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CLINICAL INVESTIGATION   NON-VASCULAR INTERVENTIONS

CT-Guided Interventions Using a Free-Hand, Optical Tracking System: Initial Clinical Experience

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Abstract

Purpose The present study was designed to evaluate the geometrical accuracy and clinical applicability of a new, free-hand, CT-guided, optical navigation system.

Methods Fifteen procedures in 14 consecutive patients were retrospectively analyzed. The navigation system was applied for interventional procedures on small target lesions, in cases with long needle paths, narrow access windows, or when an out-of-plane access was expected. Mean lesion volume was 27.9 ml, and mean distance to target measured was 107.5 mm. Eleven of 15 needle trajectories were planned as out-of-plane approaches regarding the axial CT plane.

Results Ninety-one percent of the biopsies were diagnostic. All therapeutic interventions were technically successful. Targeting precision was high with a mean distance of the needle tip from planned target of 1.98 mm. Mean intervention time was 1:12 h. A statistically significant correlation between angular needle deviation and intervention time ($p = 0.007$), respiratory movement of the target ($p = 0.008$), and body mass index ($p = 0.02$) was detected. None of the evaluated parameters correlated significantly with the distance from the needle tip to the planned target.

Conclusions The application of a navigation system for complex CT-guided procedures provided safe and effective targeting within a reasonable intervention time in our series.

Keywords Computed tomography · Navigation · Image guidance · Biopsy · Image-guided therapy

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Introduction

Computed tomography (CT)-guided percutaneous procedures are widely used for a variety of different purposes. In general, they can be classified according to diagnostic or therapeutic intentions. Due to the reliable depiction of the target and structures along the needle path, CT-guided interventions are safe and precise [1, 2]. However, these minimally invasive procedures require a certain experience of the operator, because the needle is advanced without any real-time guidance, only reliant on the previously acquired CT image. Furthermore, some conditions limit the accessibility even for the experienced interventionalist. Challenging characteristics of CT-guided interventions are out-of-plane approaches, long, narrow access pathways, and respiratory mobile targets. Out-of-plane approaches from the axial CT plane can be compensated to a certain degree by tilting the CT gantry [3]. However, this technique is limited by the maximal angulation achieved by the gantry. In addition, not all helical multislice CT systems are capable of modifying the reconstruction algorithms used to create CT images without significant artefacts when the gantry is tilted [4]. A technique introduced to overcome the problem of maximum gantry tilt is the triangulation method; however, a comparably high number of needle readjustments and multiple CT controls were reported [5]. An alternative technique to perform out-of-plane approaches is CT fluoroscopy (CTF) [6]. In contrast to intermittent CT controls, CTF allows real-time guidance of the needle with high precision. However, CTF is associated with high radiation exposure to both patient and interventionalist [7]. A more recently introduced technology to counter the high demands of out-of-plane approaches or very small targets with narrow access pathways are CT-guided navigations systems. In contrast to conventional, cross-sectional, image-guided procedures, navigation systems provide interactive visualization of the needle in a preoperatively acquired 3D-dataset. The determination of the virtual 3D-dataset to the patient‘s body and the probe is performed via fiducial markers on the patient‘s body and the needle captured by the navigation system [8, 9]. Most navigation systems use surface markers on both the patient‘s skin and the probe that are captured by a camera device during intervention [8, 9]. These systems can reduce needle misplacement and repeated puncture attempts [9]. Navigation systems provide high targeting precision that is especially important in minimally invasive therapeutic interventions [9, 10]. For this type of procedure, targeting precision is essential, because it accounts for the therapy outcome [11]. Furthermore, navigation systems help to achieve reproducible results less reliant on the interventionalist’s experience than freehand punctures [9]. However, current optical navigation systems cannot compensate for internal organ movement (i.e., respiratory) or elastic organ deformation. These effects are not reliably depicted by surface markers [12]. For this reason, internal markers, such as marker needles and electromagnetically traceable vein catheters have been introduced [12–16]. Indeed, such invasive devices may cause complications and have been reported as a highly time-consuming step within the workflow [13, 14]. In the present study, the geometrical accuracy and clinical practicability of a CT-guided navigation system applied for complex CT-guided punctures has been evaluated.

