A navigated 4-DOF mechanical aiming device for percutaneous ablation of liver tumours

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Abstract:
During percutaneous interventional procedures, the orientation and position and of a needle-like instrument can be constrained relative to the patient's coordinate system using a variety of aiming devices. Physicians align the aiming device in space according to a pre-defined plan and advance the instrument without excessive bending, resulting in a higher targeting accuracy. However, available systems have been developed for non-stereotactic procedures and their use in combination with optical tracking systems is limited due to a tedious alignment process, non-intuitive usage and operational complexity. Thus, an intuitive 4-DOF aiming device, for specific integration with an optical navigation system, was developed and evaluated. Effective accuracy was assessed during 20 image-guided needle punctures (using an anthropomorphic torso phantom) carried out by three interventional radiologists. Additionally, physicians assessed usability and design properties using a questionnaire. In this work, we report on our findings in terms of the learning curve for maneuvering the device and adequacy of needle stabilization.

Keywords: interventional radiology, percutaneous liver ablation, navigation system, aiming device

Problem

For patients with early-stage hepatocellular carcinoma, thermal ablation is an established non-surgical treatment method that provides minimal invasiveness and recovery time when compared to both open surgical and laparoscopic resection [1]. The clinical outcomes of minimally-invasive thermal ablations are, however, largely dependent on accurate implantation of single or multiple treatment applicators into the tumor [2]. To decrease the dependence of targeting accuracy on interventionist's spatial orientation, skills and experience, stereotactic navigation systems have been introduced. Previous studies have shown that navigated thermal ablations may improve therapeutic outputs and achieve equivalent results to open liver surgery [3].
Apart from soft tissue deformation, the major challenges during an image-guided procedure are needle stabilization during the insertion process and minimization of needle deflection. While electromagnetic tracking systems allow the position of the needle tip to be precisely tracked using single coil electromagnetic sensors [4], optical tracking allows only for the tracking of an instruments distal end. The main shortcoming of electromagnetic navigation is that the overall tracking, and subsequently targeting accuracy is subjected to field distortions caused by ferromagnetic objects (CT table, gantry) and strongly depends on the effective emitter-sensor distance (electromagnetic field strength is inversely proportional to the cube of the distance). Optical navigation systems, which have larger measurement volumes and a high tracking precision seem to be more reliable in CT suites [5]. However, optical tracking are not without drawbacks, including a line-of-sight requirement and the assumption that tracked instruments are rigid bodies. This last assumption is not correct for the majority of ablation treatment applicators, which may deform while inserting into the soft tissue.
To provide the best possible stiffness while maintaining needle position, several aiming devices have been introduced [6], [7], [8]. The clinically available SeeStar (Radi, Uppsala, Sweden) is a needle guide which is mounted on the patient's skin; no computer guidance is provided in combination with the device, forcing the radiologist to use and iterative adjustment approach based on several control scans. To decrease the number of required CT scans during the intervention, a navigated aiming device has been also developed [7] and compared to navigated free-hand technique on a non-rigid liver phantom [9]. The lateral components of the errors measured at the needle tip were remarkably lower when an aiming device was used (2.3±1.3 mm) than in the case of free-hand punctures (4.2±2.0 mm), however use of this device required both a long learning process and demonstrated long alignment times. To decrease the time taken for needle alignment, a robotic system was employed, providing remote, semiautomatic needle alignment with a joystick and thereby preventing radiation burden to medical stuff in fluoroscopy-guided ablations [10]. Although operator errors

and intervention time are reduced, the clinical acceptance of robotic needle guidance is currently low due to the high complexity and costs of such systems. To decrease this complexity, a novel 4-degree of freedom (DOF) aiming device equipped with adjustable needle holder (iSYS Medizintechnik GmbH, Austria) was developed. Two large screws placed above and below aiming device allow an intuitive way to change needle orientation and translation. Despite that, the usage of such a device requires an iterative needle insertion that must be supervised with several controls CT scans.
Subsequently, the aim of this study was to integrate this 4-DOF aiming device into an optical navigation system dedicated for interventional radiology (IR) as well as qualitatively assessing its usability parameters in a phantom trial using a questionnaire.

