Phantom evaluation of a navigation system for out-of-plane CT-guided puncture

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Computed tomography; Phantom study; Electromagnetic navigation; Interventional radiology

Abstract
Objective: The purpose of this phantom study was to assess a new real time electromagnetically-guided navigation system and compare it to standard computed tomography (CT) guidance.

Material and methods: A prospective, randomized, comparative study was carried out over a two-day period. Operators without prior experience on the new navigation system sequentially attempted to puncture two 6 mm-diameter targets (one attempt for each target) with out-of-plane trajectories using both the standard CT-guided method and the new navigation station (NAV method).

Results: Intention-to-treat analysis was performed for 54 operators. Twenty-two operators out of 54 (40.7%) reached the target on first attempt with the NAV method versus none (0%) using CT-guidance (P < 0.001). The median distance of the puncture from the center of the target was 3.7 mm [Q1–Q3 = 2–6.7] using NAV versus 15 mm [10–20] using CT-guidance (P < 0.001). Overall planning and puncture time were shorter using NAV: 76 s [50–118] versus 214 s [181–264] using CT-guidance (P < 0.001).

Conclusion: Novice operators consistently performed faster and more accurate phantom punctures with out-of-plane trajectories using the electromagnetically-guided navigation system than with the standard CT-guided method.

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The development of new therapeutic options using interventional radiology has led to an increased number of image-guided biopsies [1–6]. In the same time, the difficulties related to actually performing such biopsies have resulted in the development of various innovative guidance systems. The last few years have seen substantial progress, as new technology developed for computer-assisted medical interventions has become available. These new techniques have been adapted to computed tomography [7–14] and are now successfully used to facilitate needle placement (in particular for out-of-plane trajectories), improve the accuracy of biopsies and reduce the amount of radiation that the patient receives.

The purpose of the present phantom study was to assess the performances of a large population of operators with no prior experience on new electromagnetically-guided system for biopsy needle placement on an out-of-plane trajectory, and to compare them with the standard CT method.

**Material and methods**

**General description of the navigation system**

The present study was carried out to assess the IMACTIS® navigation station (Grenoble, France). This system uses a magnetic field generator placed on the patient near to the puncture site and a detector contained within a needle holder to track the needle trajectory in real time using CT imaging. Following acquisition of the volume of interest, DICOM images are automatically transferred to the navigation station. During the procedure, the acquisition volume can be examined three-dimensionally by moving the needle holder directly over the patient. The most appropriate puncture site can therefore be localized in real time, just before attempting to reach the target. A video showing a CT-guided biopsy performed using this system can be accessed on the product page of the Imactis website: http://www.imactis.com/.

**Study design**

The present study was a prospective, randomized and comparative phantom study assessing the performances of operators with various degrees of experience. Users’ performances with the electromagnetic IMACTIS® navigation system (NAV group) were compared to those with the standard CT method (CT group). The study protocol imposed “one-shot” target puncturing, without allowing repeated intraprocedural CT acquisitions. Assessment therefore focused on the initial stage of the puncture procedure, analyzing the accuracy of trajectory planning and of initial positioning of the needle.

**Protocol for phantom punctures**

The phantom (Fig. 1) contained three targets. Users had to follow a double oblique, out-of-plane trajectory to approach the targets through the pre-pierced PVC plates contained in the phantom. The targets were 6 mm-diameter holes located at a depth of approximately 10 cm from the surface of the phantom. Punctures were considered successful if the needle crossed the target. Helical scans of the phantom were obtained using a Brilliance 64 CT scanner (Philips Medical Systems, Eindhoven, The Netherlands). The first target was used to train operators on both the navigation system and the post-processing console (IntelliSpace Portal, Philips Medical Systems). Performances were then assessed using the two remaining targets (A and B) of similar difficulty.

Because puncture attempts were carried out without concurrent CT monitoring, the operators had only one attempt to reach the target and could not alter their trajectory once the approach had started, nor perform intraprocedural CT scans to check on the position of the

![Figure 1](image-url). Puncture assessment phantom: a: puncture phantom. The magnetic field generator localized on the “patient” was used to perform punctures with the NAV system. CT group punctures were performed by simulating the position of the couch of the CT scanner using a graduated ruler, and visualizing the plane of the CT slice using a laser. A metal wire placed on the “patient” is used as a landmark for the entry point; b: trajectories and targets. Transparent 3D view of the inside of the phantom showing the 2 targets and the out-of-plane trajectories (A and B) that have to be achieved to reach them (represented by holes drilled through PVC layers).
needle. Although not fully clinically realistic, this phantom study protocol was appropriate to assess the accuracy with which operators planned the initial placement of the needle and its path, when trying to achieve an optimal trajectory to reach the target.

Operators first became familiar with the post-processing console in order to calculate an appropriate trajectory using the standard CT method, then tested the NAV system in an attempt to reach the training target.

