Virtual Reality (2024) 28:138
https://doi.org/10.1007/s10055-024-01038-4

ORIGINAL ARTICLE

Towards overcoming barriers to the clinical deployment of mixed reality image-guided navigation systems supporting percutaneous ablation of liver focal lesions

Dominik Spinczyk[1,2] · **Grzegorz Rosiak**[3] · **Krzysztof Milczarek**[3] · **Dariusz Konecki**[3] · **Jarosław Żyłkowski**[3] · **Jakub Franke**[3] · **Maciej Pech**[4,5] · **Karl Rohmer**[4] · **Karol Zaczkowski**[6] · **Ania Wolińska-Sołtys**[2] · **Piotr Sperka**[2] · **Dawid Hajda**[2] · **Ewa Piętka**[1]

Received: 24 March 2024 / Accepted: 11 July 2024

Abstract

In recent years, we have observed a rise in the popularity of minimally invasive procedures for treating liver tumours, with percutaneous thermoablation being one of them, conducted using image-guided navigation systems with mixed reality technology. However, the application of this method requires adequate training in using the employed system. In our study, we assessed which skills pose the greatest challenges in performing such procedures. The article proposes a training module characterized by an innovative approach: the possibility of practicing the diagnosis, planning, execution stages and the physical possibility of performing the execution stage on the radiological phantom of the abdominal cavity. The proposed approach was evaluated by designing a set of 4 exercises corresponding to the 3 phases mentioned. To the research group included 10 radiologists and 5 residents in the study. Based on 20 clinical cases of liver tumors subjected to percutaneous thermoablation, we developed assessment tasks evaluating four skill categories: head-mounted display (HMD), ultrasound (US)/computed tomography (CT) image fusion interpretation, tracking system use, and the ability to insert a needle**.** The results were presented using the Likert scale. The results of our study indicate that the most challenging aspect for radiology specialists is adapting to HMD gesture control, while residents point to intraoperative images of fusion and respiratory movements in the liver as the most problematic. In terms of improving the ability to perform procedures on new patients, the module also allows you to create a new hologram for a different clinical case.

Keywords Percutaneous liver tumour ablation · Image-guided navigation · Mixed reality · Training of interventional radiologists · Acquiring the ability to use image-guided navigation

1 Introduction

Thermoablation is a method involving the insertion of a needle into a previously visualized lesion. Once introduced into the tumor, the needle tip generates microwave , causing thermal damage to the tissues and thereby resulting in the breakdown of the tumor (Geoghegan et al. 2022). Various approaches have been developed to introduce the thermoablative needle, but most commonly, this method is employed in percutaneous and laparoscopic procedures. Due to the recent emphasis on minimally invasive procedures, reducing complications, and shortening patient hospitalization, there is a growing development of technologies enabling imaging and localized treatment. Consequently, percutaneous techniques have gained the most popularity.

✉ Dominik Spinczyk
dominik.spinczyk@polsl.pl

1 Faculty of Biomedical Engineering, Silesian University of Technology, Zabrze, Poland

2 Holo4Med Sp. Z O. O, Białystok, Poland

3 2nd Department of Radiology, Medical University of Warsaw, Warsaw, Poland

4 University Clinic for Radiology, University of Magdeburg, Magdeburg, Germany

5 Research Campus STIMULATE, Magdeburg, Germany

6 Department of Neurosurgery and Neurooncology, Medical University of Łódź, Łódź, Poland

Published online: 18 July 2024

Thermoablation is most frequently used in the treatment of liver tumours, however it also finds application in the treatment of tumours in other parts of the body. Recent studies highlight the comparative importance of this method in relation to open surgery (Puijk et al. 2018, 2022). Such procedures are usually performed under ultrasound (US) and computed tomography (CT) guidance, as combining these techniques makes it possible to locate the lesion, the surrounding organs, and the ablative needle access route. US or CT alone may not be sufficient to image the cancerous lesion during ablation, especially larger lesions requiring several needle placement positions. Indeed, US does not provide visualization of the entire lesion since the gas emitted during tumor heating limits visibility. Recent work shows that using US/CT-guided radiofrequency ablation (RFA) for hepatocellular carcinoma (HCC) reduced local recurrence rate than US-guided RFA alone (Nagasawa et al. 2023).

Thermoablations require extensive experience in performing procedures under imaging study guidance and are usually performed by specialists in image-guided procedures, i.e., interventional radiologists. Furthermore, knowledge of anatomy and pathology in CT, magnetic resonance imaging (MRI), and US images is essential for the proper performance of such procedures.

The standard procedure can be divided into four stages, including diagnosis, planning, execution, and evaluation (Puijk et al. 2018). At an early stage of diagnosis, lesions are detected by the US, but tumours are eventually identified on CT or MR images. The location of the blood vessels and their diameter, as well as the bile ducts, should be taken into account, as should the presence of other critical structures such as the intestines, lungs, kidneys, and adrenal glands. After general anaesthesia, a CT scan is performed to identify the lesions and plan the trajectory of the needle. Then, the ablative needle is inserted under CT and US guidance into the cancerous lesion. Tumours with a larger diameter must be covered by several heating zones so that the total ablation zone covers the entire neoplastic lesion along with a margin of the healthy tissue of about 5-10 mm, depending on the type of tumour.

Once the thermoablation is complete, a contrast-enhanced CT scan (arterial and venous phase) assesses the ablation zone and possible complications. Neoplastic lesion assessment can be challenging due to the isodensity of some lesions in non-contrast CT and isoechogenicity in the US, as changes are not clearly visible using these imaging modalities. One solution to such problems is the fusion of preoperative contrast CT/MR images with intraoperative US or non-contrast CT images. The choice of needle trajectory can also be a challenge due to the difficulty of imaging vessels and bile ducts, which are not particularly visible in CT without contrast. On the other hand, artifacts generated by the metal needle obscure the view and cause difficulties in locating the position of the needle in relation to the cancerous lesion during the procedure. Furthermore, the percutaneous technique requires the operator to have good anatomy knowledge, to use more difficult-to-interpret intraoperative US imaging to locate the cancerous lesion and to use fusion of the intraoperative US image with the patient's preoperative layered image (CT, MR) to improve lesion visibility.

