Electromagnetic tracking system for minimal invasive interventions using a C-arm system with CT option: First clinical results.

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ABSTRACT

To ensure precise needle placement in soft tissue of a patient for e.g. biopsies, the intervention is normally carried out image-guided. Whereas there are several imaging modalities such as computed tomography, magnetic resonance tomography, ultrasound, or C-arm X-ray systems with CT-option, navigation systems for such minimally invasive interventions are still quite rare. However, prototypes and also first commercial products of optical and electromagnetic tracking systems demonstrated excellent clinical results. Such systems provide a reduction of control scans, a reduction of intervention time, and an improved needle positioning accuracy specially for deep and double oblique access. Our novel navigation system CAPPA IRAD EMT with electromagnetic tracking for minimally invasive needle applications is connected to a C-arm imaging system with CT-option. The navigation system was investigated in clinical interventions by different physicians and with different clinical applications. First clinical results demonstrated a high accuracy during needle placement and a reduction of control scans.

1. INTRODUCTION

Image-guided minimally invasive interventions in interventional radiology are today state-of-the-art in medical technology. These techniques offer numerous advantages compared to invasive techniques. If e.g. a suspicious lesion is diagnosed in a patients lung, a minimally invasive biopsy can make clear which therapeutic steps will be indicated.

The field of applications for minimally invasive interventions ranges from biopsies of suspicious lesions over the entire body, therapy of spinal lesions, vertebroplasty, research into the cause of infections, and periradicular therapy to investigations of the clinical efficiency of different kinds of therapy. For cytological and histological diagnoses the taking of tissue samples is an indispensable part of diagnostic verification in case non-invasive procedures do not present unequivocal clarification.

Successful tissue sampling depends very critically on the exact placing of the biopsy needle in the tissue to be examined. An image-guided examination can detect even tiny lesions located at great depths and, with the aid of an image-guided biopsy, perform a histological discrimination. The imaging modalities in use are computed tomography, magnetic resonance tomography, ultrasound, and C-arm X-ray imaging with 3D option.

On the other hand, such interventions also require considerable experience and skill on the part of the radiologist. Furthermore, there are other problems as well: for interventions requiring high accuracy and for which an inaccurate positioning of the needle can cause dangerous complications, the position of the needle during its feed is monitored and corrected by repeated CT control scans. Five to ten, or even more control scans are frequently applied. This does not mean that the whole intervention will take longer, but frequent control scans increase the radiation exposure for the patient. The lack of intraoperatively available information about the skin entry point and the direction of the needle feed call for the development of "auxiliary devices". For reasons of cost and availability, sufficient conventional imaging equipment, such as a C-arm or fluoroscopy units, is not always intraoperatively available and suitable to support the physician in guiding the needle. Working under fluoroscopy produces not only additional radiation exposure for the patient, but also for the attending physician. Furthermore, the gantry opening is limited in size and therefore rules out the application of long

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needles. Many percutaneously performed interventions require very exact knowledge of the anatomy concerned. 3D information is thus required for the optimal planning of an access path. Especially obliquely oriented access paths which cannot be imaged at once or two transverse CT images complicate the overall planning or cannot be conducted, because the risk of complications resulting from an erroneous needle positioning would be to high. Difficulties arise during needle feed as well. Here, the physician has to feed the needle along an imaginary trajectory in space without guidance. Fatigue and action tremor of the hand represent further problems.

A number of the problems addressed can be entirely or partly eliminated with the use of different targeting devices. In practice, laser targeting devices[1–3] and simple cross gratings or so-called paper clips taped to the skin[4] are established. A CT-biopsy guidance device is for example the SeeStar (Dadi, Uppsala, Sweden)[5] which can be fixed at the skin of the patient. Laser targeting devices are usually mounted directly on the gantry of the imaging system or can be installed parallel to the gantry with a separate mobile frame (e.g. SimpliCT, NeoRad AS, Norway). Target and skin entry point are identified in the patient data record. Then the laser is manually adjusted so that the beam matches the trajectory to the target. The needle is subsequently inserted percutaneously at the skin entry point and aligned so that the laser beam is visible at the far end of the needle, thus defining the feed direction. This kind of technique works quite well as long as the patient does not move. Moreover, there is no information on the needle depth and the current position of the needle tip. Other auxiliary devices used are frames and rails, which can be placed above the patient.[6,7] On the rails it is possible to attach and accordingly align different needle guide sleeves.

