, and the laparoscopic view is augmented with the pre-operative data.

Methods: We performed a prospective experimental study on *ex vivo* porcine kidneys. Alginate was injected into the parenchyma to create pseudotumors measuring 4-10mm. The kidneys were then analyzed by MRI. Next, the kidneys were placed into pelvictrainers, and the pseudotumors were laparoscopically resected. The AR guidance system allows the surgeon to see tumors and margins using classical laparoscopic instruments, and a classical screen. The resection margins were measured microscopically to evaluate the accuracy of resection.

Results: 90 tumors were segmented: 28 were used to optimize the AR software, 62 were used to randomly compare surgical resection: 29 tumors were resected using AR, and 33 without AR. The analysis of our pathological results showed 4 failures (tumor with positive margins) (13.8%) in the AR group, and 10 (30.3%) in the Non-AR group. There was no complete miss in the AR group, while there were 4 complete misses in the non-AR group. In total, 14 (42.4%) tumors were completely missed or had a positive margin in the non-AR group.

Conclusions: Our AR system enhance the accuracy of surgical resection, particularly for small tumors. Crucial information such as resection margins and vascularization could also be displayed.

Keywords: Augmented Reality, laparoscopy, partial nephrectomy, resection margins.

INTRODUCTION

Laparoscopic surgery has brought considerable changes to all fields of surgery by introducing the concept of minimal invasive surgery. The main problems for surgeons dealing with minimal invasive surgery techniques are hand–eye disconnection, reduced depth perception due to the two-dimensional vision offered on the flat screen with the angle of view and haptic feedback being sometimes limited (1).

Augmented Reality (AR) is a technology allowing a surgeon to see sub-surface structures in an endoscopic video image (1,2,3). This works by overlaying information obtained from preoperative imaging, such as MRI and fusing it in real-time with the endoscopic images (1,2). AR guidance systems have been successfully developed to assist surgical procedures including adrenalectomy (2), prostatectomy (4), liver resection and neurosurgery (5). AR has not been developed however for soft and deformable organs in **laparoscopic surgery**, and despite considerable research, robust systems capable of handling soft tissue deformation are yet to be created. Furthermore, quantitative evaluation is both difficult and limited in the literature.

We have already evaluated AR with a phantom uterus model, with small intramural myomas in a synthetic 3D printed uterus model. The results of this study showed that the AR system can significantly improve the localization of myomas (6). We then demonstrated the feasibility of our AR system in a clinical situation (7). To continue the development of our system, for small inner tumors we decided to evaluate it in an animal tumor resection model. The aim of our work was to evaluate an AR system for surgery, comparing the accuracy of the resection with and without AR. **T**his is the first pre-clinical study that systematically evaluates the benefit of a state-of-the-art laparoscopic AR guidance system, by performing complete resections and measuring positive/negative margin statistics.

MATERIALS & METHODS

FIRST STEP: DEVELOPMENT OF A NEW PSEUDOTUMOR MODEL

The study protocol was covered by a request for authorization to use animals for scientific purposes (Ministry of Higher Education and Research, Ethics Veterinarian Committee). All the procedures were performed in the operating room of the International Center of Endoscopic Surgery (CICE), approval number: C63 18 113 (certificate of authorization to trade in live animals number B 63-168). We started the procedure with ex-vivo tests, on porcine kidneys, recovered from pigs operated in a context of resident training (laparoscopic nephrectomy).

Development of the Optimal Pseudotumor Material

To determine the optimal pseudotumor agent to be used, various substances were injected. For each substance, we looked at ease of preparation and injection, reproducibility, and physical palpability. The objectives were to create a pseudotumor mixture with a viscosity that would minimize extravasation from the injection site while still allowing injection through the needle. We tried silicone (Silicone plomb, Dalbe®, ref. 477001100) but the mixture was too viscous and difficult to implant. We also tried polyurethane resin (Résine polyuréthane - 2x500gr – Dalbe® ref. 477001700) but the mixture was also difficult to use as the solidification phase takes less than a minute. Finally, to create a model that would include all the characteristics required, we used alginate, a hydrocolloid (Alginate nourrisson – DTM®, ref. 477008500). The purpose was to create tumors between 5 and 10 mm in size, in order to test the system with really small inner tumors. We created two or three tumors in each kidney, depending on the kidney’s size.