The general scenario for using a mixed reality image navigation system involves visualizing the surgical field as a three-dimensional (3D) hologram via a head-mounted display (HMD) (Ultrasound and Computed Tomography Guidance in Radiofrequency Ablation for Hepatocellular Carcinoma Reduces Local Recurrence Rate. Cancer diagnosis prognosis 2023). These systems reduce the radiation dose in CT treatments (Yoon et al. 2018) and provide a clear presentation of medical images by displaying them in real-time 3D space during key moments of the procedure, increasing success (Park et al. 2020). At the same time, positional tracking systems are used to position intraprocedural imaging, potentially increasing needle placement accuracy and shortening procedure time (Park et al. 2020). However, there are few clinical evaluations of percutaneous ablation of various organs (Park et al. 2020; Kuzhagaliyev et al. 2018; Augmented reality needle ablation guidance tool for irreversible electroporation in the pancreas. 2018). Using this class of system requires the operator to master elements of the image navigation system, including position tracking systems (optical or electromagnetic) and the HMD module, and the ability to use and interpret the information contained in a personalized model of the patient's anatomy presented as a 3D hologram. An additional challenge in cases of poorly visible changes in intraprocedural US images is the ability to use the fusion image while accounting for respiratory movements that affect the liver.

On the commercial market, there are systems supporting ablation (Cascination Quality Ablation (Al-Nimer et al. 2020; Gadodia et al. 2022; Ablation and with CAS-One® IR Reproducible and Standardised Tumour Treatments the - company's own material. 2024), MeVis Liver Suite (Schaible et al. 2020; Cathomas et al. 2020; The mevis-liver-suite professional solution – the company's own material. 2024), but they do not support the presentation of a liver anatomy model in the form of a 3D hologram. The imaging navigation system presented below is also adapted to perform real ablation procedures, has successfully undergone research in the form of a medical experiment and is at the stage of initiating clinical trials.

Considering the numerous challenges presented, this paper presents a system that can be used as a training module aimed at familiarizing the user with the stages of percutaneous ablation of focal lesions in the liver using a mixed reality imaging navigation system that enables the user to acquire the ability to use these systems in the field of percutaneous ablation of liver tumours. Moreover it can be used by physicians during real procedures. Thus it contributes to both medical training as well as everyday practice. An innovative approach in the proposed educational module is: following the actual clinical workflow and the possibility of practicing the phases of diagnosis, planning and performing the procedure on real intraoperative data, and the physical possibility of performing the procedure on the radiological phantom of the abdominal cavity.

2 Methods

The system architecture developed is presented in Figure 1 and is based on the client-server architectural pattern. The central element of the system is the workstation on which the application server is running. The workstation is connected by wire to a marker position tracking system and an image acquisition card, which is connected to a US machine. The server application, among other things, supports communication with the tracking system and image acquisition card, processes data, and sends it using a Wi-Fi protocol to the mixed reality class module, which uses Microsoft HoloLens 2 (Microsoft, Redmond, WA). The application server is also responsible for processing the patient's image data into a format accepted by client applications and, on request, runs the implemented algorithms for the segmentation of anatomical organs, returning results in the form of layered images containing masks of segmented organs. Optionally, it is possible to start an additional computer with a screen (e.g., laptop) on which you can run a desktop version of the client application for the operator's doctor. Both the desktop and Microsoft HoloLens 2 applications play a presentation role for the operator and provide a user interface that allows the exchange of information with the server application. Thanks to this architecture, it is possible to connect more than one instance of the mixed reality module (HoloLens) to the system and present the data to more than one operator during the procedure.

After designing the architecture of a mixed-reality image navigation system, enabling percutaneous ablation of neoplastic lesions in the liver, a methodology for creating an educational module was developed (shown in Fig. 2).

Segmentation of abdominal organs: entire abdominal cavity, kidneys, pancreas, duodenum, spleen, ribs, liver, hepatic veins, focal lesions in the liver, in CT images is carried out according to the methodology described in the paper (Banz et al. 2016). The result of segmentation is masks of segmented organs.

Hologram generation is based on segmented masks of abdominal organs. In the first stage, a mesh is generated from segmented masks using the marching cubes algorithm. As a result, when an obj file is generated, it is sent to the application on HoloLens 2. Then an object is added on the stage based on the mesh from the file to which the configured material properties (color, metallicity, texture) are assigned for a given organ. Finally, the component of collisions detection was added.

The method of positioning a personalized hologram into the patient/phantom position is based on the use of markers visible in CT images and simultaneously placed on the phantom/patient position, whose position is tracked by a position tracking system during the procedure. Matching the hologram coordinate systems and the patient/phantom position is done by proposed registration method, using the positions of these markers as input. Details of the proposed method are described in an earlier paper by the authors (Machry et al. 2023).

The used software was produced by the company Holo4Med named HoloMIAI simulator 1.0. The presented system was used in a medical experiment mode for real procedures before and then 20 cases were selected to create a set of exercises, according to 4 scenarios presented in the text of the manuscript.

As part of the training module developed, users were invited to take part in a series of exercises that gradually familiarized them with the individual elements of the mixed reality image navigation system and the challenges occurring during the percutaneous ablation procedure used to destroy cancerous lesions in the liver. The scope of the exercises includes getting to know the patient's anatomy, locating the tumour (diagnostic phase), selecting the entry and target (procedure planning phase), interpretation of respiratory movements in US and CT fusion recordings collected during the procedure, and physical insertion of the needle into the abdominal cavity using a radiological phantom (the phase of performing the procedure). The exercises were designed in such a way that, on the one hand, they correspond to the stages of a standard percutaneous ablation procedure for the destruction of focal lesions in the liver, and on the other hand, they familiarize the user with the subsequent elements of the image navigation system. The following paragraphs describe the proposed exercises.

2.1 Exercise 1—interpreting the information contained in a personalized model of the patient's anatomy

The technical objective of this exercise is to introduce HMD use, which presents a personalized model of the patient's anatomy in the form of a 3D hologram (shown in Fig. 3). The user's task is to acquire the ability to use a hologram, for which they can choose between two methods of presenting the hologram, a volumetric view of 3D models of the patient's anatomical organs, including the pathological lesion (shown in Fig. 3–left), or a volumetric view with the possibility of