For more precise positioning of the needle in the patient, the intervention can also be performed under fluoroscopy. The needle can then be traced in real-time. The disadvantage of this technique is the additional radiation exposure to patient and radiologist. Particularly the radiation exposure to the hand of the radiologist increases. A possible solution is the use of extensions or holders directly attached to the needle in order to maintain its position in the radiation field. However, the disadvantage is that without direct contact to the needle, the radiologist has no haptic feedback in his hands during needle feed.

Another group of auxiliary devices are computer assisted navigation systems applying real-time tracking technology. Such systems provide real-time visualization of the current needle tip in the patient's data set. Various prototypes and also commercial products already exist useful for a lot of different clinical applications. Either electromagnetic tracking[8–10] or optical tracking systems are used[11] as a tracking technology.

An electromagnetic tracking (EMT) system is described by Makris et al.[12] A flexible, trackable catheter is advanced through a bronchoscope. During a study, 40 consecutive patients with lung lesions were successfully treated under guidance of this EMT system.

For different computer tomography (CT) and ultrasound (US) applikations like biopsies or punctures, an electromagnetic tracking system (Ultraguide, Israel) was used in several clinical studies.[13–16] The existing UltraGuide system is adapted for CT (UltraGuide 1010 CT-Guide) or US (UltraGuide 1000) imaging.

The presented CAPPA IRAD EMT (CAS innovations AG, Erlangen, Germany) navigation systems works with electromagnetic tracking technology which allows to track the tip of the needle and visualize it in the patient's data set. The navigation system was evaluated during different phantom studies.[17] During clinical studies, the system was evaluated in clinical environment. First clinical applications ranged from soft tissue biopsies (lung, kidney) to radio frequency ablation of spine tumors. In this paper we will describe the system and present first clinical results.

2. MATERIAL AND METHODS

2.1. System overview

The navigation system consists of an electromagnetic tracking (EMT) system AURORA (NDI, Northern Digital Inc., Canada) consisting of a field generator (FG), a control interface unit (CIU), and three sensor interface units (SIU). The EMT system is connected to a standard PC via the serial port. The PC is completely integrated into the housing of a monitor with a touch-screen interface. By using the touch-screen, no keyboard or mouse is necessary and the complete user-machine communication is performed via touch-screen. Optional additional control devices such as a joystick or a mouse can be attached. Fig. 1 illustrates the system architecture.