Materials and Methods

Patients and Lesions

Fifteen CT-guided procedures with the described system were performed in 14 consecutive patients (8 females, 6 males) between January and June 2011. Regarding the total amount of 173 CT-guided interventions performed in our department within this period, the percentage of navigated procedures was 11.5 %. The procedures were retrospectively analyzed. Three radiologists with 2, 5, and 20 years of experience in interventional radiology performed the navigated procedures. The patients’ ages ranged from 45 to 82 years (mean 64), the mean body mass index (BMI) was 25.4 (range 17.3–35.9). Interventions performed comprised of 11 diagnostic (biopsies) and 4 therapeutic interventions (1 abscess drainage, 1 thoracic vertebroplasty, and 2 nephrostomies; Table 1). One biopsy was performed after a previous, nonnavigated biopsy resulted not diagnostic. Application criteria of the navigation system were an expected out-of-plane approach of more than 5 degrees or when the projected target diameter of the approach window or lesion projected orthogonally to the needle path was below 1 cm. Conscious sedation (Midazolam/Dormicum and Alfentanil/Rapifen) was administered intravenously if regarded necessary by the interventionalist. Vital parameters (heart rate, blood pressure, peripheral oxygenation) were continuously monitored. For all procedures but the vertebroplasty, for which an 11-gauge needle was utilized, 17-gauge coaxial introducer needles were used. For procedures on respiratory moving organs, the breath-hold technique was explained to the patient and practiced immediately before intervention.

Lesion volume was approximately calculated using the formula for ellipsoid-shaped bodies: $4/3 \times \pi (a \times b \times c)$; a, b, and c were the radii of the main axes.

Navigation

The applied, stereotactic, CT-guided navigation system (ActiViews, Haifa, Israel) has been commercially available since 2010 and received U.S. Food and Drug Administration marketing approval in 2011. The navigation system provides planning of virtual trajectories in a previously acquired CT-dataset as well as planning of entry and target point in the data volume.

After the planning procedure, a single-use reference pad with CT-visible fiducial markers is attached to the patient’s skin. A specifically collimated navigation CT scan is then performed (slice thickness 1 mm, 96×0.6 collimation, pitch 1.4), where the definite needle trajectory is to be planned. Mapping of the biopsy probe is achieved via optical tracking. For this purpose, a miniature, single-use video camera is attached to the end of the probe. During navigation, the mapping of the camera and the probe are determined relative to the fiducial markers on the reference pad on the patient’s skin. The combination of the above mapping enables determination of the needle position relative to the actual target (Fig. 1). The actual position of the probe in the navigation dataset is depicted in two planes on the navigation screen (Fig. 2). The needle course is controlled through intermittent CT scans as during purely manual interventions. All interventions were performed in

Table 1 Patient and target lesion specifications

Patient	Age (yr)	Sex	BMI	Depth of target (mm)	Target volume (ml)	Intervention time (min)	Organ/region	Out of plane	Respiratory mobile target	Underlying condition	Procedure type	Distance from probe end to planned target	Deviation of probe to planned needle path	Number of needle passages	Diagnostic/ therapeutic success
1	66	f	31.2	125	3.02	65	Right iliac lymph node	n	n	Endometrial carcinoma	Biopsy	Navigation aborted	Navigation aborted	Navigation aborted	y, without navigation
2	82	m	22.5	60	0.15	90	Sacral neuroforaminal lesion	n	n	Oropharynx carcinoma	Biopsy	0	0	3	y, metastasis
3	60	m	32	110	17.09	60	Pulmonary nodule	n	y	Leiomyosarcoma	Biopsy	2	2	1	y, metastasis
4	62	f	35.9	120	188.5	90	Intercologastric abscess	y	y		Abscess drainage	1	0	1	y, metastasis
5	45	m	25.2	130	14.38	70	Adrenal gland	y	y (transhepatic access)	Bronchial carcinoma	Biopsy	2.3	1	1	y, metastasis
6	45	m	25.2	125	0.35	50	Para-adrenal lesion	y	n	Mb. Hodgkin	Biopsy	1.8	2	1	y, reactive tissue
7	67	f	17.3	157	57.81	45	Left lobe liver lesion	y	y	Base of tongue carcinoma	Biopsy	3	0.5	1	y, metastasis
8	60	f	18.5	100	2.71	58	Para-adrenal lesion	y	n	Bronchial carcinoma	Biopsy	3	1	3	y, metastasis
9	78	f	19.5	75	11.94	150	Lumbar vertebral body	n	n	Vertebral body osteoporotic fract.	Vertebroplasty	2	2	2	y
10	66	f	19.3	95	44.23	69	Left lobe liver lesion	y	y	Ovarial-CA	Biopsy	1.8	1.5	2	y, metastasis
11[a]	66	f	31.5	127	38.68	65	Presacral tissue	y	n	Melanoma	Biopsy	1	0.3	1	y, metastasis
12	50	m	27.7	103	8.38	105	Pulmonary nodule	y	y	TBC	Biopsy	5.7	3	1	n
13	72	m	23.8	104	3.02	68	Left iliac mass	y	n	Lymphangioleiomyosarcoma	Biopsy	1	1	1	y, primary tumour
14	68	f	25.6	98	0.34	67	Renal pelvis	y	n (general anesthesia)	Aconuresis	Nephrostomy	2	1	1	y
14	68	f	25.6	84	0.34	35	Renal pelvis	y	n (general anesthesia)		Nephrostomy	1	0	1	y