Methods

A stereotactic image-guidance system (CAS-One IR, CAScination AG, Switzerland) dedicated for percutaneous radiological interventions on the liver has been developed and evaluated in several phantom studies [9], [11], [12]. The base of a navigation system is an optical position measurement system (NDI Vicra, Northern Digital, Canada) that tracks the needle holder of the aiming device (iSYS Medizintechnik GmbH, Austria) through a dedicated custom-made optical reference attached with retro-reflective passive spheres (Figure 1, left). The geometry of the marker shield was optimized for continuous line-of-sight during the needle insertion (avoiding marker coverage by the needle) as well as for visibility under the range of insertion angles required for needle placements on the liver (lateral and posterior trajectories). The aiming device is pre-calibrated and attached via a mechanical arm (iSYS Medizintechnik GmbH, Austria) to a custom-made fiberglass plate situated under the patient. Additionally, a set of single retro-reflective marker spheres (SM) is fixed onto the patient skin around the area of the expected needle incisions to enable real-time patient tracking and respiratory motion control [13].
In the standard hospital workflow the patient is placed on the CT table with their head inside the gantry, providing access for anesthesia from the other side of the gantry. The navigation system is placed opposite the radiologist while the tracking camera is positioned above the patient, directed caudally (Figure 1, right). The intervention then begins with the radiologist attaching the single-use needle holder to the aiming device; the aiming device and the mechanical arm are then draped with a sterile cover. After an initial imaging sequence, the image data is transferred and needle placements are planned on the navigation system. Subsequently, the radiologist places the aiming device in an approximate

Figure 1: A navigated 4-DOF aiming device with attached marker shield placed above the torso phantom (left) that has been tested with navigation system in a realistic radiological setup (right).

position near the expected needle insertion location using guidance information provided by the navigation system. A final precise alignment of the aiming devices position and orientation is performed under visual control by viewing the navigation systems targeting viewer. Once the aiming device is precisely aligned, the distance between the reference mark and the target are displayed on the navigation system. A biocompatible pen is used to put a mark of the required distance on the needle; the needle is then inserted to this depth.
In this experiment, one series of 20 needle punctures were performed on an anthropomorphic torso phantom, in which liver tissue was simulated by polymer foam. The end of five 0.018-inch fibered platinum coils (length 20 mm, diameter 3 mm), were randomly inserted in the phantom, and served as targets. A navigation dataset of the phantom was acquired (128-slice Philips Ingenuity, Voxel size: $0.79 \times 0.79 \times 0.80$ mm^3). Each target was reached by a 17 gauge, 168 mm long co-axial needle (BioPince, Angiotech, Canda) from two different trajectories, varying in length, orientation, position of incision point (lateral, posterior, anterior) and plane (oblique, in-plane). The trajectories were planned at extreme positions in order to challenge the usability of the aiming device.

After completion of the experiment, physicians with varying experience levels (experienced: n=2, novice: n=1) were asked to fill out a questionnaire regarding the benefit and feasibility of using the 4-DOF aiming device with the optical navigation system. The questionnaire included questions referring to the usability of the aiming device in interventional radiology (IR) suite, its movement capabilities, the advantages and disadvantages of needle stabilization during insertion, as well as questions concerning mechanical design. The closed-end questions could be answered based on a following scale: “Strongly disagree (0%)”, “Disagree (30%)”, “Agree (70%)”, “Strongly agree (100%)”. Average agreements above or equal 70% were considered as positive indication for given statements.

3 Results

10 needle trajectories (average length 119.0 mm) were planned on the CT images. Five different targets were reached from different orientations using the navigated 4-DOF aiming device. One of twenty trajectories could not be reached because of a loss of line-of-sight in the vicinity of the CT table, despite repositioning of the camera.

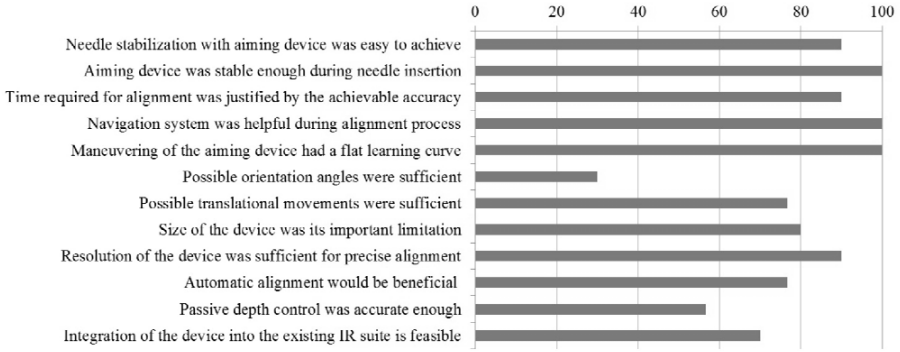

Figure 2: The average percentage of agreement in questionnaire regarding navigated 4-DOF aiming device.