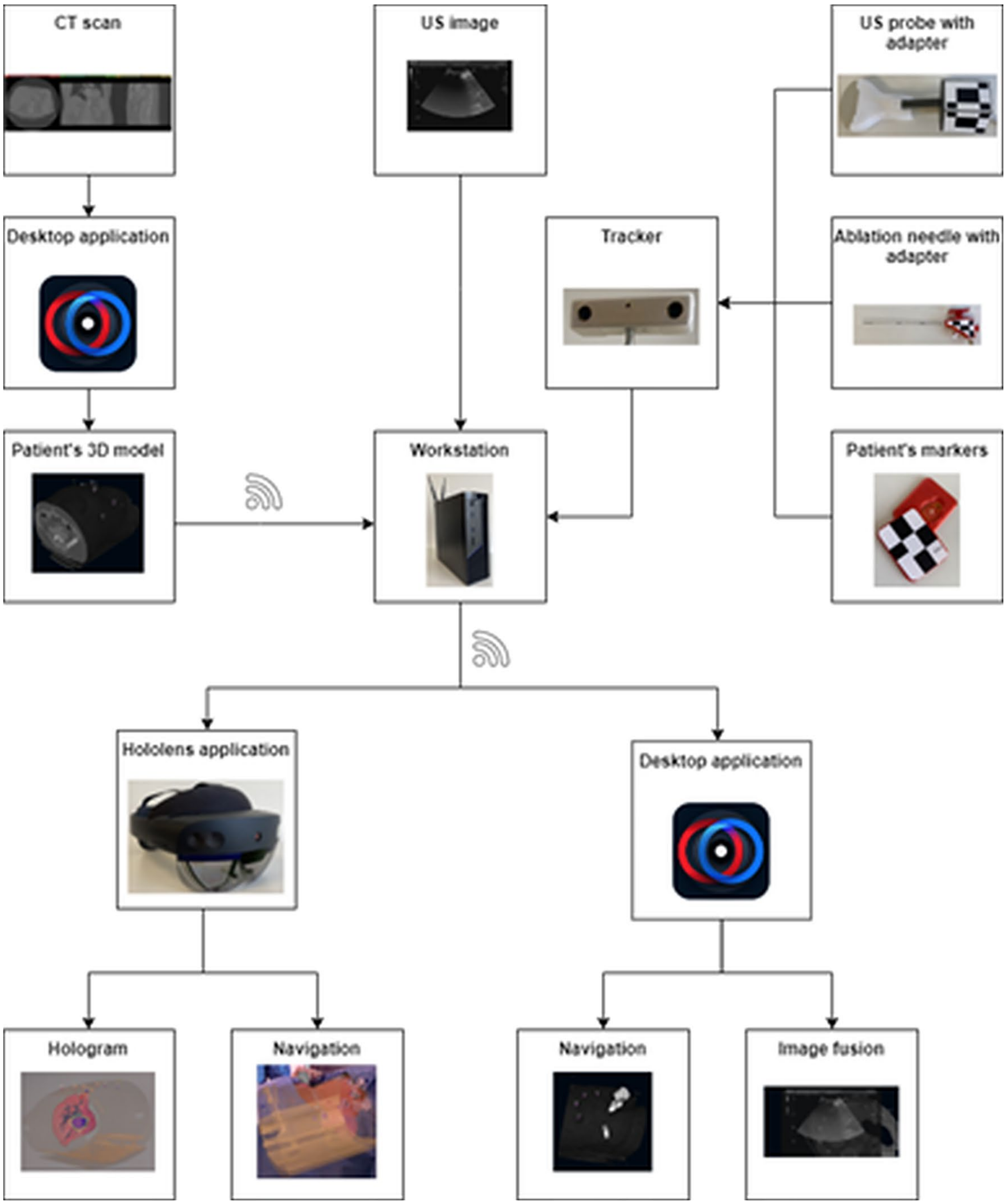

Fig. 1 Mixed reality supported percutaneous liver tumour ablation diagram

superimposing a cross-section of the original CT examination in the oblique slice mode (shown in Fig. 3–right). The user can switch between two modes, rotate, zoom and manipulate the images as well as scroll through the CT images to obtain a better understanding of the anatomy, location of the target lesion and it's relation to critical structures such as hepatic arteries, veins or adjacent organs. The main goal of this exercise is to familiarize the user with the interface and various functions it provides. The user's skills are verified using their answers to a multiple-choice question-based assessment.

2.2 Exercise 2—planning an entry at a preset target or planning for both entry and target

The technical objective of this exercise is to acquire the ability to use a 3D hologram to plan the trajectory of