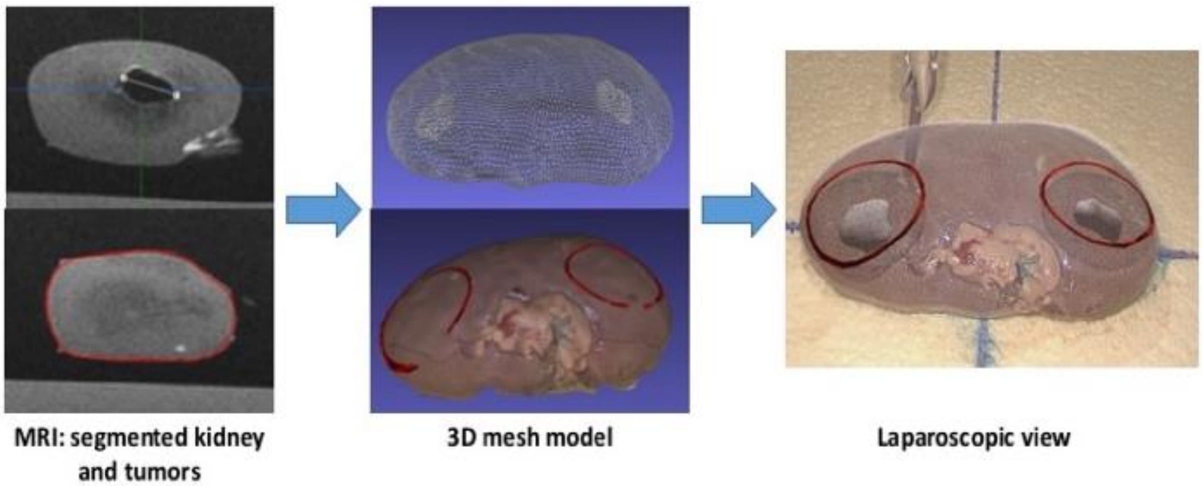
Pseudotumor creation

The alginate mixture was prepared by adding lukewarm water to the alginate powder and stirring for 1 minute. Solidification took between 1 to 4 minutes, after 3 minutes the mixture reached a semisolid state and was no longer injectable through the needle. The optimal concentration of alginate mixture was assessed by injecting different concentrations of mixtures in ex vivo porcine kidneys. Finally, a concentration of 0.5 gram/mL proved to result in a mixture that was easily injected and formed firm tumours in the kidney parenchyma. After mixing, the alginate mixture was loaded into a 5mL syringe and 1-2mL of the mixture was slowly injected into the renal parenchyma using an 18-gauge needle.

MRI: Imaging of pseudotumors

T1-weighted MRI examinations were made of the kidneys with a 3T MR scanner along the three planes (axial, coronal and sagittal). We adjusted MRI settings to have a 0.4mm resolution, with a slice thickness of 1.5mm. Pseudotumors were easily identified as hypointense focal lesions (Figure 1).

Figure 1: Overview of our AR system.



SECOND STEP: EVALUATION WITH A STATE-OF-THE-ART AUGMENTED REALITY SYSTEM

AR software

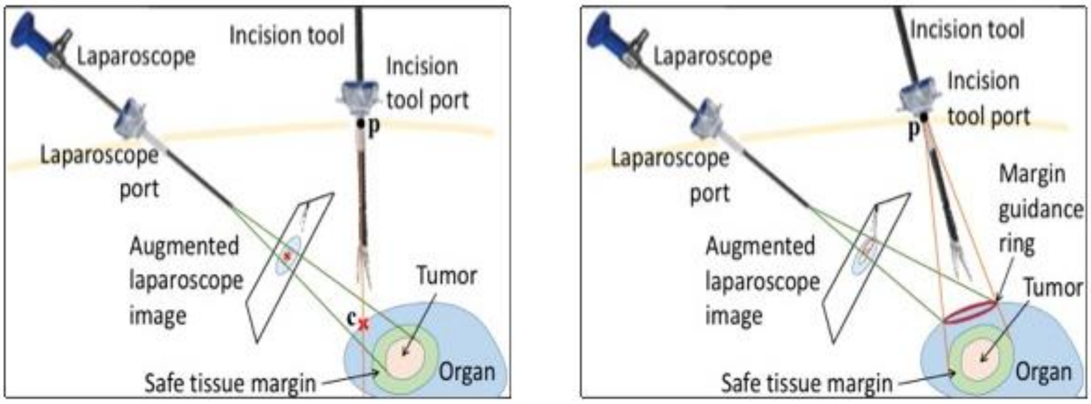
For soft organs, AR is very challenging and robust systems capable of handling soft tissue deformation are yet to be created. To achieve AR in this context, three main challenges have to be overcome:

