CT-guided percutaneous interventions
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Document Version
Publisher’s PDF, also known as Version of record

Publication date:
2019

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA):

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CHAPTER 3

Validation of a Robotic Needle Placement System for CT-guided Percutaneous Liver Ablation, using an Anthropomorphomorphic Phantom

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Submitted
CHAPTER 3

**Abstract**

*Purpose*
To evaluate a novel needle placement system (NPS) in an anthropomorphic phantom model for computed tomography (CT)-guided percutaneous liver tumor ablation and compare performance of experts with novices.

*Materials and methods*
The NPS (DEMCON, Enschede, the Netherlands) was tested using an in-house developed, 3D-printed anthropomorphic phantom, with 12 point targets at a mean depth of 9cm (range: 4-17cm) and different angulation categories. Two experts and two novices in CT-guided needle placement, approached all targets with regular CT-guided freehand antenna placement and with NPS guidance.

The lateral error between antenna and target was measured as accuracy. The antenna was not repositioned when within 5mm of the target or after 4 repositionings. The median (range) error, number of antenna repositionings, number of CT scans, and procedure time, were determined for the NPS and freehand group and compared using Mann Whitney-U tests. Furthermore, results were compared between experts and novices, stratified by method of approach.

*Results*
For the NPS and freehand group, respectively, the median accuracy was 2.2mm (1.0-3.4mm) and 4.5mm (3.6-5.4mm; p<0.001), the median number of antenna repositionings 0 (0-2) and 1 (0-4; p<0.001), the median number of CT scans 2 (2-3) and 3 (2-5; p<0.001), and the median procedure time 8 min (7-12) and 12 min (8-17; p=0.017). There were no differences in results between novices and experts, for freehand or NPS procedures (all p>0.05).

*Conclusion*
The NPS increases accuracy of MWA antenna placement and reduces the number of repositionings, CT scans and procedure time in a phantom model, for experts and novices.
**Introduction**

Over the last two decades, computed tomography (CT)-guided radiofrequency ablation (RFA) and microwave ablation (MWA) have proven to be successful treatment methods for hepatic malignancies [1–3]. Compared to surgery, the main drawback of thermoablation is the rate of local recurrence, reported to range from 5.0% to 67% [2, 4–7]. Known risk factors for local recurrence are larger tumor size, peritumoral vascularity and inadequate ablation safety margin around the tumor [5, 6]. In order to achieve adequate ablation of tumor and surrounding safety margin, accurate ablation needle (antenna) placement is critical. In CT-guided needle placement procedures, needle angulation is generally performed by hand (freehand method). It requires skill and experience and can therefore be expected to be operator dependent.

Recently, the Needle Placement System (NPS) has been developed as a robotic system to help the operator to guide the needle towards the target, in CT-guided interventions [8]. Because this device eliminates the difficulty of manually angulating the antenna, it can be expected to be less operator dependent, compared to freehand antenna placement. The NPS has been demonstrated to have a high accuracy in a simple phantom set-up [9].

However, during freehand procedures, operators rely on anatomical structures for accurate selection of the entry point and for antenna angulation. Therefore, the first aim of the study is to compare robotic antenna placement with freehand antenna placement in a newly developed, realistic anthropomorphic liver ablation phantom. The second aim of this study was to compare the performance of novices versus experts in CT-guided percutaneous liver ablation, in both freehand and NPS guided procedures.

**Materials and Methods**

*The NPS*

The NPS (DEMCON Advanced Mechatronics, Enschede, the Netherlands) is a table mounted 3 degrees-of-freedom navigation system for CT-guided needle placement. It can be positioned over an entry point on the skin manually and is than locked in place with a push button. A fiducial CT scan is acquired, making sure the target and all four device fiducials are within the scanner’s field of view. This fiducial scan is analyzed with the NPS software in which the spatial position of the fiducials in relation to the target is extracted. Next, the device orients the needle guide towards the target and provides a depth measure. The ablation antenna is clipped to the needle guide and inserted to the specified depth by the operator. A more detailed description of the system is published earlier and an animation of the procedure can be found online [8].