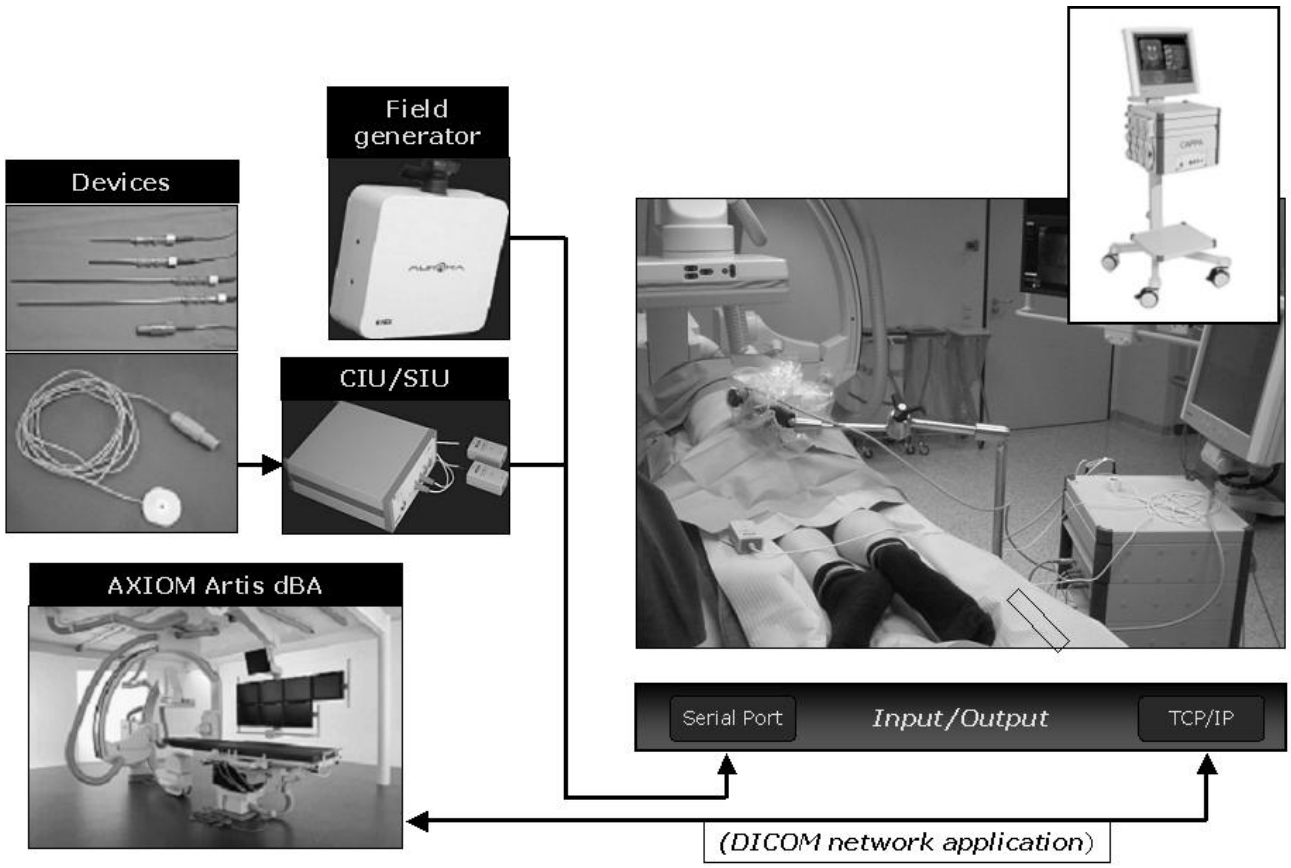

Figure 1. Overview of the system architecture and components: Devices (needles, skin sensor), Field Generator (FG), Control Interface Unit (CIU) and two Sensor Interface Units (SIU), rack with standard PC and connection to the AXIOM Artis system.

The EMT system and the navigation PC are mounted in a single rack in order to make the complete hardware unit usable in a standard surgical ward.

For image acquisition, the navigation system can be connected to different imaging systems such as C-arm systems with CT option, CT scanners, or MR tomographs. The prerequisite is a DICOM interface to send and receive DICOM images. A DICOM interface was available at the workstation of the imaging system. For the clinical trials, the navigation system was connected to a C-arm system with CT-option (AXIOM Artis dBA with DynaCT option, Siemens Healthcare, Forchheim, Germany).

2.2. Devices

We developed different needle sets for different clinical applications and two reference sensors as devices. In order to track the needles, small coils (5 mm / 9 mm) were placed in the tip of the needles. The offset (see Fig. 2), i.e. the distance from the needle tip to the coil center, is stored in an EPROM which is located in the connector of the device. The EPROM is recorded prior sterilization for every needle individually. For biopsies and puncture interventions we developed different needle sets (standard tracking needles) with lengths of 50/100/150/200 mm and diameters of 11/14/18 Gauge. For verteoplasty and kyphoplasty the lengths were 100/150 mm and the diameters were 11/14 Gauge, respectively. Every needle set consists of a probe needle with the sensor in its tip and two trocars (hollow needles). For radio frequency ablation, a standard tracking needle 11G/50 mm and 11G/100 mm was used as guidance for the ablation needle (ProSurge, Celon, Germany).

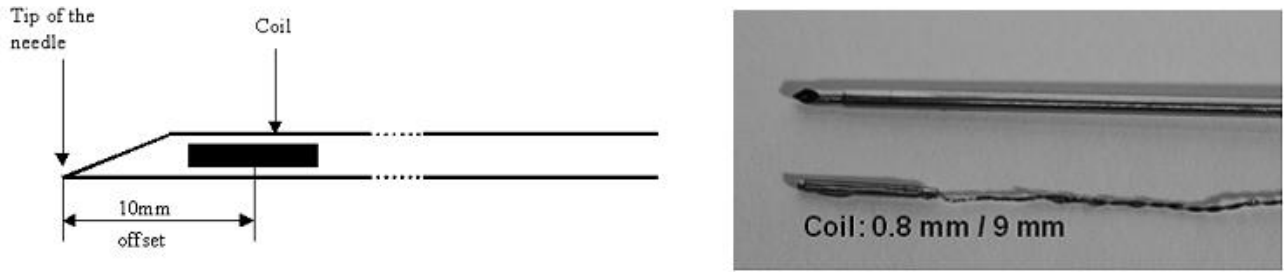

Figure 2. left: Drawing of the needle with a sensor coil in its tip. The offset of the needle is the distance from the center of the coil to the needle tip. right: picture of the tip of a biopsy needle and an example of a sensor coil which is located in the tip of the needle.