- In the segmentation phase with the MRI images, the kidney and pseudotumor surfaces are determined in order to construct a 3D mesh model. This process is the least time-critical because it can be done before the intervention and typically performed with semi-automatic facilities (8). This segmentation phase was performed with the use of interactive segmentation software (Medical Imaging Interaction Toolkit; German Cancer Research Center).
- The second challenge is real-time registration, where the goal is to transpose the pre-operative organ model into the per-operative model. To conform to the deformation between the pre and the surgical model, we used a biomechanical model. The objectives of the registration paradigm is to construct a pre-operative biomechanical model from pre-operative data and then to texture the external surface of this pre-operative biomechanical model. The initial registration stage is non-live. There is then a need to follow the organ deformation and movements. It is the live stage which is called tracking. For the tracking stage, we used an existing method based on 'feature-matching' (9) proposed in our group. This method is called Wide-Baseline Multi-Texturemap Registration.

Visualization with the AR software

The 3D pre-operative model is automatically deformed, positioned (or "registered" whatever the movements of the organ) and fused with the laparoscopic view of the kidneys (9). This blending gives the impression that the kidney is semi-transparent and the surgeon can see the exact location of the tumor inside (Figure 1). The goal of the visualization is to augment the laparoscope image with data from the organ model in order to guide the surgeon. Our AR software ran on a mid-range Intel i7 desktop workstation with an NVidia 980Ti GPU and visualizations shown on a 26-inch monitor. The software was improved while we developed and used it (6). Our AR system guides surgeons, by showing them how to access the tumor with an incision tool. The main improvement we brought is called Tool-port Projection visualization. What the surgeon actually wants is to be shown how to reach the tumor using the incision tool, while seeing the tumor's safe tissue margin. We provide both types of information, as illustrated in figure 2.

Figure 2 : Tool-port Projection



Our system works by showing the tumor's safe tissue margin projected onto the organ's surface as a ring which we call the tumor guidance ring. The projection is made so that if the surgeon were to cut into the organ along the tumor guidance ring, the tumor would be segmented with a minimal tissue margin, set depending on the surgeon's requirements.

On the 2D images in real time, in order to improve the depth localization of the tumor, the AR software also allows the kidney's surface mesh to be displayed in addition to the tumor meshes. Our software also provides the display of the resection margins defined pre-operatively by the surgeon (5mm margins in our model) and landmarks on the kidney's surface, giving an orthographic projection of the tumors and showing the surgeon the place to incise whilst respecting the margins. We also tried different colors of meshes (Figure 3) and different types of landmarks (Figure 4) to improve the visualization and we also modified transparency depending on the depth.

Figure 3: Tests with different colors for meshes and different light effects on a synthetic uterus model placed in a pelvic trainer box

