Needle and catheter navigation using electromagnetic tracking for computer-assisted C-arm CT interventions

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ABSTRACT

Integrated solutions for navigation systems with CT, MR or US systems become more and more popular for medical products. Such solutions improve the medical workflow, reduce hardware, space and costs requirements. The purpose of our project was to develop a new electromagnetic navigation system for interventional radiology which is integrated into C-arm CT systems. The application is focused on minimally invasive percutaneous interventions performed under local anaesthesia. Together with a vacuum-based patient immobilization device and newly developed navigation tools (needles, panels) we developed a safe and fully automatic navigation system. The radiologist can directly start with navigated interventions after loading images without any prior user interaction. The complete system is adapted to the requirements of the radiologist and to the clinical workflow. For evaluation of the navigation system we performed different phantom studies and achieved an average accuracy of better than 2.0 mm.

1. INTRODUCTION

Today, image-guided minimally invasive interventions are a well-established clinical procedures for histopathological diagnostics. The field of intervention covers soft tissues biopsies, particularly therapy of the spine, reconstruction of the spine (vertebroplasty), or tumor therapy (radio frequency ablations) of the liver and lung.

To ensure an exact needle placement in the tissue to be examined the intervention is carried out image-guided. CT, MR and US devices are the most commonly used imaging systems.[1] The main challenge for these image-guided interventions is the exact puncture of a previously defined target by the needle.

There are different methods to locate the entry point for puncture on the skin and to determine the entry angle. In clinical practice, laser marking systems, cross-grids, or special markers which can be stuck on the skin[2–5] are used. With such interventional tools the number of consecutive control scans can be reduced. Especially, the laser marking systems offer a high improvement regarding to the needle puncture.[5] Other auxiliary devices are frames and rails which can be placed above the patient.[6,7] Various needle guiding jigs can be mounted onto these rails and can be aligned. The positive aspects of these auxiliary devices are their simplicity and their low price.

While the above-mentioned auxiliary devices are used for clinical applications in the field of interventional radiology, computer-assisted interventions are still rather rare. There are hardly any solutions available for convenient computer-supported planning and a following intraoperative realization. The position of the instruments (needles) in the patient during an intervention can only be determined by additional radiation for the patient and/or the radiologist. None of the above-mentioned auxiliary devices allows for a visualization of the needle directly in the patient‘s data on the monitor. This is the main advantage of computer-navigated systems.[8–10]

The CAPPA IRAD system (CAS innovations, Erlangen, Germany)[11] is a commercially available navigation system developed especially for minimally invasive interventions. Using a special needle holder and a passive optical tracking system, various standard needles can be aligned along a planned trajectory in the CT data and

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be navigated towards a final target. The system works with a fully automatic patient-to-image registration and can use DICOM data of most clinical CT systems. In order to fix the patients position on the intervention table and to reduce unintentional patient movements, the BodyFix™mattress is used. Phantom studies showed an inaccuracy of about 1.1 mm[12] and clinical trials showed that bone biopsies as well as soft tissue biopsies (e.g. lung, liver, pancreas) are possible with a high accuracy.[13]

An electromagnetic tracking system (Ultraguide, Israel) for executing CT-navigated operations is described by Holzknecht.[10] The CT-guided navigation system uses the images of the video output of a CT device. A limiting factor of the system is that the tracking sensor is fixed at the top of the needle. In contrast to a sensor embedded into the needle tip, tracking of the needle takes place outside of the patient and needle bending is ignored. During a study, 50 patients were punctured with the system yielding an error rate of 2.2 ± 2.1 mm. The Ultraguide system was also tested by several other groups.[14,15] However, it is no longer commercially available.

The Magellan navigation system (Biosense Webster, Israel) is another electromagnetic navigation system for tracking instruments with small tips, catheters or endoscopes. Similar to the Ultraguide navigation system, instruments with small coils can be located in an electromagnetic field. The system was used in neurological surgery[16] and in cardiology in order to place catheters.[17]

In spite of the advantages of the computer-assisted navigation systems described there are also disadvantages. The immobilization of the patient, the preparation of the setup and the initialization of the components increase the intervention time. Most navigation systems have additional navigation hardware (reference frame, needle holder, or robot system/components) which are expensive and susceptible to errors. When using optical tracking systems, only external tracking and no detection of needle bending is possible. Calibration of the components during the intervention requires additional steps during the intervention. Service of the hardware (robot) produces additional costs.