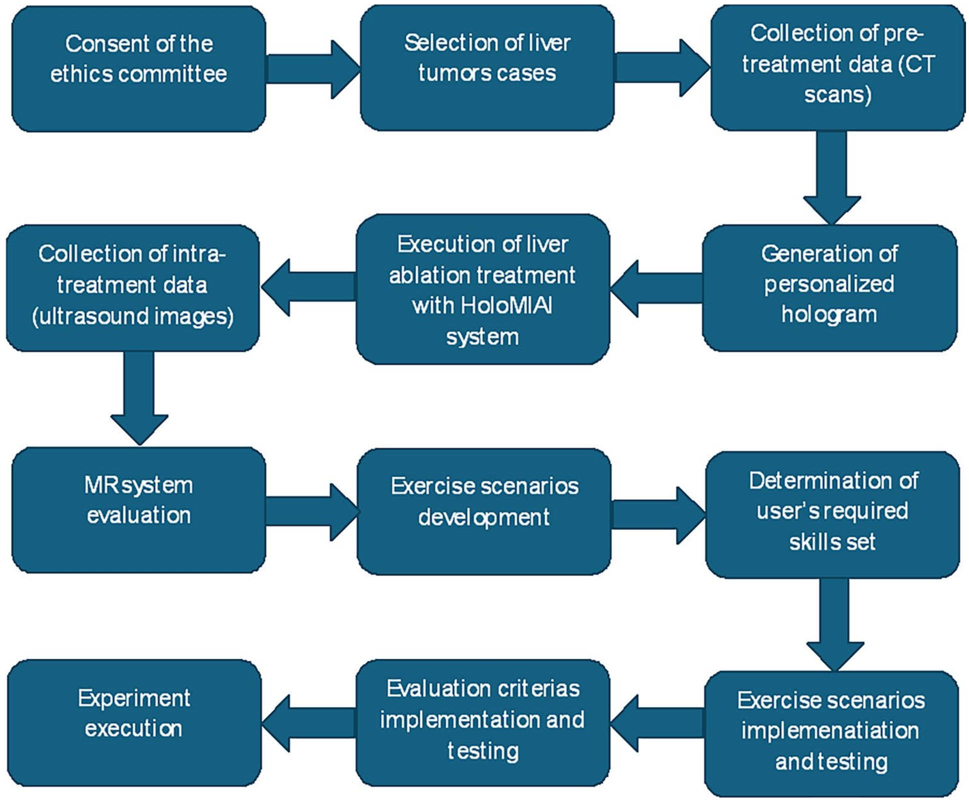

Fig. 2 Methodology for developing the educational module

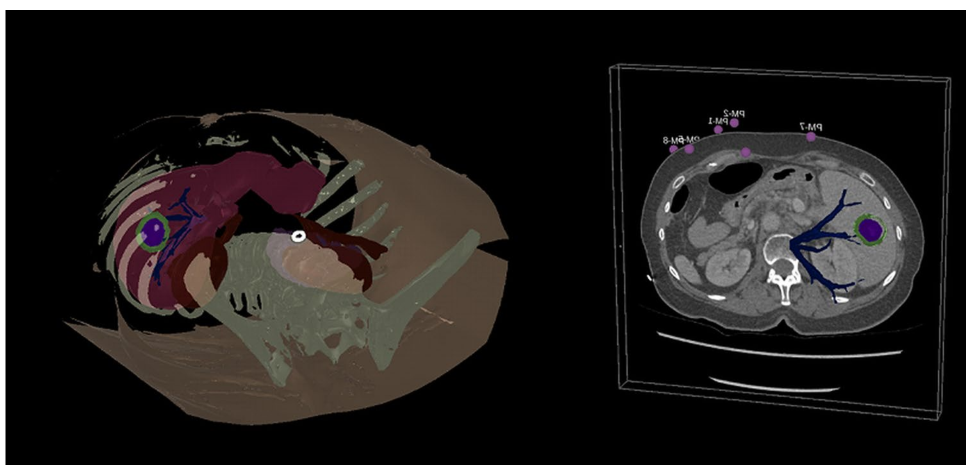

Fig. 3 A personalized model of a patient's anatomy. Volumetric view (left) and volumetric view with simultaneous overlay of the cross-section of the original computed tomography slice in oblique slice mode (right), focal lesion (dark purple) with intended ablative margin (green rim) (colour figure online)

the needle in the percutaneous ablation of a focal liver lesion. After the user has uploaded a personalized model of the patient's anatomy and found the pathological lesion on the hologram, the main element of the exercise is to plan the procedure. The first step is to define the suitable entry position using the uploaded model, that is a point on the skin in which the needle will be inserted into the patient's body. In the simpler version of the exercise the user defines only the entry point whereas the target location is predefined. More advanced version of the exercise, which also better depicts real life scenario, requires the user to define entry point on the skin as well as target point inside the liver in which the needle has to be placed to ablate the target lesion. Based on the points defined by the user, the system displays the potential trajectory of the needle, appearing in the form of a line, thus facilitating verification of feasibility and safety of proposed trajectory showing possible collisions occurring, e.g., with ribs or vascular structures inside the liver (shown in Fig. 4).

2.3 Exercise 3—interpreting the fusion of ultrasound and computed tomography images during ablation

Ability to use and properly interpret the fused images of CT and live US images is one of the more difficult and important skills used during ablations. Additionally respiratory movements of the liver is one of the factors which has to be accounted for while performing ablation. US provides a radiation free option to visualize the lesion as well as to monitor the needle pathway. Therefore superimposed US and CT images which are properly synchronized constitute a great navigation system. The technical objective of the exercise is to acquire the ability to interpret the fusion of intraprocedural US images with the preoperative CT model of the patient's anatomy while accounting for the respiratory movements of the liver. After the user has uploaded the video from the actual procedure, the first element of the exercise is to set a proper degree of overlay between live US images and uploaded CT scan to obtain fusion images which provide maximum information from both modalities. Subsequently the user has to find the target lesion using fused US/CT images as well as assess the amplitude of respiratory motions of the liver which will have to be taken into account while inserting the needle. (shown in Fig. 5).

2.4 Exercise 4—physical insertion of the needle according to the planned trajectory

The technical objective of the exercise is to acquire the ability to insert an ablative needle under hologram guidance using a position tracking system and intraprocedural US. After the user has uploaded the personalized model of the patient's anatomy, the main part of the exercise begins, which involves inserting the needle according to a preset trajectory using a sight (shown in Fig. 6). With already predefined entry and target position as well as verified needle trajectory the user has to physically place the needle inside the target lesion. The user has to puncture the skin with the needle at the entry point and keep the needle in proper axis in all three planes to reach the target point. Doing so without any navigation systems is one of the main challenges during ablation procedures. To facilitate this challenge the system present the patient's model and the crosshair. The crosshair visible to the user depicts the required angle of insertion and movement of the needle so that the user has to manipulate the needle in such way to keep the crosshair at the target. Simultanously as the needle is gradually inserted towards the target lesion it's position is shown at the patient's model.

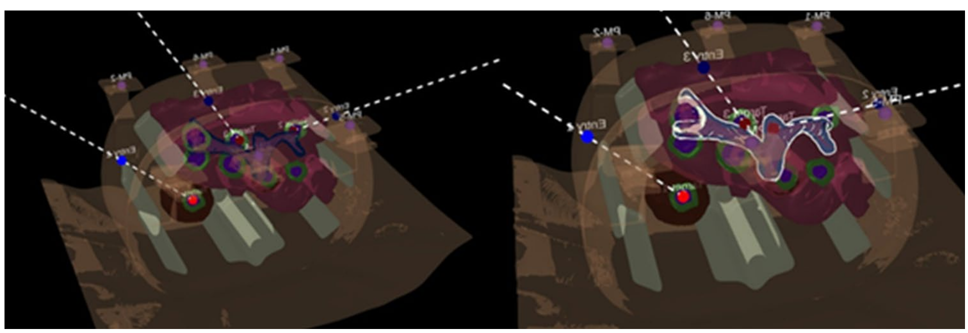

Fig. 4 Selection of entry/target points on a hologram. Target points—red dots, entry points—dark blue dots, focal lesions (dark purple) with intended ablative margin (green rim), potential needle trajectories—white dashed lines (left), collision with vascular structures in the liver—white outline (right) (colour figure online)