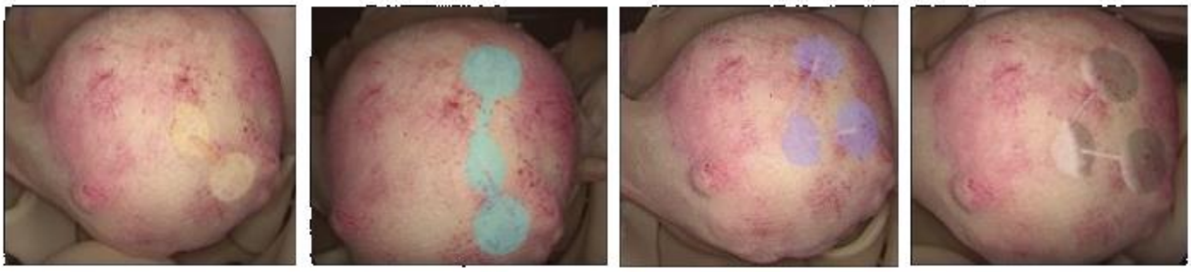
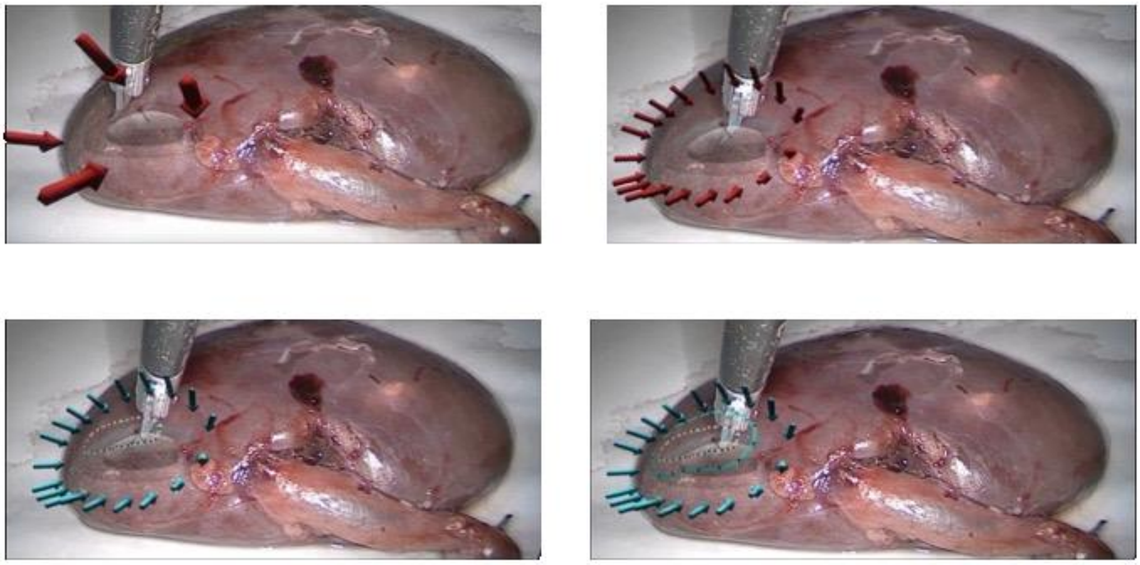


Figure 4: Different types of visualization

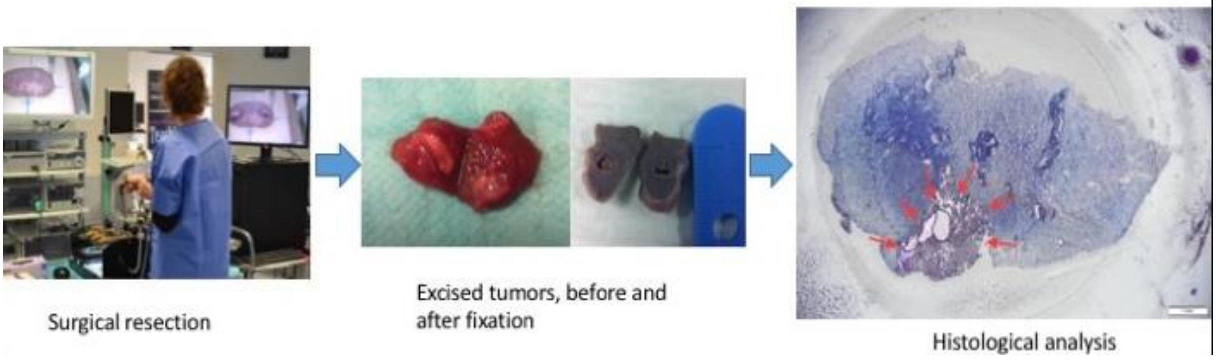


Surgical procedure (Figure 5)

The surgical equipment consists of a laparoscope (Karl Stortz 10-mm HD laparoscope SPIES system) with CLARA image enhancement activated, a laparoscopic pelvic trainer, a standard surgical grasper, a standard incision tool and an instrument with a surgical marker pen attached at the tip (the marker instrument).

Laparoscopic surgery was performed using a box pelvic trainer, with the kidney inserted on the bottom surface and the laparoscope and instruments inserted through three ports. The same port configuration was used in all cases.

