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*Usability and performance studies of an
Augmented Reality Laparoscopic System for
Minimal Invasive Surgery*

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Contents

Zusammenfassung / Summary in German	6
Acknowledgement	8
Table of abbreviations.....	9
1 Introduction.....	10
1.1 Laparoscopic surgery	12
1.2 Retroperitoneal organs	16
1.2.1 Kidney.....	19
1.2.2 Pancreas	20
1.2.3 Rectum	22
1.3 Challenges of laparoscopic surgery	23
1.4 Augmented reality (AR) and image modality	25
1.5 Preliminary work in the field of AR and laparoscopy	27
2 Problem and task statement	32
3 Method and Material.....	34

3.1	Analysis intervention	34
3.2	Segmentation of Datasets.....	36
3.3	Laparoscopic Augmentation System (LAS)	37
3.4	User Studies and Phantoms.....	38
3.4.1	User study I: Augmentation techniques	39
3.4.2	User Study II: Verification of Augmentation	44
3.4.3	Validation Phantoms	56
4	Results.....	58
4.1	Results of User Study I	58
4.1.1	Objective Performance Measures	59
4.1.2	Subjective Survey	62
4.2	Results of User Study II.....	67
4.2.1	Objective Performance Measures	69
4.2.2	Subjective Survey	71
5	Discussion.....	78

5.1	User Study I	78
5.2	User Study II	81
6	Conclusion	84
7	References	86
	Appendix	95
	Appendix A – Survey User Study I	95
	Appendix B – Survey User Study II	108
	Appendix C – Intervention list	126
	Affidavit	132

Zusammenfassung / Summary in German

Deutscher Titel der Arbeit: Untersuchung der Benutzerfreundlichkeit und Leistungsfähigkeit eines Augmented-Reality-Laparoskopiesystems für die minimalinvasive Chirurgie

In dieser Arbeit konnte anhand von zwei Nutzerstudien gezeigt werden, dass das laparoskopische Augmentierungssystem (LAS) die Einblendung von DICOM-Segmentierten Daten im Endoskop-Video robust darstellen kann. Die Augmentierungen können z.B. Risikostrukturen wie Gefäße oder andere Objekte wie Tumore umfassen. Die Ergebnisse der Nutzerstudie II zeigen, dass die Genauigkeit des Trackings und der Darstellung der Augmentation ausreichend zu sein scheint, um den Nutzer minimalinvasiv zu einer Region zu führen. Das System wird als hilfreich empfunden und von den Teilnehmern als eine Verbesserung gegenüber der klassischen laparoskopischen Anwendung in den Nutzerstudien I & II wahrgenommen. Die Ergebnisse in der Testumgebung zeigten auch quantitativ, dass das LAS einen positiven Effekt auf die Invasivität und die Behandlungszeit hat. Insbesondere wurde ein signifikant geringeres Maß an Invasivität gemessen. Wenn möglich, sollten weitere Probanden die Anwenderstudie II absolvieren, um die Ergebnisse weiter zu festigen. Die Augmentationstechnik bzw. Visualisierung der Augmentierungen scheint nicht so relevant zu sein wie angenommen, obwohl es deutliche Favoriten unter den Teilnehmern der Nutzerstudie I gab. Es sollte jedoch weiter untersucht werden, insbesondere bei realeren und damit komplexeren Aufgaben, ob dieses Merkmal wichtiger ist, als es die Nutzerstudien derzeit zeigen. Die Aufgabe der Benutzerstudie II hat sich als hilfreiches Trainingsinstrument erwiesen, aber das Material sollte weiter verbessert werden, um eine noch bessere Vergleichbarkeit mit einem realen Situs zu erreichen. Die Anbringung notwendiger Trackinginstrumente an dem Laparoskop und zusätzlicher Geräte muss in weiteren Validierungen gut untersucht werden, um die Nutzbarkeit des LAS sicherzustellen. Die Aufbereitung der Daten - Segmentierung der Organe und insbesondere der Gefäße - ist nach

wie vor sehr zeitaufwendig, so dass zu erwarten ist, dass der Aufwand in der Routine nicht verhältnismäßig sein wird. Die Weiterentwicklung der automatischen Bildsegmentierung kann diesen Aufwand reduzieren und ausgleichen. Hochauflösende Daten (insbesondere Schichtabstände) und gut an den Anwendungsfall der Segmentierung angepasste Scanprotokolle sind notwendig, um ein effektives Verfahren zu gewährleisten. In der Rektum- und Pankreaschirurgie ist die Kontrastmitteldarstellung derzeit oft kein Standard, was die Segmentierung von Gefäßen unmöglich macht.

In den ersten Vorarbeiten zur Validierung konnten bereits erste Rückmeldungen gesammelt werden. Auch hier hat sich der Einsatz des LAS als hilfreich erwiesen. Wichtig scheint zu sein, dass die Augmentation nur die aktuell wichtigen und notwendigen Informationen enthält.

Acknowledgement

I would like to thank the team members of the ATLAS team for the good cooperation and the pleasant work.

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I wish the whole team continued success and look forward to the progress of the LAS system.

Table of abbreviations

MIS	Minimal-invasive surgery
AR	Augmented reality
VR	Virtual reality
LAS	Laparoscopic augmentation system
ROI	Region of interest
CT	computed tomography
MRI	magnetic resonance imaging

1 Introduction



Figure 1: The 3 Partners of the BMBF Funded ATLAS Project. Industry partner: Maxer Endoscopy GmbH, clinical partner: Ludwig Maximilian University Munich and the technical partner: Technical University Munich – CAMP Institute

The goal of the ATLAS project is to provide an augmented reality visualization of image data in-situ on the laparoscope image in 3D. This provides the surgeon with the required information (vessels, nerves, lead structures, etc.) in the correct position at the right time. The aim of the project is to show the surgeon what he cannot see with the eye or the laparoscopic image. Preoperative and intraoperative diagnostic image data are displayed on separate monitors during routine operation. The surgeon must therefore mentally establish a spatial assignment and correspondence between preoperative (e.g. CT or MRI) and intraoperative imaging (e.g. laparoscopy, sonography) on the monitor and the surgical site of the treated patient. The aim of augmentation is to achieve shorter operating times, greater safety, fewer conversions, fewer peri- and post-operative complications, shorter hospital stays and a higher number of cases of minimally invasive procedures even for more complex operations. Another advantage of the ATLAS laparoscope is the navigation support for laparoscopic surgeons in training and early years. By superimposing and displaying risk structures, safety during the surgical procedure can be increased and a faster learning curve achieved. Surgical training to learn the above mentioned procedures has so far been reserved for only a few specialists and the learning curve is relatively long. With the current shortage of doctors and surgeons, concepts for faster training

with the same or better quality will have to be developed in the next few years to ensure a broad supply to society. While the experience of the individual surgeon has so far been the most important factor, such a surgical 3D map can greatly simplify procedures and make them much safer, especially in centres with a low number of operations. The ATLAS project can further simplify operations and improve their quality. Thus, a minimally invasive and gentle procedure can be offered everywhere.

In the context of the ATLAS project, the working group of the Clinic for General, Visceral, Vascular and Transplant Surgery (LMU) will be responsible for the design, development, testing and validation of the Augmented Reality Laparoscope for clinical use.

In close cooperation with Maxer and the TUM, the LMU will first conduct a requirements analysis for the planned augmented reality laparoscope. For this purpose, research results in the field of Medical Augmented Reality for Laparoscopy will be evaluated, clinical use cases will be defined in expert interviews and test cases will be developed. The research group of the LMU with its clinical experience in the field of laparoscopy will support the software and hardware development by Maxer and the software experts of the TUM. After completion of the requirements analysis, LMU will design a phantom model on which the prototype will be developed and tested. In this way, product quality and clinical benefit can be improved at an early stage of development. The phantom model will be used to prepare the augmented reality laparoscope for animal experiments in an iterative process.

We plan to use augmentation initially for retroperitoneal fixed organs (rectum, pancreas and kidney), since one of the skin problems of augmentation in visceral surgery is the deformity of the organs during the interventions. The interventions defined in the use case analysis are evaluated in animal experiments after the tests in dry rennet. For this purpose, the LMU will conceptualize and submit the study design and the ethics application. Furthermore, the surgeons of the working group will perform the animal experiments and evaluate the results.

Here, too, an iterative process will be carried out in close cooperation with the Maxer company and the TUM research institute to optimize augmentation.

The contribution of the LMU working group represents a central aspect of the Augmented Reality Laparoscope to be developed. The LMU will define the requirements of the clinicians, evaluate the development steps and test the product in phantom and animal experiments before clinical use. This is the only way to ensure the promising development of such a product. In the course of development and validation on phantom and animal models, a number of publications are planned in the fields of laparoscopy, computer-assisted surgery and, in particular, in the areas of oncological use cases. With the completion of the product, further clinical studies are planned to investigate the benefits and possibilities of augmented reality.

1.1 Laparoscopic surgery

In laparoscopic surgery, surgical procedures are performed in a minimally invasive manner by inserting miniaturized surgical instruments into the body via trocars to reach the area to be operated on.



Figure 2: Standard laparoscopic instruments: (1) Disposable trocar for 5-12mm instruments, (2) Laparoscopic scissors, (3) 10mm optical trocar with CO2 connection, (4) 10mm optics (taken from: [1])

CO2 gas is injected into the abdominal cavity to create sufficient space for the instruments to move. This is called capnoperitoneum, “capno” = carbon dioxide gas, “peritoneum” = abdominal cavity. This is done via a gas hose, usually connected to the optical trocar. Typical values for the CO2 insufflation are:

- 4-6 liters per min
- Pressure of 10-20 mmHg

During this process the abdominal wall elevates to build the room needed for manipulation and handle of laparoscopic instruments.

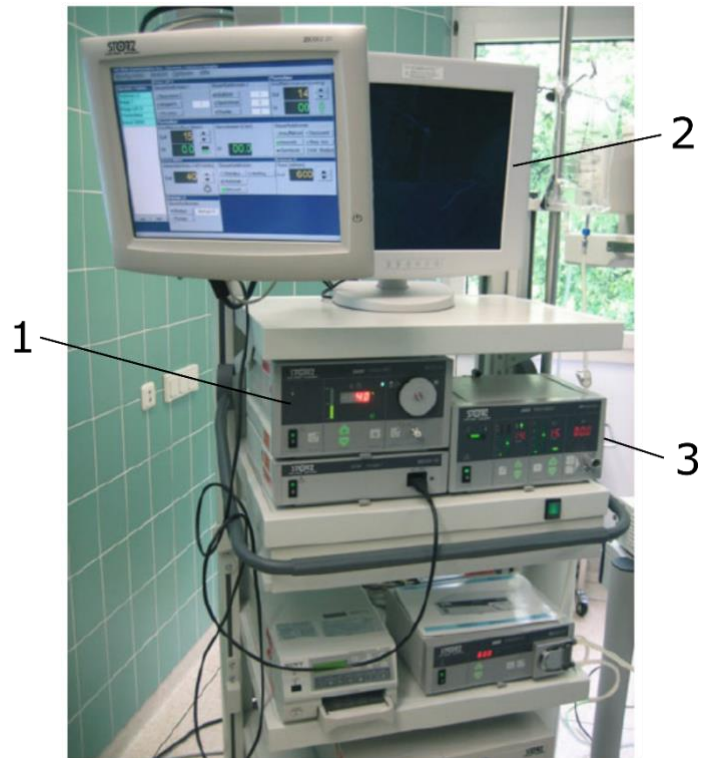


Figure 3: **Left:** laparoscopic surgery with four trocars enable access to the surgical field. The capnoperitoneum enables view and manipulation with effectors at the region of interest (ROI). **Right:** Typical endoscopic tower with (1) light source, (2) endoscopic screen and (3) CO2 gas supply. (both taken from: [2])

The surgeon monitors the operation with a rigid endoscope and a screen displaying the endoscopic video image [2].

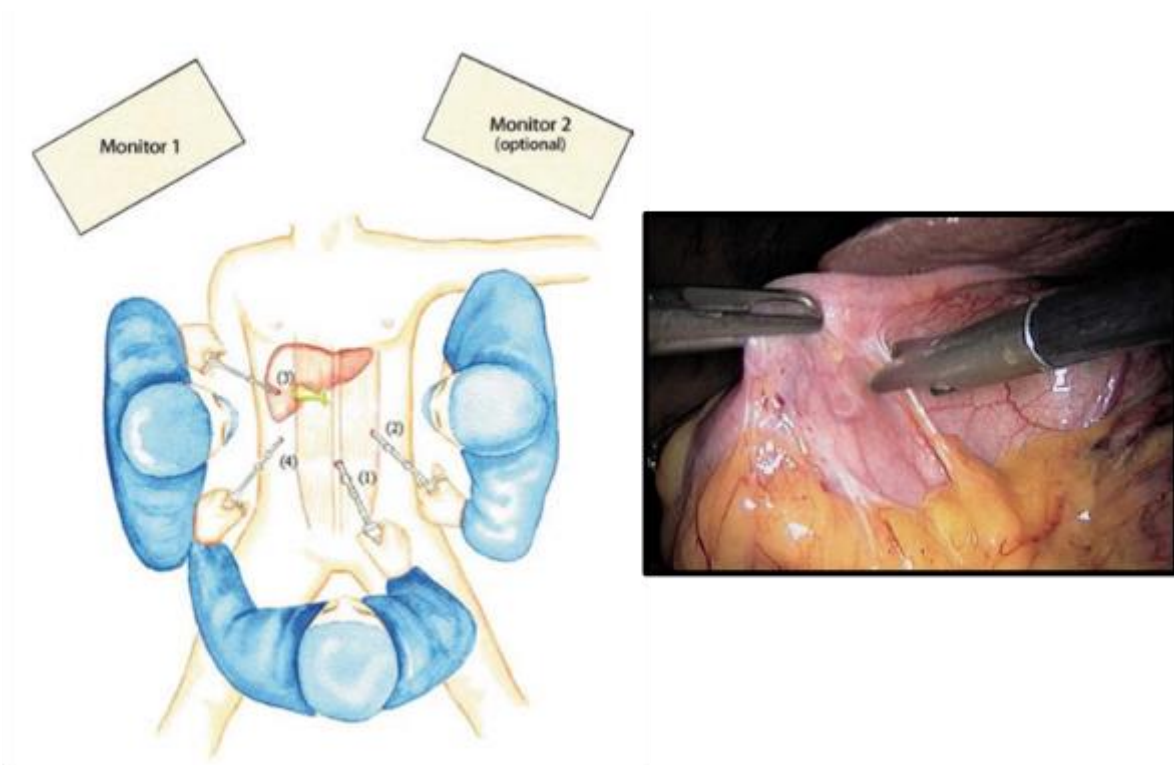


Figure 4: **Left:** Typical operation setup for a laparoscopic cholecystectomy. The surgeon stands between legs, “French position” and is supported by two assistants. (taken from: [3])
Right: Endoscopic camera image while freeing omental adhesions. (taken from: [4])

The continuous improvement of endoscopic technology and laparoscopic instruments has made great progress in reducing access trauma. This can be positively assessed on the basis of various surgical parameters, such as effects on the immune system, lung function, postoperative pain, length of stay and, last but not least, the quality of life of the patients. [5]

1.2 Retroperitoneal organs

Various abdominal surgical procedures are performed with laparoscopic techniques and the trend is rising. In this project it will be focused on organs in the retroperitoneal space, e.g. kidneys, pancreas and rectum (Figure 5). The kidneys and ureter are directly fixed to the back wall of the abdominal cavity, called primary retroperitoneal. Pancreas and main part of the rectum are secondary retroperitoneal – meaning organs originally attached to the mesentery, which, however, has receded in the course of development. As a result, the organs are firmly attached to the dorsal wall of the abdominal cavity. In addition to the organs, other structures such as the aorta abdominals or vena cava inferior are also located completely retroperitoneal. It is assumed that during a laparoscopic procedure these organs or structures will shift little in their spatial position until a direct intervention at the region of interest (ROI) occurs. In a later chapter it will be explain why this property is important and the following three MIS interventions have been chosen for this project.

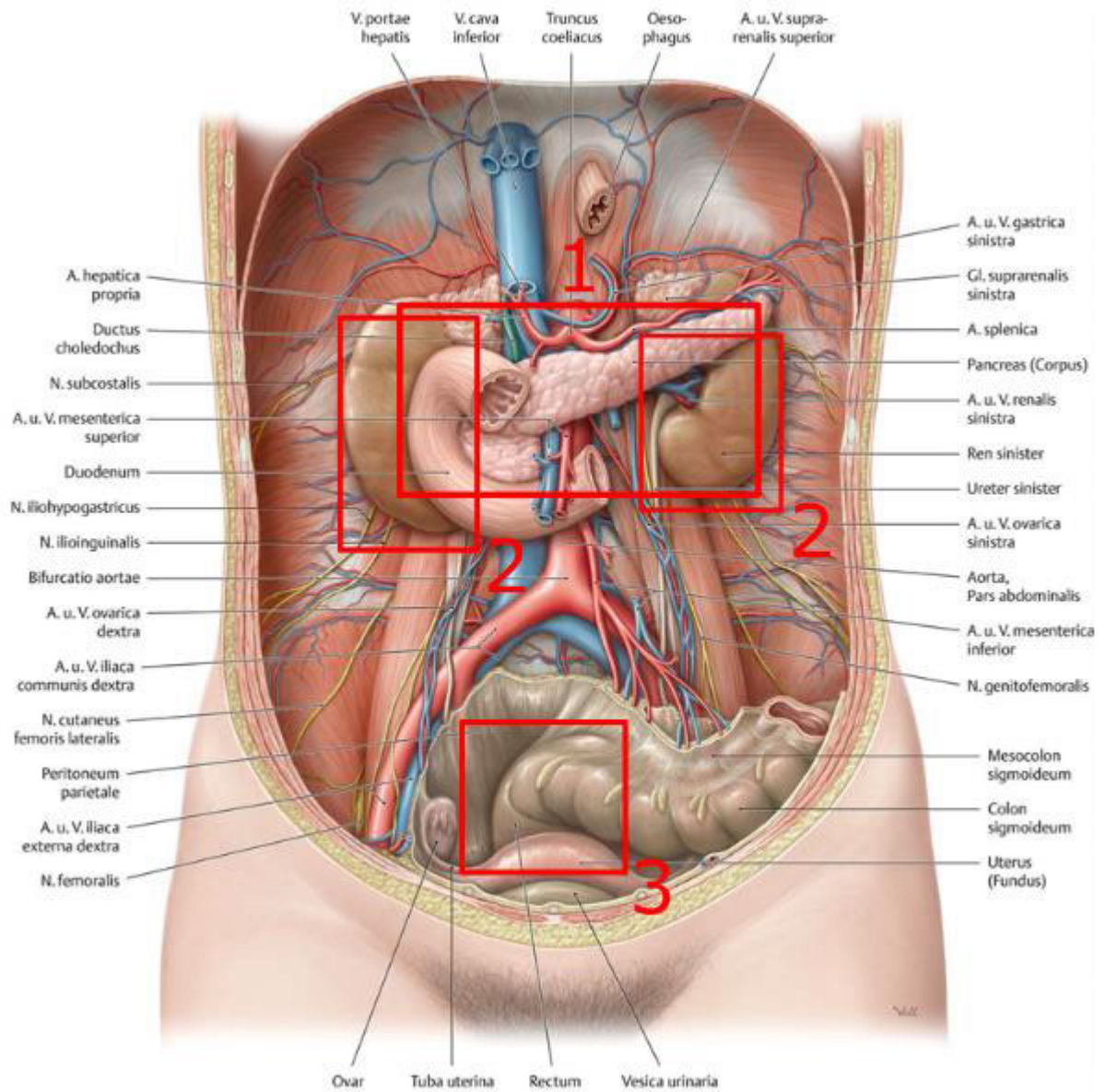


Figure 5: retroperitoneal organs: (1) pancreas, (2) left and right kidney (ren sinister and dexter), (3) rectum (taken from: [6])

1.2.1 Kidney

The kidneys serve to regulate the water, acid-base and salt balance of the human body and to excrete urinary metabolic products. Both Kidneys weigh about 160 g and 12 x 6 x 4 cm in size. They are located between the thoracic vertebral body 11/12 (T11/T12) and lumbar vertebral body 2/3 (L2/L3). The right kidney is half a vertebral body lower due to the liver. Each kidney is supplied with blood from renal arteries originating directly from the aorta. The renal vein leads the blood directly into the inferior vena cava. Additionally, both kidneys are connected to a ureter which end at the bladder (Figure 7 left). Above the kidneys are the adrenal glands, which are supplied with blood by three arteries and discharge via one vein (Figure 7 right):

- arteriae suprarenalis inferior, starting from the a. renalis
- a. suprarenalis media, starting directly from the aorta
- a. suprarenalis superior, starting from a. phrenica inferior
- left adrenal glands: vena suprarenalis and connects with the vena renalis sinister
right adrenal glands: vena suprarenalis dexter connects directly with vena cava

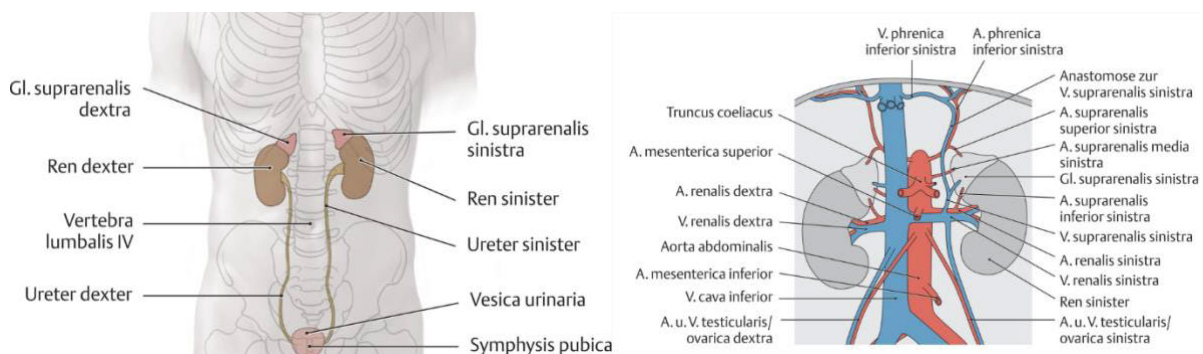


Figure 7: **Left: (sinister) left and (dexter) right (ren) kidney** each connected to an ureter. The ureter ends at the bladder (**vesical urinaria**). **Right: Schematic view of ventral right kidney with adrenal gland.** It shows the vascularization of the kidneys. (both taken from: [7])

1.2.2 Pancreas

The Pancreas is part of the digestive system and has both an exocrine – secret substances onto an epithelial surface - and an endocrine – releasing hormones directly into the circulatory system – gland. The exocrine part of the pancreas produces 1.5-2 l of a digestive secretion per day, which contains bicarbonate (pH about 8) and enzymes for the breakdown of proteins, lipids, carbohydrates and nucleic acids. The endocrine main function of the organ is the regulation of glucose metabolism. The pancreas is 13-18 cm long and weighs 70-80g. The organ head lies in the duodenal arch and the pancreas body in the height of L1/L2 (Figure 8).