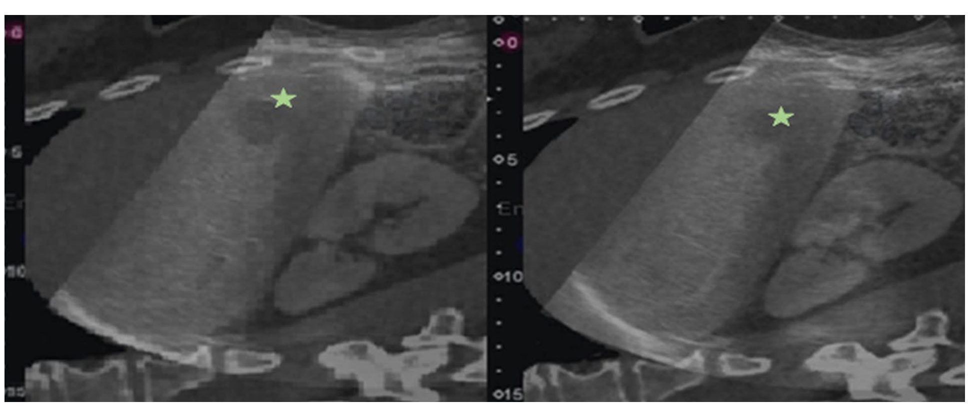

Fig. 5 Fusion of intraoperative two-dimensional ultrasound images with the corresponding computed tomography cross-section of the preoperative examination in concordant respiratory phases (left) and opposite respiratory phases (right), green asterisk–target lesion in the liver (colour figure online)

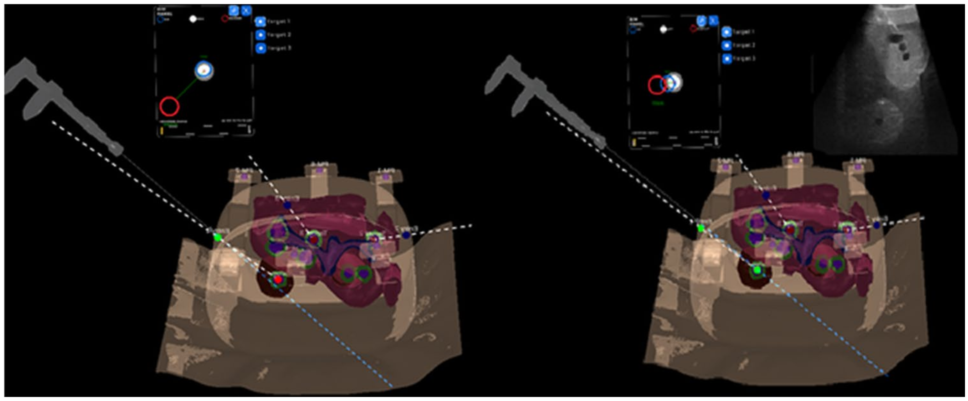

Fig. 6 Insertion of the needle into the abdominal phantom under the control of the position tracking system. Selecting the entry point (green, left) and reaching the target point (green, right). At the top, there is a crosshair indicator light and an ultrasound image with a visible outline of the ablative needle (colour figure online)

3 Material

The Bioethics Commission of the Medical University of Warsaw approved the study (KB/33/2018), and all patients signed informed consent forms to participate. Cases of 20 patients with focal liver lesions were collected, for whom percutaneous ablation of liver tumours were performed, which involved different tumour types, including metastatic neuroendocrine (Puijk et al. 2018), metastatic gallbladder cancer, metastatic colorectal cancer (Gadodia et al. 2022), HCC (Nagasawa et al. 2023), metastatic melanoma, and metastatic breast cancer (Puijk et al. 2018). A detailed description of the cases is given in Table 1.

3.1 Evaluation

10 radiologists and five residents were included in the study group. The radiologists had at least five years of experience performing percutaneous ablation procedures, while the group of residents included doctors who were in the process of their residency training, with the stipulation that they were in the first three years of residency.

Table 1 Characteristics of collected cases of focal lesions in the liver

No.	Tumor type	Tumor localization	Tumor dimensions (RIxAPxCC) [mm]	Tumor shape
1	Metastatic neuroendocrine	segm. 8	11 × 10 × 9	Round
2	Metastatic gallbladder	segm. 6	21 × 20 × 24	Round
3	Metastatic colorectal	segm. 2/3	47 × 40 × 47	Round
4	HCC	segm. 5	25 × 26 × 25	Round
5	Metastatic colorectal	segm. 6	40 × 37 × 45	Oval
6	HCC	segm. 6/7	30 × 30 × 30	Round
7	Metastatic neuroendocrine	segm. 2	10 × 10 × 10	Round
8	Metastatic colorectal	segm. 8	20 × 20 × 20	Round
9	Metastatic melanoma	segm.2/3; segm.4B; segm.5; segm.8	19 × 19 × 17; 11 × 12 × 10; 13 × 15 × 13; 9 × 8 × 9	Round
10	Metastatic colorectal	segm. 2/3	19 × 21 × 20	Round
11	Metastatic breast cancer	segm. 8	18 × 20 × 17	Round ×
12	Metastatic breast cancer	segm. 6	28 × 21 × 25	Oval
13	HCC	segm. 6	25 × 38 × 25	Oval
14	Metastatic colorectal	segm. 4/8	13 × 14 × 14	Round
15	Metastatic colorectal	segm. 8	20 × 21 × 20	Round
16	Metastatic colorectal	segm. 6	11 × 11 × 11	Round
17	HCC	segm.4A/2;segm.2; segm.3	12 × 15 × 15; 17 × 22 × 25; 23 × 23 × 23	Oval; oval; round
18	Metastatic colorectal	segm. 6	32 × 35 × 34; 15 × 15 × 15	Round
19	Metastatic colorectal	segm.4A	13 × 12 × 12	Round
20	Metastatic colorectal	segm.7; segm.7; segm.5/8; segm.5/8, segm.2	8 × 8 × 8; 7 × 7 × 7; 8 × 8 × 8; 18 × 18 × 19; 11 × 11 × 14	Round

The developed module was piloted in two interventional radiology clinics that perform percutaneous ablation of liver tumours. The 2nd Department of Radiology of the Medical University of Warsaw performs percutaneous ablation procedures using the quick-check technique, and the University Clinic for Radiology, University of Magdeburg, uses the CT fluoroscopy technique. Before the procedure, helical scans are performed in both clinics.

The training module assessment consisted of four skill groups, including HMD use, position tracking system use, fusion image interpretation, and percutaneous ablation of a liver tumour using a mixed reality imaging navigation system. The tasks included in the first three exercises were evaluated by a total of four radiology specialists; two from each centre where the study was conducted. They did not participate in the study themselves but were previously trained in equipment usage by the equipment manufacturer. Regarding the method of assessing participants in the study, the sessions of the participants was recorded anonymously. Then, the sessions were subject to "cross validation", i.e. individual participants were assessed were assessed by a total of 4 radiologists, 2 from two centers. The evaluators were blind – they did not know who they were judging. The final score obtained by the user in each category was an average of the ratings of individual experts. The study was designed deliberately, with the participation of 2 centers from 2 countries, then the risk of bias is minimal. The study participants performed all exercises using only HoloLens, generally using voice commands, indicating the entry and target position using manual gestures. Only the physical needle insertion exercise was performed by physically inserting the needle into the radiological phantom of the abdominal cavity.

