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Evaluating the EVA surgical navigation system for ureteral identification in an in vivo porcine model

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Surgical safety has emerged as a significant public health concern. Ureteral injury (UI) is one of the most common forms of iatrogenic urological issues, lacking non-invasive prevention strategies. In this context, computer-assisted technologies offer a promising solution for enhancing intra-operative safety. This paper presents an in-vivo study focused on evaluating the feasibility of using an augmented reality (AR) surgical navigation system (EVA) for intra-operative ureteral identification on an animal model. An experienced surgeon performed a technical assessment of the system. The clinical evaluation was conducted by four general surgeons tasked with identifying the left or right ureter, both with and without EVA. The technical assessment highlighted that EVA is easily integrable with operating room instruments, achieving a calibration accuracy of $1.7 \text{ cm} \pm 0.002$, and the virtual ureter effectively overlapping with the real ureter. The questionnaires indicated that surgeons appreciated EVA, with a $SUS_{score} = 73.75$. The perceived mental demand, task complexity, and distractions were lower when using the EVA system. Future work will focus on increasing the number of subjects and exploring the efficacy of the system on other clinical tasks.

According to the World Health Organization (WHO), unsafe surgical care causes substantial problems, such as major complications, occurring at an alarming rate of 25% during major surgeries and leading to a mortality rate of 0.5%–5%¹. Minimally Invasive Surgery (MIS) and the introduction of robotic systems in the Operating Room (OR) have brought various advancements in surgical techniques in terms of manoeuvrability, precision and enhanced surgical field visualization. Despite that, a series of complications remain closely associated with the surgeon's experience level.

Specifically, Ureteral Injury (UI) is one of the most common forms of iatrogenic urological injuries, arising in approximately 0.2–1% of pelvic surgeries. Among these cases, 50% are observed during obstetric and gynecological surgeries, with 30% specifically occurring during radical hysterectomies^{2,3}. UI also occurs in colorectal surgery with an incidence ranging between 0.2 and 1.5%⁴. Other less common causes of UI include ovarian tumor removal, transabdominal urethropepy, and abdominal vascular surgery. More than 50% of UI that occurs intra-operatively are not immediately recognised and treated, especially during emergency surgery⁵. Consequently, these injuries are associated with increased morbidity, mortality, hospital stay, and healthcare costs that can exceed 30,000 US\$ per case⁶. UI also represents a frequent reason for legal disputes with serious psychological, economic and professional burdens for both patients and doctors⁷; in fact, this complication represents 17% of non-obstetric lawsuits filed against gynecologists in the USA².

Currently, there is not a single non-invasive prevention strategy that effectively reduces the risk of UI⁸. Surgical exposure of the ureter and prophylactic ureteral stenting can help in its identification, but are both invasive approaches, not free from risks and therefore not included in any management protocol⁸. Nonetheless, in case of high-risk patients, prophylactic placement of ureteral stents can be considered as an important strategy for the prevention of ureteral injury. Pokala et al. conducted a comparison between simultaneous intra-operative vs sequential ureteral stent placement. Their findings revealed that simultaneous stent placement significantly reduced the overall operative time by 19 minutes, without leading to an increase in morbidity⁹.

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Studies investigating the identification of ureters using ureter-specific vital dyes are still in the preclinical phase, showing promise for future applications¹⁰. Notably, indocyanine green, the most extensively studied vital dye, does not undergo renal metabolism. Consequently, direct instillation into the ureter is required, either via cystoscopy using a rigid cystoscope or by pre-placing a ureteral stent. However, these procedures are invasive and significantly elevate the risk of complications, along with prolonging operative times¹¹.

The use of computer-assisted technologies during intra-operative surgical procedures offers a promising solution for enhancing safety in clinical settings. These technologies aim to improve the surgeon's awareness and capabilities by providing additional information from pre-operative examinations, monitoring the surgical site, and alerting the surgeon to potential adverse events. Virtual Reality (VR) and Augmented Reality (AR) tools, particularly in laparoscopic assistive technologies, have shown significant potential in achieving these objectives over the past decade^{12–15}. Atallah et al. demonstrated that stereotaxic surgical navigation in rectal cancer surgery is a valid technique for guiding dissection during surgery^{16,17}. This technique enables the identification of the optimal dissection point using radiological imaging, thereby facilitating the pre-operative localization of anatomical structures before their visualization in the surgical field. However, it is important to note that while radiological anatomy remains static, surgical anatomy inherently exhibits deformable characteristics, which may lead to disparities between the two. On the other hand, Kiyomatsu et al. demonstrated that during minimally invasive surgery in a porcine model, the difference between radiological anatomy and surgical anatomy, especially concerning pelvic vessels, is minimal, being less than 2.1 mm¹⁸. These results support the idea that an intra-operative navigation system capable of integrating radiological and endoscopic images could serve as a significant support for surgeons.