*The phantom*

The phantom was created in-house by 3D-printing a partial segmentation of ribs and pleural cavity inside an 18x18x22cm box. The floor and walls of this box contained a grid of small holes facilitating precise and consistent placement of the to-be-reached targets. Twelve point targets (1-mm lead balls) were attached to skewers and placed inside the phantom using the grid of holes. They were placed at approximately three levels of depth ranging from 4-16 cm, with a mean depth of 9.3 cm and at three levels of angulation difficulty: in-plane horizontal or vertical approach (angulation category 0,
n=4); in-plane oblique approach (angulation category 1, n=5); and out-of-plane approach (angulation category 2, n=3). Different angulation categories were achieved by placing targets behind the 3D printed lung and/or ribs. The potential needle paths toward the targets did not cross. Figure 2a shows a photograph of the phantom with the targets in place. A lid made from a mannequin torso was put in place and approximately five liters of 12%-by-weight gelatin was cast into the phantom. The gelatin was left to set overnight and the lid was removed. To simulate skin, a chamois leather cover was stretched over the phantom after it was placed inside the mannequin torso (figure 2b).

Procedures were performed on the Somatom Force (Siemens, Erlangen, Germany) using CARE kV with a reference value of 120 kV, tube current modulation with a quality reference tube current of 120 mAs, a pitch of 0.8 and 48x1.2mm collimation. Images were reconstructed using a Br40 kernel, with a slice thickness of 1.5 mm and an increment of 1.0 mm.

The two experts had over 6 years of experience in CT-guided liver tumor ablation (KJ and JP) and the two novices were radiology residents with approximately 10 CT-guided procedures of experience (MW and SR). They approached all targets twice: once using the NPS and once by freehand approach, the order of which was randomized and per operator divided into two sessions. The phantom’s gelatin was being re-cast in between sessions to avoid the influence of existing needle paths from previous approaches. This resulted in 8 sessions with 96 approaches.

The physicians were asked to approach the targets with a microwave ablation antenna (Emprint, Covidien/Medtronic, Dublin, Ireland) in a way similar to a clinical setting, where they could choose a suitable entry point for each approach with the use of a radiopaque biopsy grid (GuideLines, Beekley Medical, Bristol, USA). If deemed necessary for the freehand approach, a small hypodermic needle could be inserted to find the correct orientation and they could opt to first partially insert the MWA antenna and verify its orientation to make fine adjustments. The use of the hypodermic needle

![Fig. 1: Placement of the antenna through the needle guide, after automatic orientation of the device.](image)
was not counted as a needle (re)positioning, as it will not result in significant tissue damage. For both methods, antenna placement is checked using CT. The targets were considered to be reached when the distance between antenna tip and target was measured to be ≤5 mm, with a maximum of 5 needle manipulations, excluding the use of the hypodermic needle.

The accuracy was determined by measuring the error of needle placement in three ways: the Euclidian error, the lateral error, and the angle error. These were manually measured using the MM Reading module in Syngo.Via (v. VB10B, Siemens, Erlangen, Germany) and represent the absolute distance from antenna tip to target, the shortest distance from needle path to target, and the angle between target, entry point and needle path, respectively (figure 3).

**Statistical analysis**
The median (range) number of needle repositionings required to reach the target, the Euclidian (EEucl) and lateral error (ELat), the angle error (α), the time required to reach the target, and the number of CT scans required were compared for the freehand and NPS guided approaches using Chi-square or Mann Whitney U tests.

To compare the performance of novices with the performance of experts, the number of needle manipulations and the Euclidian error were compared, stratified by freehand and NPS approach. This comparison was done using the Mann-Whitney U test.

| Table 1: Overall results for freehand and NPS needle placement. Data are presented as median (range). |
|-----------------------------------------------|-----------------------------------------------|----------|
| Number of needle repositionings | 1 (1-4) | 0 (0-2) | <0.001 |
| Euclidian error (mm) | 4.5 (3.6-5.4) | 2.2 (1.0-3.4) | <0.001 |
| Lateral error (mm) | 3.6 (2.4-5.0) | 1.7 (0.4-2.1) | <0.001 |
| Angle error (degrees) | 2.3 (1.6-4.0) | 1.1 (0.6-1.6) | <0.001 |
| Number of CT scans | 3 (2-5) | 2 (2-3) | <0.001 |
| Time (min) | 12 (8-17) | 8 (7-12) | 0.017 |

*Fig. 2A. 3D printed phantom insert containing lung, ribs and twelve point targets. Gelatin is poured into this insert. B: Chamois leather skin stretched over phantom insert, after being placed in torso. The radiopaque grid is used during the procedures to determine the entry points.*
The effect of depth and angulation on accuracy was assessed by determining the correlation between the number of repositionings, the Euclidian, lateral and angle errors, and procedure time with depth and angulation using the Spearman rank test, stratified by freehand and NPS approach. Correlations with rho < 0.5 were considered weak. P-values < 0.05 were considered statistically significant. All analyses were performed in SPSS version 23 (IBM Corp, Armonk, USA). WH wrote the first draft of this manuscript. This study does not involve human or animal subjects, IRB approval was not required.