Each skill was assigned a value of the Likert score. The following Likert scale was adopted: 1—very weak, 2—poorly, 3—good, 4—very good, and 5—excellence. Detailed skills and mean Likert score values for the indicated skill categories are presented in the results section. Two quantitative measures related to exercise four were introduced in the ability to insert a needle. The radiological phantom used (071B, CIRS, VA, USA) has several pathological lesions, the geometrical means of which were used as planned target points for needle insertion. All tasks were performed three times, and the measurements and skill assessments represent the average of the attempts. The time was measured with an accuracy of 1 second, while the precision of insertion, expressed as Target Registration Error (TRE), where TRE is the absolute value of the distance between the planned and actually achieved target was assessed with an accuracy of 0.01 cm. Tracking of the ablative needle position relative to the phantom used a video metric position tracking system (Hx40, ClaronNav, Ontario, Canada).

4 Results

Table 2 presents a detailed assessment of the skills acquired by the study participants and scores assigned by the rater. For residents, the best scores were obtained for HMD and position tracking system skills.

Prior to the analysis of the data, the normality of the distribution of accuracy variables and the time of needle insertion was checked. Due to the small sample size, normality was analysed on the basis of histograms, on which it was found that there was no normality in the distribution of both quantitative and ordinal variables.

In both of these exercises residents scored highly in all subtasks (median: 5.0) with lower score in the usage of sterile markers (median: 4.0). Noteworthy far worse results were obtained for image fusion interpretation and assessment of liver respiratory movements in exercise three (median: 3). For radiologists, very good results were obtained for the HMD module and position tracking system use and the ability to interpret image fusion where medians were equal 5.0. Similarly to residents radiologist scored slightly lower in the usage of sterile markers subtask (median: 4.0). Moreover they received lower scores also in HMD support via gesture interface subtask (median: 4.0) The mean needle insertion time for residents was more than double the corresponding time for radiologists, while puncture precision was 2.0 and 1.2 mm for residents and radiologists, respectively (Fig. 7, 8).

Due to the lack of normal distribution of variables, a non-parametric test for independent samples in Mann Whitney was used. Statistically significant differences in the value of needle insertion time were shown ($p_{u\ Mann\text{-}Whitney'a} = 0.002$ two-tailed asymptotic significance), where for residents and radiologists observed $median_{residents} = 51$ s (min = 48 s; max = 56 s) $median_{radiologists} = 24{,}5$ s (min = 20 s; max = 28 s) and analogously for the accuracy of needle insertion ($p_{u\ Mann\text{-}Whitney'a} = 0.002$ two-tailed asymptotic significance) $median_{residents} = 2.0$ mm (min = 1.8 mm; max=2.4 mm) $median_{radiologists} = 1.2$ mm (min = 0.9 mm; max = 1.4 mm). Ordinal variables (expressed on the Likert scale) due to the small size of the groups were tested with the Fisher exact test. This test showed statistically significant differences in the distribution of the following variables: Fusion interpretation ($p_{Fischera} < 0.001$ two-tailed asymptotic significance) $median_{residents} = 3$ $median_{radiologists} = 5$ and interpretation of breathing movements ($p_{Fischera} < 0.001$two-tailed asymptotic significance) $median_{residents} = 3$ $median_{radiologists} = 5$.

Table 2 Summary of acquired skills in the use of image guided navigation system elements. For Exercises 1–3 scores assigned by independent radiology specialist

	Res1	Res2	Res3	Res4	Res5	Rad1	Rad2	Rad3	Rad4	Rad5	Rad6	Rad7	Rad8	Rad9	Rad10
Ability to use HMD (Exercise 1)															
Calibration of the HMD module optical properties for a specific operator	5	5	5	5	5	5	5	4	5	5	4	4	5	4	4
HMD support via gesture interface	5	5	5	5	5	4	4	3	4	5	4	4	4	4	4
Switching between different modes of information presentation in the 3D Hologram:															
- volumetric view	5	5	4	5	5	4	5	4	5	5	4	5	4	5	5
- volumetric view with ultrasound/CT image plane view	5	4	5	5	5	5	5	4	5	5	4	5	4	5	4
Ability to use tracking systems (Exercise 2)															
Providing optical visibility between the camera and markers	5	5	5	5	5	5	5	5	4	5	4	5	4	5	5
Providing power to sensors in the case of an electromagnetic system	5	5	5	4	5	5	5	5	4	5	4	5	5	5	5
Procedure for the use of sterile markers	4	4	4	4	4	4	4	4	4	5	4	4	4	4	5
Ability to interpret US/CT image fusion (Exercise 3)															
Personalize the fusion image	5	5	5	5	5	5	5	5	5	5	4	5	5	5	5
Interpretation of ultrasound image with preoperative CT image superimposed	2	3	3	4	3	5	5	5	5	5	5	5	5	5	5
Interpretation of respiratory movements seen in ultrasound images	3	3	4	3	4	5	5	5	5	5	5	5	5	5	5
Ability to insert a needle (Exercise 4)															
Average time for single needle insertion [s]	56	48	51	49	54	24	20	26	24	23	28	22	25	26	25
Average accuracy Target Registration Error [mm]	2,1	2,4	1,8	1,9	2	1	0,9	1,1	1,2	1,4	1,3	1,3	1,2	1,1	1,3

Value interpretation: 1—very week, 2—poorly, 3—good, 4—very good, 5—excellence; Target Registration Error (TRE) = | target value achieved—Planed target position|

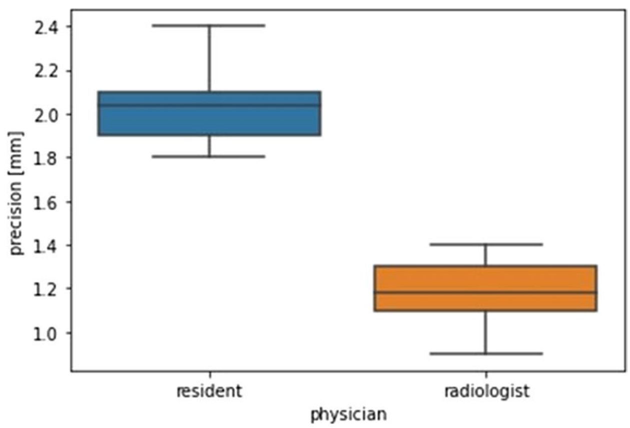

Fig. 7 Boxplot showing average precision for single insertion of a needle [mm] in residents and radiologists subgroups