The CT method included an initial planning step on a post-processing console. This step was used to localize the puncture point on the surface of the phantom, as well as the in-plane and out-of-plane angles of the double oblique trajectory. A second step consisted in defining the entry point using the laser and a lead fiducial, reproducing the planned needle path angles and finally attempting the puncture itself (Fig. 2).

The first stage of the NAV method consisted in moving the needle in its needle holder (localized by the navigation system) over the surface of the phantom while visualizing the puncture trajectory in real time. Once the user considered that the trajectory was appropriate (i.e. crossing through the center of the target), he/she attempted the puncture itself (Fig. 3).

For both methods, the duration of each individual step was measured for each operator and the total duration time calculated. For the CT method, the total duration included the planning step (needle path calculations and localization of the entry point) and the actual time needed to perform the puncture itself. For the NAV method, these two phases were simultaneous.

Target-centered cross-hairs were used to measure the distance of the tip of the needle from the center of the target. This distance was set at a default value of 20 mm, representing the maximum measurable distance, if the needle did not pass the first of the two holes outlining the trajectory to be used, or if the point of puncture was out of the measurement area.

Operators were randomized manually by drawing lots to determine which target should be attempted first (A or B) and in which order the methods should be used. Four groups were thus formed: group 1 (target B using CT then target A using NAV), group 2 (A-NAV then B-CT), group 3 (A-CT then B-NAV), and group 4 (B-NAV then A-CT).

**Statistical analysis**

The results were analyzed by intention-to-treat analysis. When the operator gave up during his/her attempt using either the CT or NAV method, the missing values for distance and time were replaced by the maximal values observed for each modality. Significant differences between quantitative variables were analyzed using Wilcoxon’s test on paired data. McNemar test was used to compare qualitative variables. P-values were considered statistically significant when < 0.05.

**Results**

Fifty-four navigation system users took part in the study. Following randomization, each user used both methods to attempt to reach the two targets (each target was attempted with one of the methods only; Fig. 4). Except for one user, none of the other users had prior experience on the IMACTIS navigation system. Users showed varying degrees of experience in performing CT-guided biopsies: the user population consisted of senior interventional radiologists (n = 11), senior mostly diagnostic radiologists (n = 8), radiology residents (n = 30), radiology technicians (n = 4) and a veterinary experienced in CT-guided procedures (n = 1).

Two users left the study during data collection without finishing the tests. A user from group 1 did not finish the procedure with the navigation station due to inability to conceive three-dimensional position and orientation. Owing to time constraints, another user from group 4 did not perform the attempt using the standard CT method.

Out of a total of 54 attempts, 22 (40.7%) were successful with the NAV method (needle reaching the target at first attempt) versus 0 (0%) with the CT method (P < 0.0001; Table 1). The success of the NAV method demonstrated that users managed to position the needle on an optimal
Figure 3. Performing punctures with the navigation system (NAV): a: use of the navigation system for the NAV group. The user attempts to find the optimal trajectory by moving the needle (fixed in an electromagnetically localized needle holder) directly over the "patient"; b: screen of the navigation system during the procedure. The needle’s trajectory is displayed in real time. Two perpendicular views demonstrate here that the needle path planned by the user is aligned with the required puncture trajectory in the phantom.

Figure 4. Study design. *For the two users who gave up before the end of the study, missing values for distance and time were replaced by the maximal values observed in the CT or NAV groups.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Performances for each group.</th>
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<tbody>
<tr>
<td></td>
<td>NAV (n = 54)</td>
</tr>
<tr>
<td>Successful punctures (%)</td>
<td>40</td>
</tr>
<tr>
<td>Median distance to center of target (mm)</td>
<td>3.7 [2; 6.7]</td>
</tr>
<tr>
<td>Median total duration of puncture (s)</td>
<td>76 [50; 118]</td>
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<tr>
<td>Median planning time (s)</td>
<td>142 [114; 173]</td>
</tr>
<tr>
<td>Median puncture time (s)</td>
<td>66 [53; 90]</td>
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Numbers in brackets are first and third quartiles [Q1; Q3].
trajectory with a margin of error of ±3 mm (i.e. the radius of the target).

Needle trajectory accuracy was higher in the NAV group with a median distance from the center of the target of 3.7 mm [Q1–Q3 = 2–6.7] versus 15 mm [10–20] in the CT group (P < 0.001; Table 1).

Overall biopsy time was significantly shorter for the NAV group (P < 0.001) with a median time of 76 s [Q1–Q3 = 50–118] versus 214 s [181–264] in the CT group (Table 1). For the CT method, the median times of the planning step and of the biopsy itself were 142 and 66 s, respectively.

For a given method (NAV or CT), no significant differences were observed in the distance from the center of the target and biopsy times for targets A and B. This finding validates the design of our phantom and confirms that targets A and B were of equivalent difficulty.