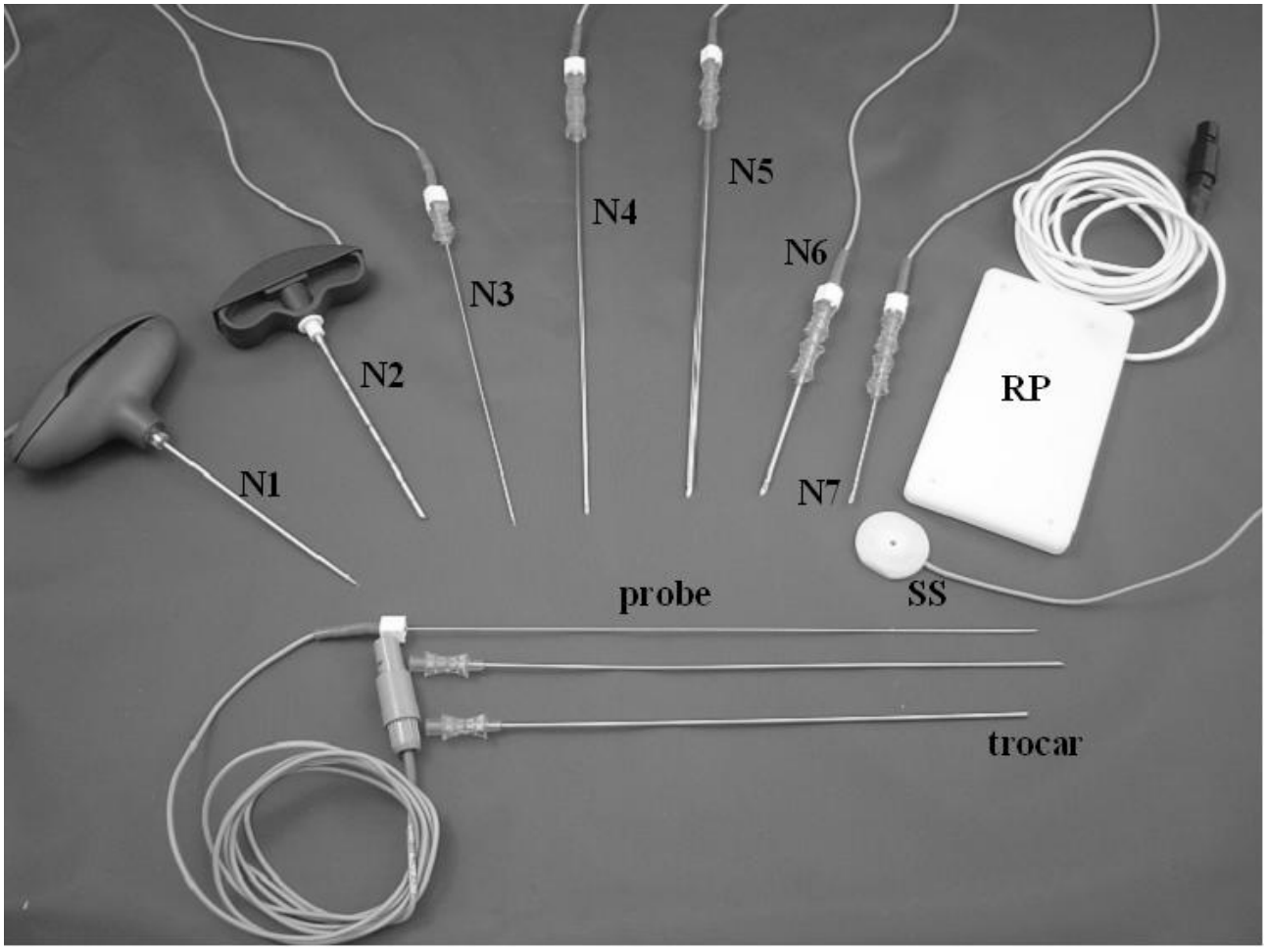

Figure 3. Overview of the devices: N1: bone biopsy needle; N2: vertebroplasty needle; N3 - N7 standard needles (18G/150 mm, 14G/200 mm, 11G/200 mm, 11G/50 mm, 14G/50 mm); referenz panel (RP); skin sensor (SS); probe with two trocars (hollow needles).

In order to track the patient motion, an additional reference sensor tracking 6 degrees of freedom (DoF) with two orthogonal coils was developed. The skin sensor (SS) can be fixed with adhesive tape to the skin of the patient. During patient preparation, the 6 DoF sensor will be initialized and monitoring the current

motion behavior of the patient afterwards. For that purpose, the sensor is fixed to the skin of the patient in the abdominal or chest area. Subsequently, the position of the sensor is measured by the motion tracking software module (MTSM) of the navigation system with 20 frames per second. The position of the sensor is recorded and used to display inhalation and exhalation of the patient on the screen of the navigation system. The visualization of the breathing curve can be activated during the intervention at any time.