One of the major problems during interventions with local anesthesia is the patient movement. It directly influences the precision of the system and the patient can accidentally be seriously injured. If, for example, the patient moves after the laser marking of the point of puncture on the skin has been set, the surgeon does not necessarily notice this change of position. In this case the pre-planned point of puncture will not correspond to the actual point of puncture any more and the needle will be guided wrong. Therefore, the movement of the patient poses a risk for the patient and must be minimized and controlled by suitable measures, procedures, and methods. Especially, patients with low pain tolerance and uncooperative patients are more likely to move unintentionally.

Based on our clinical experience with optical tracking systems we designed a new system with less components to achieve a faster workflow. A freehand navigation with internally tracked instruments allows the detection of needle bending (tracking the tip of instruments). Another goal was to reduce the additional navigation hardware. An integrated motion monitor for body movements and breathing allows the radiologist to react adequately to patient movement. Finally, to expand the field of applications, besides an interface to clinical CT also C-Arm systems (AXIOM Artis, Siemens Medical Solutions, Forchheim, Germany) were integrated and tested.

2. MATERIAL AND METHODS

2.1. Navigation system architecture and components

In order to track medical devices such as needles/catheters the AURORA tracking system (NDI, Waterloo, Ontario, Canada) was used. The tracking system consists of a field generator producing an alternating electromagnetic (EM) field for operation in a volume of 500 mm × 500 mm × 500 mm. The EM field induces a voltage in small coils implemented in the tips of the devices. The voltage is measured by the AURORA system and used to calculate the current position and orientation of the coil inside the EM field thus determining the sensor coordinates in five degrees of freedom (DoF). For our project we had new needles and catheters developed and produced (Amedo, Bochum, Germany) with small coils (9 mm × 0.8 mm) embedded in their tips. For clinical use we developed two different needles (probes) with diameters of 1.1 mm and 2.0 mm, respectively. Both probes can be used with additional hollow needles. In order to increase the clinical applications the needles are