This paper presents an in-vivo study focused on evaluating the feasibility of using the surgical navigation system EVA for intra-operative ureteral identification on an animal model. EVA is a system previously developed by the authors to enhance surgical navigation, aimed at improving the quality and safety of MIS¹⁹. In fact, acting like an intra-operative GPS for surgery, it allows the visualization of a dynamic VR and/or AR environment that shows 3D models of patient-specific organs in real-time, aligned and synchronized with the endoscopic view. The EVA-VR system was evaluated in a laboratory setting by 14 surgeons, as reported in previous publication¹⁹. Results showed a navigation precision lower than 5mm, a reduction in task execution time by 15% and a reduction in the size of the peritoneal incision (to reach the lesion) by 46% compared to the control group. Surgeon's feedback highlighted how the use of EVA system improves the sense of orientation during surgery, therefore also helping in the identification of structures of interest.

Based on the preliminary findings, this study aims to further explore the potential of AR technology as a step forward from the VR GPS technology in surgical navigation. To this end, this paper reports the outcomes of a feasibility study focused on evaluating the EVA-AR system under conditions closely resembling those of real surgery, using a live porcine model during MIS (Fig. 1). The primary objective of this study is to evaluate the efficacy and usability of the system in identifying the ureter during MIS. The secondary endpoint involves assessing the system's initialization and calibration in an OR setting, measuring both the time required for these processes and the calibration error. Here, the description of the in-vivo study follows the ARRIVE 2.0 guidelines^{20–22}.

This paper is structured as follows: Section “**Materials and methods**” provides a brief overview of the EVA surgical navigation system and describes the study design and protocol. Technical and clinical results are presented in Section “**Results**”, followed by “**Discussion and conclusions**” in Section Discussion.



Fig. 1. An example of AR visualization of EVA Surgical Navigation System during the in-vivo study on animal model.

Materials and methods

EVA-AR surgical navigation system

EVA-AR is a surgical navigation system designed to offer an AR view of the surgical field. It provides a dynamic AR environment that shows in real-time 3D models of patient-specific organs overlaid and synchronized with the endoscopic view, showing Structures Of Interest (SOI) identified during the pre-operative planning (i.e., lesions, critical vessels, etc.). This overlay is obtained by manually registering the 3D organ models with the actual ones, using fiducial landmarks selected on rigid structures, such as bones. This process will be referred to as *patient calibration*. The alignment is then continuously updated during the surgical intervention based on the movements of the endoscope, monitored by an external Optical Tracking System. The idea behind EVA is to make the pre-operative planning easily accessible in the surgical room, relieving the surgeons' cognitive load required to mentally remember and fuse the plan with the intra-operative endoscopic images. To this end, EVA allows intuitive navigation and guidance, supporting the surgeon's decision-making process. The system capabilities are enhanced by advanced functionalities, such as changing the transparency of organs to visualize internal structures (e.g., tissue abnormalities, vessel structures, etc.). As shown in Fig. 2, the system is configured as a medical cart that integrates (i) an Optical Tracking Camera to track the endoscope motions, (ii) a full-HD monitor for the visualization of the AR functionalities, and (iii) a computer for the generation of the AR view. The tracking of the endoscope is achieved through a marker tool positioned on the body of the surgical endoscope.

Patient-specific 3D models reconstruction

The EVA system requires patient-specific 3D models as input, which can be obtained from diagnostic images such as CT scans or MRI scans. For this study, the HA3D™ service (Medics Srl, Italy) was used to generate the 3D models using CT scans, as illustrated in Fig. 1. HA3D™ technology integrates engineering modeling knowledge with clinical know-how in order to obtain 3D patient-specific medical-grade models based on 2D images²³. HA3D™ reconstructions can be manipulated by the surgeon, generating 3D model views that can be fitted, rotated, zoomed and virtually dissected, allowing a clearer study of the lesion itself. The reconstruction can also reveal possible anomalies near the neoplasm, such as inflammation, lymph nodes or smaller adjacent lesions. This service has already been verified in a pilot study aimed at evaluating the efficacy of high-resolution preoperative 3D reconstructions for lesion localization in oncological colorectal surgery²⁴.

Study protocol

The assessment study of EVA-AR was conducted at the Mini Invasive Advanced Surgery (MIAS) Academy with approval from the Italian Ministry of Health n°654/2023-PR (Risp. a prot. AC827.8). All experiments involving a live animal were performed in accordance with the ARRIVE guidelines and relevant regulations^{21,22}. Experiments involving human participants were conducted in compliance with the Declaration of Helsinki and all applicable ethical standards and regulations. Informed consent was obtained from all participants for study participation and publication of any identifying information/images in an open-access format.