For image-to-patient registration a registration panel (RP) was developed. Five CT-markers which can be easily detected by an integrated software registration module (ISRM) are embedded in the RP together with an additional 6 DoF sensor as described above. Before scanning the patient for the first time, the RP is placed under the patient to prevent any movement of the RP during the intervention. The CT-markers have a diameter of about 5 mm and a characteristic Houndsfield Unit value. The position of the CT-markers relative to the 6 DoF sensor is known. The latter establishes the reference coordinate system. After scanning the patient together with the RP, the markers will be identified in the images by the ISRM and their position will be registered in the imaging coordinate system. In this way the image-to-patient registration can be performed fully automatically.

2.3. Clinical workflow with the navigation system

During the development of the CAPPA IRAD EMT, attention was paid to make the navigation workflow and the workflow of the medical application compatible to each other. Of particular importance is that the interactions with the navigation system are reduced to a minimum.

Preparation of the patient: With the aid of a BodyFix^{TM}(Medical Intelligence, Schwabmuenchen, Germany) mattress, the patient is positioned on the intervention table as comfortable as possible for the intervention to follow. The patient reference plate is placed between the patient and the BodyFix^{TM}mattress, securely fixed directly to the patient, if necessary. The plate must, however, be fixed in such a way that the CT markers inside are in the field of view during the whole scan. The skin sensor for measuring the patient movement is attached to the skin of the patient.

Importing and loading the images: Following the acquisition and 3D reconstruction, the images are sent from the respective imaging modality to the navigation system in DICOM format. The navigation system loads them and performs the patient-to-image registration automatically. After successful registration, the system immediately changes to navigation mode.

Selection of needles: According to the intended intervention, the radiologist selects a suitable needle set and plugs it into the the sensor interface unit. The navigation system automatically identifies the needle and integrates it in the software. This allows immediate navigation of the needle, and the needle will be displayed on the monitor in the patient data record.

Navigated needle feed: During the entire needle feed, the position of the needle in relation to the patient data is continuously displayed on the monitor.

Planning an access path (optional): During the navigated intervention with the navigation system, the physician can plan (even complicated) access paths with the system. This step is optional, and planning is carried out in the patient images by means of the touch-screen. Other auxiliary views are displayed, which support the physician during the targeted needle feed.

2.4. Clinical evaluation of the navigation system

Within the scope of a clinical study for the evaluation of the navigation system, two different radiological departments performed more than 20 navigated interventions based on C-arm CT images. Their clinical use had been approved in advance by the Institutional Review Board. After each intervention, an inspection scan was made to verify the position of the needle.