Discussion

The results of our phantom study demonstrate that the navigation system assessed here allows users with no prior experience of the system to perform faster and more accurate CT-guided biopsies with out-of-plane trajectories.

This navigation system is based on electromagnetic localization of the needle and overcomes several of the difficulties associated with optical-based systems. Optical-based systems use fiducial markers localized on the instruments and on the patient’s skin that are tracked by stereoscopic cameras, and thus require a direct line of view between the cameras and fiducials. It is often difficult to achieve such direct lines of view in interventional radiology situations [7,12,14,15].

Electromagnetic systems have been developed to overcome these issues; however, their reliability needs to be assessed due to possible interferences with the metal components of CT scanners. Two different types of system have been developed depending on detector position. In systems like the Inactis system used here, the electromagnetic detector is located in a needle holder, whereas in other systems, a highly miniaturized detector (potentially more sensitive to electromagnetic interferences) is located in the tip of the needle [8,9,15,16]. For the system assessed in the present paper (detector located in needle holder), a median error of 3.7 mm from the center of the target was observed. This is consistent with previous phantom study findings for optical systems with fiducials on the needle holder for which errors ranging from 3.5 to 4.6 mm were reported [13,14]. The error is nevertheless greater than those obtained with electromagnetic systems with the detector located in the needle tip, for which errors ranging from 0.8 to 1.6 mm were reported [8,9]. However, the experimental conditions of such studies differ from ours since the (costly) use of needles with detectors located in the needle tip means that the trajectory can be corrected once the needle has progressed towards the target and that any potential needle bending can be compensated [7]; this is not the case for the system assessed here which has the detector in the needle holder.

The partial success rate observed in our study is most probably due to the experimental protocol used (only one attempt without intraprocedural monitoring or readjustment of the trajectory) and the small size of the targets. Indeed, due to the distance from the entry point to the target (10 cm), even the smallest inaccuracy when positioning the needle (or needle bending) could result in an error >3 mm and failure to puncture the target. In clinical practice, such inaccuracy would not necessarily result in an unsuccessful puncture, but rather in additional monitoring and correction of the trajectory after the following intraprocedural CT scan. Our study demonstrated that punctures performed with the NAV method were significantly more accurate than with the CT method and therefore suggests that such navigation systems could facilitate successful punctures while reducing the number of intraprocedural CT scans. It would be interesting to conduct a clinical study to test this hypothesis.

In our study, the procedure time using the navigation system (median = 76 s) is greater than those reported in other phantom studies evaluating electromagnetic systems: 28.6 s for single oblique trajectories [9], and 36 s for 76 in-plane punctures performed by two operators only [8]. However, in our study operators were systematically assessed on out-of-plane trajectories and to our knowledge, it includes the largest population of different users with no prior experience of the system. Previous studies have up to now generally included less than 10 experienced users [16–20]. When compared with the standard CT method, our study shows that use of the navigation system allows a gain in time of 128 s. This seems to reflect the good maneuverability and ease of use of the system.

This navigation system was designed exclusively for use under CT-guidance; its ergonomics were therefore optimized notably with completely automated and practically instantaneous registration. Other navigation systems have been developed for use under ultrasound-guidance, and some even display image fusion features for combining ultrasound and CT images. Combining electromagnetic guidance and image fusion features means that two imaging modalities can be used and their respective limitations overcome, if however prior registration of both modalities has been performed successfully. This can be particularly useful for example when targeting liver nodules that are sometimes better visualized with ultrasound or, on the contrary, when dealing with gas or bone interfaces that are better overcome with CT [16,20,21]. When ultrasound tracking of the needle is not possible, electromagnetic guidance enables clinicians to observe the needle advancement in real time.

Nonetheless, navigation systems will still benefit from improvement. One of these future improvements will be to synchronize needle movements with the patient’s breathing pattern. Simple non-invasive devices such as pneumatic straps around the patient’s waist or chest have led to promising initial results as regards to the duration, complication rate (pneumothorax) and number of needle readjustments during a procedure [22,23]. To help the electromagnetic guidance system take into account the patient’s breathing pattern when localizing the biopsy needle, other studies on mobile phantoms have assessed the use of internal fiducial needles in addition to detectors placed on the skin [24].
Conclusion

In conclusion, the results reported in this phantom study demonstrate that the use of an electromagnetic navigation system results in a significant gain in time and accuracy compared with the standard CT-guided method when performing complex out-of-plane punctures. Interestingly, our study was performed by a large population of operators with no prior experience in navigation systems. Further assessment of this guidance system is necessary in clinical conditions to evaluate its benefits compared with traditional guidance methods.

Disclosure of interest

Ivan Bricault works as a research scientist in the TIMG-IMAG Laboratory and took part in designing the IMACTIS navigation system; he is also a member of the Medical Advisory Board of Imactis.

References