**Results**

The NPS resulted in significant improvements as compared to the freehand approach in all analyzed variables. With the freehand method, the median number of needle repositionings to reach the target was 1 (range: 0-4). In the NPS group, this number was zero (range: 0-2; p<0.001); the target was reached in the first attempt (46/48) 98% of the time. For all procedures combined, the total number of needle manipulations was 134 (freehand) and 51 (NPS). The accuracy, in terms of Euclidian and lateral error halved to 2.2 mm and 1.7 mm, respectively, using the NPS. Additional overall results can be found in table 1.

**Experience**

There was no difference in any results between novices and experts, with freehand approaches or with the use of the NPS. The freehand procedures resulted in a median Euclidian error of 4.3 mm (range: 1.6-8.6 mm) and 4.8 mm (range: 1.2-33.8 mm; p=0.248), for novices and experts, respectively. The median number of needle repositionings was 1 (range: 0-4) and 1 (range: 0-4; p=0.573), for these groups. Both novices and experts improved significantly using the NPS, with the median number of needle repositionings reduced to 0 (range: 0-2, p<0.001) and 0 (range: 0-0, p<0.001), and with median Euclidian errors of 2.4 mm (range: 0.5-9.6 mm; p<0.001) and 2.3 mm (range: 0.9-4.4 mm, p<0.001), respectively.
**Depth and angulation**

The effect of depth and angulation on needle repositioning and accuracy can be found in table 2. In the freehand group, only the angle error revealed a negative correlation with depth (\(\rho = -0.478, p<0.001\); more deeply localized targets resulted in a lower angle error). In the NPS group, depth was positively correlated with the lateral error (\(\rho=0.322, p=0.025\); deeper targets resulted in higher lateral errors). Figure 4 shows three boxplots of the angle category versus the number of needle repositionings, the lateral error, and time, grouped by method of approach. In freehand needle placement, the number of needle repositionings correlates with the angulation category (\(\rho=0.569, p<0.001\)). The number of needle repositionings is weakly correlated to the angulation category when using the NPS (\(\rho=0.29; p=0.045\)). For both groups, the angulation category is highly correlated with procedure time.

**Discussion**

The aim of this study was to compare robotic antenna placement with freehand antenna placement in a newly developed, realistic anthropomorphic liver ablation phantom. The secondary aim was to analyze the influence of experience on antenna placement accuracy. With the use of NPS guidance, the novices and experts made significant improvements in antenna placement accuracy and required fewer manipulations to reach the target in comparison to freehand needle placement. We could not demonstrate an effect of operator experience on any of the outcomes.

The median number of antenna repositionings reduced from 1 to 0. When including the initial antenna placement, the total number of antenna manipulations in the NPS group was 70% lower in the NPS group compared to the freehand group. If there had been no maximum of five antenna manipulation per approach, this difference would have even been larger. In the NPS group, 3 out of 48 approaches did not reach the target during the first antenna insertion. The three approaches that required additional antenna placement, were towards the deepest target that was placed just behind the dorsal pulmonary lobe, at a depth of 16 cm. The antenna deflected on the 3D printed lobe that was just between the entry point and the target, resulting in an error over 5 mm. This event clearly demonstrates the value of the anthropomorphic phantom, since in a real clinical scenario this might also occur. After repositioning of the device and reinsertion of the antenna, the target was reached adequately. The use of the NPS significantly reduces the number of antenna repositionings and was associated with a shorter duration of the procedure. In clinical practice, these factors might contribute to a decreased chance of hemorrhage, infection and tumor seeding.

**Table 2.** Correlation between technical outcomes and depth and angulation categories.

<table>
<thead>
<tr>
<th></th>
<th>Depth category</th>
<th>Angulation category</th>
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<tbody>
<tr>
<td></td>
<td>Freehand</td>
<td>NPS</td>
</tr>
<tr>
<td>Needle repositionings</td>
<td>Rho(^*)</td>
<td>p-value</td>
</tr>
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<td>Rho(^*)</td>
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<td>0.839</td>
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<tr>
<td>Euclidian error</td>
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<td>0.233</td>
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<tr>
<td>Lateral error</td>
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<td>0.880</td>
</tr>
<tr>
<td>Angle error</td>
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<td>0.001</td>
</tr>
<tr>
<td>Time</td>
<td>0.001</td>
<td>0.997</td>
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</table>
With the use of the NPS, the overall lateral error was approximately halved from 3.6 mm to 1.7 mm (p<0.001). In our opinion, the lateral error is clinically the most relevant accuracy measure. First, because repositioning the antenna along its path is easily achieved by further inserting or retracting the antenna. Secondly, because microwave ablation antennas generally produce an ellipsoid ablation volume along the antenna’s path. Both factors make a precise depth control less relevant than a minimal lateral error. In a previous phantom study, without entry point selection the lateral error of the NPS was determined to be 1.2 mm at a depth of 8 cm, which is comparable to the results in the present study [8].