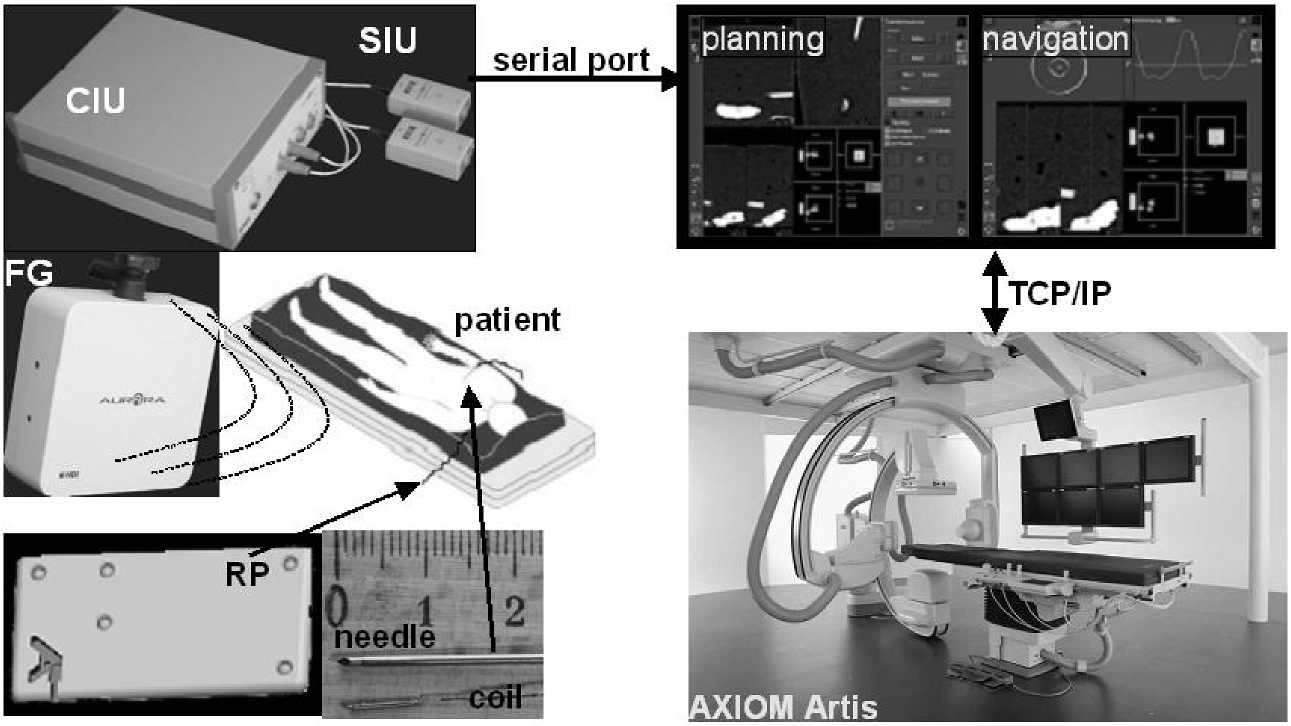


Figure 1. Overview of the system architecture and components: (Registration Panel (RP) and Markers, needle, catheter, Field Generator (FG), Control Interface Unit (CIU) and two Sensor Interface Units (SIU), software screen shots and the connection to the AXIOM Artis system)

available in different lengths (50 mm to 200 mm). The tools are connected via a sensor interface unit (SIU), working as an analog-to-digital converter, to a control interface unit (CIU). The CIU transmits the needed data prepared for navigation to the navigation system using a serial port. Also catheters with coils in their tips were developed. But in contrast to the needles, the catheters are not produced for clinical use up to now.

For image-to-patient registration a registration panel (RP) was developed. The RP (130 mm × 60 mm × 13 mm) comprises 5 markers (diameter 4.5 mm) that can be detected automatically in CT images as well as a six DoF sensor detectable with the AURORA tracking system. The RP is not only used for registration but also as a reference system during the tracking of the medical tools. The RP shall be placed under the patient during the CT scan. It is required that the markers of the RP are in the field of view during image acquisition.

The navigation station consists of an industrial PC with integrated touch screen as an user interface and dedicated navigation software (CAPPA IRAD EMT, CAS innovations, Germany). The PC is mounted on a mobile rack. For image acquisition the navigation system is connected to a C-arm system with CT option (AXIOM Artis dBA with DynaCT). The C-arm system is equipped with a 300 mm × 400 mm flat panel detector. For the communication of the navigation system with the C-arm, a DICOM network application was implemented to enable image transfer using a TCP/IP connection. The DICOM network application is implemented as a background process and set up to receive images as soon as the navigation software is running. An AXIOM Artis joystick is integrated into the navigation system and is used as a mouse. Furthermore, the navigation display can be switched to the AXIOM Artis monitor wall. In that case, the navigation rack with PC can be located at any place in the intervention room. Thus, space for the intervention is made and the complete navigation can be performed by using the AXIOM Artis components (joystick and monitor). It is also possible to connect the navigation system to any CT scanner by using the DICOM protocol. The system architecture is illustrated in Fig. 1.

The navigation software is designed for intuitive use. Transmission, loading of images from the C-arm system, and registration work fully automatically. Once the images have been loaded, the software switches directly into the navigation mode. The planning of trajectories is optional and can be performed with the AXIOM Artis joystick or by using the touch screen. Although the complete planning module is kept as simple as possible, it contains comfortable planning features like oblique MPRs and allows for an accurate planning of trajectories with sub-voxel accuracy.

In order to reduce patient motion we used a patient fixation device BodyFix^{TM}(Medical Intelligence, Schwabmuenchen, Germany). The system consists of a vacuum mattress and a vacuum pump. After positioning the patient on the soft mattress, the air in the mattress is removed and the mattress becomes solid. Thus the patient is fixed securely on the intervention table. To control residual patient motion, an additional six DoF sensor (skin marker) of the AURORA tracking system is attached to the skin of the patient (abdomen/breast). The tracking system is able to detect the sensor and send its position relative to the RP to the navigation system. The motion information generated by the skin marker is used for both visualization of respiration by a continuous curve and an integrated alarm system for unintended body motions.

2.2. Clinical workflow with the navigation system

Based on the clinical experience with the optical tracking system CAPPA IRAD, the new system was designed in a way to integrate navigation workflow better into clinical workflow. The user interactions with the navigation components are reduced to a minimum.