Figure 5: Surgical procedure



The objectives were to remove each tumor and the safe tissue margin thereof by cutting out a cylinder-shaped section of tissue (Figure 2), from the superficial to the deep ends of the kidney. The kidneys were divided equally and randomly into two groups (the AR group and the Non-AR group), with 12 kidneys with 29 tumors in the AR group and 12 kidneys with 33 tumors in the Non-AR group. In the AR group the task was first to mark out the safe tissue margin on the organ's surface using the marker instrument, guided by the AR visualization. Then we started surgical resection with AR visualization and when the kidney became deformed by the resection, the marks were used to guide resection (with AR deactivated) as our guidance system is not designed to handle the significant deformation which occurs when a tumor is resected. In the Non-AR group, the surgeon had to carry out resection in conditions simulating the gold standard method (where only MRI was available): the surgeon had to first look at the MRI data using the interactive slice-based method (8), then remove the tumor without AR guidance using the same safe tissue margin of 5mm.

All surgical procedures were performed by the same surgeon who practiced surgical resection during training sessions with and without AR before starting the protocol.

Pathological analysis

The specimens were transported in formalin to the laboratory, embedded in paraffin and manually sectioned with a microtome to obtain 5µm paraffin sections. The sections were then stained with toluidine blue and analyzed with a 10x magnification OlympusBX51® microscope. To measure the margins, we used the CellSens standard® software.

We evaluated the quality of each resection with histological analysis: the healthy parenchymal margins were measured at the superior, inferior and both lateral ends of the surgical specimen. We also measured the superficial and deep ends, even though in our protocol these margins were not taken into account to evaluate the accuracy of the AR system. Indeed, in our protocol we decided to not take into account the deep margin of the lesion. Indeed, the objectives were to remove each tumor by cutting out a cylinder-shaped section of tissue from the superficial to the deep ends of the kidney, and because some really deep tumors would have add contact margins because of the tumors creation and deep localization, and not because of the surgical resection. The parenchymal margin was considered "complete" when a continuous ring of healthy parenchyma/tissue surrounded the lesion (we measured these margins), and "incomplete" when the tumor abutted the enucleation capsule (positive margin).

Statistical analysis

Statistical analysis was performed using the Stata software (version 13, StataCorp, College Station US). The tests were two-sided, with a type I error set at $\alpha=0.05$. Continuous data were presented as mean (± standard deviation) or median [interquartile range]. The assumption of normality was assessed using the Shapiro–Wilk test. The number of kidneys and associated percentages were presented for categorical parameters. Then, to take into account between- and within-subject variability (due to several repeated measurements), random effects models (linear for quantitative dependent outcome, with logarithmic transformation to achieve normality when appropriate, logistic for dichotomous dependent variable) were used rather than the usual statistical tests which would not be appropriate due to the hypothesis of independence data not verified. To measure the impact of group effect, this variable was considered as a fixed effect and the kidney was studied as a random effect.

RESULTS

Tumor creation and MRI

In total we created 128 tumors: 38 were not segmented because of faults in the pseudo-tumor creation phase (tumor visible on kidney surface, or mixture accidentally injected in the urinary tract). We thus finally segmented 90 tumors. 28 were used to test the AR software, improve visualization and for surgeon training.

Next, 62 tumors were surgically resected (29 with AR/33 without AR). The pigs' kidneys ranged in size from 63.88 to 85.05mm. The measurements were not statistically different between our two groups. At MRI, the tumors ranged in size from 4.03 to 15.4 mm. We also analyzed the kidney and pseudotumor volume estimation after segmentation (Table 1).

	Pig kidney size (mm)	Tumor size (mm)	Kidney volume (mm^3)	Tumor volume (mm^3)
AR group	75.13 ± 6.88	8.15 ± 2.34	32,818 ± 8722	163 ± 117
Non-AR group	75.22 ± 4.49	8.71 ± 2.87	29,719 ± 5252.	132 ± 93
Total	75.18 ± 5.69	8.45 ± 2.63	31,169 ± 7198	146 ± 105

Table 1: kidney and tumor volume statistics

Pathological analysis

The volume of the specimens was analyzed macroscopically and the specimens ranged in size from 0.720 to 8.57cm^3 (mean 3.39 ± 1.67). There were no differences between the two groups ($p=0.44$).