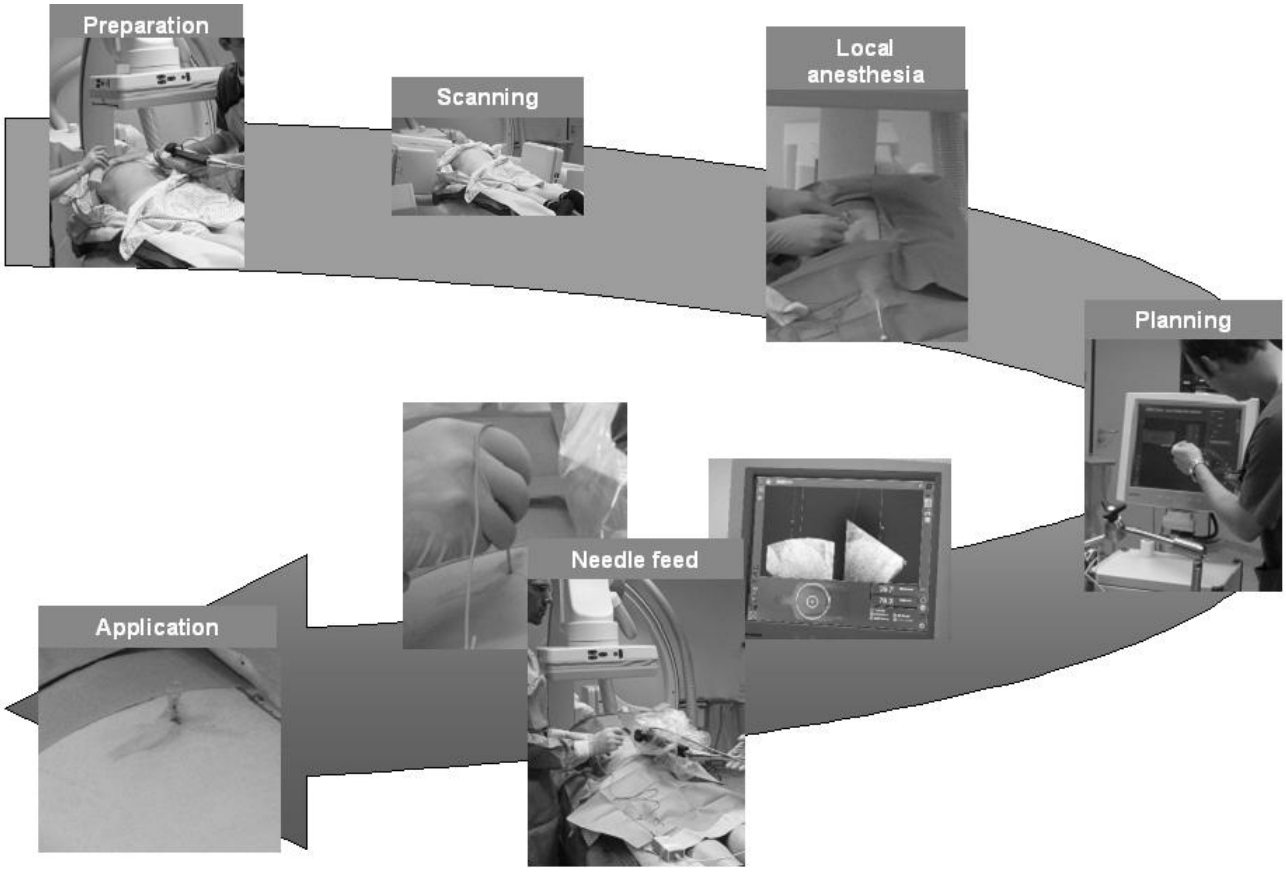

Figure 4. Workflow steps of the complete intervention with the navigation system. Starting with the patient preparation and ending with the clinical application.

3. RESULTS

3.1. Workflow with navigation

The navigated workflow was investigated with a view to make it optimally matching to the clinical workflow. Experience has shown that every redundant interaction with the system should be avoided. The clinical workflow, as described above, is relatively simple compared to most radiological interventions.

Both, the navigated and the non-navigated intervention, require patient preparation. The patient has to be positioned on the intervention table. The BodyFix^{TM}mattress serves not only as an aid for the navigated intervention, but also for the secure and painless positioning of the patient during the entire intervention. The BodyFix^{TM}mattress showed extremely positive results, especially in the case of patients who suffered from pain and were unable to remain immobile over a longer period of time on the CT couch. The fixation process was finished in all cases in less than 5 minutes.

Moreover, for navigated interventions the reference plate and the skin sensor have to be fixed to the patient. The reference plate is placed under the patient and, if necessary, fixed with a tape to the patient. According to different users, this is no problem, since different instruments (cannulae, drapes) or cables (radio frequency ablation) are occasionally fixed with tape as well. The additional effort required for fixing the plate and attaching the skin markers is seen as non-critical and will not prevent to use the system.

After preparation (clinical preparations are not described here, since they are identical for navigated interventions), the patient is scanned. Here the same scan protocols are used like for non-navigated interventions. However, the scanning volume must be defined in a way ensuring that the registration plate with all CT markers

will be always completely displayed inside the reconstructed 3D volume. This can be checked in advance with fluoroscopy images. The RP was designed small enough to be placed inside the field of measurement. However, the position of the RP had to be checked to make sure that the RP was inside the field of measurement.

After scanning, the technician sends the images to the navigation station, where they are automatically loaded. After loading, the patient-to-image registration and the initialization of the skin marker take place. All steps referred to are performed automatically.

Alternatively, the physician has the possibility to perform manual registration. Since the geometry of the markers on the RP is well-defined, it is impossible for the physician to define incorrect marker positions in the data record. Navigation is enabled only when the registration of the RP finalized correctly. The next step is the needle selection for the intervention. There is no difference compared to a conventional intervention. The sensor cable is plugged into the sensor interface unit, and the navigation system automatically recognizes the needle and enables it for the navigated intervention. From this moment on, the physician can see the position of the needle relative to the patient in the 3D patient data record displayed on the monitor of the navigation station.

During the entire needle feed the position of the needle in the data record can be followed on the monitor of the navigation station. Control scans for the verification of the needle position in the patient are possible at any time. When the needle has reached the target, the navigation is completed and the intervention can continue in the same way as in a conventional, non-navigated intervention. In general it can be stated that, apart from the extra effort required during preparation, no additional effort is to be expected. The navigated workflow was exactly integrated into the clinical workflow, and no additional steps are required.