m male, *f* female, *y* yes, *n* no

[a] This case has previously been published [28]

Fig. 1 Setup of the navigation system: the screen is located vis-a-vis to the interventionalist (*empty arrow*), usually on the contralateral side of the patient

a 64-slice CT scanner (Somatom Sensation 64, Siemens Medical Solutions, Erlangen, Germany).

Target and Planning Specifications

Mean lesion volume was 27.9 ml (range 0.34–188.5). The mean distance from the skin to the target lesion measured 107.5 mm (range 75–157). Localization of the lesions is depicted in Table 1. Eleven of 15 trajectories were out-of-plane approaches regarding the axial CT planes in contrast to 4 in-plane approaches.

Six targets were located in respiratory mobile body regions, and eight targets were located in body regions not influenced by respiratory motion (Table 1). One biopsy of a suprarenal gland was regarded as respiratory mobile because of the chosen transhepatic access. Two nephrostomies were regarded respiratory immobile because the (bilateral) procedure was performed under general anesthesia, and a reproducible breathing position could be achieved. A mean of 3.8 intermittent CT scans were performed during interventions.

Measurement Methods

Measurements of the deviation angle and the distance of the needle tip to the planned target were performed on the basis of procedural controls. After the intervention, the planned trajectory was manually plotted in the control scan with the needle in place by comparing the slice position of entry and target points for longitudinal position and anatomical landmarks and morphology of the target for axial position. If the needle was not advanced until or beyond the planned target, the closest distance from the needle trajectory to the target point was taken as distance from probe end to target. That distance was measured in a plane perpendicular to the planned trajectory (Fig. 3), which led to only one error value instead of lateral and longitudinal error values as depicted in other studies [10, 16]. In case we counted more than one needle passage, we used the initial passage to measure the deviation angle of the final probe

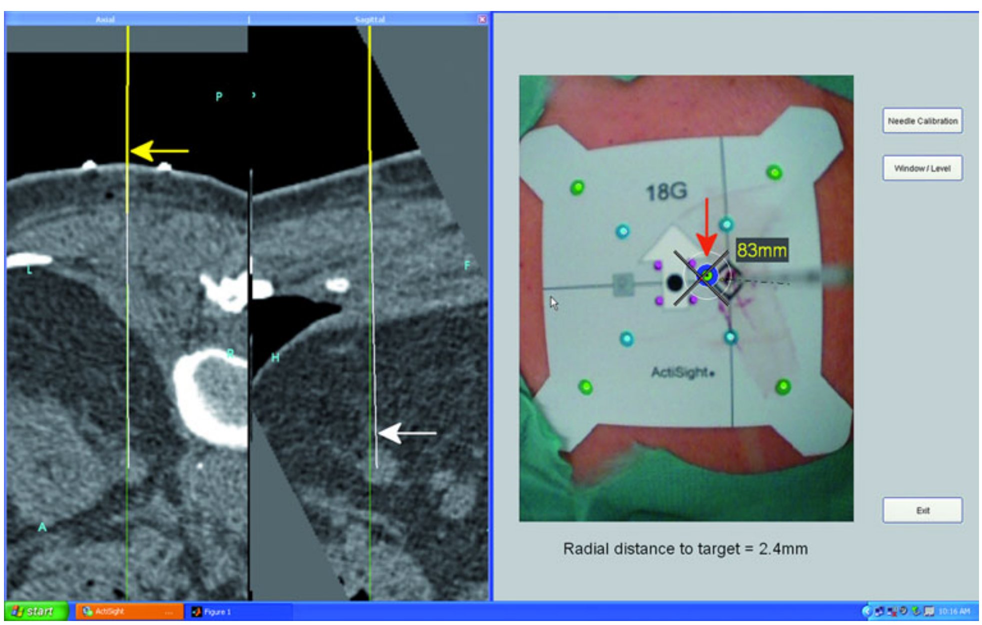

Fig. 2 Biopsy of a pararenal mass (tip of *white line* on the *left side* of the screen). On the screenshot of the navigation system, the *yellow line* depicts the needle and its actual position (*yellow arrow*), and the *white line* shows the planned needle path (*white arrow*). Targeting is possible via following the *white line* on the biplanar orthogonal view on the *left side* or via centering the *green dot* (*red arrow*) on the *crossed lines* on the *right* segment of the screen