Preparation of the patient: The patient is placed on the table of the C-arm system, the RP is put under the patient, and he or she is immobilized with the BodyFix^{TM}system. It has to be made sure that the RP is positioned inside the field of view of the AXIOM Artis system throughout the whole scan. After starting the navigation software, the software stays in a standby mode waiting for images. The skin marker is fixed with adhesive tape on the skin of the patient.

Import of scanned images: After scanning, the images are sent from the workstation to the navigation system. All images are analyzed by the software and the image-to-patient registration is performed. After valid registration the software switches automatically to navigation mode.

Selection of navigation needle: The radiologist chooses the appropriate needle for the desired intervention. The needle is taken out of the sterile packing and plugged in the navigation system by the radiologist. The navigation system automatically identifies the needle and initializes it to the navigation system. From that time on the needle is visualized in the patient data set on the screen.

Navigated needle feed: During any needle feed, the needle is visualized in the patient data set in realtime (60 Hz).

Planning of trajectories (optional): For difficult (e.g. oblique) access the radiologist may plan a trajectory. In that case the user selects the planning module and defines an entry and target point in the patient data set. Once planning has been completed, the navigation system displays three colored circles which the user has to bring into coincidence to make sure that the needle is placed and fed according to the plan.

2.3. Evaluation of the navigation system

To evaluate the navigation system we performed three different phantom studies. In the first study we measured the technical accuracy of the system under ideal conditions using a plexiglass phantom. In the second study we were able to measure the needle positioning accuracy. For that, we used a wax phantom simulating human tissue and we tested the usability of the system in general. Finally, in the third study we measured the accuracy of the system with a dynamic wax phantom taking motion into account.

Plexiglass phantom: The plexiglass phantom consists of a base plate of 300 mm $\times$ 300 mm comprising 13 plexiglass rods with tips. 6 of the tips have a length of 60 mm and 7 a length of 80 mm. The phantom was placed on the C-arm table (AXIOM Artis dBA) and for a further test into two CT gantries (SOMATOM Definition Dual Source CT and Sensation 64, Siemens Medical Solutions, Forcheim, Germany). The registration panel was positioned underneath the phantom. Both, the phantom and the RP, were scanned and the images were sent to the navigation system. After loading the images and registration, the tips of the rods were defined

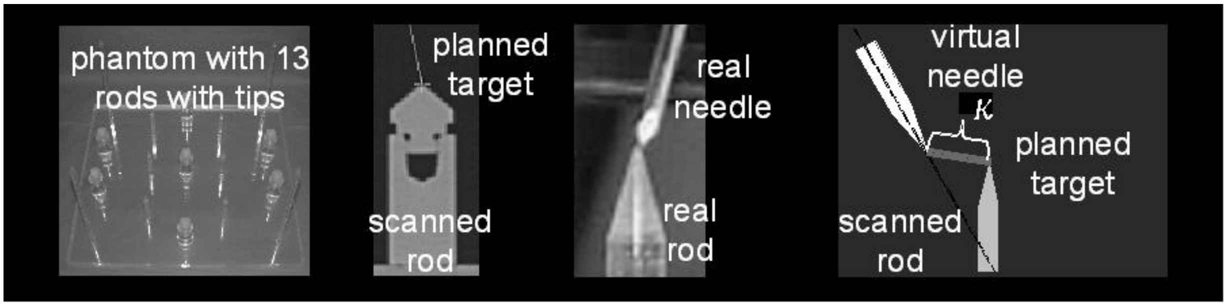
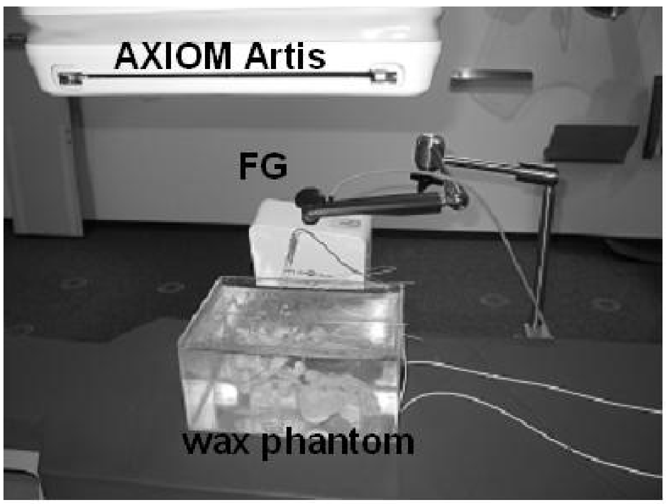


Figure 2. Plexiglass phantom study. Left to right: Plexiglass phantom, scanned rod with a planned trajectory, the real needle adjusted to the rod, the calculation of the error κ.