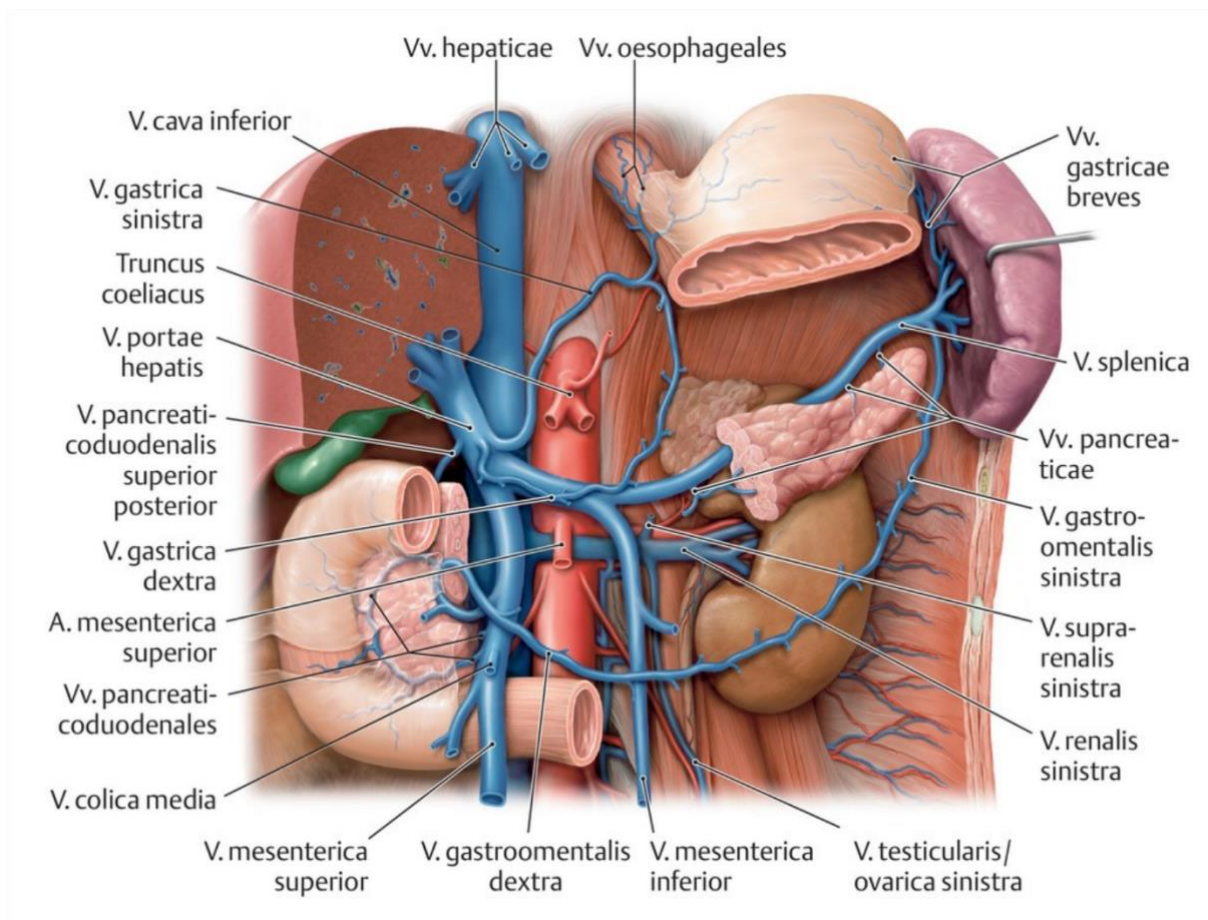


Figure 8: Location and venous system of the pancreas (taken from: [8])

The venous blood from the body and tail of the pancreas is carried from small pancreatic veins (vena pancreaticae) via the splenic vein (vena splenica or vena linealis) into the portal vein (vena portae). The blood from the head of the pancreas passes through the pancreaticoduodenal vein (vena pancreaticoduodenalis) into the superior mesenteric vein (vena mesenterica superior) and then also into the portal vein.

The arterial supply covers three larger vessels: The upper pancreaticoduodenal artery (Arteria pancreaticoduodenalis superior), the large pancreatic artery (Arteria pancreatica magna) and the lower pancreaticoduodenal artery (Arteria pancreaticoduodenalis inferior) branch out into further smaller arteries, some of which connect with each other. (Figure 9)

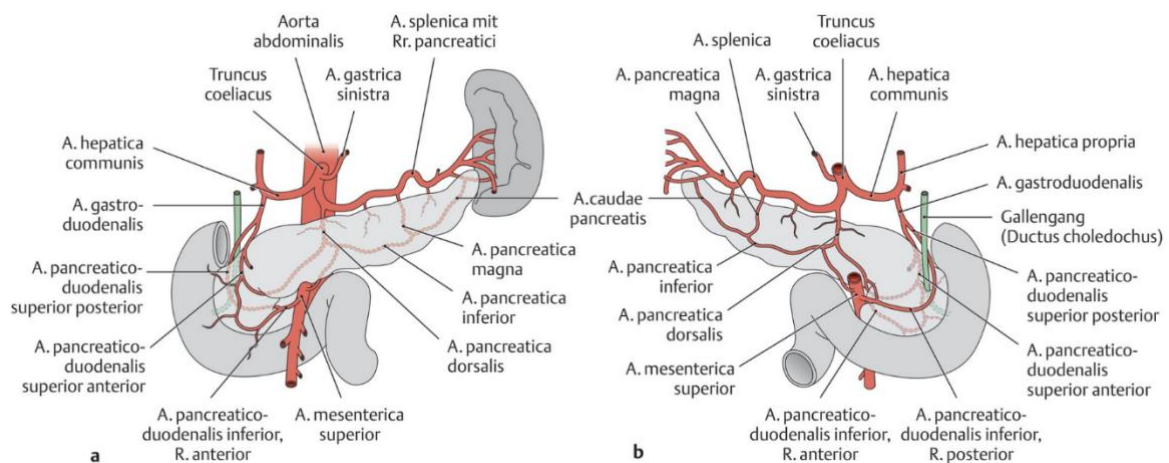


Figure 9: Arterial supply of the pancreas. (a) view from ventral and (b) dorsal (taken from: [7])

1.2.3 Rectum

The approx. 12-18 cm long rectum immediately follows the sigmoid colon and passes into the anal canal shortly before passing through the perineum. The arterial blood supply of the rectum is divided in two parts: the upper part is supplied via a. rectalis superior – originated from a. mesenterica inferior – and the lower part on each side via a. rectalis mediae sinistra/dextra – originated from a. iliaca interna sinistra/dextra. The venous system corresponds to the arterial system and therefore has the same name groups. It is important that the vena rectalis mediae and inferiores are connected via the vena iliaca to the vena cava inferior. The vena rectalis superior on the other hand conducts its blood to the vena mesenterica inferior and the vena portae hepatis and thus to the liver. (Figure 10)

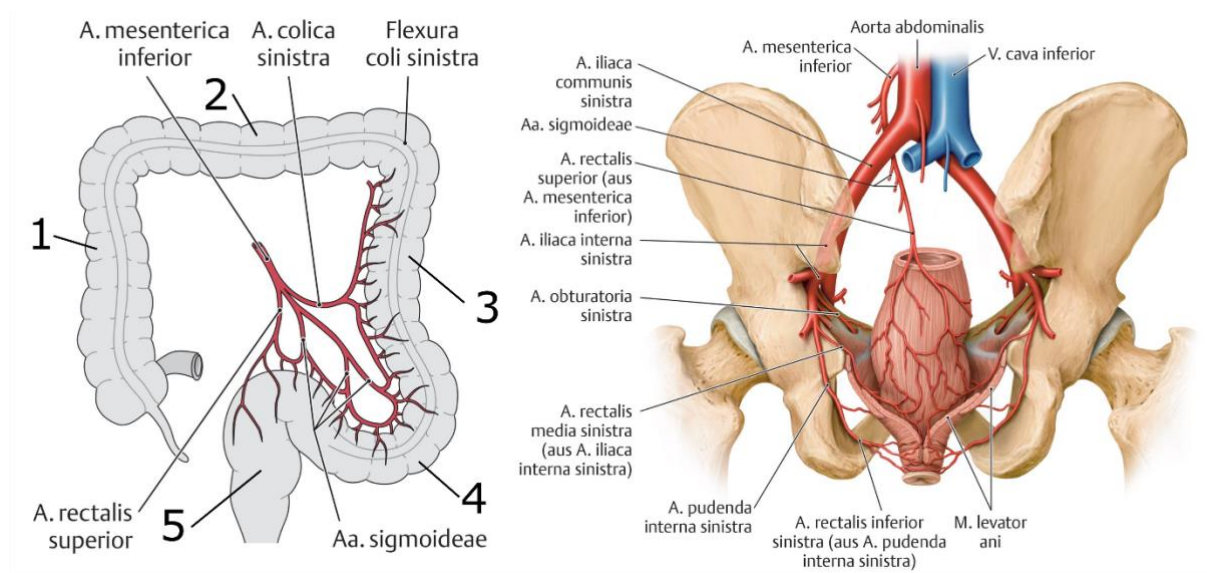


Figure 10: **(Left)** colon **(1)** -ascendens, **(2)** -transversum, **(3)** -descendens and **(4)** -sigmoideum and **(5)** rectum. **(Both)** arterial supply of the rectum originating from a. mesenterica inferior and a. iliaca interna sinistra (taken from: [9])

The organ along with the anal canal acts as a reservoir for the stool. Three muscle systems form the sphincter system and jointly ensure with other mechanisms to seal the rectum (Figure 11):

- Musculus sphincter ani internus
- M. sphincter ani externus
- M. puborectalis (part of the m. levator ani)

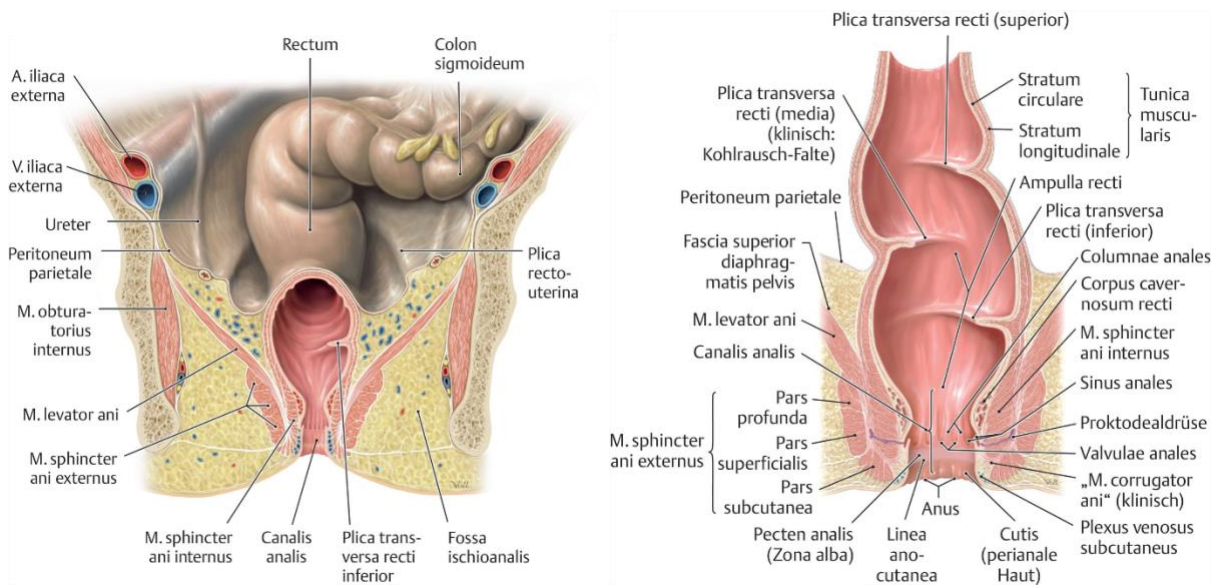


Figure 11: **(Both)** form and structure of rectum and anal canal (taken from: [9])

1.3 Challenges of laparoscopic surgery

In addition to the previously mentioned strengths of laparoscopic surgery, new challenges are also presented to the surgical technique. First and foremost, the new techniques and instruments must be learned by both the surgeon and the surgical team. E.g. laparoscopic suturing is a difficult task and needs extensive training [10, 11]. The long learning curve leads frequently to increased operation times [12] and higher complication rates at the beginning [13–15]. A meta-

analysis by Finoche et al [16] suggests that in the process of "conversion" of a surgeon, an increased in anatomic leakage, overall morbidity and wound abscess rates can occur. A potential result of those challenges shown by Ghadban et al. [17]: "Minimal invasive surgery for colorectal cancer remains underutilized in Germany". They investigated a higher mortality rate for open surgery (4.7%) than minimal-invasive surgery (MIS) (1.8%) ($P < 0.001$). Another Meta-Analysis by Nanidis et al. "Laparoscopic Versus Open Live Donor Nephrectomy in Renal Transplantation" analysed 73 studies came to the conclusion, that open nephrectomy is still associated with shorter operative [18].

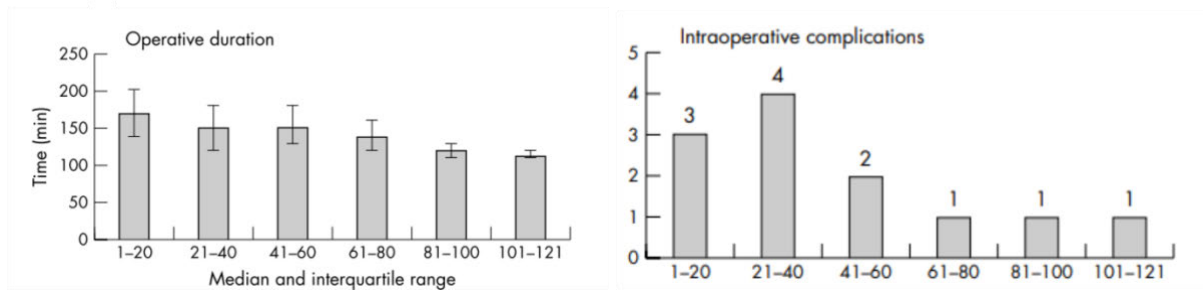


Figure 12: OR time and intraoperative complications of laparoscopic nephrectomy over patients shows the learning curve effect (both taken from: [19])

One of the main challenges for the user is the lack of depth perception during laparoscopic procedures as presented in [20]. The publication reviews innovate approaches to improve the depth perception in laparoscopic techniques.

1.4 Augmented reality (AR) and image modality

Additionally to the above mentioned challenges, direct vision and tactile feedback get lost with laparoscopic techniques. AR attempts to overlay computer graphics with the real world and create a coherent perception of both sources [21]. The technology of augmented reality could help to reduce the effect of the disadvantages of MIS [22]. A search for citations in the area of AR in laparoscopic surgery was performed by Bernhard et al. in June 2016 and is shown in Figure 13 left. An continuous increased in publications in recent years can be seen.

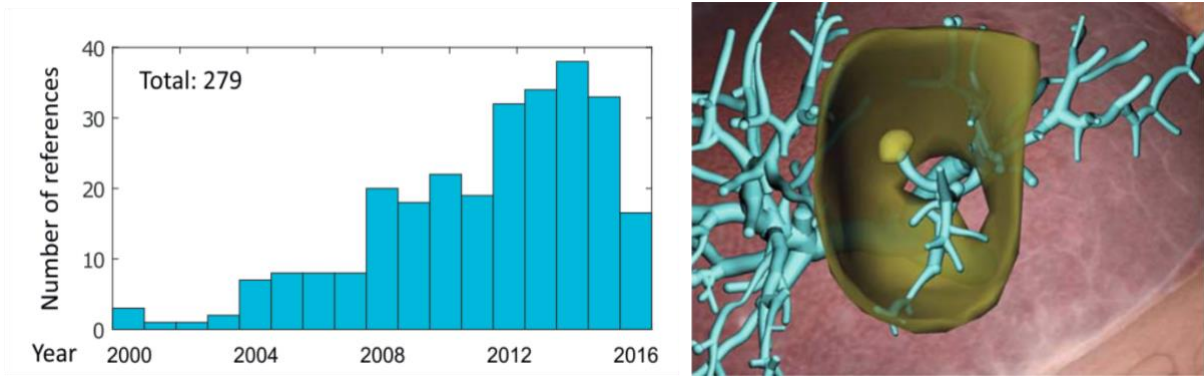


Figure 13: **(Left)** search for citations in the field of AR in laparoscopic surgery (taken from: [23]). **(Right)** Laparoscopic image showing the pig cadaver liver with AR extension of vessel and object structures (taken from: [24])

AR in other surgical domains can be seen as further established, e. g. neurosurgery. A review in 2017 by Meola et al. concluded that AR in surgery improve the already established neurosurgery navigation system [25]. So far the Microscope is the most common platform for AR in the neurosurgery field. Cranial and spinal surgery are suitable for AR because the spatial position of objects on image data differs acceptable between the time of acquisition, i.e. generation, and the time of use, i.e. during the intervention. Furthermore, high-resolution 3D imaging procedures are already standard in these areas.

Preoperative Computer Tomography (CT) with contrast agent is standard for many abdominal indications by today [26–28]. The ability to outline and segment vascular structure is key in this project. An advanced imaging protocol for pancreatic cancer to generate 3D objects was presented by Abe et al. [29]

1.5 Preliminary work in the field of AR and laparoscopy

There are different approaches and use cases for AR in laparoscopy. A large area of AR is the support in training. There are studies that show the efficiency of simple instructions in the training environment [30–35] by using augmented reality techniques.

In 2016, a comprehensive review on the status of AR in laparoscopy and its potential clinical use was conducted by a Strasbourg group. One conclusion of the review is, that there is currently insufficiently validated data on AR systems in laparoscopy to meet the strict requirements of certification and therefore no products can be released for patient use. [23]

To enable and improve AR in soft tissue surgery, there are several projects in the field of camera vision. This includes registration, detection of deformation, segmentation of instruments and much more. A number of recent publications on this subject were presented at the MICCAI Congress 2021: [36–39]

In the recent work (2020) of Akladios et al., the usefulness of AR in gynecologic laparoscopic surgery was evaluated by animal model. With surveys it has been shown, that the AR system is perceived as helpful for the identification of the ureter compared to the classical method of direct vision or direct vision with stimulation - Figure 14. [40]

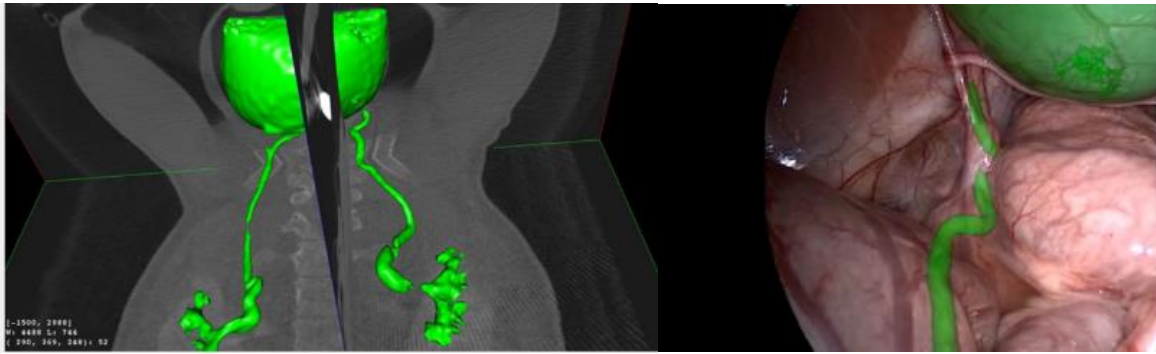


Figure 14: **(Left)** 3D segmentation of the ureter **(Right)** AR of the 3D segmentation in the laparoscopic image (both taken from: [40])

Another group showed 2021 the benefits of an AR guidance system in laparoscopic liver surgery by using sheep liver and pseudo-tumors. In 22 livers 90 tumors were surgically resected (30 Ultrasound, 30 AR, 30 Ultrasound + AR). The study claims, that AR or Ultrasound + AR is more efficient than Ultrasound only. [41, 42]

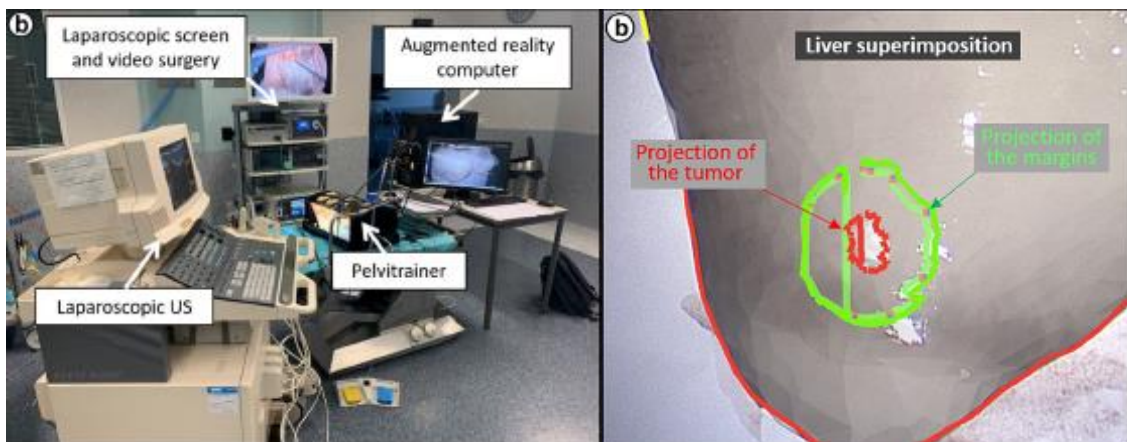


Figure 15: **(Left)** Surgical setup for the resection **(Right)** AR in the laparoscopic image. The margin is projected to the axis of the laparoscope (both taken from: [41])

Ritter et al. have investigated the methods for spatial representation of vascular structures in 2006. In the investigations no colors were used for the representation of 3D information, since the medium color is to be used for further context information. Mainly texture and shadow illusions were used. They could show, that showing shape and topology could be presented efficiently by texture [43]. Other concepts for better depth perception of vascular structures have been emerged. [44, 45]

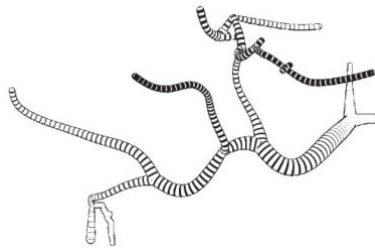


Figure 16: Encoding of distance of a vascular structure with a strike-width texture (taken from: [43])

A later work by the same group [24] investigated the new illustration methods in three clinical scenarios, but a statistical analysis was not carried out.

In a publication by Choi et al. [46] it was presented, the main difficulty by using a navigated AR system is depth perception. It was already mentioned in chapter 1.3 that the lack of depth perception in classical laparoscopy is one of the main challenges for the user anyway. The study presented a system, where the user was able switch between a VR (virtual reality) and AR representation. Furthermore, a third test series the user was provided with an additional numerical minimal distance (MD) value. The results of the study showed, that the combination of AR+VR+MD is improving the depth perception as shown in Figure 17.

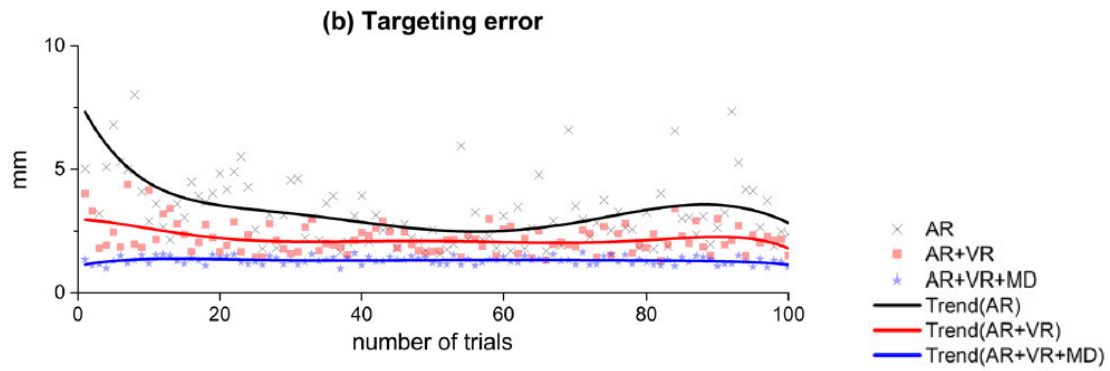


Figure 17: Different targeting errors with only AR, AR+VR, AR+VR+MD. (taken from: [46])

Another study invested AR techniques in an VR simulation environment. Two different augmentation techniques were used and evaluated with 11 participants. The task was to perform a correct needle placement in the liver. With the 11 participants, no significant difference between the two augmentation techniques, and therefore no superiority, was observed.

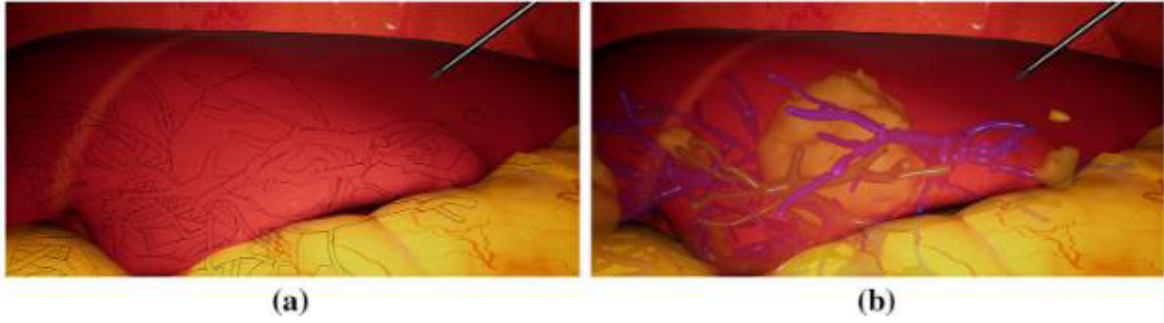


Figure 18: VR simulation with internal anatomy represented as contour (a) and 3D object rendering (b) (taken from: [47])

2 Problem and task statement

Image-guided intraoperative navigation in visceral surgery is more difficult to access due to the deformable soft tissue and the absence of high-quality 3D imaging. As already mentioned, in other disciplines such as neurosurgery, AR is less difficult to apply, due to the good spatial allocation based on the skeletal system. For the present time, this has not yet been possible in oncological surgery of organ systems. Within the scope of the ATLAS project, a CT-supported augmentation of intraoperative target and risk structures during laparoscopic interventions in visceral surgery is to be carried out.