The navigation system also enables planning of access paths in the patient data record. This step is optional and accordingly represents additional effort. However, for the first time it allows the physician to plan a trajectory in advance of the intervention (before puncture) for the definition of the optimal puncture path. The system then assists the physician with the execution of the planned intervention. Without navigation, this is possible only with additional auxiliary equipment or with additional radiation exposure.

3.2. Clinical applications

For the evaluation 20 clinical interventions were performed in two different hospitals by four different physicians. Clinical interventions: 2 discographies at the lumbar region of the spine, 5 tumor radio-frequency ablations at the spine (Fig. 6), 7 biopsies/punctures (Fig. 6) and 6 drainages. The average depth of the target was about 72 mm (minimum 16,73 mm / maximum 131,41 mm). The time from the skin entry of the needle up to the final position of the needle was about 3 min. 16 out of 20 interventions were performed with a planned trajectory, 4 interventions were performed without planning. Planning was completed in less than 5 minutes. It was possible to place the needles exactly in all cases and the verification scans showed that the needles were at the desired positions. For all 20 interventions only one planning scan and one verification scan, respectively, were needed to place the needles at their final positions. During the interventions no complications occurred.

4. CONCLUSION

Within the scope of the clinical evaluation, different interventions were performed at the Charité Hospital in Berlin, Germany, and Otto-von-Guericke University in Magdeburg, Germany. In all cases, the navigation system operated perfectly. With all interventions, the operability of the system in the hospital showed that, even under difficult conditions (anesthesia and contrast medium injection equipment), navigation is possible. The presence of a navigation system in the operating room is fully accepted by medical experts. In each case, the field generator could be positioned so that both 6 DoF sensors (SS/RP) were within the region of measurement. During the 20 interventions, two needles were not detected during system initialization and regarded as defective by the system. A new sterile needle was connected to the system, which was detected and initialized without any problems. The intervention could then be successfully performed with the new needle. The evaluation of different navigated interventions with CAPPA IRAD EMT also gave information about the time required to perform the individual steps. It was found that planning could be completed in about one minute, the navigated alignment required about two minutes. During the phantom study,[17] values of about one minute were obtained.

