GE HealthCare

IMACTIS Navigation

Technical and clinical white paper on electromagnetic navigation for guided percutaneous needle interventions

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Content

Introduction

Image-guided percutaneous approaches are increasingly used during interventional radiologic procedures with either diagnostic purposes or therapeutic aims. The objective in non-vascular 3D-image guided interventional radiology is to accurately place one or more needles from a skin entry point to a target via a safe path, during interventions such as biopsies, ablations, drainages. Adequate positioning of the instrument tip at the predefined target is crucial to achieve interventional success, but may be challenging due to small lesion size, deep target location or the need to adopt out of anatomical planes (in particular axial plane) trajectories.

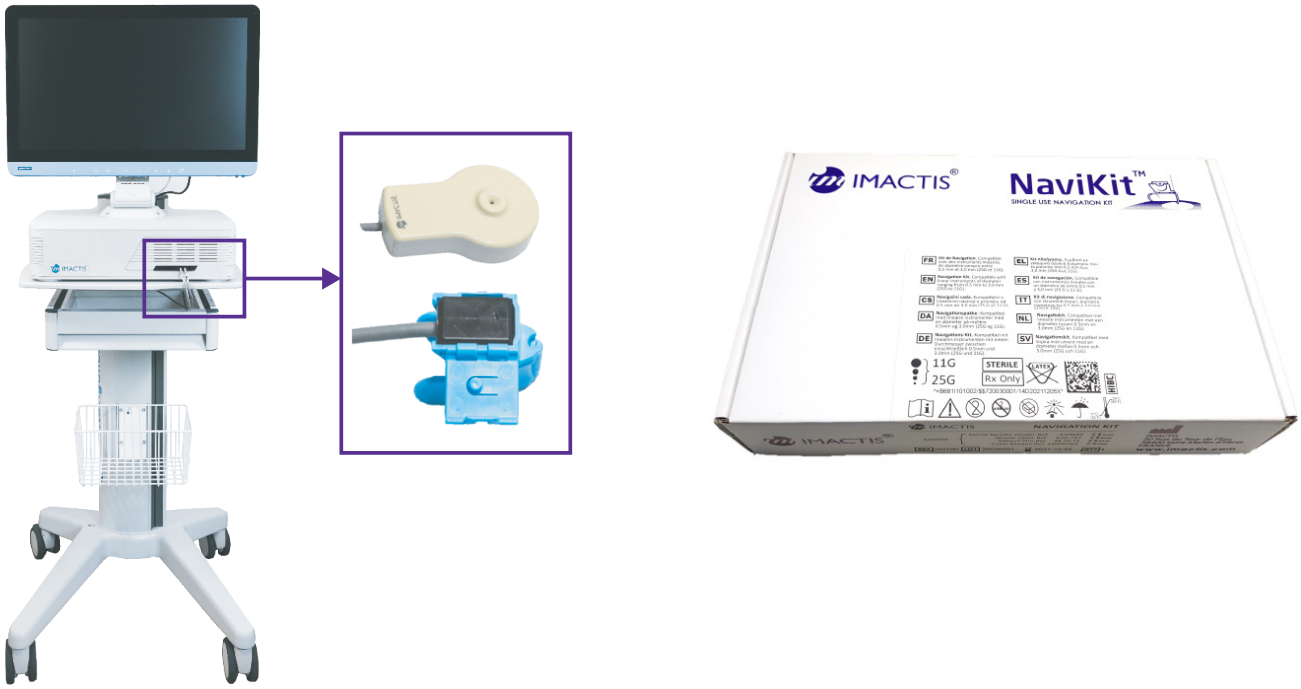
Conventional practice involves planning needle paths on per-procedural axial computed tomography (CT) images and then reproduce the planned trajectory on the patient, requiring the physician to mentally map the 3D patient anatomy to position the instrument according to the planned location and orientation. Needle insertion is often done following a stepwise approach during which, after each instrument placement, its position is checked using an imaging control to evaluate deviations of the needle course with respect to the planned path. Multiple adjustments may be made during needle insertion to coincide with the initial plan to reach the target.

This approach can cause collateral tissue damage, high radiation doses and prolonged procedures, particularly during clinical cases where there is little room for error or complex approaches such as out-of-axial-plane trajectories.

Product description

IMACTIS CT-Navigation is an electromagnetic (EM) navigation system that provides assistance to the physician for anatomical exploration, trajectory planification and needle insertion during percutaneous interventions performed under 3D CT controls.