The preliminary work by other groups presented in chapter 1.5 shows, that there is already work in the field of AR and laparoscopy. Initial investigations in the field of different augmentation techniques in a laparoscopic setting have already been carried out. However, the studies conducted to date leave many questions unanswered in the area of usability and performance of various augmentation techniques. Another problem that studies have already shown is the so-called "inattentive blindness", whereby the user may be overwhelmed by the amount of information, which can lead to unfavorable distractions. [22] Further, the preliminary work is limited to clearly differentiated clinical operations or case types (mostly liver).

From a medical point of view, suitable interventions for augmentation by laparoscopy must first be evaluated. Furthermore, a needs assessment for augmented reality visualization must be carried out. For this purpose, suitable use cases have to be determined. Questionnaires and interviews with experts from our own network must be conducted. From the collected data the optimal use cases for an augmentation have to be developed.

In cooperation with the software developers of TUM and Maxer, relevant visualization methods have to be developed and tested in order to achieve an optimal increase in visualization

efficiency for the respective interventions. The visualization methods must be tested by laparoscopic surgeons and the data must be evaluated. In cooperation with the Maxer company and the TUM, a software control via the laparoscope that is as intuitive as possible must be developed and evaluated.

The development of a suitable phantom model - based on the use cases - of the different organ models for testing and developing the prototype. The results of this work should provide the foundation and knowledge necessary to start pig testing with an effective functional prototype.

3 Method and Material

In this chapter the methods of the project, workflows and user studies are shown. Additionally the laparoscopic augmentation system, the phantoms and other material are presented.

3.1 Analysis intervention

As presented before, AR in laparoscopic surgery is challenging. The deformability of organs and shift in the abdomen is one main reason. One of the main hypothesis of this project is: retroperitoneal organs and surrounding structures like vessels show limited tendency to shift and therefor good candidates for AR on laparoscopy. This is why the project focused on those organs having close relation to the abdominal wall. Additionally, the chosen interventions should have a reasonable case load and should be in the challenging area of laparoscopic interventions. Three of the most promising minimal-invasive interventions where selected: kidney transplantation, pancreas cancer and colorectal cancer where selected.

Around 1,500 kidney transplants and live kidney donation account for about 20% of annual transplants. The technical challenge for the laparoscopic removal of life donors is the preservation of long vessels. MR reconstructions of organs prior to transplantation have been a standard procedure in many places for more than 10 years. In reality, the structures (vessels etc.) under the fatty tissue are very difficult to see and this makes laparoscopic surgery more difficult. Advantages of the minimally invasive procedure for kidney transplantation over the open procedure are the faster rehabilitation of the patient, the reduction of pain and the better cosmetic result. [48]

For 2016, the Robert Koch Institute Germany reported (ICD10 Code: C25) about 18,000 new cases of pancreatic cancer. They report as well, that the relative 5-year survival rate is about

9%. In order to be able to offer optimal oncological care to the increasingly elderly patients, gentle procedures are required for the often multimorbide pre-diseased patients. Minimally invasive surgery is already being used in some cases. However, the surgical experience to perform such complex operations is only possible at specialized centers.

Colorectal carcinoma is one of the most frequent malignant diseases and causes of death in Germany, with about 60,000 new cases. Among the most difficult parts of laparoscopic oncological surgery are Estimation of the distance of the tumor from the sphincter, identification of the correct surgical layer (TME layer), identification of the ureters and vessels. There is scientific evidence for an advantage of laparoscopy for elderly patients in terms of shorter hospital stays, less trauma and reduced morbidity. [49]

For each interventions a detailed step by step list of the surgical procedure can be found in Appendix C. To define the AR visualizations during the surgical workflow, target structure and the need segmentation pointed out as well.

3.2 Segmentation of Datasets

In cooperation with the radiology department, data sets of suitable prospective data was searched. Requirements were high resolution CT - in all axes under 1 mm slice distance. In the data sets, both the arterial and venous contrasted phase had to be present in order to detect all necessary structures per patient. For rectum carcinoma cases, normally the arterial phase is not performed. Staging of tumor is performed on MRT by standard. These is why a trauma patient without rectum tumor was chosen to gather all needed data for this study. For kidney donor patient a MR angiography is performed instead of a CT. The reason is the extensive radiation exposure of a high resolution CT, which is not acceptable. This is why a kidney tumor patient was chosen to continue with the project. Those limitation and how they should be addressed will be discussed in Chapter 6. The segmentation of the data was performed by a company specialized in annotation abdominal image data (Visible Patient, France). The surgical step list mentioned in the previous chapter was used to clarify all needed structures. The results are reviewed with the radiology department of the LMU Clinic.

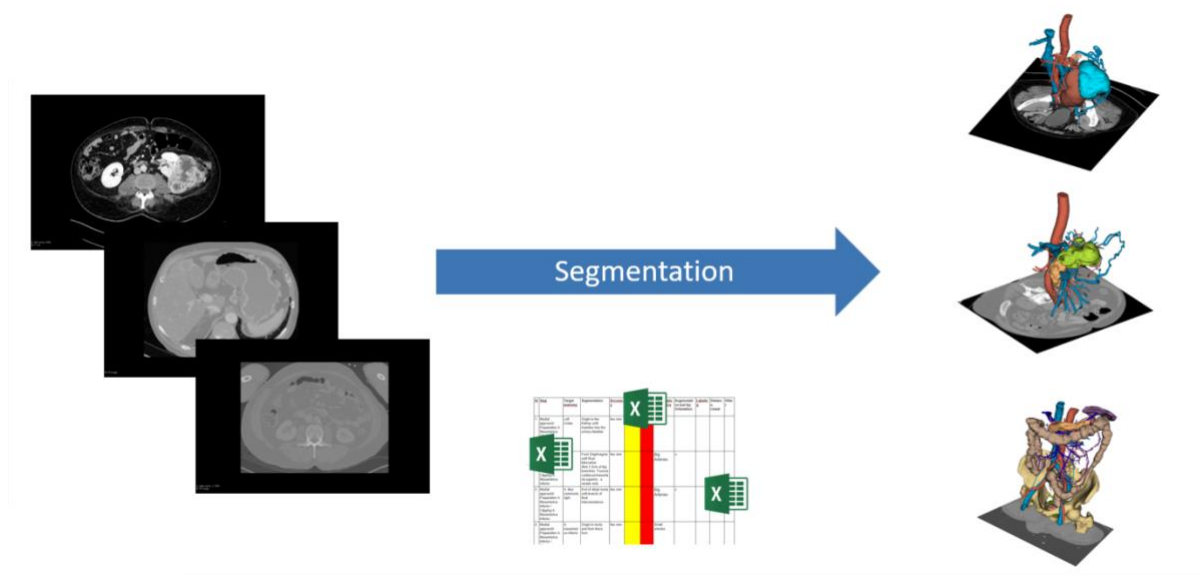


Figure 19: The selected image data is segmented according to the surgical step lists for each indication. As a result, 3D objects in relation to the DICOM data are created. Those can be reviewed with a DICOM viewer.

3.3 Laparoscopic Augmentation System (LAS)

The Laparoscopic Augmentation System (LAS) is a standard laparoscopy system setup, but will be extended by a powerful computer and a spatial tracking system. Thus the system consists of the following five main components:

1. Computer with low latency capture card, a powerful graphic card (NVIDIA GeForce RTX 2060) and an Ethernet input for the tracking camera
2. NDI Polaris Vega infra-red-tracking camera
3. Viron3 endoscope with an tracking array and spherical marks attached to it
4. Video source for processing the endoscope image data and direct transmission on one of the screens
5. Second screen to show endoscopic image enriched with the augmentation

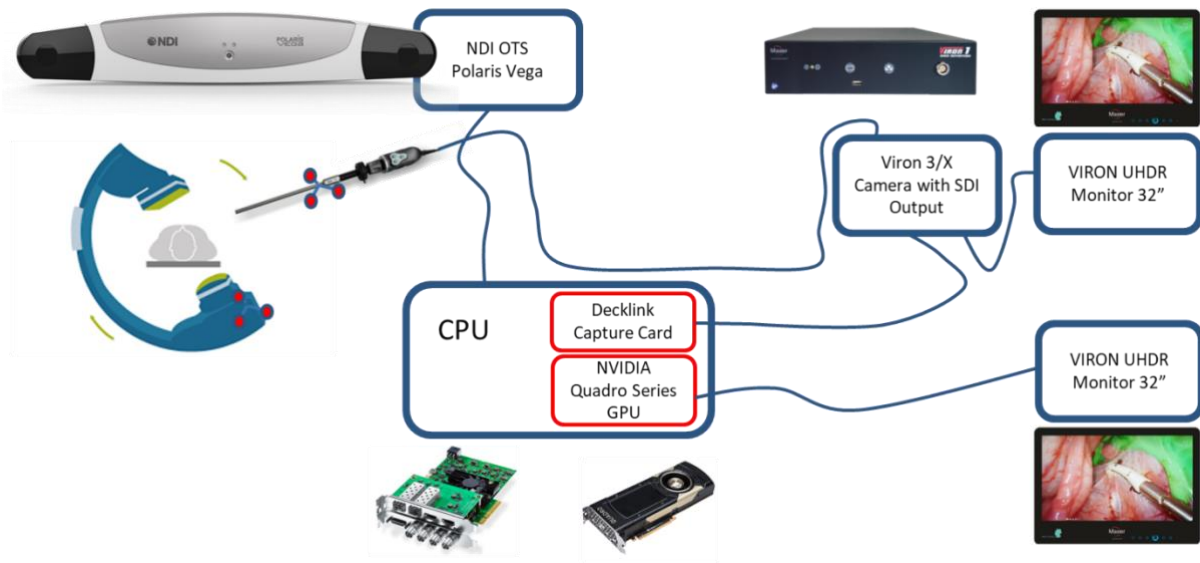


Figure 20: The LAS structure with computer, tracking camera, endoscope, video source and screens

The volumetric data described in the previous chapters must be spatially correctly registered on the patient. This registration should be done with a C-arm. An infrared tracking array is located on the scanner for this purpose. Using two 2D X-Ray shots from different angles, the spine - visible in CT and X-Ray - is used to fuse and register the image data. Potentially, another patient tracker can be attached to the patient's bedside or surrounding area. This will make the registration more robust – e.g. camera movement during surgery.

3.4 User Studies and Phantoms

In this chapter the studies and required material will be described and explained. Two user studies to evaluate performance of the LAS are scheduled. Insights into a meaningful device design are to be shown using validation phantoms.

3.4.1 User study I: Augmentation techniques

Various visualization concepts in laparoscopy have been described in the literature. To our knowledge, there are no attempts to differentiate which visualization works better in this area. In a first comparative study the problem of depth perception was addressed [50].

In this user study - a prospective data collection - surgeons are using the LAS and perform a task consisting of the interpretation of five different augmentations techniques. The comparison is intended to provide information about the effectiveness – focused on depth perception - between the augmentation techniques.

3.4.1.1 Task and Study design

Figure 21 shows the setup for User Study I with the LAS and the user interface for the participant. The test group consists of medical students, residents or consultant surgeons from the LMU clinic. The individual test person had to fill in a consent and data protection form according to the EU Data Protection Regulations followed by a short survey to collect information about his level of education and experience in laparoscopic surgery. Afterwards a short written explanation of the LAS and the task is presented. The actual task begins. After completing five repetitions with each time a different augmentation technique, a final qualitative survey must be completed (review Appendix A – Survey User Study I). The Endoscope is inserted into an empty laparoscopic trainer. A virtual cavity together with a augmented vessel structure are projected in the video image. The surgeons are asked to sort several points marked on the augmentations with respect to the distance to the endoscopic axis.

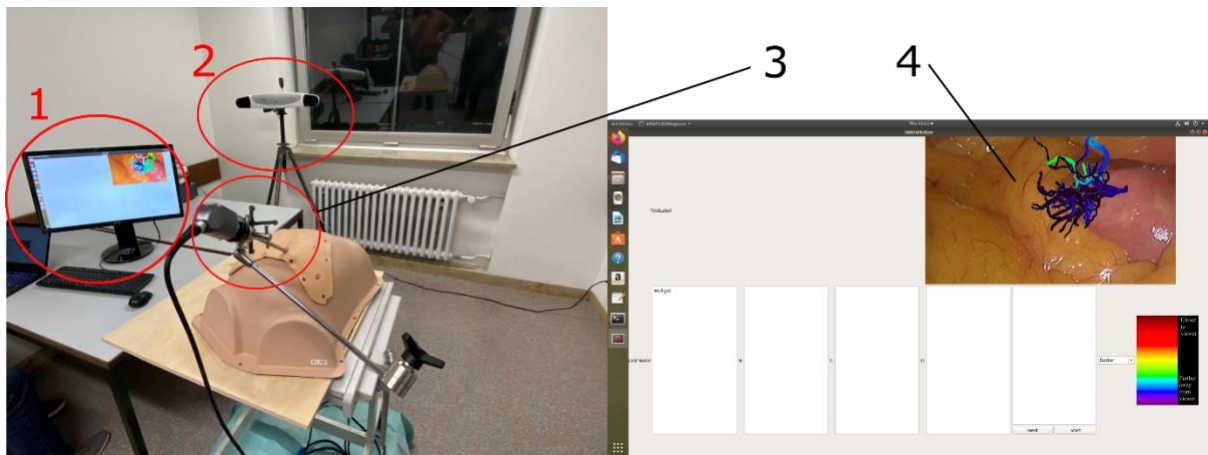


Figure 21: Setup of the LAS with (1) computer, (2) tracking camera, (3) endoscope with tracking array and (4) graphical user interface with endoscopic video signal and augmentation. For this study, the second screen of the LAS is not needed

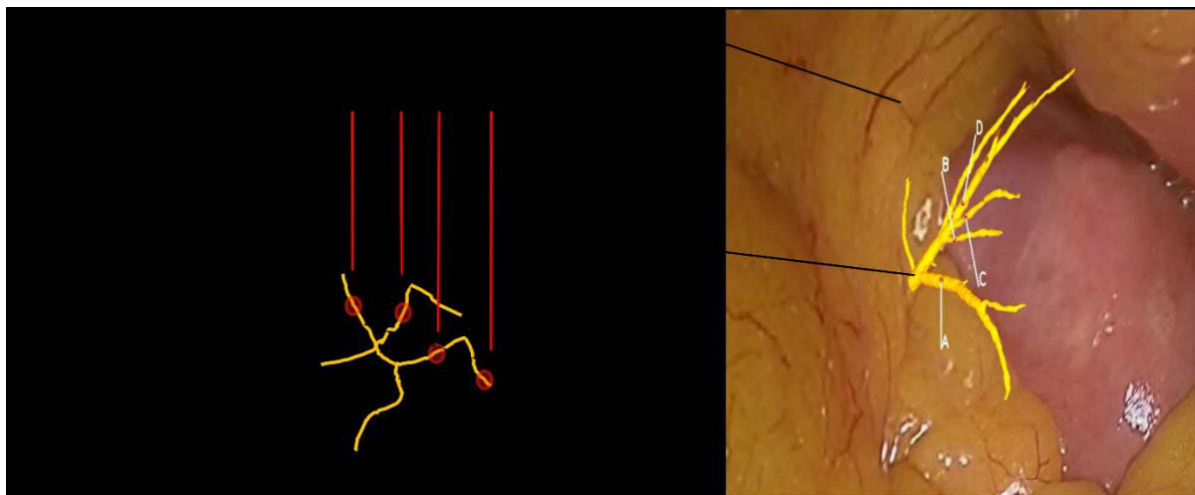


Figure 22: The figure explains the task of the user study. (1) virtual cavity is projected into the endoscope image. On top is a (2) vessel tree with four points named from A to D. The task is to order to points from near to far according the (3) endoscope axis. In this example the order is **A, C, D, B**

The user can move the endoscope around what will cause a dynamic movement of the cavity and vessel tree linked to the movement of the user. With the parallax-effect it should be easier to interpret depth and correct ordering of the points.

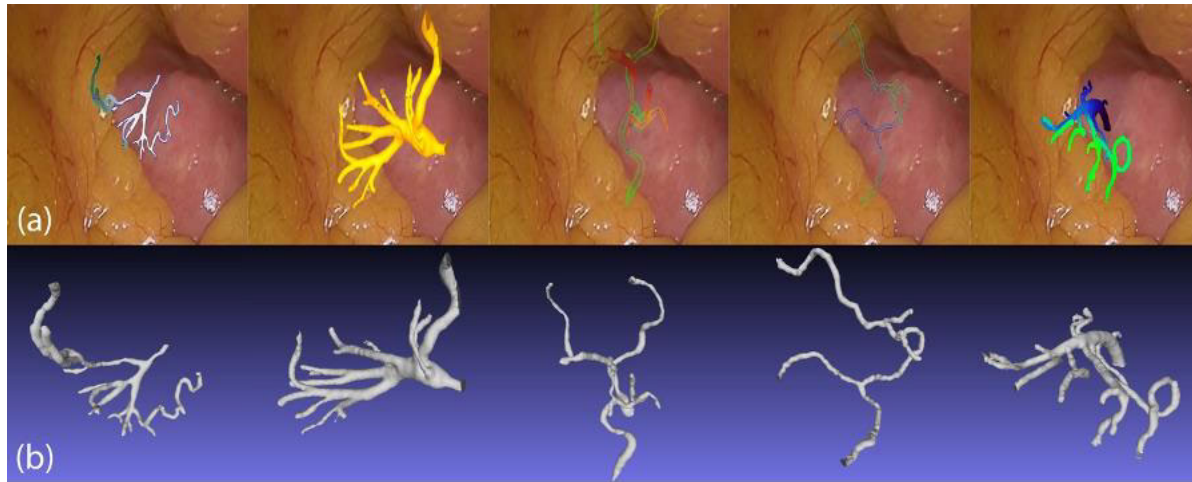


Figure 23: (a) five different visualization techniques, from left to right: a. Visualization I, “Opaque Chromadepth with outlines,” shows an opaque representation of the vessel with colored outlines; color encoded depth both for the inside and outline; b. Visualization II, “Opaque with Fresnel highlights,” presents itself as opaque and unicolor yellow, with orange edge highlights; c. Visualization III, “Chromadepth Fresnel highlights,” shows the vessel as semi-transparent with color-coded edge highlights for depth, ranging from red (very close) to yellow (medium vicinity) and green (distant); d. Visualization IV, “Chromadepth Fresnel highlights with reduced color range,” presents the vessel again as semi-transparent with edge highlights for depth, albeit with a reduced color range from green (close) to blue (distant); e. Visualization V, “Opaque chromadepth with reduced color range,” shows the vessel fully opaque, again with the color-coding green (close) to blue (distant). (b) from left to right, the different vascular trees: a. vascular tree I; b. vascular tree II; c. vascular tree III; d. vascular tree IV; e. vascular tree V

Besides the five different augmentation techniques, five different vessel trees will be used. For each visualization technique a different vessel tree will be presented to the participant to reduce learning effects.

The five different visualization techniques can be described as following:

I - Opaque Chromadepth with outlines: we rendered the object of interest fully opaque without shading. Depth is encoded with a chromadepth approach for the outlines encoding depth as a color between green (close) and blue (distant), and the inside in shades of gray, from black (close) to white (distant).

II - Opaque with Fresnel highlights: this visualization technique renders the object in a solid yellow color. It also includes an orange edge highlighting effect by modulating the orange color based on the angle between the surface and the view direction, sometimes called the Fresnel effect.

III - Chromadepth Fresnel highlights: here, the vessel is mostly rendered transparent to block the view of the underlying anatomy less than with opaque techniques. Depth is encoded with chromadepth, ranging from red (very close) over yellow (medium vicinity) to green (distant).

IV - Chromadepth Fresnel highlights with reduced color range: this visualization is similar to III. However, the color range encoding depth is reduced to interpolate from green (close) to blue (distant).

V - Opaque chroma depth with reduced color range: this technique encodes depth similarly to IV, however, without transparency. The entire vessel is therefore colored without shading.

Several techniques apply a chromadepth approach, which encodes the distance of each point in the vascular branches from the viewer to a spectrum of color. For instance, in augmentation III, the vascular branches' color ranged from red (meaning very close) to yellow (medium vicinity) and finally green (distant). Visualization types IV and V applied the same approach, albeit with a swapped color palette and transparency level, with green suggesting proximity

and blue, instead, farther distance. It is worth mentioning that 6 augmentation type II, opaque and unicolor yellow, was the only opaque representation conveying shape through Fresnel shading.

3.4.1.2 Study outcomes

The qualitative gathered data from the survey shown in Appendix A – Survey User Study I should provide the ability to separate user groups from another – e.g. students and more experienced surgeons. Main outcome is the qualitative opinion regarding the augmentation technique. Each participant will be asked to rank the augmentation technique (4-point Likert scale, from “best” to “worst,”) after the completion of the task.

Quantitative data is the correctness of the answers during the task with respect to the order of the point. The distance of the points are defined by the initial presentation and orientation of the vessel tree when a person enters the task. In other words, the distance between the points along the viewing axis of the endoscope. Although the test person can move the endoscope, the distance of the points from the initial viewing direction applies. An evaluation formula is used that tries to take the difficulty into account. More precisely, if two adjacent points are swapped by mistake, the penalty of the end result is less than if the nearest point is swapped with the furthest point. The distance is In addition, the total distance is also taken into account in the formula. The penalty p_n for each answer is defined below. Each penalty gets multiplied by the factor 2 for scaling of the penalty. This factor can be investigated later. The net score is four minus potential penalties from each answer.

$$p_n = \frac{2 * |(d_c(n) - d_a(n))|}{||v_{furthest} - v_{nearest}||}$$

$$Netscore = 4.0 - p_1 - p_2 - p_3 - p_4$$

$p_n =$ denotes a penalty for the $n - th$ point of a given visualization technique

$d_c(n) =$ denotes the corresponding correct depth

$d_a(n) =$ participant's answer

$v_{furthest} =$ furthest point

$v_{nearest} =$ nearest point

3.4.2 User Study II: Verification of Augmentation

The aim of the prospective User Study II is to compare augmentation methods in laparoscopy under controlled conditions. The LAS will be challenged against the current standard procedure without augmentation. The comparison shall give information about the usefulness of the augmentation in a non-clinical setting.



Figure 24: Setup of User Study II, (1) NDI infrared camera, (2) computer, endoscopy tower, two screens shown the endoscopic camera image with and without augmentation and (3) the endoscope and laparoscopic trainer

This is to be achieved by printing vascular structures in 3D – explained in the next chapter - and making them available to the test persons with the same laparoscopy trainer from User Study I. The vascular structures are covered in a non-transparent wax that need to be removed to reach the region of interest (ROI) previously defined. The test persons are first provided with the structures as a CT data set and the target structure will be displayed in the augmentation during the test. The volunteers are randomly assigned to two different 3D augmentation technique and no augmentation at all, so in total repeat three test runs.

3.4.2.1 Phantoms for User Study II

Three vascular structures are needed and therefore generated from random sections of a lung CT. These were then post-processed with a Gaussian smoothing operator in a DICOM Viewer (ImFusion Suite, ImFusion GmbH, Germany) and arrangement in a box and other post-processing steps with a mesh file editor (Meshmixer, Autodesk Inc. USA).

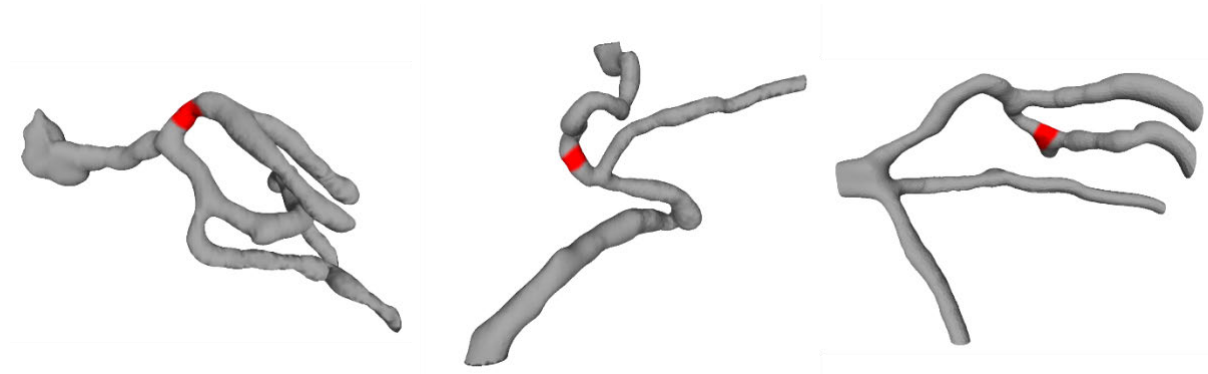


Figure 25: Naming of all three vessels within the study from left to right: vessel_01, vessel_05 and vessel_06. The red marking shows the ROI

The box was created with CAD – FreeCAD, Freeware – and is used to hold the tissue mimic material. Furthermore there are landmarks for registration, which can be taken by a navigation pointer. A box holder was generated with CAD as well is angled by 30° to have an optimal approach axis for the test person. The holder was printed with the institute 3D Fuse-Deposition Printer in PLA material and the vessel boxes are printed via selective laser sintering and polyimide material (Materialise NV, Belgium).