A single male Yorkshire pig weighing between 20 to 30 kg, without genetic modification and in good health status, was used for the study. The animal was housed at the MIAS site and allowed a 12-hour acclimatization period before undergoing an abdominal CT with contrast under general anesthesia. The CT scan included an arterial phase, a late venous phase, and a urographic phase with contrast medium bolus to simultaneously enhance all anatomical structures, including arterial, venous, and urological components.

Before image acquisition, the animal was positioned supine in the same orientation it would assume during surgery, with the goal of minimizing position-induced anatomical deformation. The radiological images were acquired with a slice thickness of 1.5 mm. Subsequently, the animal was returned to the MIAS animal facility

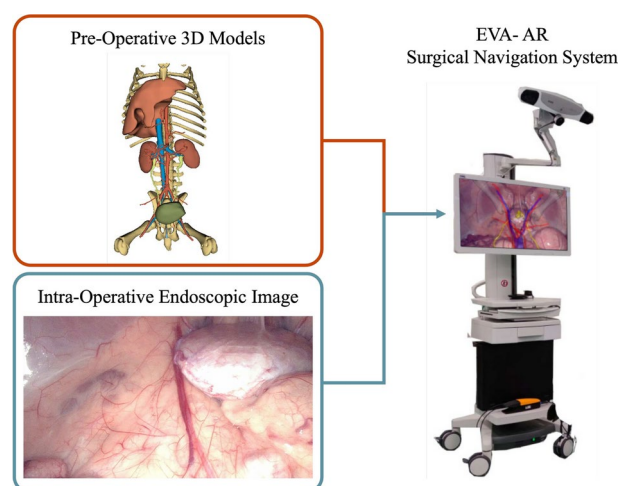


Fig. 2. The EVA surgical navigation system: on the left, the 3D models of the pig's selected organs generated with HA3D™ (Medics, Italy) and the intra-operative endoscopic image; on the right, the system medical cart, composed of a screen, an optical tracking system and a computer.

and remained there until the day of the experiment. The radiological images were transmitted via the Medics platform and used to generate 3D graphical reconstructions within three working days. The reconstructed structures were the retroperitoneal and pelvic organs, which are minimally affected by position-induced changes and pneumoperitoneum.

The experiment took place in the MIAS operating room, where the animal received general anesthesia administered by a trained veterinarian. The animal was positioned supine and in Trendelenburg position. Three trocars were used at the level of the transverse supra-umbilical line, and the bladder was emptied and anchored to the upper abdominal wall with a fixed trans point. At the conclusion of the study, euthanasia was performed in accordance with approved veterinary protocols. Standard minimally invasive surgery instrumentation, including a laparoscopic column equipped with TIPCAM 1 S 3D LAP, 0° optics (KARL STORZ - ENDOSKOPE, Tuttlingen, Germany), and dissecting and grasping instruments were used.

All anesthetic and euthanasia procedures followed current veterinary best practices. The animal received an intramuscular administration of tiletamine at 4 mg/kg, zolazepam 4 mg/kg (Zoletil), along with dexmedetomidine at 10 mcg/kg (Dexdomitor). Intravenous access was established in both ear veins using 20-gauge catheters. Subsequently, after IV administration of propofol at 4 mg/kg (Propovet) the animal was intubated and mechanically ventilated with a tidal volume of 10–13 mL/kg. General anesthesia was maintained with 2–3% sevoflurane (Sevflo) throughout the procedure. Analgesia was provided by an IV constant rate infusion of fentanyl at 30 mcg/kg/h (Fentadon). At the end of the procedure, the animal was euthanized using the pharmacological procedure of intravenous administration of pentobarbital sodium (150 mg/kg). This method ensures a painless procedure, as it rapidly depresses the central nervous system, leading to loss of consciousness and cessation of respiratory and cardiac functions.

The experimental evaluation was divided in two phases. The first phase was focused on assessing the system's initialization and calibration in an OR setting, later referred to as *Technical evaluation*. The second phase was focused on evaluating the efficacy and usability of the system in identifying the ureter during MIS, later referred to as *Clinical evaluation*.

Technical evaluation

A trained surgeon, with 10 years of experience in MIS and RMIS, and 5 years of experience with animal surgical experimentation, was asked to conduct a technical evaluation of the EVA system. The evaluation consisted in:

OR feasibility Qualitative assessment of the feasibility of integrating EVA's cart in an operating room;

Configuration assessment Qualitative assessment was performed for the system start-up configuration, to evaluate its proper initialization and ease of use; while a quantitative assessment of the *patient calibration* accuracy (*patientCalib_{acc}*) was performed by computing the re-projection error between the corresponding virtual and real points selected on the models and on the pig, respectively; Specifically, the reprojection error was measured as the Euclidean distance between corresponding virtual points (selected on the preoperative 3D model) and their real counterparts (manually identified on the pig's anatomy), which were re-projected onto the virtual 3D model using the rigid transformation identified during the calibration process. These points were selected based on anatomical landmarks visible in both the virtual and real environments. The real points were acquired by pointing the tip of a pointer tracked by the tracking system on the skin of the animal model.