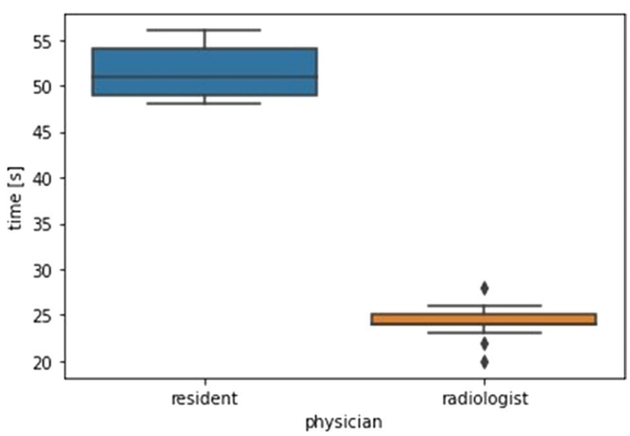

Fig. 8 Boxplot showing average time for single insertion of a needle [s] in residents and radiologists subgroups

5 Discussion

Several conclusions can be drawn based on the findings of the current study. Even residents without any experience in percutaneous liver ablation procedures can perform an ablative needle puncture using HMD and US imaging. Radiologists participating in the study will ultimately use a combination of CT and US imaging techniques. CT mode includes a helical scan before the procedure (acquiring a significant volume of the patient/organ) and a quick-check scan (showing three slices at a single pedal step) or CT fluoroscopy (showing live images of the area of interest when the pedal is pressed). The mixed reality image-guided system developed produces a 3D hologram containing a personalized model of the patient's anatomy based on a helical scan and is used in all stages of the clinical workflow. Secondly, thanks to the simultaneous use of a position tracking system that positions the hologram and patient during the procedure and the US image of the ablation needle in relation to each other, there is potential to reduce the X-ray dose taken by the staff and patient during the procedure. Indeed, fewer CT scans are required during needle insertion with the quick-check technique, and less time is spent using this mode during CT fluoroscopy.

Based on our results, further planned research will evaluate the introduction of the needle near the target point under the control of the hologram, and achieving an exact target point will use US image guided positioning. Such an approach is consistent with the results obtained on a radiological phantom, where other authors have noted a decrease in needle placement time and a dose reduction (Ultrasound and Computed Tomography Guidance in Radiofrequency Ablation for Hepatocellular Carcinoma Reduces Local Recurrence Rate. Cancer diagnosis prognosis 2023).

Both subgroups adequately mastered the HMD, though it was more difficult for radiologists than residents to master gestures. This finding can be explained by the age difference and the different levels of initial proficiency in the use of HMD systems. Based on these results and the general scenario of using augmented real-world or mixed reality image navigation systems, mastering the HMD is one of the primary challenges of implementing this class of system into clinical practice (Nagasawa et al. 2023).

Comparable results were observed in both subgroups in the position tracking skills group, with both groups putting the most effort into mastering the sterile markers procedure. Generally, using mixed reality image navigation systems assumes the ability to use various positioning systems to position the hologram in relation to the patient during the procedure (Nagasawa et al. 2023). The primary quantitative measure of accuracy in positional tracking systems is the patient anatomy model and position during procedure. The most commonly used measure is TRE, which, under real life procedure conditions, ranges from 4 to 13 mm

Spinczyk et al. 2019). The radiologist's TRE results were similar to the rigid registration obtained on a radiological phantom using the ClaronNav Hx4o tracking system (1 mm), highlighting the significant skill of radiologists. However, the residents scored worse, indicating further opportunities to improve their ability to guide the ablative needle into a given target point. Similarly the difference in required time to place the needle between residents and radiologists can be probably attributed to greater experience of radiologists.

In the group of skills related to the interpretation of fusion images, radiologists obtained much better results than residents, which can be explained by their experience in interpreting CT/US fusion images during procedures gained in previous clinical practice. Such experience is not possessed by beginning residents. The greatest difficulty for the residents was interpreting the images of fusions and breathing movements, empirically confirming the need for training systems to shape this skill. The direction of the training module development is consistent with the importance of using image fusion in percutaneous ablation procedures described in the literature, where US/CT-guided RFA for HCC reduced the local recurrence rate compared to US-guided RFA alone (Nagasawa et al. 2023). In a previous study using mixed reality on pigs, a mean TRE of 5 mm was obtained (Spinczyk et al. 2020), while a TRE of 3.4 mm was achieved in real treatments (Acidi et al. 2023). Considering radiologists achieved an average TRE of 1.2 mm using a radiological phantom with no respiratory movements, focusing on including respiratory movements in intraoperative US/CT fusion images offers the potential to reduce the TRE.

Despite the generally correct application of the technique in both subgroups, it is important to highlight that a major limitation of our study is the small number of participants, which precludes reliable statistical testing. Additionally, it should be noted that the study was conducted in only two centres, and the results are preliminary in nature. Further research with a larger number of participants is necessary to assess the utility of mixed reality image-guided navigation systems in clinical practice and specialist training.

Pointing out other limitations of the study, it can be pointed out that the collected database of cases comes from actual procedures from one clinical center. However, the module also allows you to create a new hologram for a different clinical case and use the acquired skills when using it during a real procedure in the medical experiment mode.

Another important aspect, treated as a direction for further development of the proposed approach, is the fact that MRI imaging was not used, which in some cases better differentiates liver cancerous lesions and additionally images the bile ducts in the liver. They are an important element of the internal anatomy of the liver organ. Their damage during the procedure may cause postoperative complications. It is also possible to collect a database of cases of patients with liver cancer who have had both CT and MRI imaging performed. In the future, this raises the potential possibility of superimposing information from both modalities on the hologram.

Author contributions DS, GR, DK, MP, KR, KZ conception or design of the work. GR, JŻ, DK, KM, JF, MP, KR, DS acquisition, analysis, or interpretation of data. DS, AWS, PS, DH, EP preparation the using mixed reality image guided navigation system.

Funding This study was not supported by any sponsor or funder.