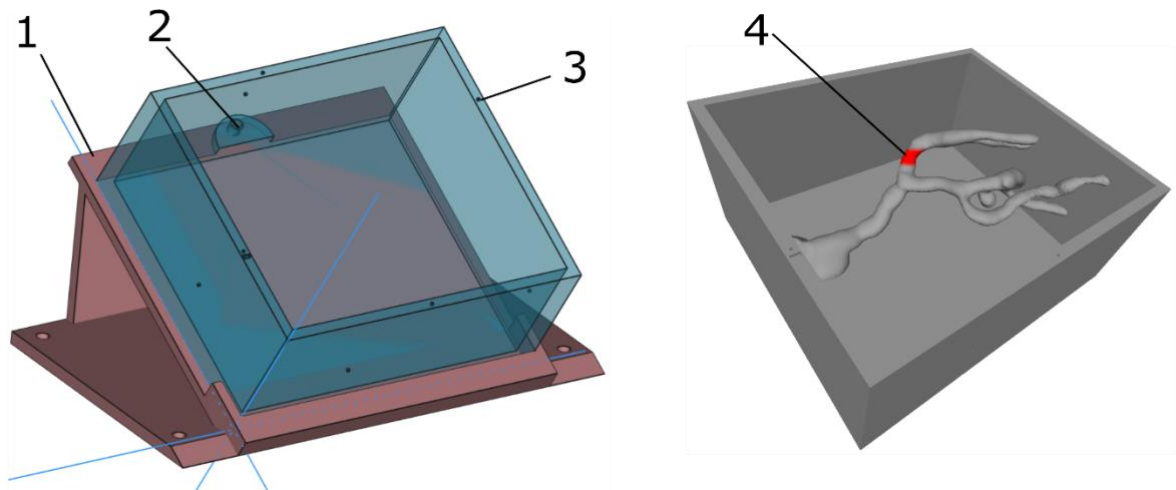


Figure 26: **(Left)** The **(1)** box holder is angled by 30° and holds the **(2)** vessel boxes via a pin in place. Eight **(3)** pockets serve as landmarks for the registration of the vessel box. **(Right)** Vessel box with the **(4)** ROI

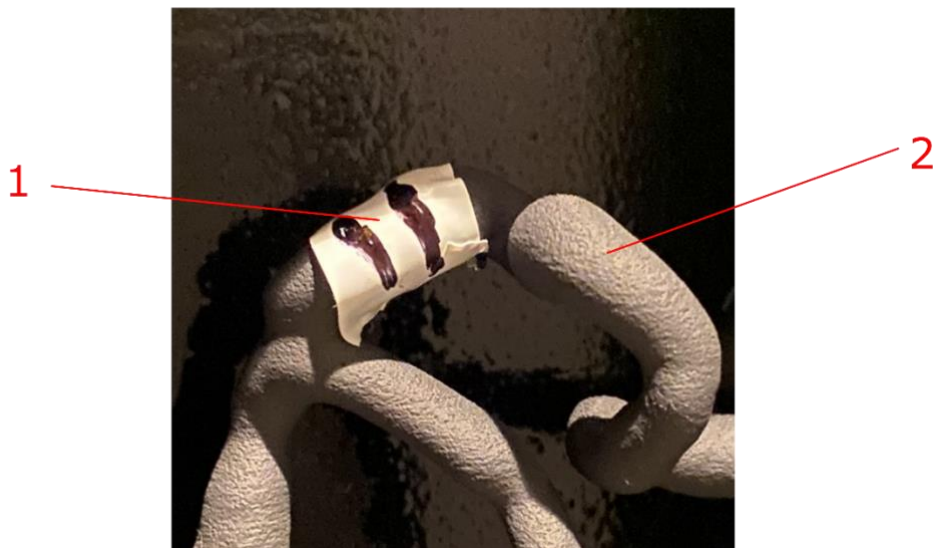


Figure 27: The (1) code represented by lines on a white surface is attached at ROI of the (2) vessel tree

Two materials were examined as tissue mimic material – gel candle wax [51, 52] and ballistic gel [53, 54]. The requirements were: inexpensive, a reasonable cutting sensation with the instruments and electrically insulating. Ballistic gel was excluded due to the electrical conductance. Gel-candle wax plus wax color (Exagon GmbH, Germany) was chosen for the study. To improve the grasp and cutting sensation, cotton wool is added to the tissue mimic material. The inside of the vessel tree box is sprayed with graphite to become an electrical conductor. White insulation tape is attached to the ROI and a code with a permanent marker is written down.

Item	Costs per Box
3D printed vessel box	~ 200 Euro
Candle wax (~1,5 kg / box)	(10.90 Euro / kg) ~ 17 Euro
Graphit spray (10 boxes / spray can)	(15.99 Euro / spray can) ~ 1.60 Euro
Cotton wool (50 boxes / pack)	(5.00 Euro / pack) ~ 0.10 Euro
Total / box	~218.7 Euro

Table 1: Production cost per vessel box

The cotton wool is added inside the vessel box and the wax is heated up to 80° C before it is poured into the box.

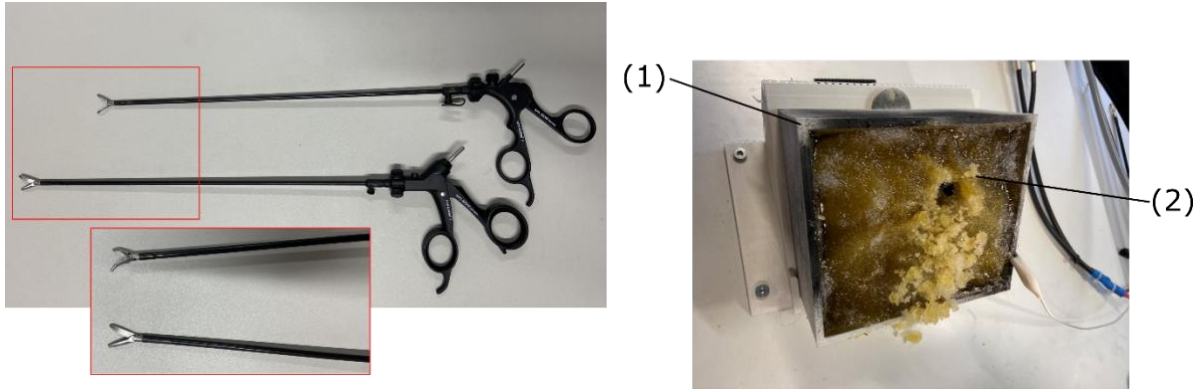


Figure 28: **(left)** With two laparoscopic instruments - pliers and scissors – the test person need to prepare the tissue mimic material. **(1)** Example of a vessel box filled with **(2)** coloured and opaque tissue mimic material

The two laparoscopic instruments are connected through electric cables to a two-channel USB-Oscilloscope (Analog Discovery 2, Digilent Inc., USA). The vessel box is linked to a 16V voltage source as shown in Figure 29. If one of the instruments is touching the vessel, the voltage can be measured.

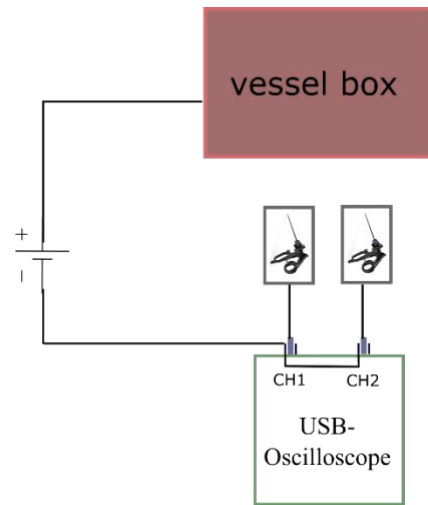


Figure 29: **(Left)** The graphite coated vessel box and **(right)** circuit diagram of the instruments, vessel box and USB-Oscilloscope

3.4.2.2 Tasks for the participants

The main tasks (1-2) and subtasks (3-5) of the participants are:

1. Remove the tissue mimic material to reach the ROI
2. Identify code at ROI
3. As little tissue mimic material as possible should be removed or cut
4. It should take as little time as possible
5. Touching the vascular tree with the instruments shall be avoided



Figure 30: (1) Displayed target structure at vessel_01 for the user, (2) vessel_01 augmentation, (3) instrument – here the instrument segmentation is activated

3.4.2.3 Study design

As shown in Figure 31, User Study II consist of four steps for each volunteer. Only residents of common trunk visceral surgery are invited for the first step, the skill assessment survey. With the outcome of the first survey, a decent level of homogenous level of skill and experience within the participants should be achieved. The survey can be found in Appendix B. In total six test person will be selected after the skill assessment survey and will be invited to a test run appointment.

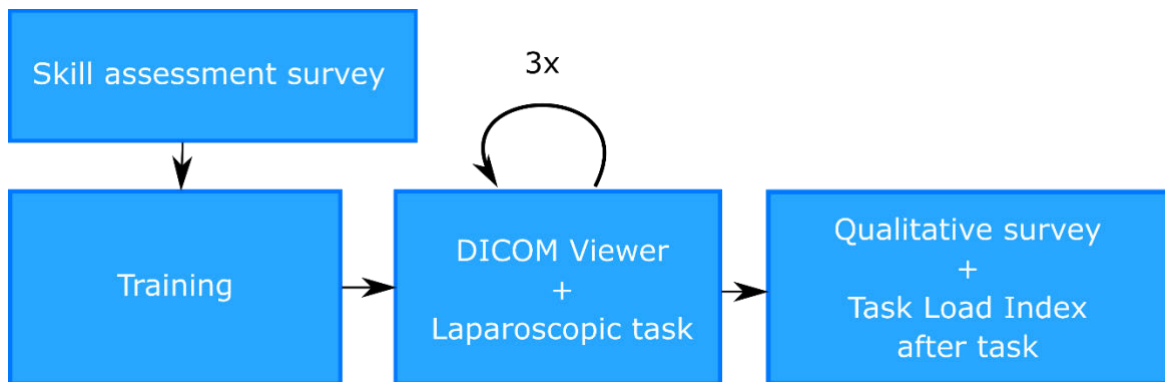


Figure 31: User Study II consist of four steps for each volunteer: **(I)** Skill assessment survey to select candidates, **(II)** training for the test participant, **(III)** reviewing the target structure and performing the laparoscopic task three times and **(IV)** a final qualitative survey at the end - the task load index assessment based on the SURG-TLX [26] is part of the survey

On the day of the test run and the 2nd point of the study, the participant start with the training of the LAS and review of the 3D target structure is the start of the daily task. A 3D representation of the vessel boxes can be reviewed via a DICOM Viewer (ImFusion Suite, ImFusion GmbH, Germany). A training duration of about 5 minutes is targeted.

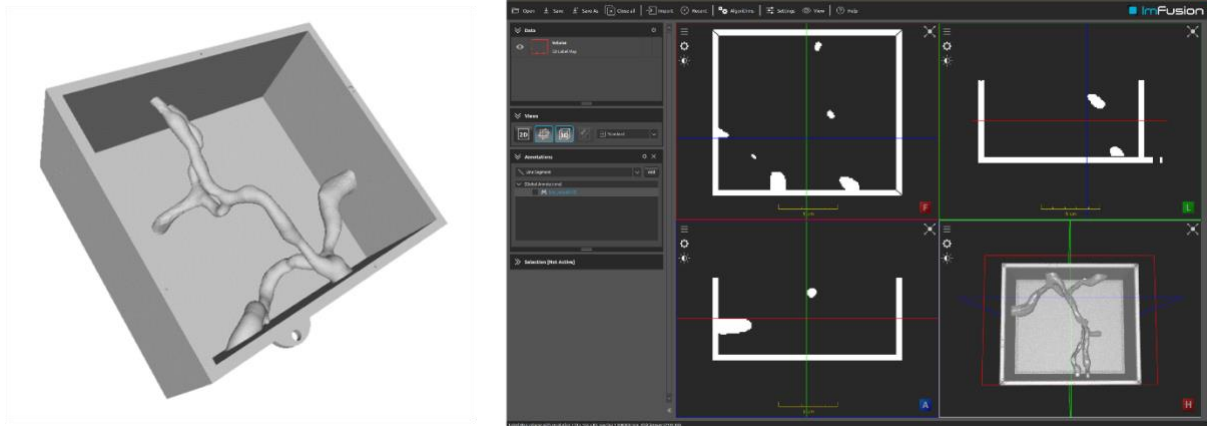


Figure 32: **(Left)** Computer aided designed vessel tree example, **(right)** ImFusion Suite DICOM view to review the vessel box in 3D and axial-,coronal- and sagittal-view

After finishing the review, the test person starts to uncover the ROI with the help of the instruments. He will mention to the supervisor that he is ready and wants to begin. The timing thus starts and stops when the test person has correctly identified the ROI. If the subject reports an incorrect code to the ROI, he will be notified by the study manager and may continue. The participant can cancel the test run after 20 minutes and the test run will be declared as failed.

In Table 2 the composition of the test runs are shown. The last test run of each participant is always the control run without augmentation, in order to benefit maximum from the learning effect. The participant is not informed about the two different augmentation techniques - instrument tracking on or off - and is not informed in which run he gets which augmentation displayed. The augmentation techniques are described in Figure 33.

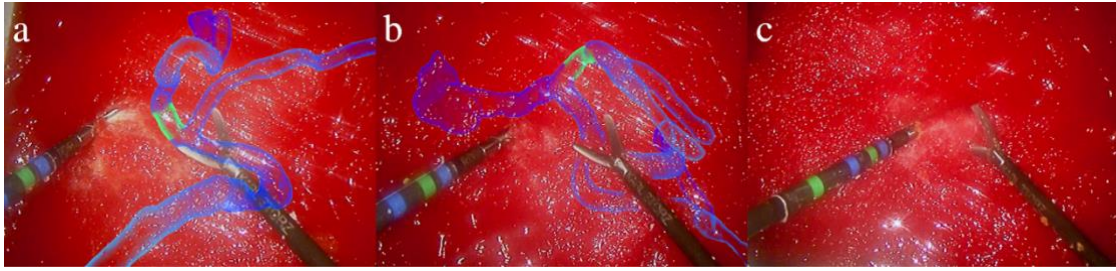


Figure 33: Output of the three different visualization conditions of the AR system. In all AR conditions, the vessel is depicted in a semitransparent rendition, with the edges highlighted using a Fresnel-Derivative approach and the color intensity modulated by the distance to the observer. The green area represents the target (a) In AR without occlusion handling, occlusions of the tools with the vessels are not handled correctly, as the virtual scene will always be superimposed on top of the video stream. (b) In AR with occlusion handling, the instruments may occlude the anatomy behind them through pixel-wise classification of the video stream by a random forest predictor. (c) In the Baseline condition, participants only see the unaltered output of the laparoscopic camera without any AR guidance.

Augmentation instrument segmentation disabled	1X		
Augmentation instrument segmentation enabled	2X		
Without augmentation	0X		
vessel_01	XA		
vessel_05	XB		
vessel_06	XC		
Test person	Run I	Run II	Run III
1	1A	2B	0C
2	1B	2C	0A
3	1C	2A	0B
4	2A	1B	0C
5	2B	1C	0A
6	2C	1A	0B

Table 2: Composition of test runs, test person and test condition

3.4.2.4 Study outcomes and parameters

The study outcome and parameters are defined as following:

- Skill assessment survey outcome to identify level of experience of each test person.
- The time will be recorded for each test run. As mentioned before, time count starts when the participant starts to remove the tissue mimic material. The time recording will be stopped after the test person recognized the Code at the ROI.
- Each weight of the vessel box will identified before and after – all lose material will be removed - the intervention to build the delta. The Precision balance 440-49N (KERN & SOHN GmbH, Germany, weight capacity 4 kg, readability and repeatability 0,1 g) was used to determine the weight.

- The video signal of the endoscope, the tracking camera information and USB-oscilloscope signal for both instruments will be recorded during the time recording. Video signal and tracking information will be used to identify unexpected or unclear events during the test run. The oscilloscope signal peaks will be identified and a number of touches per test run defined.
- Qualitative survey after all test runs outcome to collect the qualitative opinion of each participant. Additionally, a task load index will be determined with this survey. The index is based on the SURG-TLX [55]. The assessment is resolved with seven point possibility (ranging from 1 = “very low” to 7 = “a lot”) [56].

After all three experiment runs, the participants answered a qualitative questionnaire on the usefulness of the presented AR visualization on 4-point Likert scales, ranging from “very helpful” to “not helpful at all.” Then, the participants indicated if they would like to have any form of AR visualization for the following laparoscopic surgeries: rectal resection, left pancreatic resection, sigmoid resection, liver resection, splenectomy, transabdominal preperitoneal (TAPP) hernia procedures, cholecystectomy, appendectomy, and nephrectomy. The participants also reported whether they found the attached optical tracking target interfering with their manual work and if any delays in the transmitted signal distracted them. Finally, they submitted their opinion concerning the potentially positive impact of AR on multiple surgical parameters (patient safety, complications, learning curve, oncological outcome, operative time, blood loss) and selected which of these would most benefit from AR.

3.4.3 Validation Phantoms

In the two user studies, the performance of the LAS is examined in particular and experiences regarding its applicability and effectiveness are observed. Further experiments concerning for example the most reasonable representation of the anatomical structures and when they should

be displayed are to be investigated using validation phantoms. These must be closer to the clinical reality.

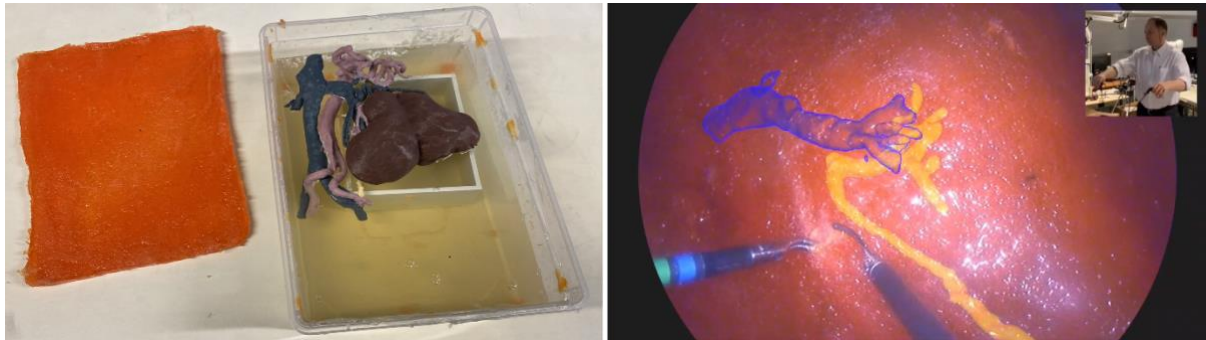


Figure 34: **(left)** Validation phantom of the kidney and tissue layer that can be prepared with laparoscopic instruments. **(Right)** Endoscopic image enriched with augmented reality

Therefore an STL file of each use case presented in 3.2 are generated. The structures are then printed with the same polyimide material used for the vessel boxes. The vessels and organs are then painted in a color comparable to that of the endoscopy image. Acrylic paints from art supplies are used for this. The costs for the three 3D printed phantoms are shown in Table 3. A layer of tissue shall first cover the structures. This layer can be prepared with the laparoscopic instruments. As in User Study II, the material consists of candle wax and cotton wool.




Phantom	Rendering	Cost
Kidney		465.00 EUR
Pancreas		430.00 EUR
Rectum		1430.00 EUR

Table 3: Overview of the three rigid validation phantoms and the manufacturing costs by Materialise NV, Belgium.

4 Results

In this chapter the results of User Study I and II will be presented. As noted above, the results of both User Studies were obtained from a survey and data logged by the LAS. Furthermore, a test protocol was completed by a test supervisor for each test subject in User Study II.

4.1 Results of User Study I

In total 50 participants with 25 students and 25 doctors during two weeks did participate – further descriptive data can be found in Table 4. The median age was 28. Among the physicians, 17 (68 %) were surgical residents, 7 (28 %) were surgical attending physicians, and one participant (4%) was a senior attending physician.

User Study I: n = 50 participants												
Gender	34 male (68%)	16 female (32%)										
Age												
Level of Training	<table border="1"> <caption>Level of Training Distribution</caption> <thead> <tr> <th>Level of Training</th> <th>Count</th> </tr> </thead> <tbody> <tr> <td>Student</td> <td>25</td> </tr> <tr> <td>Resident</td> <td>17</td> </tr> <tr> <td>Consultant</td> <td>7</td> </tr> <tr> <td>Senior Consultant</td> <td>1</td> </tr> </tbody> </table>		Level of Training	Count	Student	25	Resident	17	Consultant	7	Senior Consultant	1
Level of Training	Count											
Student	25											
Resident	17											
Consultant	7											
Senior Consultant	1											

Table 4: Descriptive statistics of User Study I.

4.1.1 Objective Performance Measures

For further investigation, the penalty score is examined in a simplified manner. A distinction is made between correct ($p_n = 4$) and false ($p_n < 4$). Participants 44, 45 are excluded from further analysis. Participant 44 sees augmentation number 3 twice and 45 only sees the first vessel across all augmentations. The remaining individuals appear only once in each mode of augmentation. Based on this distinction, the Cochran Q statistical test implemented in the R programming language analyzed the nominally paired scaled variables. Our analysis considered values of $p < 0.05$ as statistically significant.

The “Cumulative error rate across all vessel trees, sub grouped between students and doctors and female and male” data show no significant differences in error ranking between the

augmentation modes ($p > 0.05$). Further, the difference between the student and doctor subgroups in the accuracy ranking ($p > 0.05$) was not statistically significant. Vessel trees III and IV yielded the least number of correct answers across all participants compared to types I, II, and V ($p < 0.05$). However, there were no significant differences in the performance of the visualizations in vessel trees III and IV ($p > 0.05$).

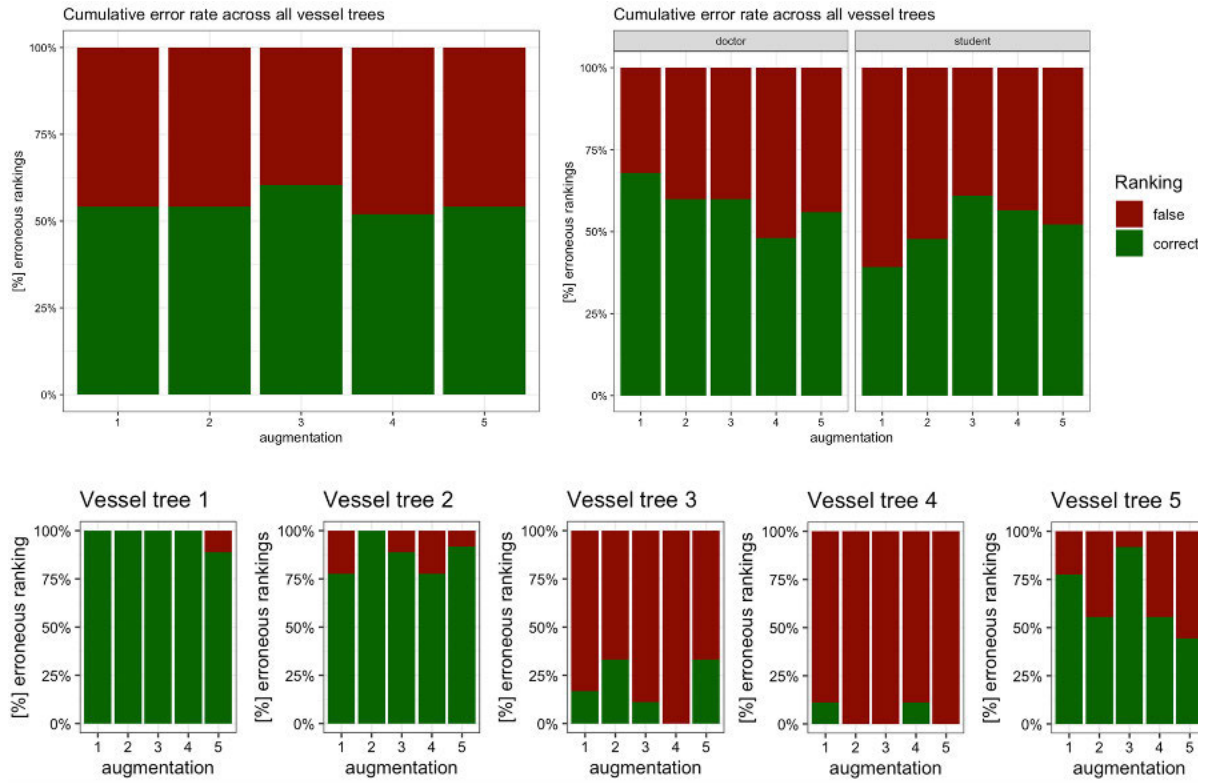


Figure 35: This figure shows the experimental results concerning the cumulative accuracy across all vessel trees, between the visualization techniques: across all participants (left upper image), no statistical difference was observed ($p > 0.05$); for the student vs. doctor subgroup (right upper image) there was also a no statistically significant difference in the error ranking ($p > 0.05$), nor in the female vs. male subgroup ($p > 0.05$) (not shown); Results based on the different vessel trees are instead shown below: vessel tree type I and II showed the majority of correct answers.