The standalone hardware platform includes a touchable screen and an EM localization system. It ends with two components: the patient fiducial and an EM sensor.



IMACTIS CT-Navigation system including the workstation, fiducial and EM sensor. Also shown the kit of the assosiated disposable accessories NaviKit.

The patient fiducial includes a small EM field generator as well as specific geometric components used for spatial registration between the images and patient. During clinical use, the patient fiducial is fixed on the patient, close to the puncture site, before image acquisition. Using a small EM field generator has the benefit of reducing metallic disturbance as well as not requiring additional hardware mounted on an arm attached to the platform.

When the EM sensor is set in the magnetic field, the system is able to track, in real-time, the position and orientation of the magnetic sensor. During clinical use, the sensor is set in a needle holder allowing the surgical instrument to be tracked. Using EM localization allows real-time tracking of the instrument regardless of orientation and without any constraints on keeping a free line-of-sight between camera and instrument, much like an optical localizer.

Any instrument angulations can be used, without concern for instrument tracking continuity or field of view obstructions, such as surrounding ablation probes, hydro/carbodissection probes or thermal monitoring needles.

Disposables used during the percutaneous intervention are all provided in a kit.

The system has been designed to be intuitive, easy to use and requiring short learning-curve. It can be easily integrated in the clinical workflow. No mouse nor keyboard are necessary. The system is mounted on a trolley and can be moved from one interventional room to another. It is compatible with existing and new CT scanners.

Use of the system

Before use of the system, the fiducial is fixed on the patient's skin close to the puncture site for inclusion in the acquisition volume. After acquisition, images are pushed to the IMACTIS CT-Navigation system from the CT console using the local network.

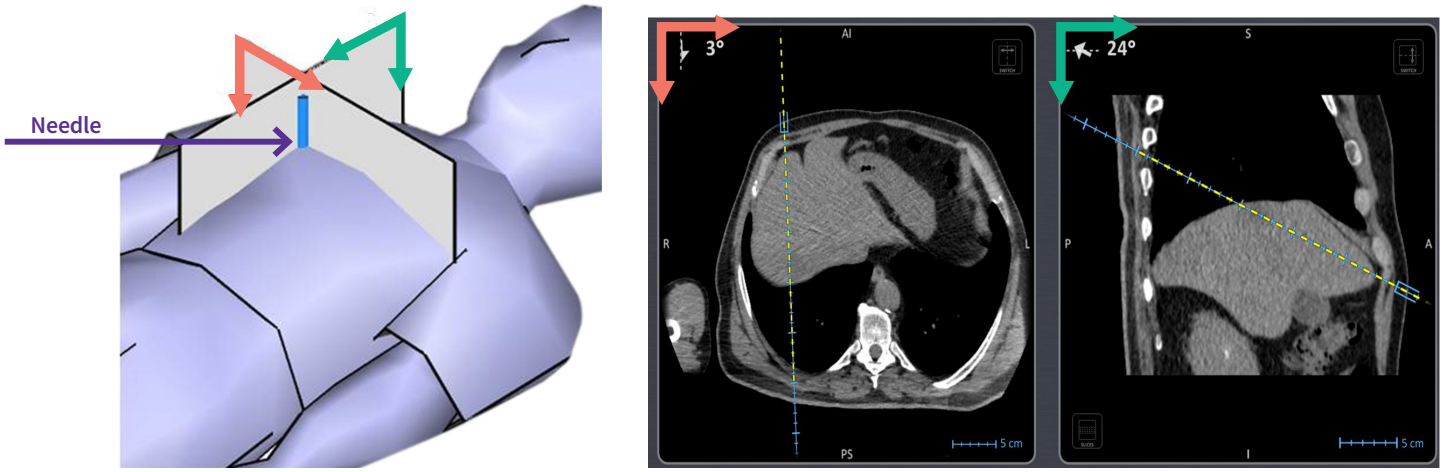
Computed Tomographic images that can be loaded on the IMACTIS CT-Navigation system are DICOM axial images acquired on CT imaging system.

Images are then loaded on the IMACTIS CT-Navigation system without any modification to maintain original image quality and a 3D volume is built. A quick and fully automatic registration is then performed to register clinical images with the patient. Automatic registration is performed by detecting fiducial specific geometric components in the images. Those easily recognized, air-filled components avoid artifacts and provide accurate registration (patented solution).