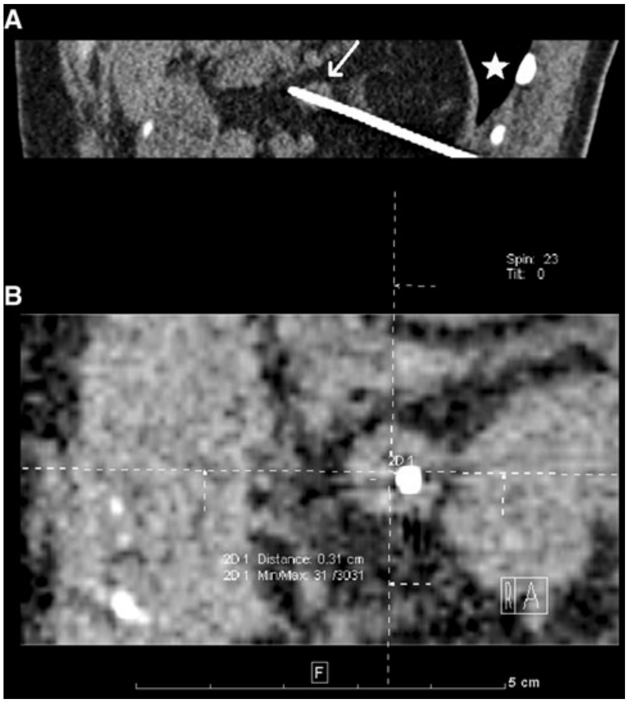

Fig. 3 **A** Final needle placement of the procedure depicted in Fig. 2 in the pararenal mass (*white arrow*). An out-of plane approach was chosen to avoid the puncture of the posterior pleural recessus (*). **B** Orthogonal view to the needle to measure the deviation from the planned needle path

trajectory to the planned needle path. More than one needle passage was defined as pulling the needle back and advancing it again.

Control Group

In order to rank the intervention time and the number of intermittent CT scans, we randomly chose 15 CT-guided interventions out of the same period as the study group. This cohort comprised seven biopsies, six drainages of fluid collections, one diagnostic aspiration, and one lumbar periradicular infiltration. The mean intervention time was 46.8 min. The mean number of intermittent CT scans during intervention was 4.7.

Results

In total, 14 of 16 procedures (87.5 %) were performed successfully. Ten of 11 biopsies were diagnostic (91 %); 1 was diagnostically unsuccessful due to excessive, pain-related patient movement. In one biopsy, the application of the navigation system had to be aborted due to hypermotility of the subcutaneous tissue, due to which the reference pad could not provide exact determination of the actual position of the probe in the 3D-dataset. This procedure could be finished without use of the navigation system but was counted as a failure of the system. Six biopsies revealed malignancy, and one showed reactive inflammatory tissue. In the latter case, CT controls did not show recurrence 10 months after biopsy. One abscess was evacuated, and the thoracic vertebroplasty was successfully performed via the planned trajectory. Bilateral nephrostomies were performed successfully in an anesthetized patient. In this case, the navigation system was applied because the pyelon was not dilated. The procedure was performed due to severe incontinentia.

Mean deviation of the final probe trajectory to the planned needle path was 1.18 ± 0.91 degrees (standard deviation). Mean distance from the probe end to the planned target was 1.98 ± 1.46 mm (range 0.5–5.7). Mean number of needle passages was 1.3 ± 0.76 (range 1–5). Intervention lasted from patient positioning to postinterventional CT control 1:15 h in average (0:35–2:30). No periprocedural complications occurred, and no postprocedural complications were mentioned in the patient records.

Statistical Analysis

Deviation angle of the probe to the previously planned path and distance from the probe end to the planned target showed a significant correlation ($p = 0.01$). After evaluating both parameters for Gaussian distribution, a multivariate linear model with difference of planned to final trajectory angle and distance from planned target as dependent variables and respiratory movement, in-/out-of-plane approach, BMI, intervention time, lesion size, number of needle passages, and needle path length as independent factors was applied.