We considered a resection to be a failure if either the tumor was completely absent from the core (a complete miss), or if it was intersected by the perimeter of the core (a positive margin).

- Complete miss and positive margin (Figure 6)

In terms of tumors, our results showed 4 tumors with at least one positive margin (4/29=13.8%) in the AR group and 10 tumors with contact margins (30.3%) in the non-AR group (with p=0.01). There was no complete miss in the AR group, while there were 4 complete misses in the non-AR group. In total, there were 14 (42.4%) tumors with a positive margin or completely missed in the non-AR group (p<0,01) (Figure 6).

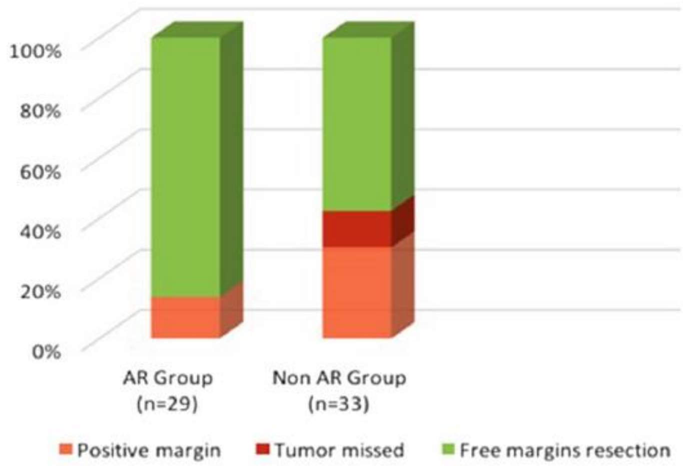


Figure 6: Difference between the two groups

DISCUSSION

Historically, the reference standard for treatment of renal cell carcinoma has been radical nephrectomy. However, during the past two decades partial nephrectomy has gained acceptance for treatment of small tumors. During partial nephrectomy, the surgeon tries to preserve as much healthy renal tissue as possible while ensuring all tumor cells are removed (10). Partial nephrectomy has been shown to provide cancer-free survival comparable to radical nephrectomy (11–13), as it seems to significantly decrease the risk of developing renal insufficiency (14) and is associated with better quality of life (15). Recent series have demonstrated a local recurrence rate of less than 5% after partial nephrectomy (11,12,16). Positive surgical margins after partial nephrectomy form a rare event, occurring at a rate of 2-13% (17–21) but obviously for much larger tumors with larger resection (mean tumor size around 3.5 cm into the literature vs 4.03 to 15.4 mm in our study). The clinical significance of positive surgical margins is highly controversial, but local tumor recurrence can be attributed to residual tumor at the surgical margin due to inadequate tumor resection, so margin negativity remains an oncologic imperative to decrease this risk of local recurrence (22,23). The traditional practice has been to excise an additional 1 cm of tumor parenchyma, although recent studies have indicated that narrower margins are sufficient (24). Currently, the precise amount of normal renal parenchyma that must be removed to ensure a safe surgical margin is still a subject of great concern. The only imperative rule is negativity of the margins. If the tumor is completely excised with a surrounding margin of normal renal tissue, the width of the resection margin does not correlate with long-term disease progression (25). Accurate localization of small renal tumors could allow the surgeon to excise only the tumor with a small healthy margin and could help to reduce the learning curve for partial nephrectomy.

In our study, the choice of small tumors was made in order to model cases where tumors do not deform the surface of the kidney, making them harder to localize.

Inaccurate tumor localization can lead to the excision of an inordinate amount of normal parenchyma in an effort to obtain a complete resection or, even worse, could result in positive margins. AR allows real-time and precise localization of the lesion and adjustment of the extent of the resection accordingly. Virtual exploration with AR may assist the surgeon during the preliminary phase of a surgical procedure, through interactive and visual planning of the operative strategy, which can be simulated and corrected at every step.

Surgical resection and pathological analysis

With our AR guidance system, we first evaluate the potential benefit of the use of AR to localize small inner tumors.