After registration, the system displays two 2D reconstructed views, that contain the anticipated needle path. The two images are orthogonal, one to the other, allowing the localization in 3D of the needle in regard to patient anatomy.

The 2D views displayed on the screen are extracted in real-time from the 3D volume depending on the position and orientation of the needle holder, allowing real-time navigation in patient images. Images displayed on the system are pseudo-axial, pseudo-sagittal or pseudo-coronal depending on the needle holder position and orientation allowing the system to provide the most understandable and efficient views.

Images displayed during navigation can be zoomed and translated, using two finger manipulation like on a smartphone, allowing focus on a specific region of interest or to compensate for a large acquisition field of view.



Clinical images displayed and their orientation

Use of the system *(cont.)*

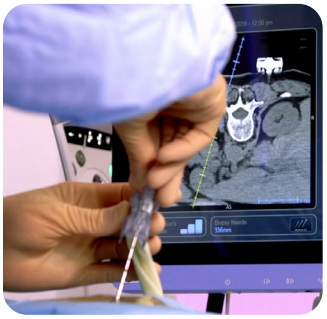
A benefit of moving the needle holder close to the patient skin and changing the needle holder orientation is that physicians can explore patient anatomy in a very intuitive way, and are able to plan trajectories while bedside, close to the patient.

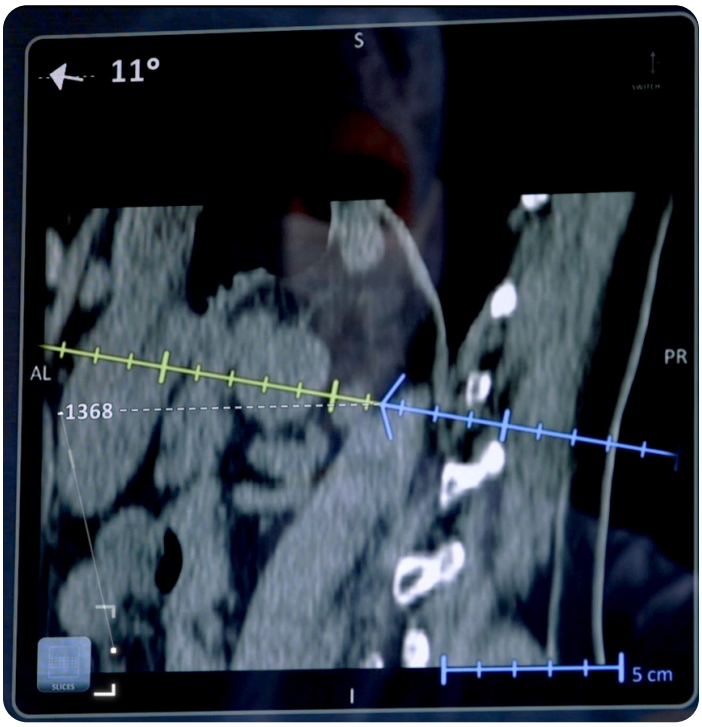
If the event skin entry point is not clearly defined, before switching to sterile conditions, physicians can explore patient anatomy using the non-sterile needle holder under non-sterile conditions. Once the trajectory is determined, the entry point can be marked on the skin and the trajectory can be saved. Defining the skin entry point will help placement of the sterile drape window in the correct position.

If already under sterile conditions the process is the same, except the instrument can be inserted in the needle holder. This allows for exploration of the patient's anatomy to find the best path to the target and simultaneous placement of the first needle.

During navigation, once needle length has been set in the software, the system is able to provide the instrument tip position. This is accomplished by sliding the needle holder at the needle hub. The software then displays the tip position allowing physicians to recognize where the needle is in regard to critical organs. Physicians can then decide to continue needle insertion or to perform an imaging control.