4.1.2 Subjective Survey

In this part, the results of the survey of all participants are presented. The questions, in which intervention, parameters and in which areas is the LAS helpful were examined only the answers of the physicians, because for the evaluation a clinical experience is assumed. General questions were studied with all participants.

The five augmentation techniques have already been presented in 3.4.1.1. The results of the ranking are shown in Figure 36. Augmentation technique II (Opaque with Fresnel highlights) was chosen as the favorite by 27 subjects or 54% of the participants followed by Augmentation technique III (Chromadepth Fresnel highlights) by 13 (26%) as their favorite. Augmentation technique IV (“Chromadepth Fresnel highlights with reduced color range) was ranked as least favorite by 24 (48%) subjects.

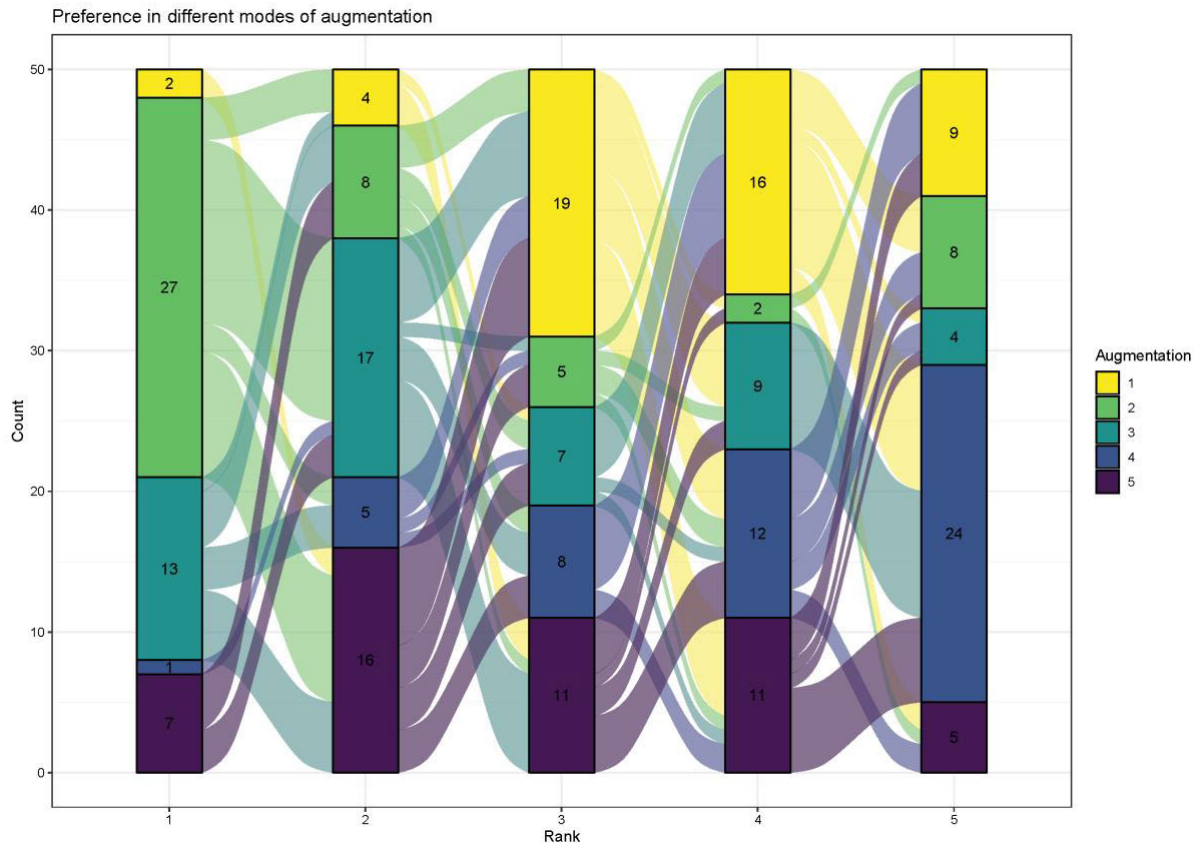


Figure 36: Mode of augmentation ranking by all participants. Augmentation technique II (Opaque with Fresnel highlights) was chosen as the favorite by 27 subjects or 54%. Augmentation technique IV (“Chromadepth Fresnel highlights with reduced color range) was ranked as least favorite by 24 (48%) subjects.

For the interventions rectal resection, pancreas left resection, sigmoid resection and liver resection 75% or more of the surgeons classified the LAS as beneficial in the clinical practice as shown in Figure 37. The following interventions more than 50% of the participants didn’t see the benefit: splenectomy, TAPP, cholecystectomy, appendectomy and nephrectomy.

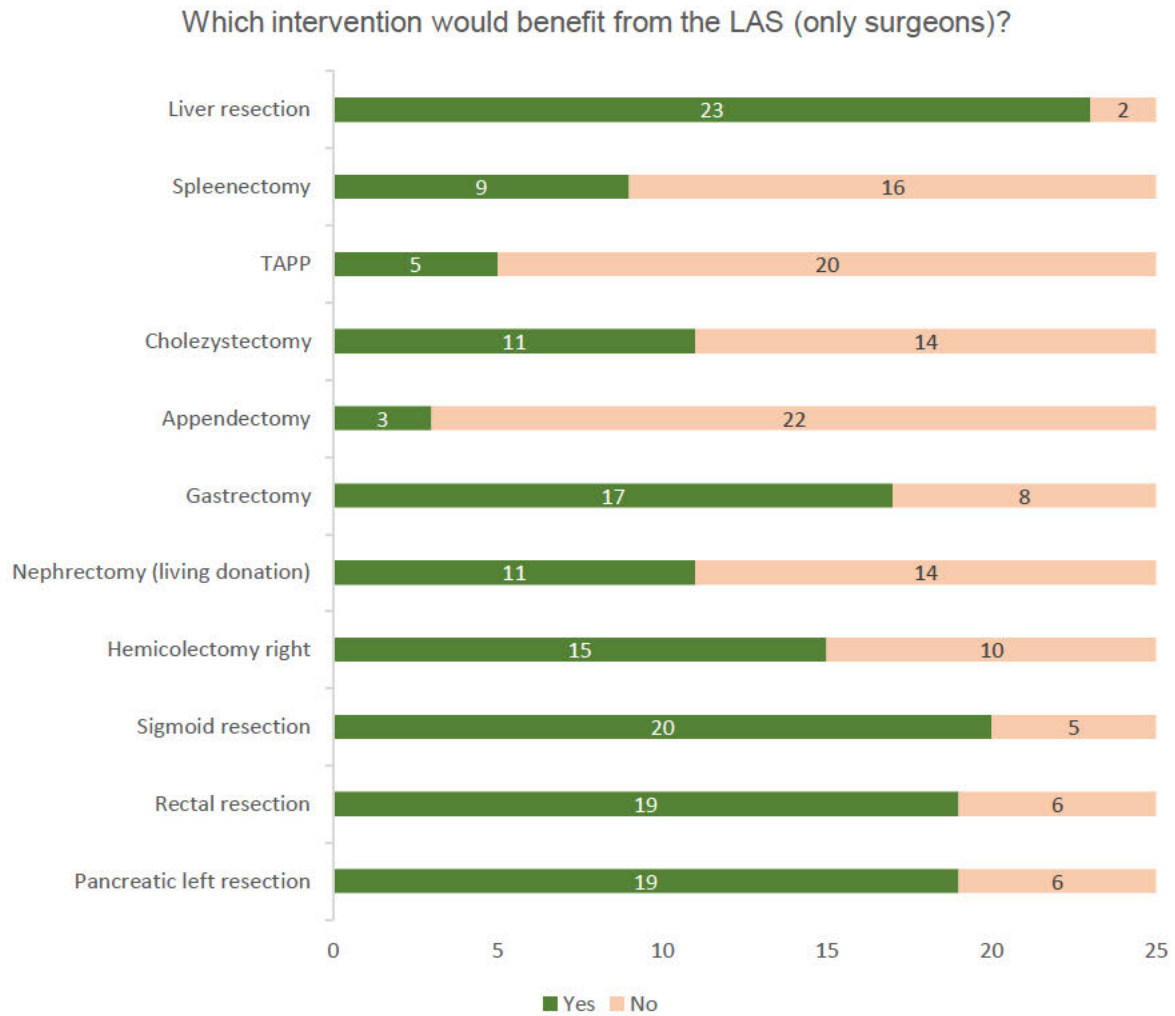


Figure 37: Answers from the participants – Which intervention would benefit from the LAS (only surgeons)? 50% of the subgroup classified the LAS as beneficial: liver resection (92 %), sigmoid resection (80 %), rectal resection (76 %), left pancreatic resection (76 %), and gastrectomy (68 %), right hemicolectomy (60 %). Instead, less than 50% of the subgroup rated the following indications: cholecystectomy (44 %), nephrectomy (44 %), splenectomy (36 %), TAPP (20 %), and appendectomy (12 %).

All surgeons agreed that the LAS will influence the surgical parameters positively. The graph shows that physicians expect a lower risk of complications with LAS and that overall patient

safety can be increased. Other parameters, such as better outcome, faster learning curve, shorter surgery time and reduced surgery time, were not so clearly selected, although the majority (more than 50%) expected an improvement with LAS.

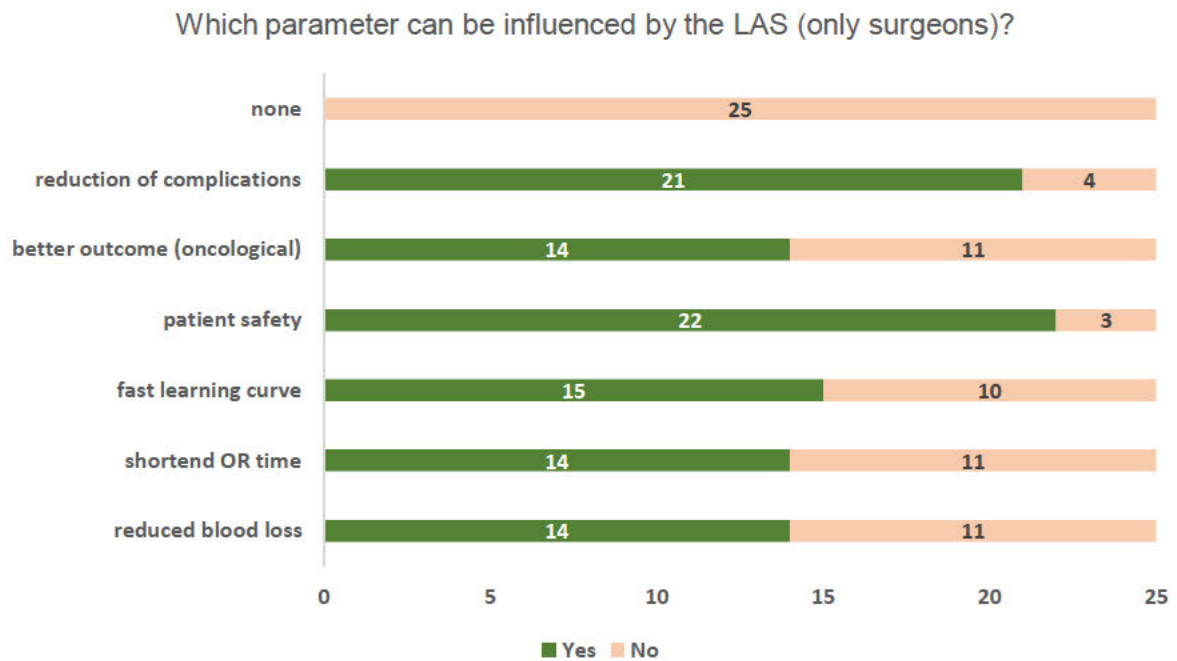


Figure 38: Which parameter can be influenced by the LAS (only surgeons)? All surgeons expect, that the LAS will influence the surgical parameters positively. Especially the patient safety (88%) and reduction of complications (84%) are perceived as beneficial influenced.

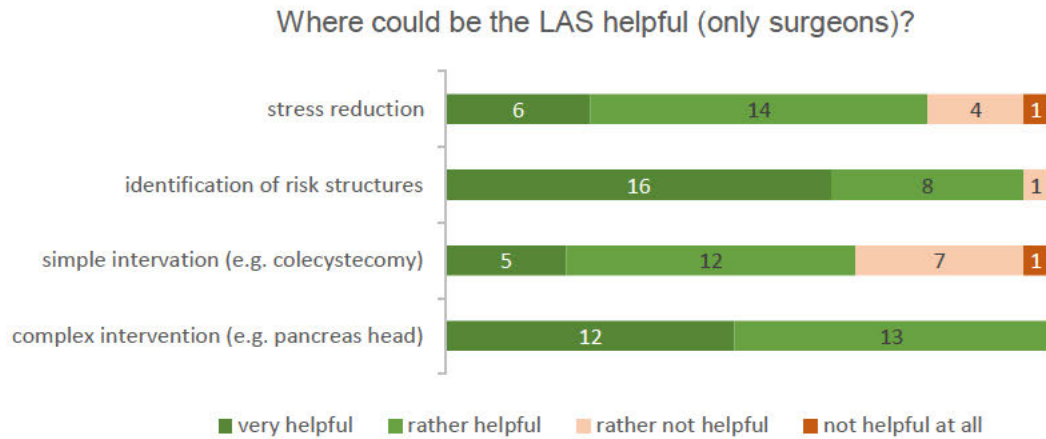


Figure 39: Where could be the LAS helpful (only surgeons)? For complex interventions, the subgroup perceived the LAS as rather helpful (13, 52%) or more (12, 48%). For the stress reduction and simple interventions one surgeon (4%) expect the LAS to be “not helpful at all”

In all categories the LAS is seen as rather helpful or more. About two-thirds of the participating physicians rated the system as very helpful in identifying risk structures. One person considers the LAS to be rather not helpful. All surgeons rated the system as very or rather helpful for complex interventions.

As already described in the previous section, an attachment to the endoscope, the tracking star, is required. More than three quarters of the participants found this attachment rarely or not at all bothersome. Two test subjects out of 50 (4%) frequently found the tracking star disturbing. Latency is an important performance factor for augmentation systems [57]. 44 of the 50 participants said they did not perceive any disturbing delay with the augmentation.

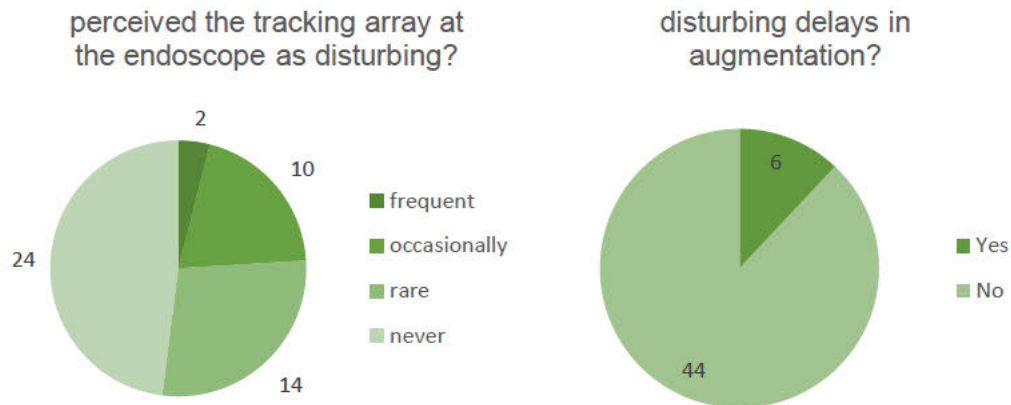


Figure 40: Questions regarding the performance and impact of the LAS in terms of usability. Only 4% perceived the tracking array attached to the endoscope frequently disturbing. More than three quarters (76%) of the participants found this attachment rarely or not at all bothersome.

4.2 Results of User Study II

The final 6 candidates (11 candidates were invited to the skill assessment survey; all recruited through personal contact) are all between the 4 and 6 clinical year and part of the LMU Clinic Munich ($M_{age} = 31.00$, $SD_{age} = 3.68$). All participants had experience in laparoscopic surgery with simple intervention such as appendectomies and cholecystectomies. Five of them were assistant physicians and one resident physician of visceral surgery. All of the participants were male. They were in the fourth, fifth, or sixth year of residency ($M_{residency} = 4.83$, $SD_{residency} = 0.98$). They rated their laparoscopic skill on average at 2.50 ($SD_{lap-skill} = 0.55$). The Study outcomes and parameters has been described in 3.4.2.4.

User Study II: n = 11 skill assessment survey, n = 6 final candidates

Final candidates, **only male**

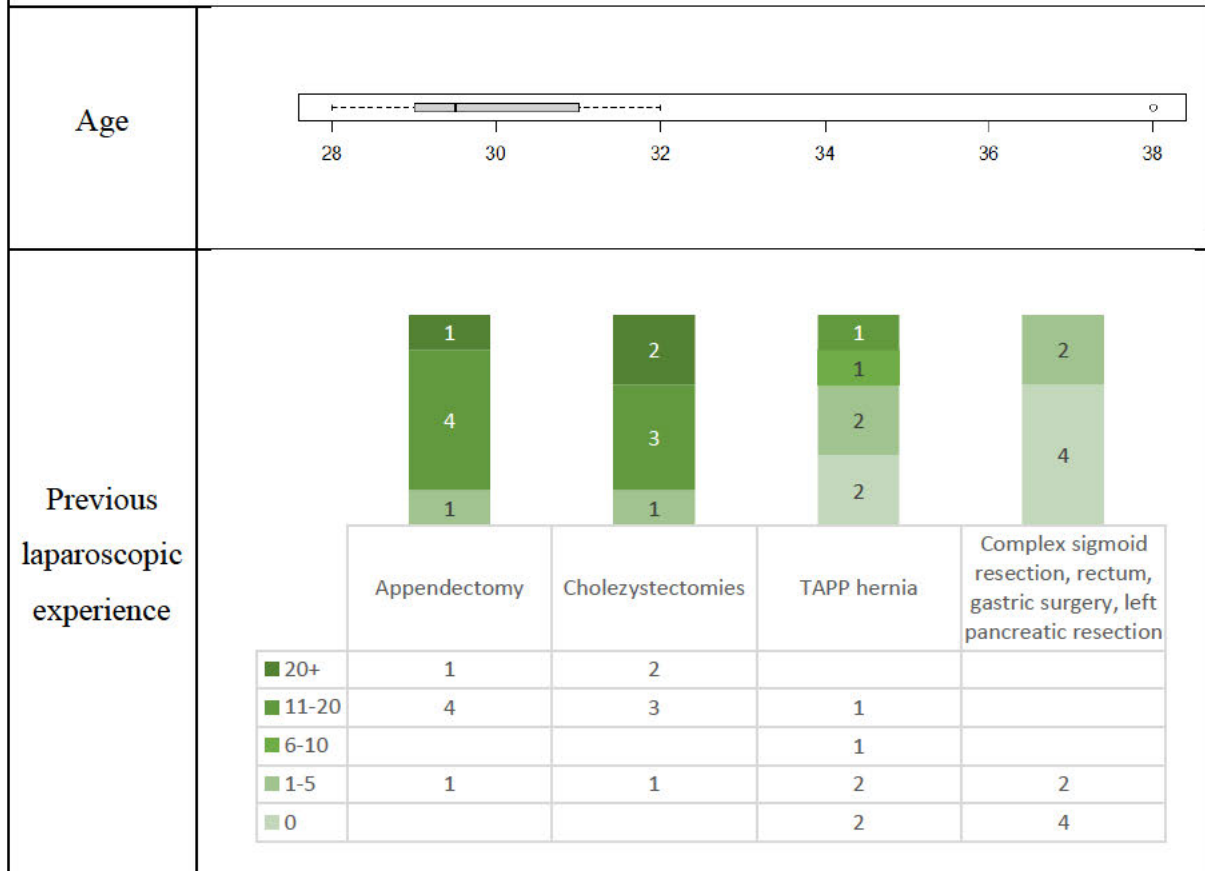


Table 5: Descriptive statistics of User Study II showing the 6 final male candidates with the age and previous laparoscopic experience (performed appendectomies, cholecystectomies, TAPP hernia, complex surgeries)

4.2.1 Objective Performance Measures

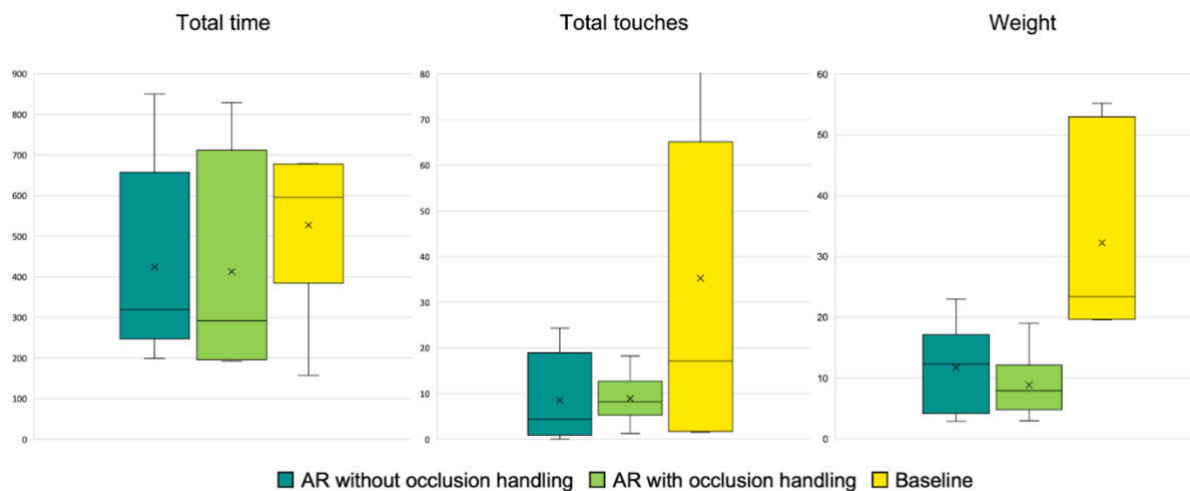


Figure 41: Box plots of the object performance measurements results. From left to right: total time (scale from 0 to 900 s); time of touches (scale from 0 to 80s); weight loss (scale from 0 to 60 g). Comparison between AR without occlusion handling , AR with occlusion handling and the Baseline condition revealed a difference of no statistical significance ($p > 0.05$) in the total time and touches. When comparing the amount of weight loss the comparison revealed a statistically significant difference ($p = 0.009$).

Data analysis was performed using SPSS Statistics (IBM, USA, RRID:SCR_002865). As the data were not normally distributed, the non-parametric Friedman test was employed to determine the significance in difference between the delta weight, total time, and time of touching among participants using AR or traditional laparoscopy. Our analysis considered values of as statistically significant. All participants $p < 0.05$ completed the primary requirements of all experiments in the allotted time, none of the participants withdrew from any of the trials in any of the conditions.

As you can see in the Table 6, there is no statistical relevance between the three conditions Baseline, AR without occlusion and AR with occlusion ($p > 0.05$). Nevertheless shows the Baseline condition consistently longer exaction time (Figure 41). Similar effects can be seen

with the total touching time of the vascular structure. Greater time with the Baseline condition, but in comparison no statistical significance ($p > 0.05$). The Baseline condition of wight loss or invasiveness of the simulated procedure showed consistently a higher degree of invasiveness compared to AR with occlusion or AR without occlusion. Friedman tests revealed, in this case, a statistically significant difference ($p = 0.009$) between the three conditions. In particular, pairwise Bonferroni corrected comparison between AR with occlusion handling and Baseline showed a statistically significant difference ($p = 0.012$). Bonferroni corrected comparisons between AR without occlusion handling and Baseline as well as between AR with occlusion handling and AR without occlusion handling showed a difference of no statistical significance ($p > 0.05$ in both cases).

Condition	Total execution time	
	M _{time}	SD _{time}
Baseline	527,6s	198,8s
AR with occlusion	412,8s	270,0s
AR without occlusion	424,0s	248,3s
Condition	Total touching time	
	M _{time}	SD _{time}
Baseline	35,2s	49,3s
AR with occlusion	8,8s	5,6s
AR without occlusion	8,5s	9,9s
Condition	Weight loss	
	M _{time}	SD _{time}
Baseline	32,5g	16,9g
AR with occlusion	8,9g	5,5g
AR without occlusion	11,7g	7,4g

Table 6: Statistical data regarding total execution time, total touching time and weight loss (related with Figure 41). Friedman tests revealed, in this case, a statistically significant difference ($p = 0.009$) between the three conditions. In particular, pairwise Bonferroni corrected comparison between AR with occlusion handling and Baseline showed a statistically significant difference ($p = 0.012$).

4.2.2 Subjective Survey

In addition to the fixed surveys presented here, participants were also asked for free comments. Three of the participants commented that they used the 2 screen setup (one with the augmentation and one original endoscope image). This could also be noted by the test observers. The augmentation was mainly used for orientation. However, the original image was used for interaction with the tissue. None of the participants addressed the difference between instrument tracking on “AR with occlusion” or off “AR without occlusion”.