Intervention time (0.007), respiratory movement ($p = 0.008$), BMI (0.02), and a combination of out of plane approach and respiratory movement ($p = 0.003$) significantly correlated with the deviation angle of the probe trajectory. The p value of out-of-plane approach ($p = 0.06$) was marginally above the range of statistical significance ($p < 0.05$). However, none of the parameters showed a significant correlation with the distance of probe end to planned target (Table 2).

The study group and the control group were compared with respect to intervention time and intermittent CT scans. An unpaired Student's t test revealed a statistically significant difference regarding intervention time in favor of the control group (72.4 vs. 46.8 min, $p < 0.0001$). The comparison of the number of intermittent CT scans (3.8 in the study group vs. 4.7 in the control group) revealed a p value of 0.07. However, this was not considered significant, because we set the level of statistical significance at $p < 0.05$.

Table 2 Statistical analysis

	Respiratory Movement	Out-of-plane approach	BMI	Intervention time	Lesion volume	No. of needle passages	Needle path length
Deviation angle probe to planned needle path	0.008	0.06	0.02	0.007	0.94	0.72	0.51
Distance from probe end to planned target	0.38	0.25	0.09	0.63	0.5	0.33	0.18

p values of the multivariate linear model with deviation angle of probe to planned needle path and distance from probe end to planned target as dependent variables and respiratory movement, in-/out-of-plane approach, BMI, intervention time, lesion size, number of needle passages and needle path length as independent factors. A p value < 0.05 was considered indicative of a statistically significant correlation

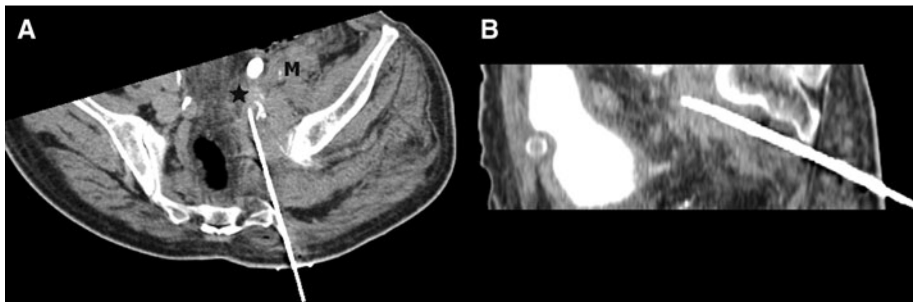

Fig. 4 Repeat biopsy of a *large, left* iliac mass (M). A solid, contrast-enhancing part (*) of the partially necrotic mass was biopsied via an out-of-plane approach through the greater sciatic foramen (lymphangioleiomyosarcoma)

Discussion

The intention of a navigation system for CT-guided interventions is to avoid deviation of the needle to the planned trajectory providing maximal targeting precision. Likewise, the risk of injuring sensitive structures along the needle path can be minimized. The results of the present study indicate that the application of a CT-based, freehand navigation system for complex percutaneous procedures ensures a high accuracy both in terms of needle path deviation and targeting precision. Targeting precision was excellent from a qualitative and quantitative point of view. The geometrical targeting accuracy of 1.98 mm in our study is in accordance to the precision of navigated liver punctures reported by Schullian et al. (3.64 mm) [10] and phantom model studies of navigation systems (Stoffner et al.: navigated: 1.94 mm, robotically assisted: 1.69 mm; Appelbaum et al. 2.6 mm) [17, 18]. In the mentioned studies, navigation systems were equipped with an aiming device fixing the needle along the planned trajectory. In contrast to these studies, we applied a freehand navigation system without aiming device or robotic assistance. Compared with aiming devices, freehand navigation systems can be used with every standard CT scanner. No additional patient preparation compared with nonnavigated procedures is required. This makes freehand navigated interventions less time-consuming than those with aiming devices or robotic assistance. A further advantage of the applied navigation system is the comparably low price of $75,000 USD, which includes disposables for a year. Subsequent disposables amount to $300 per procedure. In this context, it must be mentioned that the applied navigation system is only applicable for CT-guided punctures. In contrast, navigation systems of the above-mentioned studies are multipurpose intraoperative navigation systems that run with every cross-sectional imaging modality [10, 17, 18].