Clinical evaluation

Four surgeons participated to the study, including 2 residents and 2 expert surgeons, all male with an age range of 31 to 43 years and an average of 36 years. All of them were from the field of general surgery. Each experimental session included two trials, during which participants performed the same task with and without the support of the EVA-AR system.

To optimize the use of the animal, non-destructive tasks were selected to prevent alterations in its anatomy that could affect the task's validity for subsequent participants. The chosen task was the identification of the ureter. The anatomy of the pig's ureter, like all retroperitoneal organs, closely resembles that of humans. However, a notable difference lies in the representation of retroperitoneal adipose tissue, which is minimal in pigs. Consequently, retroperitoneal structures are easily visible through the peritoneum. For this reason, the task was designed to be performed by residents rather than experienced surgeons, who would have found it too easy. This setup allowed for a better assessment of how the EVA system supports less experienced surgeons in identifying key anatomical structures while ensuring validation from an experienced supervisor.

The participants were divided into two groups (Group A and Group B), each comprising an experienced surgeon and a resident. Group A was assigned the task of identifying the left ureter using the EVA-AR system and the right ureter without its assistance, while Group B performed the opposite. The task was considered complete when the participant confidently identified the ureter. For each group, the resident conducted the identification task, while the expert surgeon manipulated the endoscope and confirmed the position of the ureter. The task required the participant to move the intestinal loops and localize the ureter. For each task, the completion time t_{task} was measured, and the correspondence between the ureter 3D model and the real structure was qualitatively evaluated. In addition, the subjects were asked to fill the following questionnaires:

- **Face validity** A custom face validity questionnaire was developed to assess the relevance of the setup, the system and the tasks executed. The specific questions are reported in Fig. 6.
- **System usability scale (SUS)** The SUS is a widely used questionnaire-based method for assessing the perceived usability of a system²⁵. It consists of ten statements that participants can evaluate on a Likert scale ranging from “strongly disagree” to “strongly agree”. The statements are designed to cover aspects of usability, efficiency, and learnability. After collecting individual responses, scores are calculated and transformed to provide a global usability score (SUS_{score}) on a scale from 0 to 100.

- *User experience questionnaire (UEQ)* The UEQ is a fast and reliable questionnaire to measure the User Experience of interactive products²⁶. The questionnaire investigates different aspects of the user experience: classical usability aspects, such as efficiency, perspicuity, dependability, and user experience aspects, such as originality and stimulation. The questionnaire uses pairs of contrasting attributes, and participants rate their experience on a scale from 0 to 7.
- *The surgical task load index (Surg-TLX)* The Surg-TLX questionnaire is designed to assess the perceived workload experienced by individuals performing surgical tasks. It takes into account various factors contributing to the overall workload, including mental, physical, and temporal demands, as well as factors like task complexity, situational stress and distractions, on a scale from 0 to 100.

While Face Validity, SUS, and UEQ were completed by both residents and surgeons, SurgTLX was filled out only by the residents who directly performed the tasks. Moreover, the surgeons completed the questionnaire only once, after completing both tasks. The results from these questionnaires were analyzed by computing the median and interquartile values, which are represented using boxplots, except for the UEQ results that were analyzed using the standard data analysis tool provided for the questionnaire.

Results and discussion

Technical evaluation results

OR feasibility

The dimensions of the EVA system cart are similar to those of a conventional laparoscopic column. Fig. 3 demonstrates its compatibility with the placement of other instruments, indicating its potential for seamless integration into conventional ORs. The cart must be positioned such as to place the Optical Tracking Camera at a distance between 1 m and 2.4 m from the operating field, enabling installation outside the sterile area. During our experiment, we ensured that the tracking camera maintained a clear line of sight to the surgical field by instructing the surgeon to orient it toward the center of the abdomen while keeping the camera as high as possible. This positioning was chosen to optimize visibility and tracking accuracy while minimizing occlusions. No significant tracking occlusions were observed, suggesting that the selected placement was effective in maintaining a continuous and stable tracking signal. From an ergonomic point of view, the monitor for visualizing the AR environment is positioned at eye level when standing. The endoscope marker tool, attached on the laparoscopic endoscope body, is small in size and did not interfere or impede the surgical procedure, as indicated also by the results of the face validity questionnaire. Due to its position, this tool should be made of a sterilizable material.