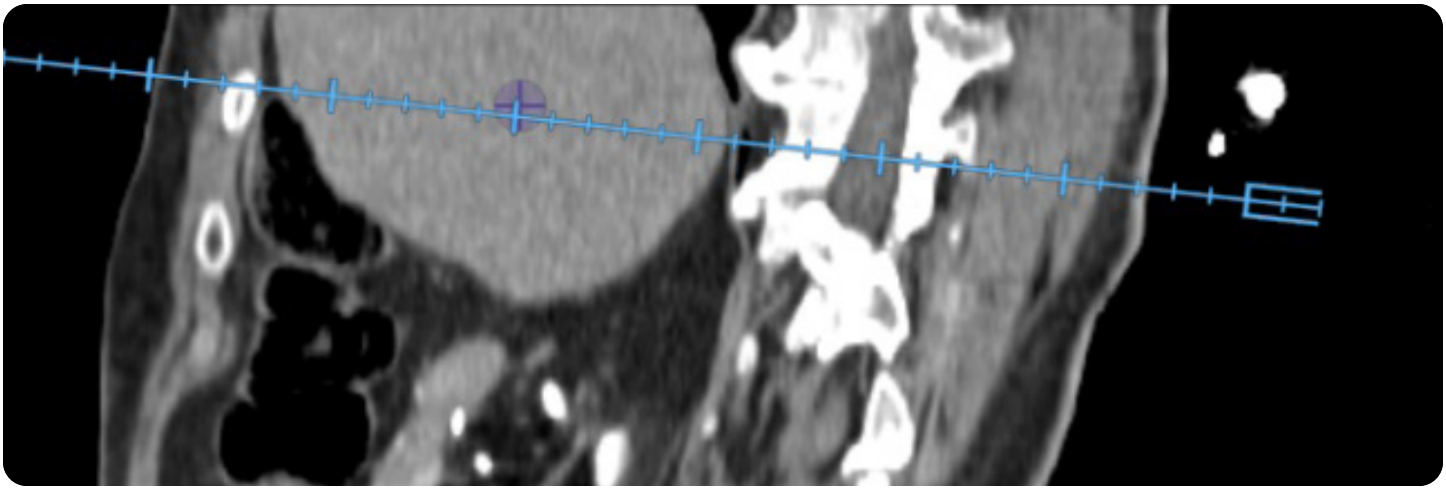
During this step, translation table value at the needle tip position is also displayed. This provides an understanding of where the table should be positioned if CT-fluoroscopic images are being used to check needle tip position, thus avoiding repetitive table translations and additional non useful x-rays emission.





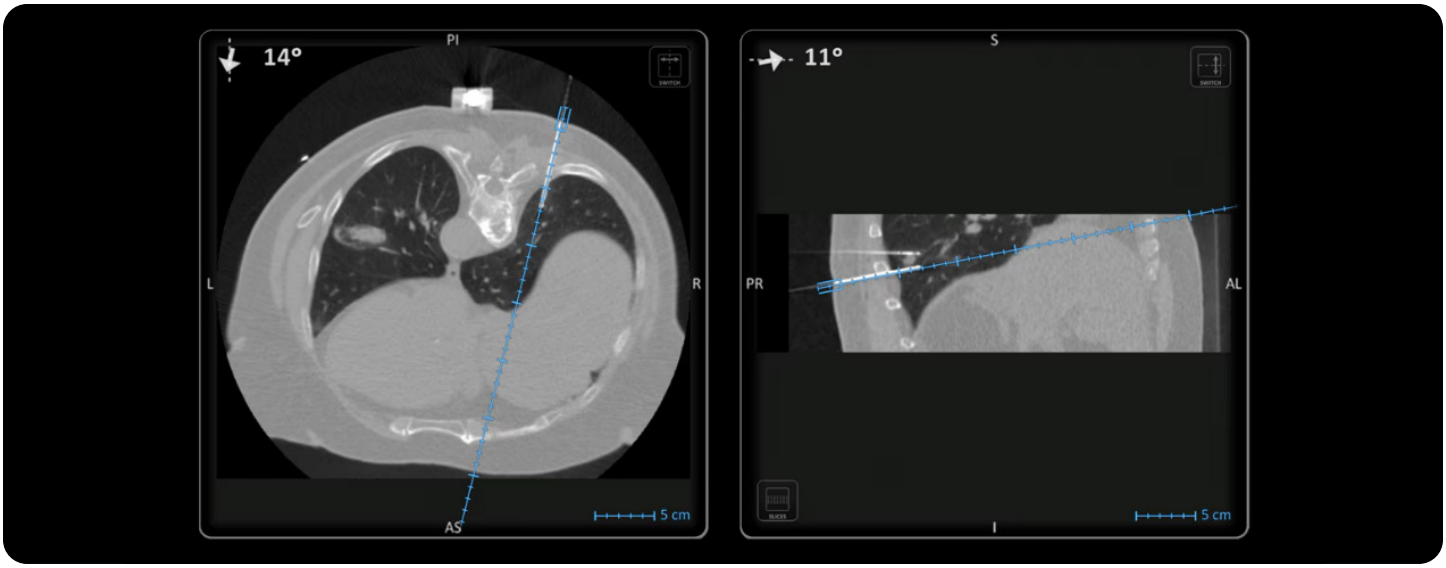
Use of the system *(cont.)*

Optionally, the marker functionality can be used allowing physicians to identify regions of interest in patient anatomy, such as tumors or a lesions visible in an injected series. In the event a new acquisition series is loaded, the marker will stay visible in this new series.