Our study shows that AR significantly improved the mean accuracy of tumor resection. The localization of tumors during laparoscopy can be simple when a superficial deformation is present, but for small tumors, it can be difficult since there is no tactile feedback. Moreover, although MR or CT provides a good cartography of tumors to transpose it for intra-operative navigation, using 2D vision remains challenging. The radiologist's anatomical landmarks are sometimes different to those used by the surgeons (26). The use of our AR guidance system provides significant benefits and allows for accurate localization of very small tumors. Other important information (like vascularization, ureters and other anatomical structures) could also be displayed.

<u>Our current AR system and the literature</u> (Table 2)

Research on the use of AR with mobile and deformable organs has not been reported. One of the reasons is most likely the technical challenge. There is no automatic segmentation available for MRI and the segmentation phase is still manual, even if achieved with the help of semi-automatic facilities (8). The process is time consuming, but not truly challenging and can be carried out before the intervention.

The most challenging phase remains the registration phase. The main problem is to achieve registration accurately, reliably and in real time. In our AR system, we do not need any external navigation tracking systems or preplaced surface markers. In our study, we describe an AR guidance system based on an existing system (6) in which we use a two-phase approach (Wide-Baseline Multi-Texturemap Registration).

Unlike SLAM-based tracking methods, which form the main classical tracking approach, our method does not use frame-to-frame tracking. Instead it performs tracking-by-detection. Consequently, our method can be used without any other hardware such as magnetic or optical tracking devices (4,27), and is usable when the surgical scene is approximately rigid. This allows it to register over long durations and can trivially recover when the organ is not visible for certain periods, such as when the surgeon removes and then reinserts the laparoscope or cleans the lens. In cases when the organ is assumed to be fixed relative to background structures, we can track using features from both the organ and background structures.

Moreover, SLAM during laparoscopy is still proving challenging, due to the repeated nature of the tissue's texture, rapid camera motion, blur and appearance changes caused by blood or coagulation. Our novel two-phase approach (Wide-Baseline Multi- Texturemap Registration) was shown to significantly outperform SLAM (9).

Our system has also undergone several important improvements. The main improvement is a considerably better way to visually guide the surgeon, by showing how to access the tumor with an incision tool. We provide both types of information with what we call Tool-port Projection, shown in figure 2. Tool-port Projection works by showing the tumor's safe tissue margin projected onto the organ's surface as a ring, which we call the tumor guidance ring. The projection is made such that if the surgeon were to cut into the organ along the tumor guidance ring, the tumor would be resected with a minimal tissue margin, set depending on the surgeon's requirements.

During partial nephrectomy, there are two stages in which an AR environment offers a potential clinical advantage. First, to facilitate rapid and accurate anatomic identification of important neighboring structures (major vessels and the renal vasculature). Second, to facilitate unambiguous dissection during tumor resection ensuring negative surgical margins while achieving a maximally nephron-sparing operation.

Around 20 cases of partial nephrectomy with AR have been reported, with different AR techniques (28) (Table 2) (different methods of registration: manual registration, surface-based registration, fiducial-based registration, 3D-CT stereoscopic image registration) and different methods for tracking, but no tracking system seems to be truly reliable, especially in case of kidney deformation. Our system does not require artificial landmarks and unlike other systems (10,27,29) it does not fail with motion blur or when the laparoscope is removed (e.g. for cleaning) and then reinserted. Our system also solves the most challenging stages of tracking and fusion in real time.

In their study, Hughes-Hallett et al. explain that the ideal AR image guidance system would use a pre-operative scan and incorporate the triad of automated registration, tracking and tissue deformation. Our system seems to be the one that agrees most with this ideal definition, because other systems have no biomechanical model, no real-time tracking and fusion and are defeated by motion blur.

The cost of a system may be a weakness. However, our system runs on a standard Intel i7 desktop PC at a cost of less than 1000 Euros (which is dropping each year for the same level of hardware) and does not need any other device.