The SurgTLX allows to distinguish between physical and mentally fatigue - especially the median is higher for the runs without augmentation. The complexity of the procedure was rated medium and showed no significant differences with or without augmentation. However, Friedman tests implemented in IBM SPSS on the raw SurgTLX score and its sub-scores revealed differences of no statistical significance ($p > 0.05$) between the conditions.

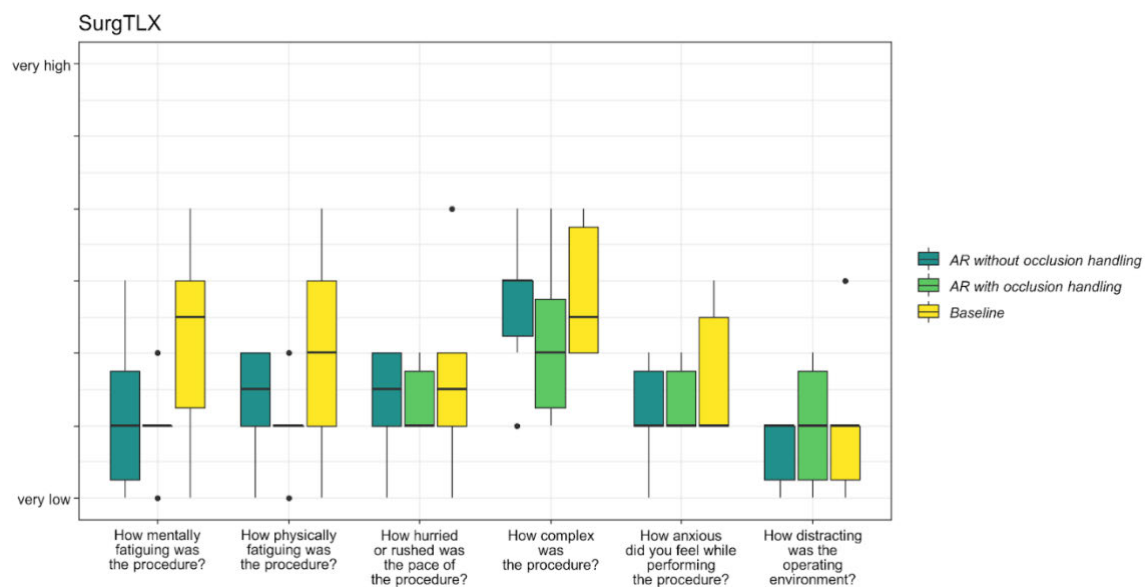


Figure 42: SurgTLX rating of User Study II with a 7-point Likert-scale (ranging from 1 = “very low” to 7 = “very high”). Questions are: “How mentally fatiguing was the procedure?”, “How physically fatiguing was the procedure?”, “How hurried or rushed was the pace of the procedure?”, “How complex was the procedure?”, “How anxious did you feel while performing the procedure?”, “How distracting was the operating environment?”.

	Baseline		With occlusion handling		without occlusion handling	
	M _{TLX}	SD _{TLX}	M _{TLX}	SD _{TLX}	M _{TLX}	SD _{TLX}
Raw	2,9	1,11	2,3	0,24	2,4	0,65
Mentally fatigue	3,2	1,5	2,0	0,63	2,2	1,17
Physically fatigue	3,0	1,5	2,0	0,63	2,3	0,8

Table 7: Statistical data of the SurgTLX rating. in the raw SurgTLXscores (taken as the mean of its sub-scores) participants assigned higher scores in the Baseline condition compared to the AR with occlusion handling and AR without occlusion handling.

As shown in Figure 43, all six participants in User Study II predict a positive effect with the LAS in the intervention liver resection, sigmoid resection and pancreas left resection (all 100%). Followed by rectal resection, nephrectomy (both 83%), cholecystectomy, gastrectomy and right hemicolectomy (67%). 50% of the participants, classified the LAS as beneficial for splenectomy (50%) and TAPP (50%). Only 33% stated a good impact of LAS on appendectomy.

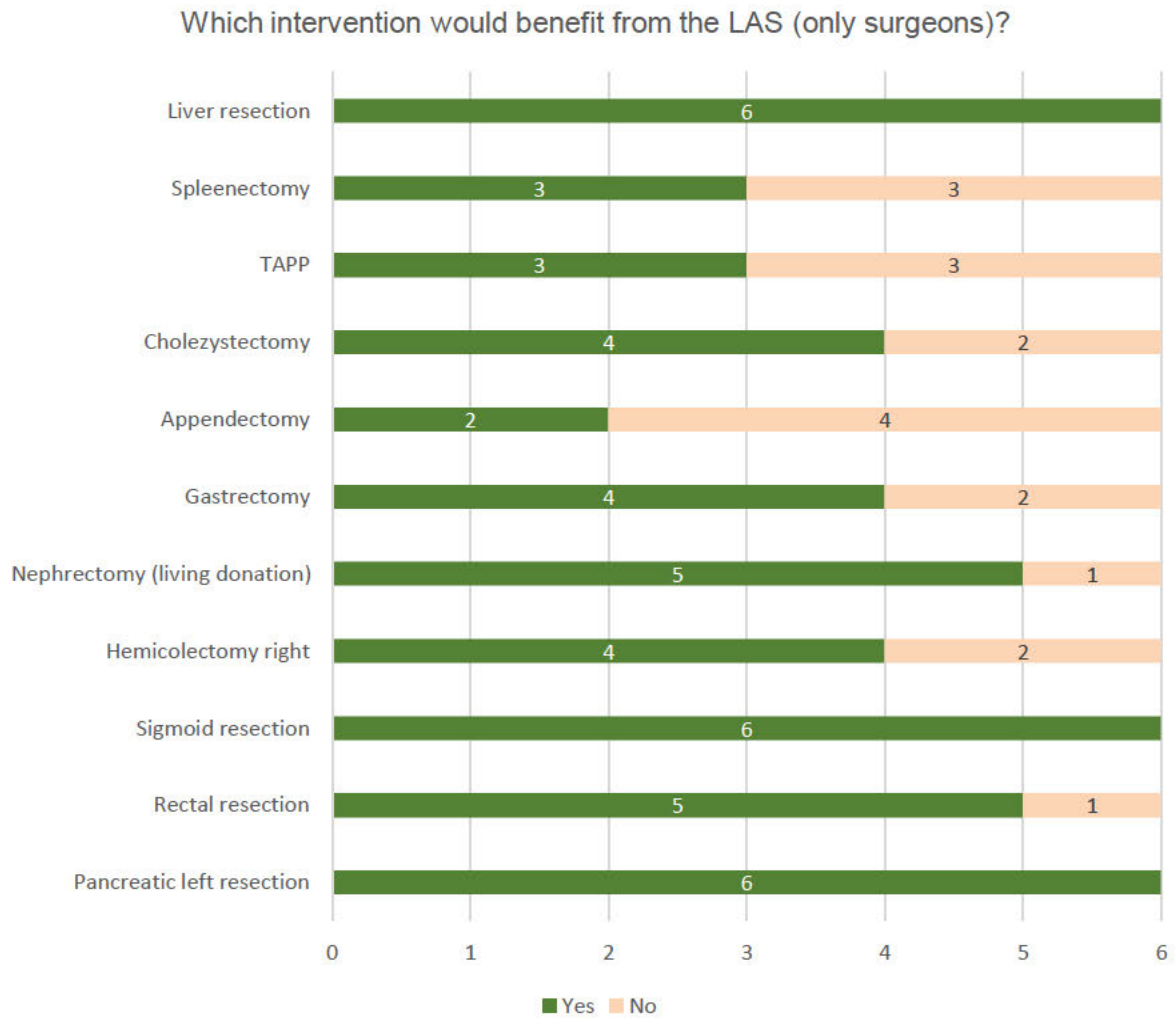


Figure 43: Which intervention would benefit from the LAS (only surgeons)? Rating results by the 6 participants. 100% of the 6 participants agreed that liver resection, sigmoid resection and pancreatic left resection would benefit from the LAS. Above 50% agreed with rectal resection, nephrectomy, cholecystectomy, gastrectomy and right hemicolectomy.

As in User Study I, all participants agreed that clinical parameters can be influenced by LAS (100%). Above 50% chose in all categories that the system will positively influence the

mentioned parameters. 5 of the 6 (83%) test persons naanten the reduction of complications and the reduction of operation time.

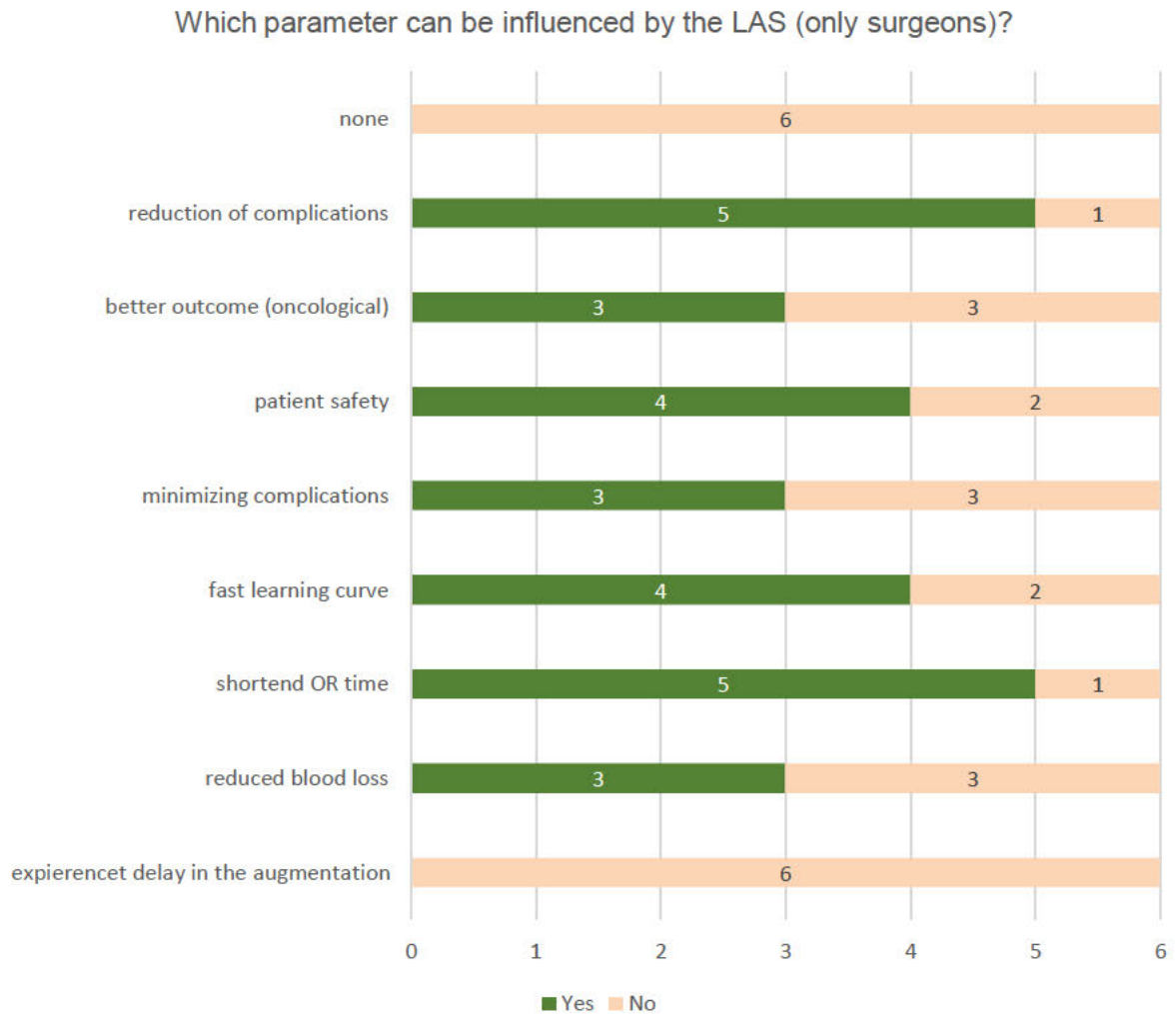


Figure 44: Which parameter can be influenced by the LAS (only surgeons)? Rating results by the 6 participants. As seen in User Study I, all 6 participants (100%) agreed on the effectiveness of the LAS system. No one voted (0%) voted for a delay in the agumentation.

There was agreement among all probands about the strength of the LAS in reducing stress, identification of risk structures and also being very helpful regarding the User Study II task overall (stress reduction 1 very helpful, 5 rather helpful vote; for the study tasks and identification of risk structures 5 very helpful and 1 rather helpful vote). Simple indication 3 (50%) people have found rather helpful, the other 3 rather unhelpful.

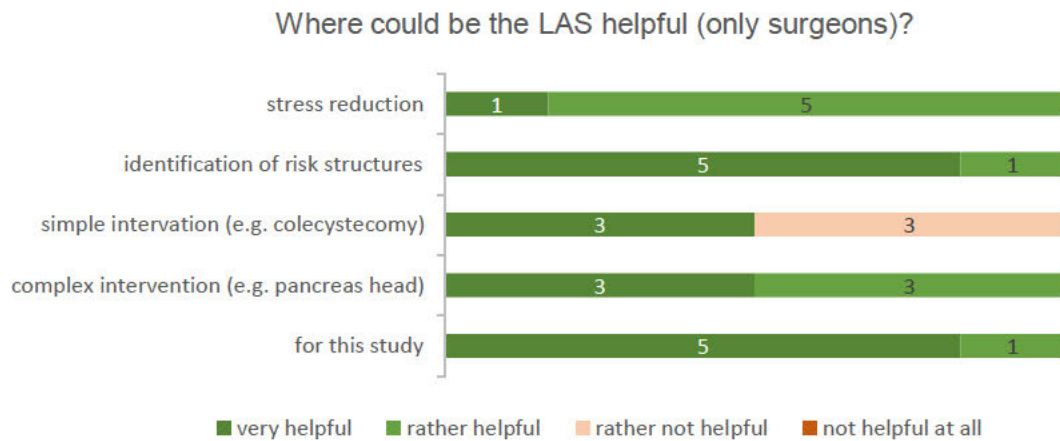


Figure 45: Where could be the LAS helpful (only surgeons)? Rating results by the 6 participants. All participants expect the LAS to be “very helpful” (1, 17%) or “rather helpful” (5, 83%). 50% of the surgeons find the LAS “rather not helpful” for simple interventions.

All subjects stated that it was true that the task of User Study II would be useful training element for laparoscopic surgery (Figure 46). 5 of the 6 probands (83%) chose that the task was comparable to a laparoscopic intervention. Three subjects (50%) indicated that the tissue material needs to be improved. Output from the 6 Participants regarding the usability - was the tracking array disturbing the user during the simulated procedure or did the user experienced disturbing delays in the augmentation - can be seen in Figure 47.

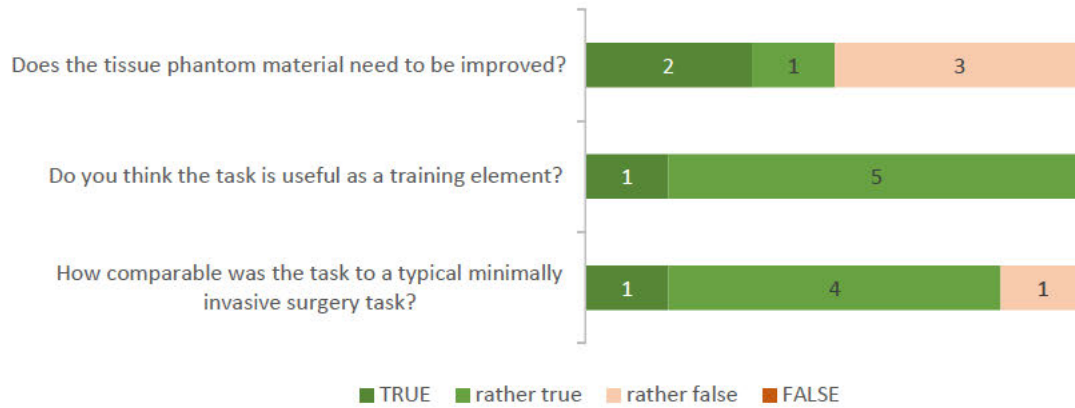


Figure 46: Evaluation of the task compared to the clinical reality. 100% of the 6 participants agreed with true (17%) or rather true (83%), that the task is a useful training element. Regarding the question, if the task was comparable to a typical minimally invasive surgery, 1 (17%) stated “true”, 4 (67%) stated “rather true” and (17%) stated “rather false”.

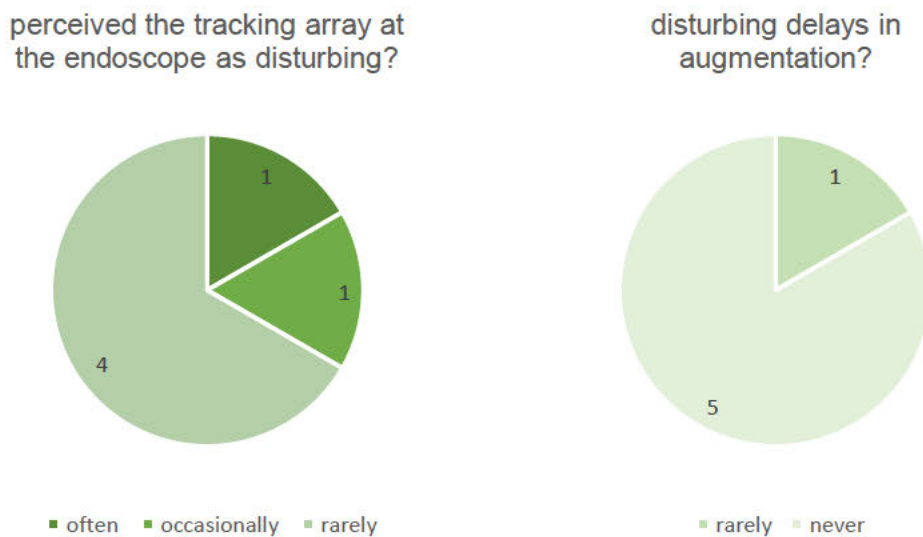


Figure 47: Questions regarding the performance and impact of the LAS in terms of usability. The tracking star on the endoscope was found to be disturbing by all 4 (66%) participants rarely, 1 occasionally (17%), and 1 often (17%). Disruptive delays of the augmentation of the LAS were experienced by 1 (17%) person rarely and never by the remaining 5 (83%).

5 Discussion

In this chapter, the results presented in section 4 - especially User Studies I and II - are discussed.

5.1 User Study I

As already shown, there is no noticeable difference in the error rates between the different mode of augmentations. Sub-grouped examinations – e.g. students and doctors, female and male - also showed no significant differences.

Based on these results, the difference in the visualization techniques used, does not seem as relevant for the objective performance as initially hypothesized. Either the selection of visualization techniques was not ideal, as they were all similar in visual representation, or the task was too easy or too hard on the proposed structures, so we could not measure enough polarizing results in performance.

The score between the different vessel trees – especially vessel tree 3 and 4 – varies significantly. Both vessel trees were more branching and spreading out over further distances compared to other structures. In our evaluation, however, all visualizations performed similarly, suggesting that different anatomical structures would be more difficult to classify with respect to depth perception. Therefore, optimized visualizations should be developed for specific anatomical structures. That seems to be a study design weakness of User Study I and confirms the importance of considering the depth perception problem - as already shown by Choi et al. [46] presented in chapter 1.5 - in the further development of the LAS system.

Moreover, the effortless task on vessel tree I and the excessively complex tasks on vessel trees III and IV essentially did not provide any meaningful data, as the performance was too similar (almost all participants were either correct or wrong). On the other hand, the developed MR simulator and artificial system setup might not sufficiently reflect the real impact of the visualization methods used. Furthermore, the simulated laparoscopic procedure may not have been a realistic task: the participants only looked at the vessel in the abdominal cavity and did not have to perform a proper surgical task, like preparing a blood vessel or cutting some structures. Moreover, the participants did not have to discriminate between different structures, which can be easily confused, like veins, arteries, or the ureter. In further studies, we would like to compare visualization techniques in different steps of the surgical workflow and include different anatomical structures.

Looking at the qualitative evaluation of the augmentation modes - Figure 36 - it has already been shown that there were favorites among the participants. Augmentation II in particular stands out, followed by augmentation III. Augmentation IV, as already mentioned, received a poor score. Augmentation II is the only shaded graphical representation and thus has probably the strongest 3-dimensional perceptible structure. There is otherwise no additional information about the distance. Apart from the shading, this mode is opaque and unicolor yellow. The four black target points are clearly visible. Augmentation III has a volumetric and medium transparent. There is a color coding for the distance. Deep red means very close and the color gradient goes from red, yellow to green coupled to increasing distance.

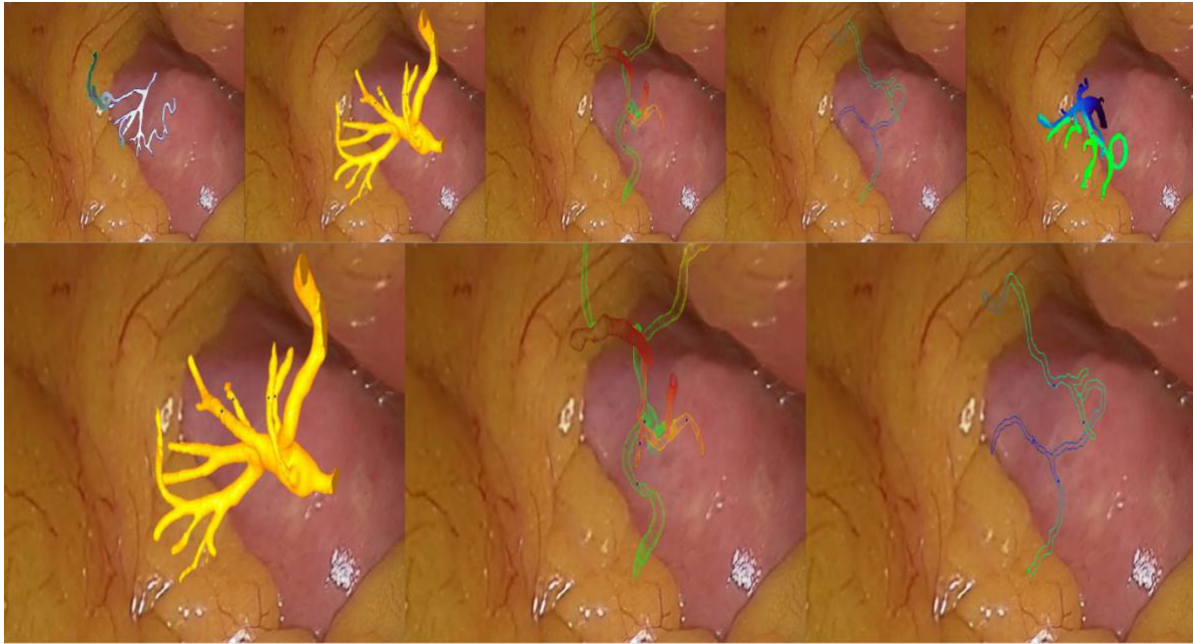


Figure 48: The five different augmentation techniques that are compared in the user study I. Highlighted below: Augmentation Mode II (Opaque with Fresnel highlights), III (Chromadepth Fresnel highlights) and IV (Chromadepth Fresnel highlights with reduced color range).

Augmentation technique IV also has a distance-color gradient. Here, however, only the outline of the structure is displayed. It is the most discreet compared to the other structures.

The benefit seen by the user – more than 50% - of the LAS in complex interventions is not surprising, since, as with any technical system, there is an increased complexity and potentially time-consuming foreseeable. As described above, the tracking star does not seem to bother more than 75% of the participants and, except for a minority, no disturbing latency of the augmentation was perceived. This may of course be related to the test setup and should be observed in further and increasingly realistic tests. It is interesting to see that especially the reduction of complications and the patient safety - both over 80% of the 25 experienced participants - can be improved according to the users perception. This evaluation confirms the

findings in the literature mentioned before [21, 22, 25]. Faster learning curves and better outcomes are also convinced by more than 50% of the benefits, but obviously not as clearly.

Choi et al., for instance, developed a switchable VR/AR visualization system incorporating detailed distance information, demonstrating a significantly improved depth perception [46]. However, such a combination required additional segmentation efforts and considerably increased surgeon interaction and familiarization with the AR system setup.

5.2 User Study II

It has already been mentioned in the results, that there are significant differences between augmentation and the baseline condition. Both the total procedure time and the invasiveness of the procedure were higher without augmentation. No significant difference could be detected between the two augmentation techniques (Instrument Tracking on and off) and seems to have no effect on the results at least in the test setup. However, this could not be shown to be statistically significant. As an important limitation of the study, the small sample size should be mentioned. Additional research with a substantially larger number of testing participants is needed. However, due to the complex experimental setup and the long time per experiment (approx. 60 min per subject), a study with more participants was disproportionate in terms of time and cost. Each participant was equipped with three individual vessel models, totaling 18. For a larger study with a similar setup, we suggest reusing the phantoms, as the 3D printed structures were not affected by the experiments, and the soft tissue material can be removed and the boxes refilled.