Data availability The collected data and developed exercise scenarios constitute the intellectual property of Holo4med and are not publicly available. If you wish to use the developed exercises, please contact the corresponding author.

Declarations

Conflict of interest Potential conflict of interest arises from the involvement of Holo4Med employees in the research. To ensure the results presented in this publication are as unbiased as possible, Holo4Med employees participated solely in the training of radiology specialists. The task evaluation process was conducted by individuals working in clinics who did not receive remuneration or have an employment relationship with Holo4Med. Furthermore, individuals without any affiliation or compensation from Holo4Med were involved in manuscript preparation, and the final version of the paper was approved by all authors.

Ethical approval The study protocol was reviewed and approved by the Bioethics Commission of the Medical University of Warsaw, approval number KB/33/2018.

Consent to participate All patients signed informed consent forms to participate.

References

Acidi B, Ghallab M, Cotin S, Vibert E, Golse N (2023) Augmented reality in liver surgery. J Visc Surg. https://doi.org/10.1016/j.jviscsurg.2023.01.008

Al-Nimer S, Hanlon A, Cho K, Kalra-Lall A, Weunski C, Yanof J et al (2020) 3D holographic guidance and navigation for percutaneous ablation of solid tumor. J Vasc Interv Radiol 31(3):526–528

Banz VM, Müller PC, Tinguely P et al (2016) Intraoperative image-guided navigation system: development and applicability in 65 patients undergoing liver surgery. Langenbecks Arch Surg 401:495–502. https://doi.org/10.1007/S00423-016-1417-0

Cathomas M, Mertineit N, Kim-Fuchs C et al (2020) Value of MRI/CT image fusion for targeting “invisible” lesions in stereotactic microwave ablation (SMWA) of malignant liver lesions: a retrospective analysis. Cardiovasc Intervent Radiol 43:1505–1514. https://doi.org/10.1007/S00270-020-02565-8/METRICS

Gadodia G, Yanof J, Hanlon A, Bustos S, Weunski C, West K et al (2022) Early clinical feasibility evaluation of an augmented reality platform for guidance and navigation during percutaneous tumor ablation. J Vasc Interv Radiol 33(3):333–338

Geoghegan R, Ter Haar G, Nightingale K, Marks L, Natarajan S (2022) Methods of monitoring thermal ablation of soft tissue tumors–a comprehensive review. Med Phys 49(2):769–791

Kuzhagaliyev T, Clancy NT, Janatka M, Tchaka K, Vasconcelos F, Clarkson MJ, Gurusamy K, Hawkes DJ, Davidson B, Stoyanov D (2018) Augmented reality needle ablation guidance tool for irreversible electroporation in the pancreas. Proc. SPIE 10576, Medical Imaging 2018: Image-Guided Procedures, Robotic Interventions, and Modeling, 1057613. https://doi.org/10.1117/12.2293671

Quality ablation with CAS-One® IR reproducible and standardised tumour treatments the—company's own material (2020) https://www.cascination.com/en/quality-ablation. Accessed 23 March 2024

Li R, Si W, Liao X, Wang Q, Klein R, Heng PA (2019) Mixed reality based respiratory liver tumor puncture navigation. Comput vis Media 5(4):363. https://doi.org/10.1007/s41095-019-0156x

Machry M, Ferreira LF, Lucchese AM et al (2023) Liver volumetric and anatomic assessment in living donor liver transplantation: the role of modern imaging and artificial intelligence. World J Transplant 13:290–298. https://doi.org/10.5500/wjt.v13.i6.290

Nagasawa S, Kuwano A, Tanaka K, Yada M, Masumoto A, Motomura K (2023) Combined ultrasound and computed tomography guidance in radiofrequency ablation for hepatocellular carcinoma reduces local recurrence rate. Cancer Diagn Progn 3(6):660–666

Park BJ, Hunt SJ, Martin C, Nadolski GJ, Wood BJ, Gade TP (2020) Augmented and mixed reality: technologies for enhancing the future of IR. J Vasc Interv Radiol 31(7):1074–1082

Park BJ, Hunt SJ, Nadolski GJ, Gade TP (2020) Augmented reality improves procedural efficiency and reduces radiation dose for CT-guided lesion targeting: a phantom study using HoloLens 2. Sci Rep 10(1):1–8

Puijk RS, Ruarus AH, Scheffer HJ, Vroomen LGPH, van Tilborg AAJM, de Vries JJJ et al (2018) Percutaneous Liver Tumour Ablation: Image Guidance, Endpoint Assessment, and Quality Control. Can Assoc Radiol J 69(1):51–62

Puijk RS, Dijkstra M, van den Bemd BAT, Ruarus AH, Nieuwenhuizen S, Geboers B et al (2022) Improved outcomes of thermal ablation for colorectal liver metastases: a 10-year analysis from the prospective Amsterdam CORE registry (AmCORE). Cardiovasc Intervent Radiol. https://doi.org/10.1007/s00270-022-03152-9

Schaible J, Lürken L, Wiggermann P et al (2020) Primary efficacy of percutaneous microwave ablation of malignant liver tumors: comparison of stereotactic and conventional manual guidance. Sci Rep 10:1–8. https://doi.org/10.1038/s41598-020-75925-6

Solbiati M, Ierace T, Muglia R, Pedicini V, Iezzi R, Passera KM, Rotilio AC, Goldberg SN, Solbiati LA (2022) Thermal ablation of liver tumors guided by augmented reality: an initial clinical experience. Cancers (Basel) 14(5):1312. https://doi.org/10.3390/cancers14051312

Spinczyk D, Badura A, Sperka P et al (2019) Supporting diagnostics and therapy planning for percutaneous ablation of liver and abdominal tumors and pre-clinical evaluation. Comput Med Imagin Graph. https://doi.org/10.1016/J.COMPMEDIMAG.2019.101664

Spinczyk D, Stronczek M, Badura A et al (2020) Initial clinical evaluation of image fusion based on rigid registration and supporting percutaneous liver tumor ablation. Biocybern Biomed Eng 40:1378–1390. https://doi.org/10.1016/J.BBE.2020.07.005

The mevis-liver-suite professional solution – the company's own material. https://www.mevis.de/en/solutions/professional/mevis-liver-suite. Accessed 23 March 2024.

Yoon JW, Chen RE, Kim EJ, Akinduro OO, Kerezoudis P, Han PK et al (2018) Augmented reality for the surgeon: systematic review. Int J Med Robot. https://doi.org/10.1002/RCS.1914