Identification of a region of interest using a marker during a hepactic procedure.

At any time during the intervention, a new acquisition can be performed and transferred to IMACTIS CT-Navigation system, allowing verification of needle position in 2 MPR views, continued navigation in updated anatomical images or insertion of a second needle in relation to first needle position. The system is continuously checking receipt of new images, meaning that no input is necessary to load updated images.



During a lung ablation, a second needle is navigated on a control CT after positioning of the first needle.

IMACTIS CT-Navigation workflow is not based on a rigid step-by-step workflow. Once images are loaded in the system, saving a planned trajectory, adding a marker or any other functionality is optional. This facilitates the integration of the system in the medical workflow without disruption of physician's procedural habits.

Scientific evidence of the benefits of IMACTIS CT-Navigation in 3D guided procedures

Several clinical studies have demonstrated the benefits of IMACTIS CT-Navigation for CT guided interventions in terms of feasibility, accuracy, procedure time and radiation dose over a various range of clinical indications*. The methodology, outcomes and limitations of these studies are described bellow and summarized in Table 1. Additional details for each study are included in the published papers referenced below.

First phantom evaluation of IMACTIS CT-Navigation for out-of-plane CT-guided procedures

A first phantom study was performed to assess the benefits and added value of electromagnetically guided navigation system in comparison to standard CT guidance[1]. The usability and accuracy of Imactis, was quantified across 54 operators without prior experience with the navigation system (11 senior interventional radiologists, 8 senior mostly diagnostic radiologists, 30 radiology residents, 4 radiology technicians, and one veterinary experienced in CT-guided procedures) who had only one attempt, following a double oblique and out-of-plane trajectory, to reach 6 mm targets located at a depth of approximately 10 cm from the surface of the phantom. In a random order, each operator attempted to reach one target using a given guidance method (standard CT guidance or Imactis) and then a second target using the other method.

Out of a total of 54 attempts, the needle crossed the target at first attempt and the puncture was considered successful in 22 cases (40.7%) using Imactis while none of the operators managed to reach the lesion with standard CT guidance ($p < 0.0001$). Needle trajectory accuracy was higher with Imactis with a median distance from the center of the target of 3.7 mm versus 15 mm with standard CT guidance ($p < 0.001$). Additionally, the overall biopsy time was significantly shorter with Imactis with a median of 76 s versus 214 s with standard CT guidance ($p<0.001$).

This phantom study showed “the use of IMACTIS CT-Navigation system significantly reduced procedure time and gained accuracy compared with the standard CT-guided method when performing complex out-of-plane punctures.”

Clinical benefits of IMACTIS CT-Navigation in comparison to conventional CT guidance

Durand et al. conducted a prospective clinical trial to assess the accuracy and usability of the Imactis CT navigation system, by comparing navigated procedures (NAV group; 60 patients; mean age =59±16.3 years) and conventional CT guided ones (CT group; 60 patients; mean age =62.2±13.5 years)[2]. A full range of percutaneous CT interventions on the chest, abdomen, pelvis and bones, including biopsy (21 vs. 17 in NAV and CT groups respectively), drainage (21 vs. 24 in NAV and CT groups respectively), tumor ablation (5 in each group), sympathicolysis (7 in each group) and joint infiltration (4 vs. 6 in NAV and CT groups respectively) were performed by 19 different radiologists (11 seniors, 8 residents).

The accuracy of the initial needle placement, defined as the maximum distance and angle between the planned trajectory and the achieved needle trajectory was significantly improved ($p<0.001$) in the NAV group compared to the CT group (distance error: 4.1 vs. 8.9 mm; angle error: 4.7 vs. 7.9 degrees; respectively). The gain in accuracy remained significant irrespective of whether the operator was a resident or a senior), whether the operator performed few (≤15) or many (>15) interventions, and whether the procedure was anticipated as being easy or difficult.