	Type of study		N=	Accuracy evaluation	blur motion	Comparison with and without AR	Instruments								
	In Vivo	Ex Vivo					Instrument tracking	Camera tracking (Inside-out tracking)	Specific material	3D camera	Robotic surgery	Manual Registration	Surface-based registration	Fiducial-based registration	3D-CT stereoscopic image registration
Nakamura et al (34)	X		2	NA	?	No	No	No	No	No	No	X			
Teber et al (10)	X	X	10/10	+	?	No	No	Yes	Yes	No	No	X		X	
Ukimura et al (35)	X		1	NA	?	No	Yes	No	Yes	No	No	X			
Altamar et al (36)		X	6	+	?	No	Yes	No	Yes	Yes	Yes		X		
Herrell et al (37)		X	13	+	?	Yes	Yes	No	Yes	Yes	Yes		X		
Benincasa et al (38)		X	1	+	?	No	No	No	Yes	No	No		X		
Nakamoto et al (39)		X	1	+	?	No	Yes	No	Yes	No	No			X	
Baumhauer et al (40)		X	3	+	?	No	No	Yes	Yes	No	No			X	
Pratt et al (41)	X	X	3/20	+	?	No	No	Yes	Yes	No	No				X
Su et al (42)	Post procedural		2	+	?	No	No	No	Yes	Yes	Yes				X
Nosrati et al. (43)	X		15	+	?	No	No	No	Yes	No	No	X			
Simpfendörfer et al (31)	X		10	NA	?	No	No	Yes	Yes	No	No			X	
Puerto-Souza et al (44)	Post procedural		2	+	-	No	No	Yes	Yes	No	No	X			
Our technique		X	62	?	+++	Yes	No	No	No	No	No		X Wide-Baseline Multi-Texturemap Registration		

Table 2: the state of the art

Limitations

One of the limitations is that we used MRI. We know that Computed Tomography (CT) has traditionally been the imaging technique of choice for evaluating potential solid renal tumors (30). We emphasize that our AR guidance system does not require any fundamental changes to use pre-operative CT images rather than MRI. For the most part, CT is limited to characterization based upon the attenuation and enhancement characteristics of a lesion and requires exposure of patients to ionizing radiation. For these reasons, MRI is being increasingly used to characterize solid renal masses (30), especially in case of lesions deemed to be too small to characterize by CT (31). To add to these arguments, segmentation is easier using MRI due to the precision of the resolution. In the future, US segmentation will be possible using the same technique as we have described, probably adding to the cost-effectiveness of our technique. Another study has already shown the feasibility of the navigation system with transrectal ultra-sonography information superimposed via AR in real time for laparoscopic prostatectomy (4).

The imaging technique of choice for peroperative evaluating potential solid renal tumors is still discussed (30). The use of an intraoperative ultrasound guidance need the use specific materials, with a important cost. A learning curve for the use of this technique is also necessary. Our AR guidance system does not require any fundamental changes to the MRI acquisition. The cost of the material of our AR system is also reduced. The next step in the development of AR will be the comparison with EUS.

In our study, the software was developed and improved while we used it. This continuous improvement could have influence the results but the main evolution concerned only the rapidity and didn't modify the principle of the fusion and the tracking phases.

Another limitation is that during surgical procedure, AR systems are not designed actually to handle the deformation that occurs after incision of the organ surface. In the next future, the technical evolution including new biomechanical model (32) will allow to maintain AR guidance after the initial incision.

Future perspectives

In this study, we show the significant benefit of the use of this AR guidance system, in this surgical model. The next step will be to work on the other anatomical structures: AR could be helpful to localize not only the tumor itself, but also all the anatomic landmarks and surrounding organs (ureter, main vessels, rectum…). AR could also improve planning the surgery for a specific case: it can be used for visualizing during surgery a preoperative optimized incision plan (which takes into account vascularization, access to all the tumors, tool ports etc.). Other surgical indication with large dissection and distortion of the normal anatomy (Deep Infiltrating endometriosis, oncologic procedure, uterine scar niche, etc.) could also benefit from this technology.

CONCLUSION

There is a significant benefit in the use of our AR guidance system in our surgical model. It provides accurate localization of very small tumors. Crucial information such as vascularization could also be displayed. In the near future, the intra-operative localization of all anatomical structures (including the ureters, arteries and complete vascularization of the tumor) will become possible. In the broader context, this study is the first to systematically evaluate an AR tumor guidance system in laparoscopic surgery by performing complete resections and measuring resection margin errors.

DISCLOSURES

Dr P. Chauvet, T. Collins, C. Debize, L. Novais-Gameiro, B. Pereira, Prs A. Bartoli and M. Canis, Dr N. Bourdel have no conflicts of interest or financial ties to disclose.

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