The questionnaire was completed by the three radiologists after completion of the experiments. All users strongly agreed on the benefit of the aligning aiming device with optical navigation system (Figure 2). Conflictingly, users expressed dissatisfaction with passive depth control during needle insertion, further details regarding active and passive depth control are available in [9].

4 Discussion

The usability of a navigated 4-DOF aiming device was confirmed experimentally through the performance of 20 needle ablations in an anthropomorphic phantom in a clinical environment by radiologists of varying levels of experience; 19 of the 20 planned targets were reached. Further usability assessment was performed by radiologists via the completion of a questionnaire.

The strongly positive attitude towards the navigated aiming device may be related to a number of factors: questionnaire participants strongly agreed that the learning curve for maneuvering the device was flat, as well as strongly agreeing that the needle stabilization achieved was adequate. Furthermore, when questioned about the combination of the navigation system with the aiming device, all participants strongly agreed that navigation was useful. Navigated needle guidance may provide a number of advantages over existing needle guidance technologies. The lack of spatial orientation for needle alignment, as well as the requirement for iterative insertion supervised by several control image acquisitions, are major limitations of existing approaches such as those presented in [6] and [8]. To our knowledge, only one solution currently provides a similar functionality [7]. This system is, however, limited by a non-automatic registration process as well as a steeper learning curve.

Respondents indicated that the guidance capabilities of the aiming device may need to be extended by active depth control, which shows, in real-time, the distance between planned target and current needle tip. Active depth control provides additional security in case of unexpected patient movements relative to the aiming device or displacement of SM on the patient skin. Interestingly, in terms of accuracy, active depth control may lead to higher lateral errors at the target [9], thus its integration into current solution should be carefully considered. Respondents also agreed that automatic needle alignment, potentially provided by a robotic systems such as [10], could be beneficial (76% agreement). Auto-

matic alignment may help to reduce the time required for needle positioning, a significant drawback of the presented technique. The time taken for to manually align the needle using an aiming device is a common issue; targeting times required by SimpleCT [14] and ATLAS aiming device [7] are 15.6 ±16.4 min and 5.03±2.65 min respectively. Furthermore, automatic alignment may be beneficial in the case of multiple parallel needles which could be quickly reached without the re-positioning of the device, or in the case of thermal ablations carried out under local anesthesia, which requires insertion of both anesthetic needle and treatment applicator exactly at the same position.
Several improvements regarding size of the device and workspace limits were suggested. The major limitation of the current solution is a narrow range of possible orientation angles (-32°÷32°,-29°÷35°) when compared to other available solutions [6], [8]; only 30% agreement was achieved when respondents were asked if the angular range of the device was sufficient. Maximum reachable angles with the SeeStar needle guide is 60° around each plane, while SimpleCT (NeoRad, Norway), which is a passive laser alignment systems fixed on the wheeled stand near the CT table, can be oriented at up to 45° in the transversal or the sagittal plane angles respectively. Additionally, the size of the aiming device (due to the translational movement capabilities) was also considered as a limitation (80% agreement). This is particularly important for trajectories starting dorsally, potentially leading to a collision of the aiming device with CT table, as was observed during the experiment, where one trajectory could not be followed.

5 Conclusions

The usability of a novel navigated 4-DOF aiming device was assessed through the completion of a clinically relevant phantom study and subsequent questionnaire; the system was found to provide both sufficient needle stabilization as well as a relatively flat learning curve. The device can be integrated into existing IR workflows, potentially improving the clinical outputs of minimally invasive, percutaneous needle procedures. Further investigations are required to both improve the angular capabilities of the aiming device and perform a quantitative assessment of achieved targeting accuracy and times required for needle alignment.

5 References

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