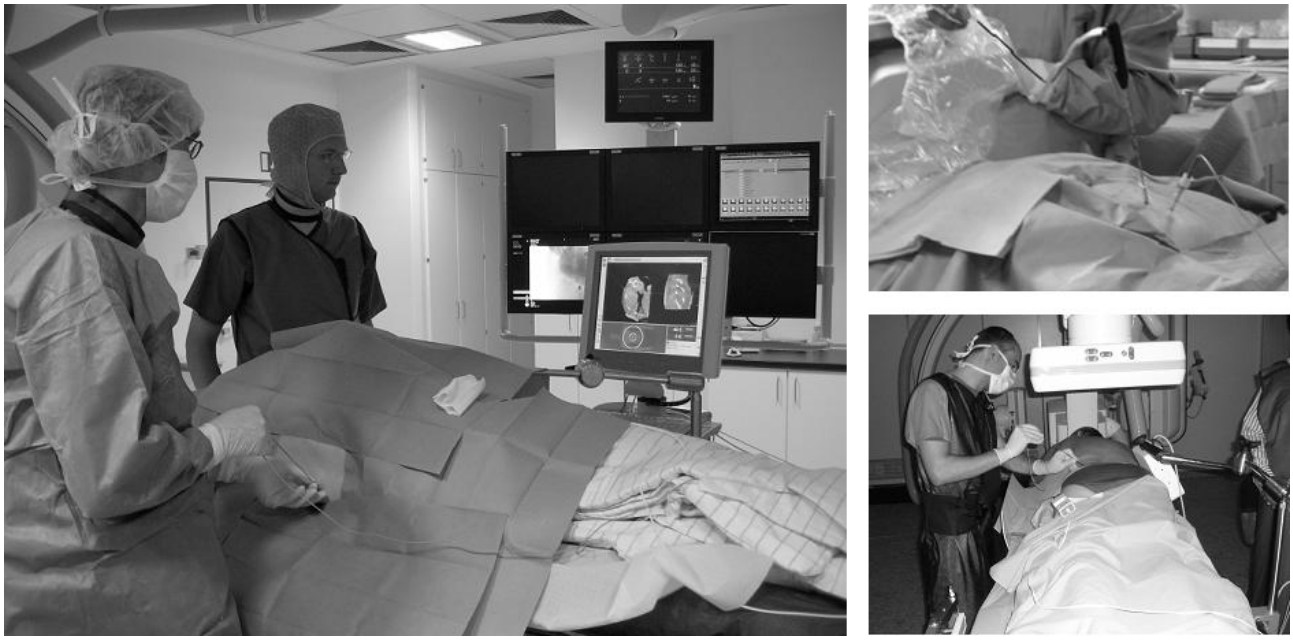

Figure 5. left: navigated intervention, lateral access by Frank Wacker and Bernhard Meyer (Department of Radiology, Campus Benjamin Franklin, Charit'e, Berlin, Germany). Right top: discography in the upper spine by Martin Skalej (Department of Neuro Radiology, Otto-von-Guericke University, Magdeburg). Right bottom: radio frequency ablation in the upper spine. After placing the needle, the probe was removed and the hollow needle was used as a guidance for the RF-needle.

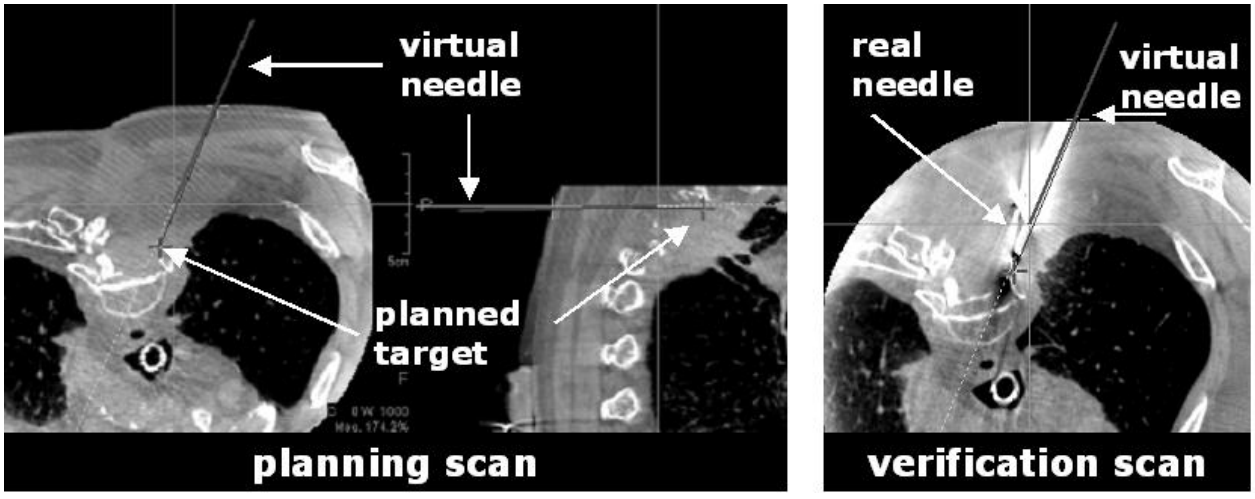

Figure 6. left: intra-operative screen shot of an RF-Ablation in the spine. A trajectory was planned into the middle of the tumor. The needle was fed with the assistance of the navigation system. The position of the needle is visualized in the patient's data set. Right: verification scan. In order to validate the navigation, we faded the virtual needle in the verification scan in order to assess the deviation between the virtual needle and the real needle.

In clinical practice, stress arising from performing the intervention is also an issue, so that a higher value might be expected. However, a time of about two minutes is not viewed as critical. The needle feed itself required only about one minute. The challenge in this step is to ensure that the feed exactly follows the planned path. Here, the navigation proved to be a great assistance for the physician. In the absence of navigation, several

control scans (3-10) and resulting needle corrections are required. This depends highly on the experience of the physician performing the intervention. In any case, feeding the needle to a target reproducibly in less than one minute is nearly impossible without navigation, especially if the access path is inclined, very deep, or if anatomically critical regions are located in the vicinity of the insertion canal. Here, the particular advantage of navigation, i.e. greater safety thanks to controlled needle feed and savings in time, could be clearly proven.

The interventional procedures performed with the system showed that fixation with the BodyFix^{TM}is sufficient for stable positioning of the patient. Patient positioning performed within the scope of the study was always completed within less than five minutes. Furthermore, the use of the patient positioning system in all interventional procedures and in clinical use with other systems showed[18] that patients experiencing difficulties in lying on the table could be comfortably positioned for the duration of the intervention. The individual adaptation of the mattress to different table positions proved to be absolutely helpful for both, the patient and the physician. The 20 interventional procedures revealed no clinical problems which would question the use of the navigation system with the patient.

5. ACKNOWLEDGEMENTS

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