Configuration assessment

The Graphical User Interface (GUI) of the system was considered simple and intuitive. In order to perform the *patient calibration* it was necessary to choose at least 3 anatomical landmarks that are fixed (i.e. located on the ribcage), easily palpable and recognisable from outside by the surgeon. We chose the pubic symphysis and the medial margin of the last ribs, bilaterally. Regarding the choice of ribcage landmarks, we acknowledge that respiratory motion affects the ribcage. However, we selected the ribcage because it is a relatively rigid

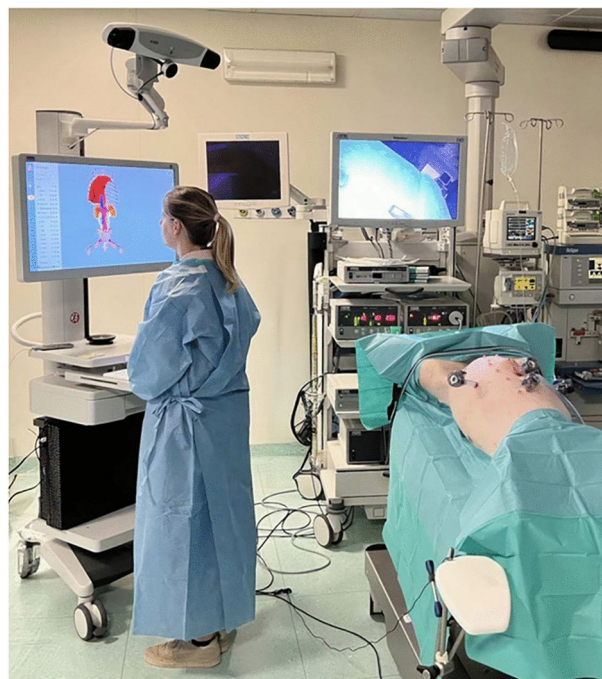


Fig. 3. Positioning of EVA surgical navigation system in a OR-like setting.



Fig. 4. An instance of identifying anatomical landmarks during the calibration process between the pre-operative 3D models and the animal model.

Trial	Execution time (s)
Trial 1 - NO EVA	125.33
Trial 1 - EVA	33.55
Trial 2 - NO EVA	49.27
Trial 2 - EVA	37.50

Table 1. Execution times for all trials with and without EVA-AR.

structure that maintains a stable spatial relationship with the preoperative 3D model and remains consistent throughout the intervention. While the ribcage moves due to breathing, this motion was minimal compared to other anatomical regions in the pig model. In human procedures, iliac crests would be the preferred landmarks for patient calibration due to their stability and independence from respiratory motion. However, in pigs, this was not feasible due to anatomical differences, making the ribcage the most viable alternative for calibration. Fig. 4 shows the process of landmarks selection. The calibration process took on average 1.04 min. A $patientCalib_{acc}$ of $1.7 \text{ cm} \pm 0.002$ was measured. The sources for this calibration error can be attributed partially to the pneumoperitoneum-induced changes and to the landmarks detection error. In fact, the virtual landmarks chosen on the 3D models did not take into account the skin-fat-muscle layers covering the bones.

Clinical evaluation results

The average task execution time t_{task} for all the tasks conducted with and without the support of the EVA-AR system were respectively $41.41s \pm 11.11s$ and $81.41s \pm 62.10s$; Table 1 shows raw values for task execution time for all the trials.

The surgeon had access to both the traditional laparoscopic column screen and EVA's screen. The EVA screen displayed AR images, where the 3D models were continuously updated in real time to align with the endoscopic view. The AR views were presented without noticeable delays compared to the endoscopic images and without any inconsistencies. Following the initial *patient calibration*, the 3D models demonstrated a high level of congruence with the anatomical structures of the pig. In both tasks conducted with the support of EVA, manual adjustment using the mouse was necessary at the beginning of the trial to refine the registration between the 3D models and the target structures. The reference points used for alignment included the kidneys and some features of the visible pelvic anatomy. In both cases, surgeons confirmed that the projected 3D model of the ureter accurately corresponded to the real anatomical structure, as shown in Fig. 5.

Figure 6 reports the boxplot of the results from the Face Validity questionnaire, indicating the median values and interquartile range for each question, with responses separated between surgeons (in blue) and residents (in orange). An analysis of the results is provided below:

1. The navigation system cart's disturbance to the intra-operative setup received a relatively low score, indicating that it may not significantly disrupt the surgical environment;
2. Both residents and surgeons reported that the markers placed on the endoscope did not interfere with intra-operative practice;
3. Participants felt that the task performed was not too simple compared to a real surgical operation, as indicated by the relatively high score.
4. Participants considered the system to be useful in MIS, in particular for the surgeons, while performing complex surgeries.