In the present study, none of the evaluated parameters showed a statistically significant correlation with the puncture precision (distance from needle tip to planned target). Indeed, several factors were significantly correlated with the angular deviation of the probe trajectory. Two parameters were directly related to the procedure type and region: out-of-plane approach and respiratory motion. Out-of-plane approaches are more cumbersome than in-plane approaches, because they require orientation in all three spatial directions (Figs. 3 and 4). Furthermore, 3D reconstructions of the CT data are mandatory in these approaches, and therefore, many operators choose in-plane access whenever possible. Access within the CT plane reduces the degrees of freedom by one to the x and y component within the CT plane. In this context, it is conceivable that even navigated, freehand, out-of-plane approaches are associated with a higher needle deviation due to lack of spatial orientation. However, when operators become more familiar with advancing the needle only guided by the visualization on the navigation monitor, needle deviation may further diminish. In this context, we experienced a learning effect both in avoiding pitfalls of the system and in coordinating the needle movements on the two-plane tracking monitor. In contrast, respiratory motion is a challenge both for navigated and conventional image-guided procedures. Internal target motion caused by respiratory movement cannot be reliably depicted by surface markers [12]. Apart from invasive internal markers to track respiratory motion [13, 14], recent publications reported promising results with a noninvasive breath-hold control system [19, 20]. In the present study, the majority of procedures in respiratory mobile body parts were successfully performed during breath hold in breathing positions previously practiced with the patient.

In our series, 1 of 14 navigated punctures was unsuccessful. Factors that led to the maximal needle deviation of the series in this case (5.7 mm) were pain-related patient movement and extensive respiratory motion. In our institution, transcutaneous biopsies are performed routinely under conscious sedation. However, in a small minority of patients, sufficient pain control and sedation may not be achieved with the maximal dosage applied without an attending anesthesiologist [21].

One procedure in a patient with a high BMI (32) had to be aborted due to hypermotility of the subcutaneous tissue. In this case, a reliable navigation could not be ensured in consequence of a highly mobile reference pad on the patient's skin. The puncture could successfully be finalized without navigation. The latter case illustrates a problem of surface fiducials especially in obese patients (BMI > 30). Regarding the applied navigation system, the fiducial markers on the patient's skin are in close proximity to the probe (in fact, the needle runs through the reference pad). Especially in ventral abdominal approaches and obese patients, advancing a coaxial needle through the subcutaneous tissue may cause significant displacement of the patient's skin and the surface fiducials. These effects are reflected in a significant correlation of BMI and angular needle deviation in our series. The effect may be reduced by fixing the skin fiducials with long sterile tape to decrease skin motility.

The mean intervention time for the nonnavigated procedures in a random comparison collective was significantly shorter than in the study group (46.8 vs. 72.4 min). However, in this collective, no out-of-plane approaches were required and none of the procedures was performed under general anesthesia. In contrast, 11 of 15 approaches were out of plane in the study group and two procedures were performed under general anesthesia. Furthermore, the optical tracking system was only applied when we expected a technically difficult procedure. Therefore, a certain extension of intervention time compared with standard procedures was expected and tolerated.

The application of a navigation system involves a certain amount of procedures performed with the system to gain and keep experience. In a recently published paper, it could be shown that an experienced user can significantly decrease the time of interventions with an applied navigation system [9]. In the present study, the applied navigation system operated reliably without technical errors, no peri- or postinterventional complications were reported in our series. The mean number of intermittent CT controls was lower in the study group (3.8 vs. 4.7, $p = 0.07$). However, this was not considered significant, because the level of statistical significance was set to $p < 0.05$. Diagnostic accuracy of nonnavigated CT-guided biopsies ranges from 64 to 97 % for pulmonary lesions [22, 23]. Sundaram et al. [24] reported an overall accuracy of 95 % for fine-needle aspiration (FNA) of abdominal masses. Accuracy of FNA for pelvic lesions ranges from 80 to 96 % [25, 26]. A series of CT-guided musculoskeletal biopsies depicted an overall accuracy of 71 % [27]. However, mean lesion volume and needle path length is not consistently denoted throughout the mentioned studies.

In conclusion, the results of the present study indicate that the application of an optical tracking system for complex CT-guided procedures provided safe and effective targeting in this series. In our experience, image-guided navigation systems can facilitate CT-guided procedures especially if out-of-plane approaches of small targets with long trajectories or adjacent risk structures are warranted.

Conflict of interest Tilman Schubert, Augustinus L. Jacob, Michele Pansini, David Liu, Andreas Gutzeit, and Sebastian Kos declare that they have no conflict of interest.

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