Significantly fewer control acquisitions were necessary to reach the target in the NAV group than in the CT group (mean number of control acquisitions: 2 vs. 3 respectively, $p = 0.01$). Indeed, because of the increased accuracy, operators in the NAV group progressed more quickly to the target and reduced their number of intermediary control acquisitions. Accordingly, the Xray dose delivered by the controls acquired during the progression to target was smaller using Imactis than using CT guidance alone (mean DLP: 225 vs. 297 mGy.cm, respectively; without statistical significance: $p = 0.076$).

* Most of the publications cited in are single center studies and varied by clinical indications, study protocols and comparison methods. The results and conclusions obtained in these studies are only applicable to the specific studies cited and may not be generalizable or reproducible in your practice.

Clinical benefits of IMACTIS CT-Navigation in comparison to conventional CT guidance *(cont.)*

Overall operator satisfaction was higher in the NAV group than in the CT group (mean satisfaction score on a scale of 10: 9 vs. 8 respectively, p=0.025). Additionally, clinicians considered their intervention to be more accurate (p<0.001) and perceived more freedom to perform out-of-plane trajectories (p=0.03) when using Imactis.

This study showed that using Imactis CT-Navigation allowed a consistent gain in accuracy irrespective of whether the operator was a resident or a senior, whether the operator performed few or many interventions, and whether the procedure was anticipated as being easy or difficult.

The efficacy of Imactis was assessed specifically in percutaneous lung biopsies in comparison to CT guidance by Lanouzière et al. over 120 patients with suspected primary or secondary lung malignancies[3]. Procedures were performed by 8 senior interventional radiologists (> 5 years of practice) and 2 residents being under the direct supervision of seniors. Half of the interventions were performed using Imactis (NAV group) and the other half using standard CT (CT group) guidance (mean age: 66 vs. 68 years, p=0.576; mean BMI: 26 vs. 24, p=0.187; respectively).

In the NAV group, lesions were significantly smaller (median size: 20 mm vs. 29.5 mm; p = 0.007), deeper from the skin surface (70.2 ± 22.1 vs. 62.2 ± 16.8; p=0.028) and required significantly larger trajectory angles to be reached (15.5 vs. 6.0 and 10.0 vs 1.0; both p < 0.001) than the CT group. Despite significantly more lesions were hence classified as “difficult” in the NAV-group than in the CT-group (27 vs. 11; p = 0.0017), there was no statistical difference in the technical success (defined as the achievement of the needle progression to the targeted lesion) and diagnostic success (when histological diagnosis was accomplished with the punctured sample) rates between the two groups (95.0% and 93.3% vs. 93.3% and 91.6%, respectively; both p=1).

The duration from biopsy planning to initial needle placement was significantly longer in the NAV-group than in the CT-group (13 vs.11 min; p = 0.018). However, there was no significant difference regarding the number of CT acquisitions required during that step and the dose length product was significantly lower in the NAV-group as compared to the CT-group (142.9 mGy.cm vs. 188.2 mGy.cm; p = 0.013).

The duration from skin puncture to needle progression toward the target lesion was significantly reduced and the Dose Length Product associated to that step were significantly lower in the NAV group compared to the CT group (mean duration: 9 vs. 12 min respectively, p = 0.042; mean DLP: 611.6 vs. 849.5 mGy.cm respectively, p = 0.001,).

Overall, there was no significant difference in whole procedure duration or in the number of control acquisitions (mean duration: 28 vs. 29 min respectively, p = 0.497; mean number on control acquisitions: 8 vs. 9, respectively; p = 0.066). However, the total radiation dose was significantly lower the NAV-group than in the CT-group (mean total DLP: 1059 vs. 1481 mGy.cm respectively, p< 0.0001).

This study showed that the use of Imactis CT-Navigation system for percutaneous lung biopsies was more efficient compared to conventional CT methods. It offered the ability to find the best trajectory quickly, decreasing the need for needle repositioning and lowering the total radiation dose.

Ringe et al. assessed the accuracy and applicability of an EM navigation system for CT-guided microwave ablation (MWA) of hepatic tumors in comparison with conventional CT-guidance[4]. Among 34 patients with liver tumors (22 primary, 14 metastases, mean size 20 mm), 17 were prospectively treated using the IMACTIS workstation for navigation (by two radiologists with more than 10 years of experience) then retrospectively matched to 17 patients treated using conventional CT-guidance (mean age: 63 vs. 63, p=0.96554; mean lesion size: 20.29 vs. 20.47, p=0.9513; respectively).