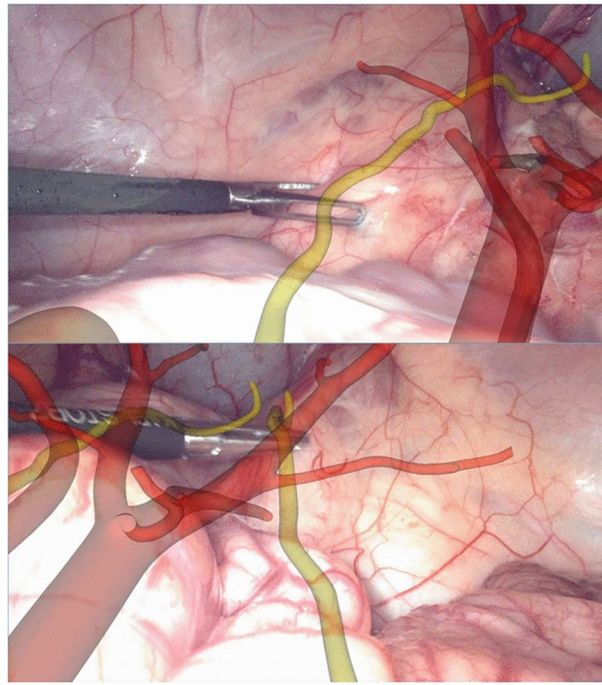


Fig. 5. Sample frames from ureter identification task with the support of EVA-AR. In these pictures, the surgeon was indicating with the instrument the location of the ureter.

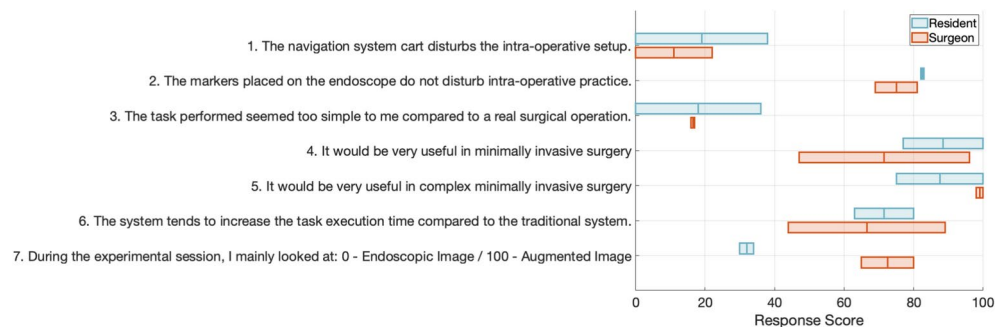


Fig. 6. Face validity questionnaire results.

5. The system's impact on task execution time compared to traditional methods received a moderately high score, suggesting that it may increase the time required for certain tasks; This opinion however is in contrast with the measure execution time, which appears to be lower when using the EVA system. We hypothesize this refers to the time to configure the system together with its usage during the surgery.
6. During the experimental session, participants' attention was divided between the traditional laparoscopy screen and EVA's augmented reality screen. A difference in preference was observed between residents and surgeons, the latter focusing more on the AR display than on the endoscopic video.

While the Face Validity questionnaire provided valuable qualitative feedback on the execution task, system usability and intraoperative integration of the EVA system, we acknowledge the potential for social desirability bias in custom-made questionnaire. This limitation is particularly relevant given the small number of participants and the exploratory nature of the study. To mitigate this, the questionnaire was designed to include both positive and critical evaluation aspects. Additionally, future studies will incorporate standardized usability assessments with a larger and more diverse participant pool to further validate these findings.

Results of the SUS questionnaire are presented in Fig. 7, where boxplots are reported with responses separated between surgeons and residents. The overall score obtained with the SUS questionnaire is $SUS_{score} = 73.75$, with very similar results from residents (72.5) and surgeons (75). This indicates a general positive perception of the system's usability, as a SUS score above 68 is considered above the average. Focusing on the single questions, the subjects expressed a high likelihood of frequent system usage and found the system easy to use. While there were mixed feelings regarding the system's complexity, subjects generally perceived good integration of system

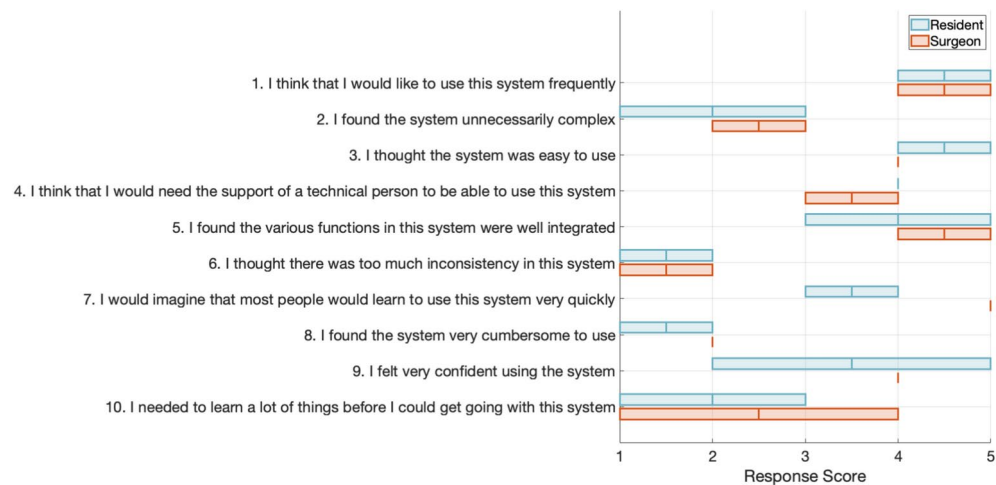


Fig. 7. System usability scale (SUS) results.