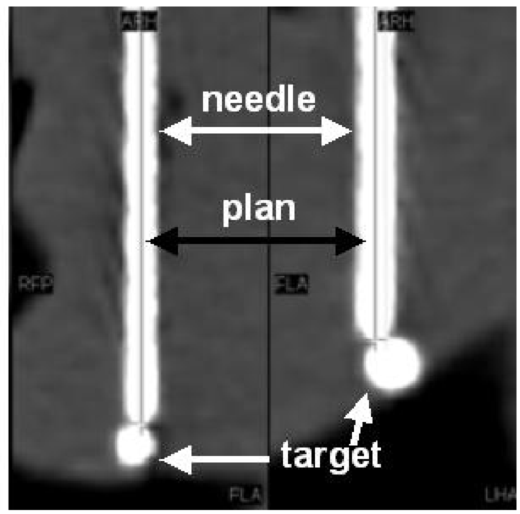


Figure 3. Wax phantom on the table of the AXIOM Artis and screen shot of the segmentation software showing segmented needle, target and planned trajectory.

as targets with the planning module of the software. The tip of a needle (200 mm/1.1 mm) was adjusted exactly on the tips of each rod. This was done manually without the navigation system. The navigation system now calculated the distance of the tip of the needle registered by the navigation system to the planned target being identical to the real rod (Fig. 2). The distance $|\vec{v}|$ was regarded as technical error κ. The phantom study was repeated using 4 different systems (2 AXIOM Artis; 2 CT scanners) by 3 different persons. The plexiglass phantom and the execution of the study are illustrated in Fig. 2.

Wax phantom: The second phantom study was performed with a spine phantom embedded into soft candle wax to simulate soft tissues of the patient. The phantom was placed on the C-arm or CT table, respectively. The RP was positioned underneath the phantom. After scanning, image transfer, and registration, 10 targets were planned along the spine at anatomical relevant positions using the planning module. Then the needle (200 mm / 1.1 mm) was adjusted and fed under assistance of the navigation system to the planned targets. The phantom together with the placed needle were scanned again. A segmentation software was used to select the needle tip in these data sets. Finally, the distances $|\vec{v}|$ from the tips of the needles to the selected targets were measured and noticed as needle positioning errors ϵ. The wax phantom and the segmentation software are illustrated in Fig. 3.

Dynamic wax phantom: A further phantom study was performed with a newly developed dynamic phantom which is able to simulate patient motion (breathing). The phantom consists of a plastic box filled with candle wax and soft targets (dried apricots and raisins). An external motor pumps and sucks water into a bellow