The comments and observations of the test observers suggest that the perceptibility of instrument tracking is low, as it was not commented on by any of the participants. The quantitative figures, as already mentioned, have not yet been able to show this either. However, the small number of participants should be taken into account. The fact that some participants

deliberately address the two-screen setup should be taken into consideration via the possibility of for example switching off the augmentation by the operator of the LAS. Remarks like this indicate that AR visualizations can sometimes overwhelm the surgeon with the amount of information presented, leading to the so-called issue of inattention blindness [22]. Dilley et al. have also shown that AR can be disturbing even with perfect registration [58]. The study, however, did not investigate whether this was due to the type of AR visualization used. The extent to which the type of visualization has an influence on the performance of AR is, unfortunately, a point that has received too little attention and should be further investigated in the future [20, 23].

The qualitative data also show that users experienced less mental and physical fatigue when performing the task with augmentation (SurgTLX survey). This reinforces what current literature already suggests: AR can be a strong addition to several surgical interventions and can assist in reducing the surgeon's stress and, thus, decreasing the number of committed mistakes. [34]

In the assessment of the effectiveness and influence of the LAS system, the participant groups of User Study I and II seem to agree on many points. It should be noted again that 50 test persons (25 of them physicians) participated in User Study I and only 6 physicians in User Study II. In both studies the LAS system is in the eyes of the participants helpful for complex interventions, but there is clearly more disagreement about simple interventions. It is striking that in User Study II, 5 out of 6 participants seem to see the OR time reduction more influenced from to the LAS. This is probably related to the more direct clinical reference of User Study II. On the other hand, the tracking star attached to the laparoscope was now also found to be annoying more often compared to User Study I. All participants in User Study II found the task rather useful for training and, with the exception of one participant, comparable to a typical minimally invasive surgical task. The material, however, can obviously be improved. Here it was also observed as a result of the test runs that the material could be cut well, but could be

gripped and removed awkwardly in some cases. This certainly led to frustration among the participants at times and does not correspond to the real clinical situation.

6 Conclusion

It was shown in the two user studies that the LAS can robustly display the augmentation of DICOM segmented data within the endoscope video. The results of the User Study II revealed, that the accuracy of the tracking and representation of the augmentation seems to be sufficient to guide the user to a region in a minimally invasive way. The system is found to be helpful and the participants perceive it as an improvement compared with the classic laparoscopic use in the user studies I & II. The results in the test environment also showed quantitatively that the LAS had a positive effect on invasiveness and treatment time. In particular, a significantly lower degree of invasiveness was measured. If possible, further test subjects should complete User Study II in order to further consolidate the findings. The augmentation technique does not seem to be as relevant as assumed, although there were clear favorites among the participants of the User Study I. Unexpected was the low effect - qualitatively and quantitatively - whether the instruments have erased the augmentation. However, it should be further investigated, especially in more real and thus more complex tasks, whether this feature is more important than the user studies currently showed. The User Study II task was found to be a helpful training tool, but the material should be further improved to present even higher comparability with a real situs. The mounting of the tracking arrays and additional equipment must be well investigated in further validations to ensure the usability of the LAS. The preparation of data - segmentation of organs and especially vessels - is still very time-consuming and accordingly it is to be expected that in the routine the investment will not be proportionate. Further development of automatic image segmentation can reduce and reconcile these efforts. High-resolution data (especially slice spacing) and scan protocols that are well adapted to the use case of segmentation are necessary to ensure an effective process. In rectal and pancreas surgery, contrast imaging is currently often not standard, which makes segmentation of vessels unfeasible.

In the first preliminary work for the validation, first feedback could already be collected. Here, too, the use of the LAS was found to be helpful. It seems to be important that the augmentation only includes the currently important and necessary information.

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Appendix

Appendix A – Survey User Study I

VIS I Umfrage: Studie zur Untersuchung der Effektivität eines Augmented Reality (AR) Systems bei laparoskopischen Eingriffen

In dieser Umfrage sind 17 Fragen enthalten.

Angaben zur Person

Geschlecht *

Bitte wählen Sie nur eine der folgenden Antworten aus:

- weiblich
 männlich

Wie alt sind Sie? (Jahreszahl, z.B. 31 Jahre) *

! In dieses Feld dürfen nur Zahlen eingegeben werden.

Bitte geben Sie Ihre Antwort hier ein:

Wie lautet Ihr vollständiger Name? *

Ausbildungsstand? *

📌 Bitte wählen Sie eine der folgenden Antworten:

Bitte wählen Sie nur eine der folgenden Antworten aus:

- Student
- Assistenzarzt
- Facharzt
- Oberarzt

Im welchem Ausbildungsjahr befinden Sie sich? *

Beantworten Sie diese Frage nur, wenn folgende Bedingungen erfüllt sind:

Antwort war 'Assistenzarzt' bei Frage '4 [LevelOfTraining]' (Ausbildungsstand?)

📌 Bitte wählen Sie eine der folgenden Antworten:

Bitte wählen Sie nur eine der folgenden Antworten aus:

- 1. Jahr
- 2. Jahr
- 3. Jahr
- 4. Jahr
- 5. Jahr
- 6. Jahr

Angaben zur Vorerfahrung in der minimal invasiven Chirurgie

Wieviele laparoskopische/minimalinvasive Eingriffe haben Sie schon durchgeführt. *

Beantworten Sie diese Frage nur, wenn folgende Bedingungen erfüllt sind:

Antwort war NICHT 'Student' bei Frage '4 [LevelOfTraining]' (Ausbildungsstand?)

Bitte wählen Sie die zutreffende Antwort für jeden Punkt aus:

	0	1-5	6-10	11-20	20+
Appendektomien	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cholezystektomien	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
TAPP Leistenhernien	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Komplexere Operation (z.B. Sigamresektion, Rektumresektion, Magen-Eingriffe, Pankreaslinksresektionen, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Wie würden Sie ihr laparoskopisches Können einschätzen? 1=gering, 5=sehr gut *

Beantworten Sie diese Frage nur, wenn folgende Bedingungen erfüllt sind:

Antwort war NICHT 'Student' bei Frage '4 [LevelOfTraining]' (Ausbildungsstand?)

Bitte wählen Sie nur eine der folgenden Antworten aus:

- 1
- 2
- 3
- 4
- 5

Welches Fachsemester?

Beantworten Sie diese Frage nur, wenn folgende Bedingungen erfüllt sind:
Antwort war 'Student' bei Frage '4 [LevelOfTraining]' (Ausbildungsstand?)

Bitte wählen Sie nur eine der folgenden Antworten aus:

- 1. Semester
- 2. Semester
- 3. Semester
- 4. Semester
- 5. Semester
- 6. Semester
- 7. Semester
- 8. Semester
- 9. Semester
- 10. Semester
- 11. Semester
- 12. Semester

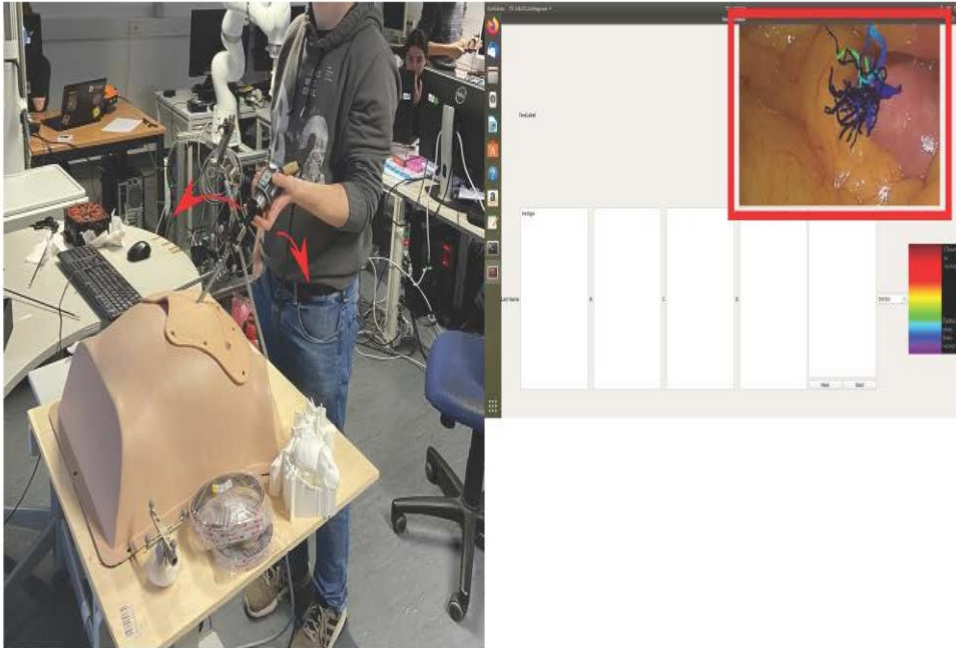
Training

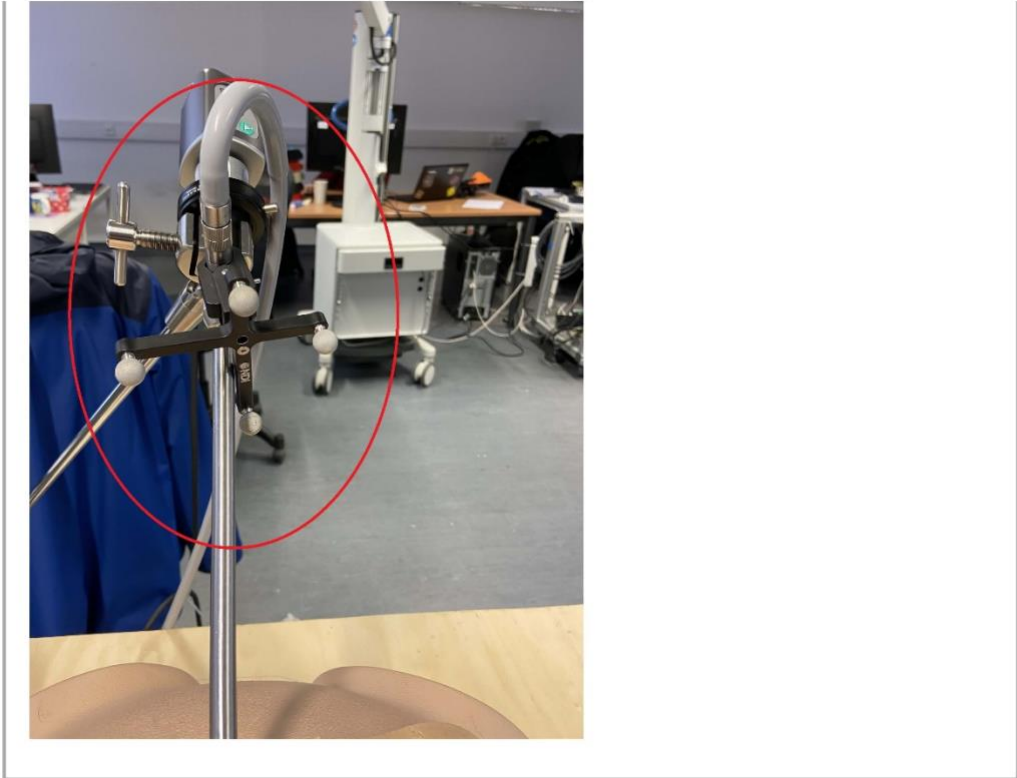
Bitte lesen Sie sich die einzelnen Schritte durch

Endoskop bewegen

Bitte nehmen Sie das Endoskop aus der Halterung und schwenken Sie das Endoskop. Auf dem Startbildschirm wird im oberen linken Fenster das Kamerabild mit der Augmentierung dargestellt. Machen Sie sich mit der Augmentierungstechnik vertraut.

Wichtig: Bitte berühren Sie das Trackingarray mit den vier Trackingkugeln während des Versuchs nicht. Dieses darf nicht verrutschen.

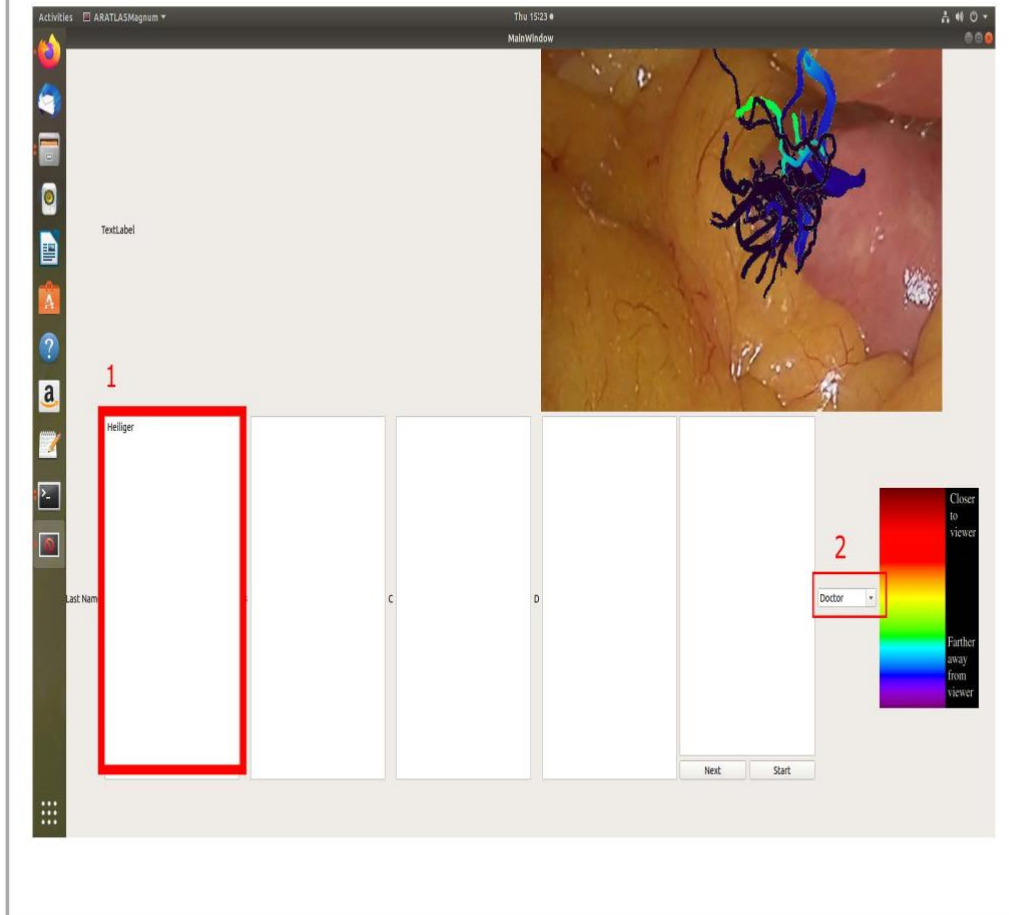




Bitte geben Sie alle nötigen Informationen ein.

1. Nachname

2. Auswahl Student oder Arzt

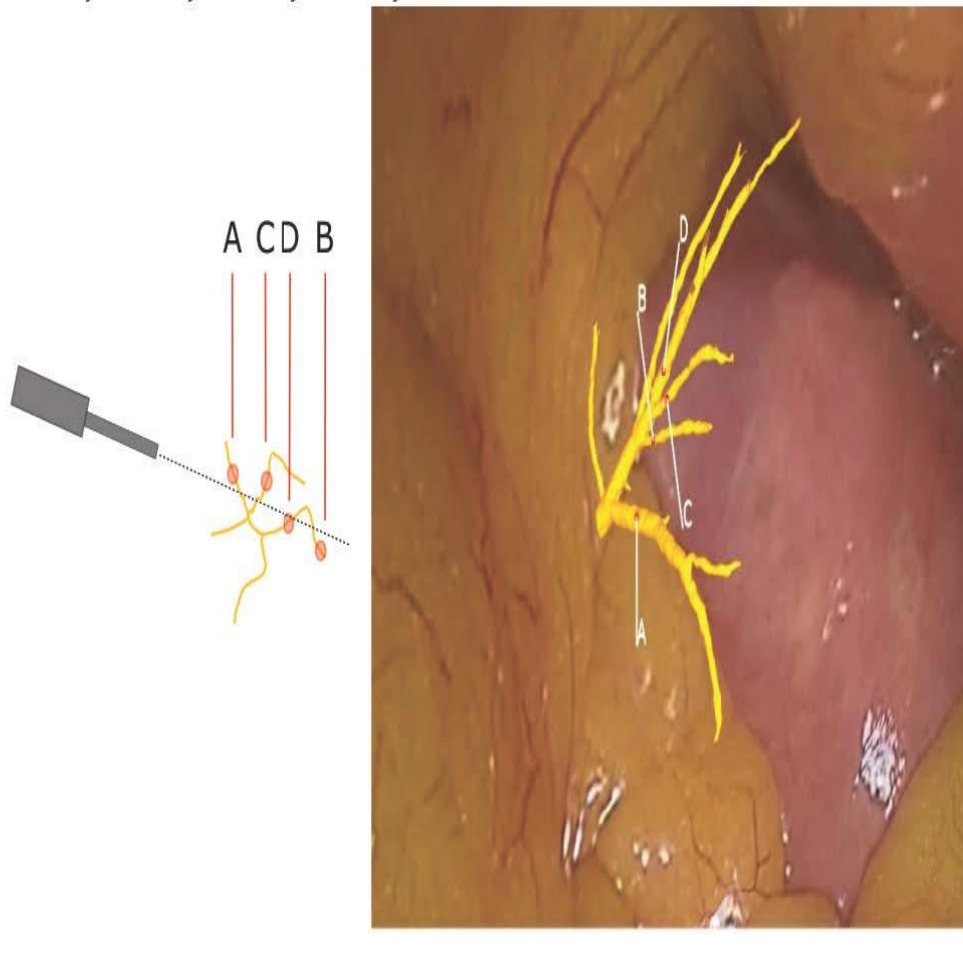


Versuchsdurchlauf

Nachdem die Aufgabe gestartet wurde, werden fünf Durchläufe mit jeweils verschiedenen Augmentierung durchgeführt. Die Aufgabe ist es, jedem Punkt anhand des Buchstabens eine Nummer zu zuordnen. Dabei ist 1 der nächste Punkt/Buchstabe und 4 der weit entfernteste im Bezug auf die Sichtachse des Endoskopbilds. Für eine bessere Übersicht können Sie das Endoskop jederzeit bewegen.

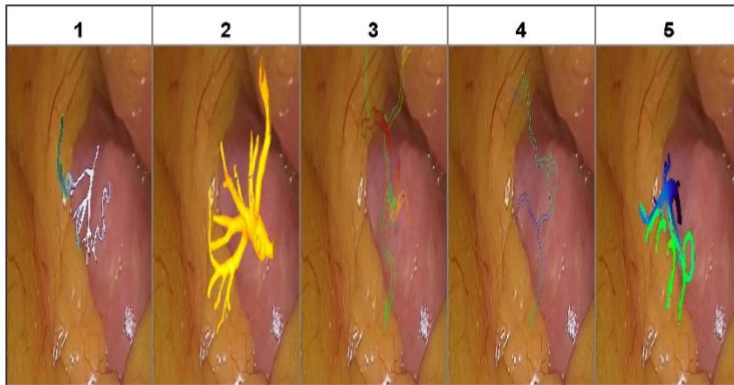
In diesem Beispiel wäre:

A = 1; C = 2; D = 3; B = 4;



Fragen bzgl. des Versuchsdurchlauf

Welche Augmentierung hat Ihnen besser gefallen?



*

Bitte nummerieren Sie jede Box in der Reihenfolge Ihrer Präferenz, beginnen mit 1 bis 5

Augmentierung 1

Augmentierung 2

Augmentierung 3

Augmentierung 4

Augmentierung 5

Wie hilfreich ... *

Bitte wählen Sie die zutreffende Antwort für jeden Punkt aus:

	äußerst hilfreich	eher hilfreich	eher nicht hilfreich	überhaupt nicht hilfreich
wäre die Augmentierung bei komplexen Eingriffen wie lap. Rektumresektion oder lap. Pankreaslinksresektion	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
wäre die Augmentierung bei einfacheren Eingriffen wie Appendektomien oder Cholezystektomie	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
wäre die Augmentierung um allg. Risikostrukturen schneller zu identifizieren?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
wäre die Augmentierung um allg. Streß zu reduzieren?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Bei welchen Eingriffen würden Sie sich Augmentierung wünschen? *

Bitte wählen Sie alle zutreffenden Antworten aus:

- Pankreaslinksresektion
- Rektumresektion
- Sigmaresektion
- Hemikolektomie rechts
- Nephrektomie (Lebendspende)
- Gastrektomie
- Appendektomie
- Cholezystektomie
- TAPP
- Splenektomie
- Leberresektionen
- Sonstiges:

Wie häufig haben Sie ...

*

Bitte wählen Sie die zutreffende Antwort für jeden Punkt aus:

	sehr häufig	häufig	gelegentlich	selten	nie
den Trackingstern am Endoskop als störend empfunden?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Haben Sie störende Verzögerungen der Augmentierung wahrgenommen? *

Bitte wählen Sie nur eine der folgenden Antworten aus:

- Ja
 Nein

Welche Parameter können Ihrer Meinung nach mittels Augmentierung verbessert werden? *

Bitte wählen Sie alle zutreffenden Antworten aus:

- Verminderter Blutverlust
 kürzere Operationszeit
 Schnellere Lernkurve
 Minimierung Stresslevel Operateur
 Patientensicherheit
 Besseres Outcome der Operation (z.B. onkologisch)
 Minimierung von Komplikationen
 keiner der genannten Parameter
 Sonstiges:

06.03.2020 – 13:10

Übermittlung Ihres ausgefüllten Fragebogens:
Vielen Dank für die Beantwortung des Fragebogens.

Appendix B – Survey User Study II

VIS II - Vorumfrage: Studie zur Untersuchung der Effektivität eines Augmented Reality (AR) Systems bei laparoskopischen Eingriffen

Wir freuen uns, dass Du an dem Versuch teilnehmen möchtest. Wie bereits in der E-Mail beschrieben, dient dieser Fragebogen dazu 6 Personen auszuwählen, die möglichst ähnliche laparoskopische Vorerfahrungen haben.

Nach dem Ausfüllen der Umfrage möchten wir dich gerne zu einem kurzen Test am Laparoskopietrainer einladen (ca. 5min im 13. Stock der LMU).

Die 6 Teilnehmer mit den ähnlichsten Scores werden dann an einem Versuch mit unserem Laparoskopie-Prototypen und 3D-Augmentierung teilnehmen. Hierbei wirst du drei anatomische 3D-gedruckte Phantome zur Verfügung gestellt bekommen, an welchen du die Präparation und weitere laparoskopische Tasks mit Hilfe von Augmentierung ausführen sollst.

Wir freuen uns über deine Teilnahme, deine Unterstützung und wünschen viel Spaß bei den Versuchen!

Dein ATLAS Team



In dieser Umfrage sind 6 Fragen enthalten.

Angaben zur Person

Geschlecht *

Bitte wählen Sie nur eine der folgenden Antworten aus:

weiblich

männlich



Wie alt sind Sie? (Jahreszahl) *



❗ In dieses Feld dürfen nur Zahlen eingegeben werden.

Bitte geben Sie Ihre Antwort hier ein:

Wie lautet Ihr vollständiger Name? *

Angaben zur Vorerfahrung in der minimal invasiven Chirurgie

Im welchem Ausbildungsjahr befinden Sie sich? *

❗ Bitte wählen Sie eine der folgenden Antworten:

Bitte wählen Sie nur eine der folgenden Antworten aus:

- 1
- 2
- 3
- 4
- 5
- 6



VIS II Abschlussfragen: Studie zur Untersuchung der Effektivität eines Augmented Reality (AR) Systems bei laparoskopischen Eingriffen

In dieser Umfrage sind 16 Fragen enthalten.