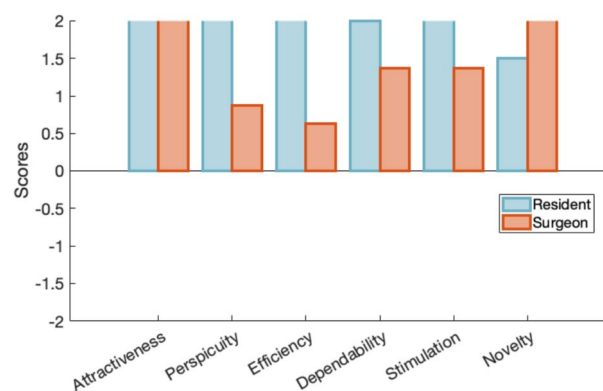


Fig. 8. UEQ questionnaire results.

functions and low levels of inconsistency. The majority of respondents felt confident in using the system and expressed confidence in its learnability, expecting most people to learn to use it quickly (more for surgeons). While there was some indication of a moderate need for learning before becoming proficient with the system, overall, the findings suggest a favorable perception of the system's usability with room for improvement in addressing perceived complexity and learning needs.

The UEQ questionnaire results, shown in Fig. 8, indicate that the EVA-AR system was rated highly across several user experience attributes. The highest mean score was for Attractiveness (2.250 ± 0.68 for both residents and surgeons), suggesting a positive overall impression of the system. Perspicuity and Efficiency were evaluated quite differently from residents and surgeons, with generally positive scores from the residents (2.25 ± 0.5 and 2.135 ± 0.28 respectively) and lower scores from the surgeons (0.875 ± 0.28 and 0.625 ± 0.28 respectively). This suggests that, in general, participants found the system relatively easy to learn and use, although there is room for improvement in these areas. Dependability and Stimulation also received favorable evaluations both groups, with residents providing slightly higher scores (2.0 ± 2.0 and 2.215 ± 1.53 respectively) than surgeons (1.38 ± 1.53 and 1.38 ± 0.03 respectively), highlighting the system's ability to engage and interest users. Finally, Novelty was the only metric evaluated more positively by surgeons (2.25 ± 0.0) than residents (1.5 ± 0.0), but it still remained positive overall.

The results obtained from the Surg-TLX questionnaire are presented in Fig. 9. These results reflect feedback exclusively from the residents who directly performed the task. Due to the small sample size, no statistical analysis was performed. However, the box plots shows an increased median and interquartile range in particular for the Mental Demand, Task Complexity and Distractions for the task executed without the support of EVA. These findings suggest that EVA may alleviate the challenges associated with surgical navigation and identification of critical structures.

Conclusion

This paper presented an in-vivo study on an animal model performed to explore the feasibility of the EVA-AR surgical navigation system for uretral identification. Based on an optical tracking system, EVA aligns 3D