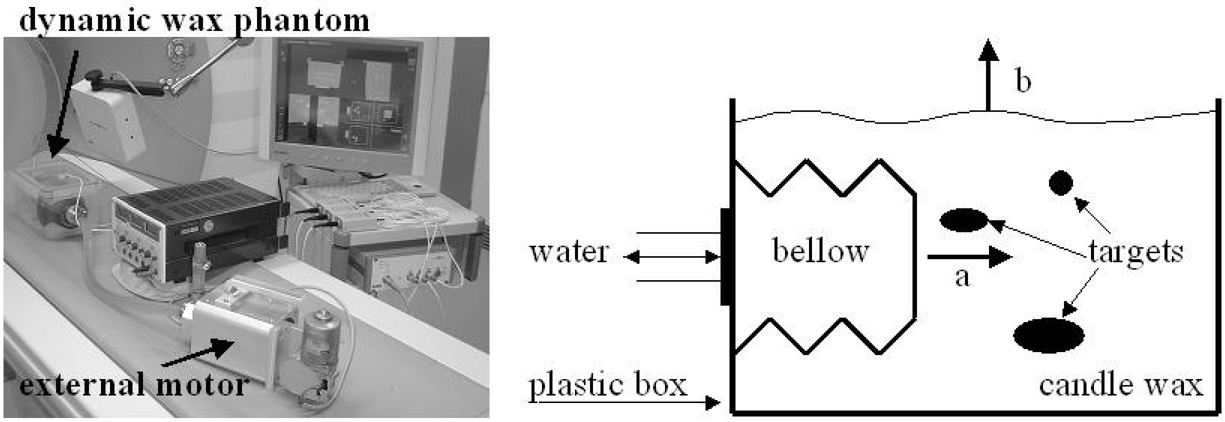


Figure 4. Left: dynamic wax phantom together with the external pump and the navigation system. Right: sketch of the phantom. The arrow **a** describes the internal movement of the bellow and the arrow **b** describes the external movement of the surface.

located inside the box. The movement of the extended/contracted bellow is perpendicular to the surface and simulates the diaphragm. The targets inside the phantom move together with the extended/contracted bellow and the surface of the phantom moves like the movement of a breathing patient. For this study the phantom was placed on the C-arm table (AXIOM Artis dBA) and the RP was positioned underneath the phantom. The skin marker was positioned on the surface of the phantom to measure and visualize the simulated breathing motion. During scanning, the movement of the phantom was stopped either in the exhalation or in the inhalation phase, respectively. The images were transmitted to the navigation system. Different trajectories were planned to the centers of the soft targets. The needle was adjusted and fed under assistance of the system whereas the pump was working again. The needle feed was only performed while the breathing curve showed the same phase in which the phantom had been scanned. After needle positioning, the phantom was scanned again and the distance $|\vec{v}|$ from the tip of the needle to the planned target was measured with the segmentation software and noticed as needle positioning error ∇ under motion. The dynamic wax phantom is illustrated in Fig. 4.

3. RESULTS

3.1. Worflow

The new design of the complete navigation system and the integration of the system into the AXIOM Artis C-arm system allows for a user-friendly navigation with focus on the clinical intervention. Once images have been sent to the navigation system, loading and registration of the patient data works fully automatically. Thus the radiologist can start navigating without pressing any buttons. Only for further planning of trajectories an interaction with the system is necessary (optional step). Here the radiologist can use the joystick and the monitor of the AXIOM Artis C-arm system. The planning module allows for an efficient planning of arbitrary trajectories which are not restricted to one or two transversal CT slices but may also obliquely cross the complete scanned 3D volume of the patient's data set. By using the CT scanner, the radiologist has to activate all steps by touching the touch screen. Here no additional monitor of the scanner or joystick are available.

Since the coils are located in the tips of the instruments, no tool calibration step is necessary during the intervention.

The immobilization with the BodyFix$^{\text{TM}}$device reduces not only the patient movements but also enables a reproducible repositioning of the patient after unpredicted movements. Based on a risk management process, risk minimization related to patient movements was achieved.

During the navigation of the needles/catheters, the display of the virtual instrument position on the screen informs the radiologist of the orientation of the instrument (i.e. to find the entry point and the correct angle) and allows for a guided, tremble-free instrument feed. This reduces the number of control scans and thereby the volume exposed to ionizing radiation, and the time needed for additional control scans. Especially, time saving is important if a fast dissolving contrast medium is used. Additionally, difficult oblique trajectories need a wider exposure area for the control scans. The possibility of reducing the exposed volume and the number of scans will also reduce the total exposure of the patient to ionizing radiation.

3.2. Plexiglass phantom study: technical error

For the measurement of the technical error κ four independent phantom studies were performed. All results are shown in Table 1. The technical errors at the AXIOM Artis systems are lower compared to the measured errors at the CT scanners. That is because CT scanners have more metal components close to the field generator of the tracking system deteriorating the tracking accuracy.