The number of CT scans was significantly lower in the NPS group, despite the need for an additional fiducial CT scan after the positioning of the NPS. This is because fewer antenna repositionings require fewer CT scans. CT-guided needle placement with the NPS therefore has the potential to reduce the patient radiation dose.

No differences in number of antenna repositionings or antenna placement accuracy were found between novices and experts in the freehand or the NPS group. Because the novices both had only limited experience in CT-guided needle positioning, we expected the experts to fare better in freehand antenna placement. From these phantom experiments this did not become apparent. Despite this the NPS improved the accuracy of antenna placement in both novices and experts and none of the operators experienced difficulties in operating the device.
There was no strong correlation between target depth and any of the outcomes for either freehand or NPS procedures (all \(\rho<0.5\)). The angulation did significantly correlate with the number of needle repositionings. For NPS procedures only very weak (\(\rho=0.290, p=0.045\)), but for freehand procedures strongly (\(\rho=0.569, p<0.001\)), which demonstrates the advantage of using the NPS for antenna placement. For a human operator, reproducing a specific angle from a standard horizontal or vertical orientation requires some spatial awareness and practice. In figure 4 this is demonstrated by an increase in number of antenna repositionings from angulation categories 0 to 1. The out-of-plane approaches (angulation category 2) add an additional angulation which makes these procedures even more difficult. On top of that, the antenna cannot be displayed on a single CT slice, without using an oblique view, making it difficult to interpret how to correct the antenna direction, when initial antenna positioning was suboptimal. When using the NPS to guide the antenna, the angulation is irrelevant as the orientation is taken care of by the needle guide. The two outliers for the NPS procedures in angulation category 2 are caused by needle deflection on the phantom and not because of the angulation.

There is a significant correlation between the procedure time and the angulation categories for both methods. For freehand procedures this was strong (\(\rho =0.734\)) which can be attributed to the multiple needle repositionings required to reach the target. For NPS procedures there was a correlation too (\(\rho=0.545\)), because the out-of-plane procedures require more planning, also for the NPS, as it is sometimes more challenging to find a correct entry point. This is a problem that can be solved using more advanced image visualization and user interface.

The anthropomorphic phantom was specifically designed for this study. The chamois leather functioned very well as a skin substitute and the antenna was inclined to follow the previous needle path in the gelatin in case of a repositioning, just like in clinical practice. A downside to the phantom was that the needle could only be deflected by the skin substitute, ribs or lung, because the gelatin was homogeneous and lacked a liver capsule substitute. However, the microwave antenna that was used is very flexible compared to other ablation antennas available, compensating for this lack of needle deflection somewhat. The main advantage of using this phantom is the realism it created. The entry points and needle paths were not predefined, but had to be chosen by the operator, depending on the target’s position relative to the intercostal space and pleural cavity. The subsequent placement of the grid, marking the entry point on the skin, and if deemed necessary, the placement of a guide needle could all be simulated. The phantom could therefore also potentially function as a training device. Another advantage is that it validated not only the accuracy, but also the practical functionality of the system: the positioning of the device whilst making sure all fiducials were in the field of view of the CT scanner and whether all targets could be reached.

Various robotic systems have been developed to facilitate accurate needle placement. In a review from 2014, Arnolli et al. provide an overview of available devices [10]. These include larger, floor-mounted devices as the MAXIO and ROBIO (Perfint Healthcare, Chennai, India), with an accuracy of 6.5 mm [11], the iSYS1 (iSYS Medizintechnik, Kitzbühel, Austria), with an accuracy of 2.3 mm [12], that utilizes CT fiducials similar to the NPS; and the CAS-One (CAScination, Bern, Switzerland) that relies on visual
fiducials, with a reported accuracy of 4.9 mm [13]. In phantom studies, no other devices have demonstrated accuracy superior to 2.2 mm, as we report here.

In conclusion, experts and novices will benefit from using the NPS in CT-guided liver ablation as it eliminates the need for needle repositioning before adequate needle placement and increases its accuracy. Differences in outcome between freehand and NPS guided approaches increase in favor of the NPS when procedures require additional angulation. Especially for these procedures, adding the NPS to the workflow of the operator might reduce the chance of incomplete ablations.
References