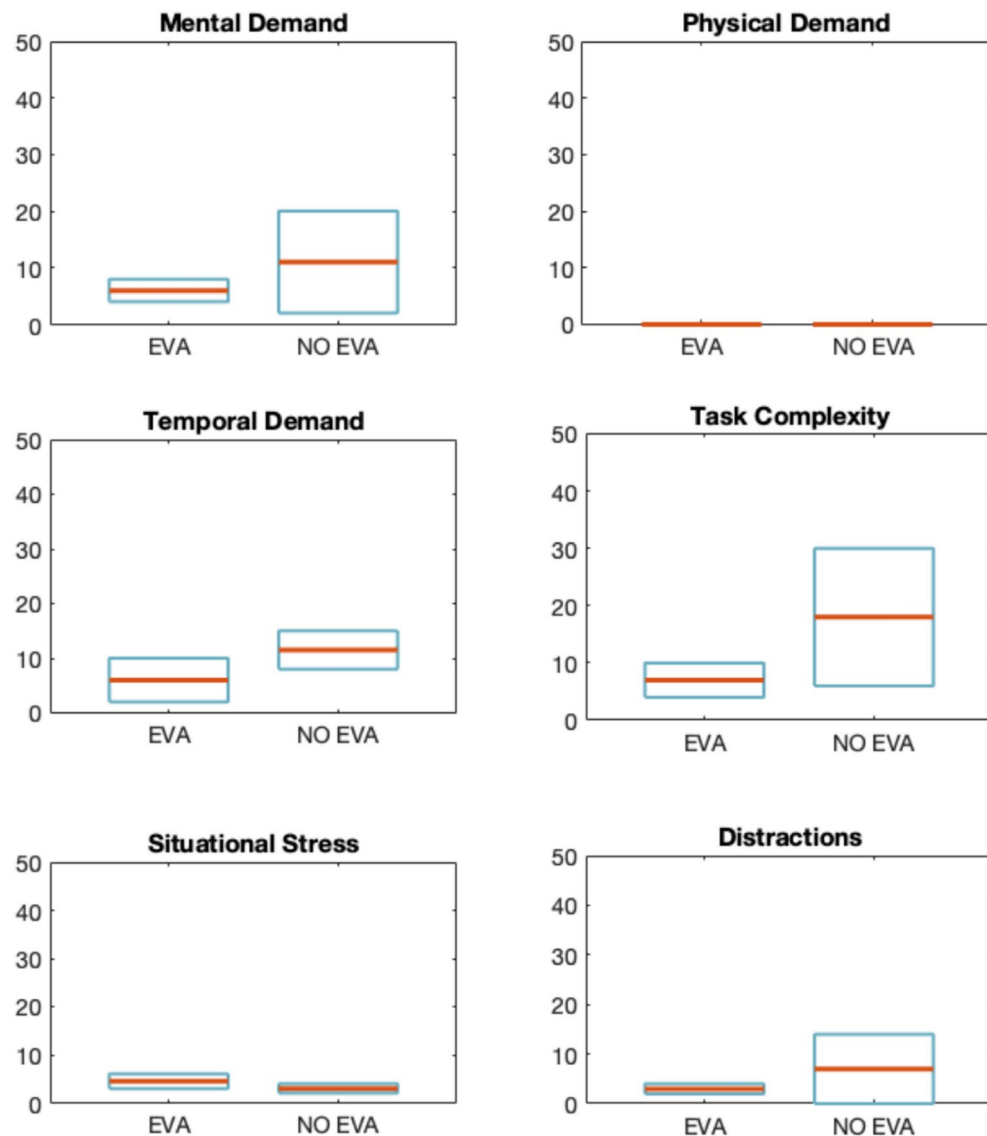


Fig. 9. Surg-TLX questionnaire results. The y-axis was truncated at 50 for better visibility of the results.

reconstructions of patient-specific organs, generated from preoperative radiological images, with intra-operative images captured by the endoscope. EVA-AR continuously updates the view of the 3D model in real-time, enabling a consistent and congruent alignment between virtual anatomical structures and those observed by the surgeon.

Being aware of the challenges associated with using an AR navigation system in general surgery, particularly due to the deformable nature of tissue organs and their susceptibility to positional changes with respect to the preoperative planning, this study was focused on retroperitoneal and pelvic organs. Despite being soft, these organs exhibit relative stability in position, with less susceptibility to modification by factors such as patient positioning and pneumoperitoneum-induced stimuli. This decision was influenced by findings from studies conducted on a porcine model by Kiyomatsu¹⁸.

This study demonstrated how EVA-AR can enable intra-operative surgical navigation. The EVA cart integrated well into the operating room and did not hinder the use of other equipment. The system was fully calibrated and operational in less than 15 minutes, requiring the involvement of two individuals, one at the cart and one at the operating table. According to questionnaire results, the participants who used EVA-AR believe that the system is functional and efficient, easy to learn, and user-friendly. The participants observed both the endoscopic video on the traditional laparoscopic display and on EVA's AR display during task execution, defining EVA as a supportive tool. This research focused on the problem of ureter identification, which is a crucial aspect in numerous surgical procedures. In this context, the support of EVA-AR navigation system appears to have positively influenced the task, facilitating the localization of the actual ureter.

However, further research is still necessary to validate this initial finding. Limitations of this study include: (i) The limited number of subjects who tested EVA; (ii) The fact that experiments were performed on a single animal; (iii) The exclusion of more invasive actions during the ureter identification trials; (iv) The absence

of retroperitoneal fat in pigs, which facilitates ureter identification through the parietal peritoneum. Further studies are already planned to address the shortcomings identified in this feasibility study before experimenting with EVA in the operating room on humans.

Data availability

The data that support the findings of this study are available from the corresponding author on reasonable request.

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Author contributions

V.P., L.S.M., A.N. and J.O. conceived the experiment, D.S., B.S., D.P., L.E., G.C. and M.A. conducted the experiment, D.S. provided the technical assessment, V.P. analyzed the results, V.P., A.N. and L.S.M. wrote the manuscript. All authors reviewed the manuscript.

Declarations

Competing interest

V.P., D.S., B.S., A.N., J.O., D.P., L.E., F.C., M.A., S.S., D.G.C., and L.S.M. have no conflicts of interest or financial ties to disclose.

Informed consent

Informed consent for publication of identifying images in this online open-access publication has been obtained from all the subjects depicted.

Additional information

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