Table 1. Results of the phantom study: technical error

System	Location	n	rms error (κ)
AXIOM Artis dBA	Forchheim	130	1.1 mm $\pm$ 0.2 mm
AXIOM Artis dBA	Berlin	130	1.0 mm $\pm$ 0.2 mm
SOMATOM Sensation 64	Muelheim	130	1.2 mm $\pm$ 0.2 mm
SOMATOM Definition	Erlangen	130	1.4 mm $\pm$ 0.4 mm

3.3. Wax phantom study: needle positioning error

For the measurement of the needle positioning error ϵ two independent phantom studies were performed. All results are shown in Table 2. The navigation system assisted the radiologist by guiding the needle tip exactly to the pre-planned target. Needle bending is compensated because the tip of the needle was tracked. Therefore, results close to those of the technical error κ can be expected. Under these conditions, EM tracking of the needle tip proved to be superior to optical tracking or tracking of the back end of the needle.

Table 2. Results of the wax phantom study: needle positioning error

Systems	Location	n	rms error (ϵ)
AXIOM Artis dBA	Forchheim	60	1.2 mm $\pm$ 0.2 mm
SOMATOM Sensation 64	Muelheim	60	1.2 mm $\pm$ 0.3 mm

3.4. Dynamic wax phantom study: needle positioning error under motion

For the measurement of the needle positioning error ∇ under consideration of motion, a phantom study with the AXIOM Artis (Forchheim) in two motion phases was performed. The results with the two motion phases are shown in Table 3. Because of the moving targets it was harder to hit a target. By the visualization of the motion phase it was possible to place the needle in all targets with an accuracy of better than 2 mm.

Table 3. Results of the wax phantom study: needle positioning error

Motion phase	Location	n	rms error (∇)
maximum	Forchheim	25	1.7 mm $\pm$ 0.3 mm
minimum	Forchheim	25	1.8 mm $\pm$ 0.4 mm

The maximum simulates a breath-hold in the inhalation phase of the patient, the minimum simulates the exhalation phase of the patient.

4. CONCLUSION

A navigation system with electromagnetic tracking was developed for minimal invasive percutaneous interventions in the field of interventional radiology. In order to increase the number of possible medical applications, the new system can be not only connected to a CT scanner but also to C-arm systems with CT option.

In contrast to optical or electromagnetic tracking systems with the tracking marker fixed to the end of the instrument (outside the patient) the new system also allows for the tracking of devices inside the patient. For that, new devices were developed with small coils in their tips. Thus bending of the needle can be detected and taken into account when feeding the needle. Flexible catheters can also be tracked and visualized on the screen for navigation in the patient data set. Together with the C-arm system, the new navigation system enables completely new applications for navigated interventions.

Because of the coils are located in the tips of the instruments a calibration of the length and orientation during the intervention is not necessary and the exact geometry of the tool is at any time correctly visualized in the patient data set.

As described in the introduction, a limitation of almost all navigation systems is that they tend to be too complicated and lengthen the intervention procedure. Additional steps like immobilization of the patient, preparation of the hardware, or initializing of navigation components need time and hamper the clinical workflow. Therefore, it is mandatory to integrate the navigation system into the clinical workflow (and not the intervention into the navigation workflow). In our system, after preparing the patient, with the navigation system presented all further steps work fully automatically and the radiologist can focus on his or her intervention task. The immobilization of the patient with the BodyFix^{TM}system needs more time (some 5-10 min) but in contrast allows a better and pain free positioning of the patient. The patient is fixed securely on the intervention table and the navigated intervention can be performed with local anaesthesia.

In contrast to our system, navigation systems working with skin markers for registration and without any fixation need a general anesthesia to exclude patient movements. This results in a call for general anesthesia by the navigation procedure, not by the intervention itself.

The accuracy of the new system was compared to systems with optical tracking. We measured technical errors of 0.6 mm and 1.2 mm for an optical tracking system (Polaris, NDI, Waterloo, Ontario, Canada) and our EM tracking system, respectively. For the needle positioning error (with consideration to needle bending) we measured errors of 1.1 mm and 1.3 mm for optical tracking and EM tracking, respectively.[11] Whereas needle bending affects the accuracy of the optical system, the bending of instruments does not play a large role in the case of EM tracking with the coils implemented into the instrument tips. Admittedly, the accuracy maybe affected by metal components near the EM field generator. The AXIOM Artis turned out to be superior since its table is completely made of carbon fibre and thus has a lower influence on the EM field of the tracking system. The table of the CT comprised also metal components as does the CT gantry, which is full of metal.

The study with the new system demonstrated, that such a system is suitable for interventions where flexible tools or needles have to be placed inside the patient.

5. ACKNOWLEDGEMENTS

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