Name

Wie lautet Ihr vollständiger Name? *

Versuchserklärung

Bitte lesen Sie sich die Aufgabenbeschreibung gut durch



Wie würden Sie ihr laparoskopisches Können einschätzen?
1=gering, 5=sehr gut *

Bitte wählen Sie nur eine der folgenden Antworten aus:

- 1
 2
 3
 4
 5



Wieviele laparoskopische/minimalinvasive Eingriffe haben Sie schon durchgeführt. *

Bitte wählen Sie die zutreffende Antwort für jeden Punkt aus:

	0	1-5	6-10	11-20	20+
Appendektomien	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cholezystektomien	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
TAPP Leistenhernien	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Komplexere Operation (z.B. Sigamresektion, Rektumresektion, Magen-Eingriffe, Pankreaslinksresektionen, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

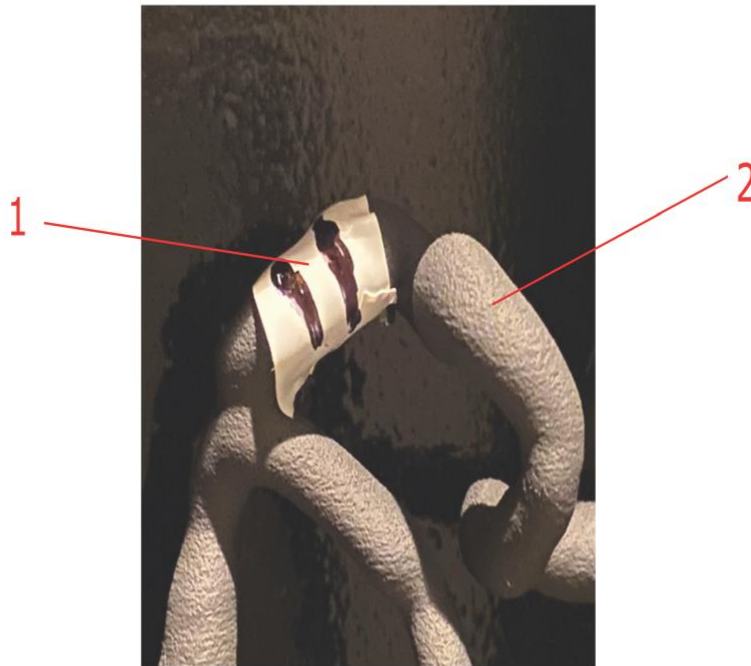
Übermittlung Ihres ausgefüllten Fragebogens:
Vielen Dank für die Beantwortung des Fragebogens.

Aufgabenbeschreibung

Es werden insgesamt drei Durchläufe absolviert. Das Hauptziel ist es, eine vorher definiertes Zeilregion/Region of interest (ROI) mithilfe von laparoskopischer Technik freizupräparieren und die korrekte Anzahl an Strichen mitzuteilen - in dem folgende Beispiel wäre die korrekte Antwort "2".

Wichtige Nebenziele sind dabei:

- So **wenig** Gewebematerial wie möglich zu **entfernen**
- Die Gefäßstruktur so **selten** wie möglich zu **berühren**



(1) Codierung an der Region of interest (ROI) (2) Gefäßbaum

Endoskop bewegen

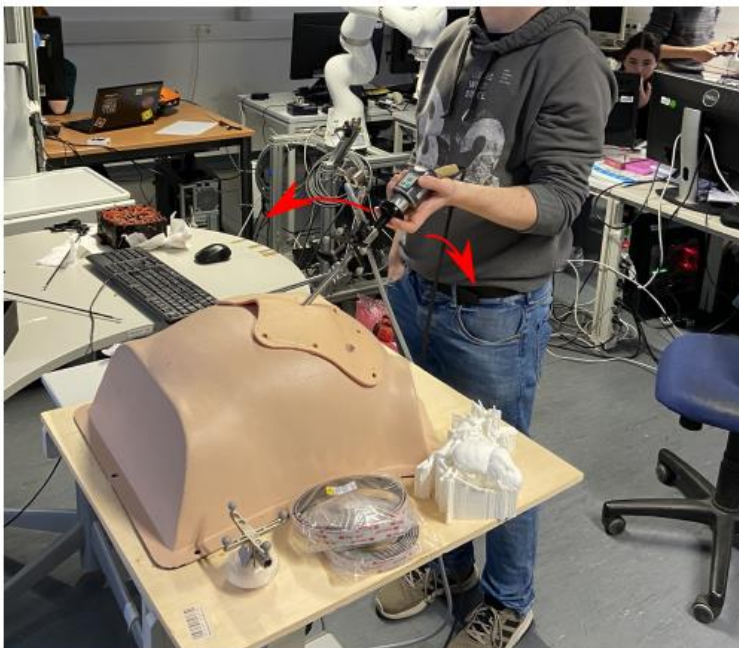
Das Endoskope wird von einem Studienbegleiter assistiert. Bitte stimmen Sie sich über die Handhabung ab. Machen Sie sich mit der Augmentierungstechnik vertraut.

Bewegungsbefehle für den Assistenten - dieser wird links von Ihnen stehen:

- Links, rechts, oben, unten
- Links oben, links unten, rechts oben, rechts unten.
- Hinein und heraus.

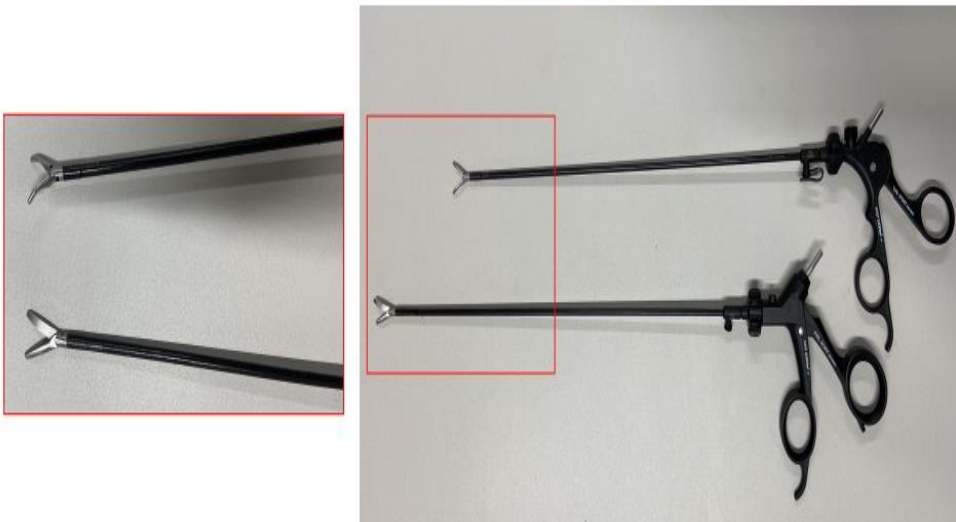
Wichtig:

- **Bitte berühren Sie das Trackingarray mit den vier Trackingkugeln während des Versuchs nicht. Dieses darf nicht verrutschen!**
- **Das Winkelobjektiv kann nicht eingestellt werden!**



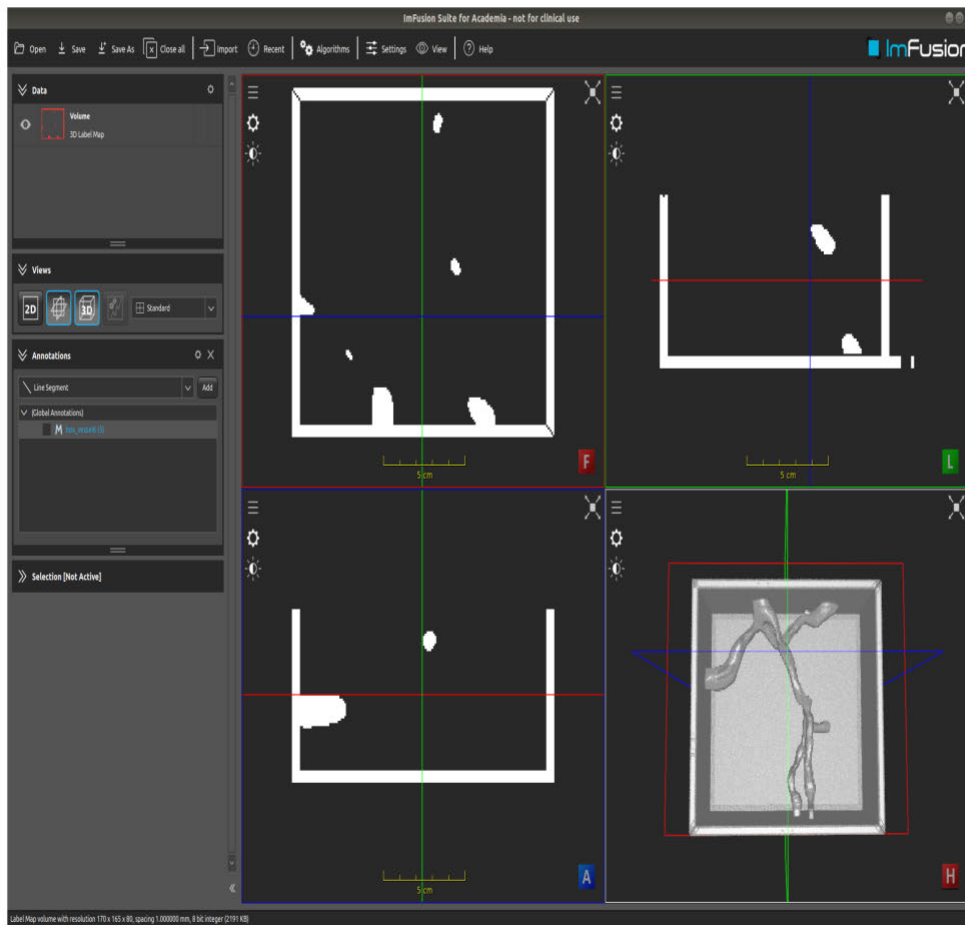
Instrumente

Ihnen stehen eine Zange und Schere als Instrument zur Verfügung. Bitte machen Sie sich mit den Instrumenten vertraut und versuchen Sie einige Schnitte und Präparationen an einer Testbox vor dem Versuch. Wie in der Aufgabenbeschreibung erwähnt, werden die Berührungen mit dem Gefäßbaum gemessen und sollten vermieden werden.



Schichtbild Viewer

Vor jedem Durchgang wird Ihnen die zu bearbeitende Struktur in einem Schichtbild-Viewer in axialer, koronarer und sagittaler Ebene angezeigt. Schauen Sie sich die Schichtbilder bitte genau an. Die Position der Zielregion wird Ihnen von einem der Studienbetreuern mitgeteilt. Versuchen Sie sich die Geometrie der "Anatomie" einzuprägen.



Jetzt kann der Test durchgeführt werden!

Nun kann mit dem Versuchen begonnen werden. Bitte geben Sie dem Studienleiter bescheid, wenn Sie bereit sind.

SurgyTLX nach erstem Versuch

Bitte kreuzen Sie an *



Bitte wählen Sie die zutreffende Antwort für jeden Punkt aus:

	Sehr gering						Sehr hoch
Wie mental ermüdend war der Eingriff?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wie körperlich ermüdend war der Eingriff?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wie eilig oder überstürzt war das Tempo des Eingriffes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wie komplex war der Eingriff?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wie unruhig fühlten Sie sich bei der Durchführung des Eingriffes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wie ablenkend war die Umgebung?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

SurgyTLX nach zweitem Versuch

Bitte kreuzen Sie an *

Bitte wählen Sie die zutreffende Antwort für jeden Punkt aus:

	Sehr gering						Sehr hoch
Wie mental ermüdend war der Eingriff?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wie körperlich ermüdend war der Eingriff?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wie eilig oder überstürzt war das Tempo des Eingriffes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wie komplex war der Eingriff?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wie unruhig fühlten Sie sich bei der Durchführung des Eingriffes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wie ablenkend war die Umgebung?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

SurgyTLX nach letztem Versuch

Bitte kreuzen Sie an *

Bitte wählen Sie die zutreffende Antwort für jeden Punkt aus:

	Sehr gering						Sehr hoch
Wie mental ermüdend war der Eingriff?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wie körperlich ermüdend war der Eingriff?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wie eilig oder überstürzt war das Tempo des Eingriffes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wie komplex war der Eingriff?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wie unruhig fühlten Sie sich bei der Durchführung des Eingriffes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wie ablenkend war die Umgebung?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Fragen bzgl. des Versuchsdurchlauf

In den beiden Augmentierungstechniken wurde die Augmentierung durch das Instrument verdeckt.
Welche Augmentierung hat Ihnen besser gefallen?

*

Bitte wählen Sie nur eine der folgenden Antworten aus:



- Mit Auslöschung der Augmentierung
- Ohne Auslöschung der Augmentierung

Wie hilfreich ... *

Bitte wählen Sie die zutreffende Antwort für jeden Punkt aus:

	äußerst hilfreich	eher hilfreich	eher nicht hilfreich	überhaupt nicht hilfreich
war Augmentierung bei der Aufgabe?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
wäre die Augmentierung bei komplexen Eingriffen wie lap. Rektumresektion oder lap. Pankreaslinksresektion	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
wäre die Augmentierung bei einfacheren Eingriffen wie Appendektomien oder Cholezystektomie	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
wäre die Augmentierung um allg. Risikostrukturen schneller zu identifizieren?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
wäre die Augmentierung um allg. Streß zu reduzieren?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Bei welchen Eingriffen würden Sie sich Augmentierung wünschen? *

Bitte wählen Sie alle zutreffenden Antworten aus:

- Pankreaslinksresektion
- Rektumresektion
- Sigmaresektion
- Hemikolektomie rechts
- Nephrektomie (Lebendspende)
- Gastrektomie
- Appendektomie
- Cholezystektomie
- TAPP
- Splenektomie
- Leberresektionen



Sonstiges:

Wie häufig haben Sie ...

*

Bitte wählen Sie die zutreffende Antwort für jeden Punkt aus:

	sehr häufig	häufig	gelegentlich	selten	nie
die Augmentierung als störend empfunden?	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
den Trackingstern am Endoskop als störend empfunden?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Haben Sie störende Verzögerungen der Augmentierung wahrgenommen? *

Bitte wählen Sie nur eine der folgenden Antworten aus:

- Ja
 Nein



Welche Parameter können Ihrer Meinung nach mittels Augmentierung verbessert werden? *

Bitte wählen Sie alle zutreffenden Antworten aus:

- Verminderter Blutverlust
 kürzere Operationszeit
 Schnellere Lernkurve
 Minimierung Stresslevel Operateur
 Patientensicherheit
 Besseres Outcome der Operation (z.B. onkologisch)
 Minimierung von Komplikationen
 keiner der genannten Paramater



Sonstiges:

Bitte kreuzen Sie die Antworten an *

Bitte wählen Sie die zutreffende Antwort für jeden Punkt aus:

	trifft zu	trifft eher zu	trifft eher nicht zu	trifft gar nicht zu
Wie vergleichbar war die Aufgabe mit einer typischen minimal-invasiven Operationsaufgabe?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Halten Sie die Aufgabe für Sinnvoll als Trainingselement?	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Muss das Gewebephantommaterial verbessert werden?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Übermittlung Ihres ausgefüllten Fragebogens:

Vielen Dank für die Beantwortung des Fragebogens.

Appendix C – Intervention list

Kidney left			
Id	Step	Target anatomy	Segmentation
1	Mobilization Colon Descendent & left Flexur	Left Ureter	Origin in the Kidney until insertion into the urinary-bladder
2		V. renalis sinistra	From V. cava to the kidney
3		V. suprarenalis inferior	From V. renalis sinistra to the kidney
4	Colon Descendens & left Flexur	V. ovarica/testicularis	From V. renalis until Ovar
5		Aorta abdominals	From Diaphragma until Ilical bifurcation
6	Preparation Gerota Faszie until Zwerchfell / Clipping V. Suprarenalis inferior	Adrenal Gland	Whole Organ
7		V. renalis sinistra	From V.cava to the kidney
8		V. suprarenalis inferior	From V. renalis sinistra to the kidney
9		V. ovarica	From V. renalis until Ovar
10	Preparation Vene	Aorta	From Diaphragma until Ilical bifurcation
11		A. renalis sinistra	From Aorta to the Kidney
12	Preparation Artery	Aorta	From Diaphragma until Ilical bifurcation
13		A. renalis sinistra	From Aorta to the Kidney
14	Preparation Ureter	Ureter left	Origin in the Kidney until insertion into the urinary-bladder
15		V. testicularis / ovarica	From V. renalis until Ovar
16	Preparation Kidney	Aorta	From Diaphragma until Ilical bifurcation
17		Adrenal Gland	Whole Organ
Kidney right			
Id	Step	Target anatomy	Segmentation

1	Mobilization Colon Ascendens & right Flexur	Right ureter	Origin in the Kidney until insertion into the urinary-bladder
2	Mobilization Colon Ascendens & right Flexur	V. renalis right	From V.cava to the kidney
3		V. suprarenalis right	From V.cava to the kidney
4		V. ovarica/testicularis	From V.cava to the ovar
5		A. renalis dextra	From Aorta to the kidney
6		V. cava	From diaphragma until ilical bifurcation
7	Preparation Gerota Faszie until Zwerchfell / Preparation triangonale Lig. Coronarium hepatis until right liver vein	Adrenal Gland	Whole organ
8		V. renalis sinistra	From Kidney to V. cava
9		V. suprarenalis	From V.cava to the kidney
10	Preparation Gerota Faszie until Zwerchfell / Preparation triangonale Lig. Coronarium hepatis until right liver vein	V. ovarica / testicularis	From V. cava until Ovar
11		V. cava	From diaphragma until ilical bifurcation
12		Right liver veins	From diaphragma until V.cava und 5cm into the liver
13	Preparation Duodenum / Pancreas	Aorta	From Diaphragma until Ilical bifurcation
14		V. cava	From diaphragma until ilical bifurcation
15		V. renalis sinistra	From Kidney to V. cava
16		V. suprarenalis inferior	From V.cava to the kidney
17		A. renalis dextra	From Aorta to the Kidney
18	Preparation Veins / Clipping V. Suprarenalis inferior	Aorta	From Diaphragma until Ilical bifurcation
19		V. cava	From Diaphragma until Ilical bifurcation
20		V. renalis sinistra	From V.cava to the kidney
21		V. suprarenalis inferior	From V.cava to the kidney
22		A. renalis dextra	From Aorta to the Kidney
23	Preparation Artery	Aorta	From Diaphragma until Ilical bifurcation

24		A. renalis dextra	From Aorta to the Kidney
25		Adrenal Gland right	Whole Organ
26	Preparation Ureter	Ureter right	Origin in the Kidney until insertion into the urinary-bladder
27		V. testicularis / ovarica	From V. cava until Ovar
28	Preparation kidney	Aorta	From Diaphragm until Iliac bifurcation
29		A. Renalis dextra	Aorta to Kidney
30		V. cava	From Diaphragm until Iliac bifurcation
31		Adrenal Gland	Whole Organ
	Pancreas		
Id	Step	Target anatomy	Segmentation
1	Präparation Pankreasunterrand	V. linealis	From Portal Vein to Spleen
2	Präparation Pankreasunterrand	Pankreas	Whole Organ
3	Präparation Pankreasunterrand	Tumor	Tumor
4	Präparation Pankreasunterrand	V. mesenterica inferior	From V. porta / V. lienalis up to 15cm of V. mesenterica
5	Präparation Pankreasunterrand	V. mesenteria superior	From V. porta behind duodenum (10-20cm)
6	Präparation Pankreasoberrand	A. hepatica propria	From common hepatic atery to hepatic atery bevor A. cystica
7	Präparation Pankreasoberrand	A. lienalis	From Origin to spleen
8	Präparation Pankreasoberrand	Arteria gastrica Sinistra	10cm
9	Präparation Pankreasoberrand	Truncus coeliacus	From origin to the branches
10	Präparation Pankreasoberrand	V. splenica	From V. porta to spleen
11	Präparation Pankreasoberrand	Pankreas	Whole Organ
12	Tunnelierung	Truncus coeliacus	From origin to the branches
13		V. lienalis	From V. porta to spleen
14		V. mesenterica inferior	From V. porta / V. lienalis up to 15cm of V. mesenterica
15		V. mesenteriac superior	From V. porta behind duodenum (10-20cm)
16		Vena portae	From Liver to confluence
17		Tumor	Tumor

18	Isolierte Pankreas links Resektion / Pankreas Präparation	A. splenica until spleen	From Truncus to the spleen
19		V. splenica until spleen	From Truncus to the spleen
20		V. porta until origin	V. porta to confluence incl. V. lienalis / V. mesenterica sup + inf
21		V. mesenterica inferior until origin	See Point 19
22		Tumor	Tumor
	Rectum		
Id	Step	Target anatomy	Segmentation
1	Medial approach/ Preparation A. Mesenterica inferior / Clipping A. Mesenterica inferior	Left Ureter	Origin in the Kidney until insertion into the urinary-bladder
2	Medial approach/ Preparation A. Mesenterica inferior / Clipping A. Mesenterica inferior Medial approach/ Preparation A. Mesenterica inferior / Clipping A. Mesenterica inferior	Aorta	From Diaphragma until Ilical bifurcation (first 1-2cm of big branches: Truncus coeliacus/mesenteria superior, .a renalis re/le
3		A. ilica communis right	End of distal Aorta until branch of ilical interna/externa
4	Medial approach/ Preparation A. Mesenterica inferior / Clipping A. Mesenterica inferior	A. mesenterica inferior	Origin in Aorta and from there 5cm
5	Preparation V. Mesenterica inferior / Clipping V. Mesenterica inferior	Aorta	From Diaphragma until Ilical bifurcation (first 1-2cm of big branches: Truncus coeliacus/mesenteria superior, .a renalis re/le
6	Preparation V. Mesenterica inferior / Clipping V. Mesenterica inferior	Pancreas	Whole Organ (as Volume; no parenchymal Vessels)
7	Preparation V. Mesenterica inferior / Clipping V. Mesenterica inferior	V. Mesenterica inferior	From V.porta / V. lienalis until first distal branches (origin V. mesenterica inferior – 15cm)
8	Preparation V. Mesenterica inferior / Clipping V. Mesenterica inferior	V. lienalis	From origin in V. porta until Spleen
9	Darstellung Ureter / Preparation medial approach in direction of Becken	Aorta	From Diaphragma until Ilical bifurcation (first 1-2cm of big branches: Truncus coeliacus/mesenteria superior, .a renalis re/le

10	Darstellung Ureter / Preparation medial approach in direction of Becken	A. iliaca communis bds	Distal Aorta until branches of A: iliaca interna / externa
11	Darstellung Ureter / Preparation medial approach in direction of Becken	Ureter left	Origin in the Kidney until insertion into the urinary-bladder
12	Darstellung Ureter / Preparation medial approach in direction of Becken	V. ovarica/ testicularis left	From Origin in V. renalis left until end (far as possible)
13	Medial Approach in direction Pancreas Scarpa-Faszie	Pancreas	Whole Organ (as Volume; no parenchymal Vessels)
14	Medial Approach in direction Pancreas Scarpa-Faszie	A./V. lineais	A: From origin at Truncus coeliacus until spleen V. from V.porta until spleen
15	Medial Approach in direction Pancreas Scarpa-Faszie	Spleen	Whole Organ (as Volume; no parenchymal Vessels)
16	Lösen linke Flexur	Pancreas	Whole Organ (as Volume; no parenchymal Vessels)
17	Lösen linke Flexur	A./V. lineais	A: From origin at Truncus coeliacus until spleen V. from V.porta until spleen
18	Preparation Rectum right until A. Rectalis medialis	Ureter re	Origin in the Kidney until insertion into the urinary-bladder
19	Preparation Rectum right until A. Rectalis medialis	A. iliaca interna + externa re	Distal Aorta up to 5 cm of A. iliaca interna/externa
20	Preparation Rectum right until A. Rectalis medialis	V. iliaca interna + externa re	Distal V. cava inferior until V. iliaca interna/externa
21	Preparation Rectum right until A. Rectalis medialis	Tumor	Tumor
22	Preparation Rectum left until A. Rectalis medialis	Ureter li	Origin in the Kidney until insertion into the urinary-bladder
23	Preparation Rectum left until A. Rectalis medialis	A. iliaca interna + externa li	Distal Aorta up to 5 cm of A. iliaca interna/externa
24	Preparation Rectum left until A. Rectalis medialis	V. iliaca interna + externa li	Distal V. cava inferior until V. iliaca interna/externa
25	Preparation Rectum left until A. Rectalis medialis	Tumor	Tumor
26	Rektumresektion ventral	Prostate	Prostate
27	Rektumresektion ventral	M. levator ani	
28	Rektumresektion ventral	Tumor	Tumor

29	Rektumresektion dorsal	Os coccygeum + S3 + S4 + 5	Just the corpus of the vertebrae
30	Rektumresektion dorsal	M. levator ani	From origin of. Os pubis and Os coccygis
31	Rektumresektion dorsal	M. sphincter	Whole muscle
32	Rektumresektion dorsal	Tumor	Tumor

Affidavit



Eidesstattliche Versicherung

Heiliger, Thomas
Name, Vorname

Ich erkläre hiermit an Eides statt, dass ich die vorliegende Dissertation mit dem Titel:

Usability and performance studies of an Augmented Reality Laparoscopic System for Minimal Invasive Surgery

selbständig verfasst, mich außer der angegebenen keiner weiteren Hilfsmittel bedient und alle Erkenntnisse, die aus dem Schrifttum ganz oder annähernd übernommen sind, als solche kenntlich gemacht und nach ihrer Herkunft unter Bezeichnung der Fundstelle einzeln nachgewiesen habe.

Ich erkläre des Weiteren, dass die hier vorgelegte Dissertation nicht in gleicher oder in ähnlicher Form bei einer anderen Stelle zur Erlangung eines akademischen Grades eingereicht wurde.

Hamburg, 02.11.2023

Thomas Heiliger

Ort, Datum

Unterschrift Doktorandin bzw.