There was no statistical difference in the meantime needed for antenna placement between Imactis and conventional CT guidance (9±7.3 vs. 11.45±6.1 min; p>0.05). However, when using Imactis, significantly fewer single slice control scans were acquired for antenna positioning (mean 2.5 vs. 5.9; p<0.0001) and the associated radiation exposure for antenna placement was significantly lower (CTDI: 0.46 vs. 1.34 mGy/BMI; p<0.0001). Additionally, the placement of the antenna was more accurate when guided with Imactis compared to conventional CT guidance (mean total distance between the anticipated position of the antenna feed and the achieved position: 2.4 vs 3.9 mm respectively, p = 0.0469); especially in sagittal (mean plane deviation: 2.2 vs. 5.1 mm respectively, p=0.008) and coronal (mean plane deviation: 2.3 vs. 4.5 mm respectively, p=0.0367) planes.

This study showed that the use of IMACTIS CT-Navigation in CT-guided microwave ablation of hepatic tumors treated with an angulated approach resulted in significantly higher accuracy and fewer control scans needed to complete the procedures as compared to interventions performed with conventional CT-guidance only.

Clinical benefits of IMACTIS CT-Navigation in comparison to conventional CT guidance *(cont.)*

Teriitehau et al. assessed the impact of Imactis on the procedure duration and the associated radiation dose delivered to patients during percutaneous CT vertebroplasty[5]. Among 37 sequential vertebroplasty considered in this study (eighty-eight vertebrae were treated), the first 21 consecutive procedures were performed with Imactis guidance while the last 16 were conducted with conventional CT guidance (mean age:65±9 vs. 60±9, p=0.079; mean number of vertebrae treated: 2 vs. 3, p=0.087; respectively).

The median total procedure duration was lower with Imactis guidance than with conventional CT guidance (50 vs 100 min, respectively; p<0.001). In average, clinicians guided by Imactis treated a vertebra in 20 min while they needed 39 min with conventional CT guidance (p<0.001).

Reductions of the median dose length product delivered during the whole procedure per patient (1883 vs 2116 mGy.cm) and per vertebrae treated (812 vs 1090 mGy.cm) was also observed when using Imactis compared to conventional CT guidance. Although these reductions appeared clinically meaningful to the authors, they did not reach statistical significance (p=0.263 and p=0.495, respectively). However, when considering only the needle insertion phase, the reduction of the radiation dose delivered to the patient was statistically significant reduced when using Imactis (median Interventional Dose Length Product: 305.6 vs. 975.2 mGy.cm using Conventional CT guidance, p<0.001). It allowed to significantly reduce by a factor of 2.3 the Interventional Dose Length Product per vertebrae treated delivered during the needle insertion phase in comparison to conventional CT guidance (153 vs. 353 mGy.cm, respectively; p<0.001).

This study showed that “IMACTIS CT-Navigation enabled the interventional radiologist to reduce both patient radiation dose and procedure duration during percutaneous vertebroplasty.”

Clinical indications	Cohort size	Benefits with Imactis compared to conventional CT guidance	Reference
Various anatomy (chest, abdomen, pelvis and bones) and interventions (biopsy, drainage and tumor ablation, sympathicolysis and joint infiltration).	120 patients	• Improvement of the accuracy of the initial needle placement (distance error: 4.1 vs. 8.9; angle error: 4.7 vs. 7.9; respectively; p<0.001). • Reduction of the number of control acquisitions necessary to reach the target in (2 vs. 3 respectively, p = 0.01). • Reduction of the Xray dose delivered by the controls acquired during the progression to target (mean DLP: 225 vs. 297 mGy.cm; p = 0.076). • Improvement of operator satisfaction (mean satisfaction score on a scale of 10: 9 vs. 8p=0.025). • Improvement of perceived freedom to perform out-of-plane trajectories (p=0.03).	2
Percutaneous lung biopsy	120 patients	• Comparable technical success (defined as the achievement of the needle progression to the targeted lesion) and diagnostic success (when histological diagnosis was accomplished with the punctured sample) rates (95.0% and 93.3% vs. 93.3% and 91.6%, respectively; both p=1). • Reduction of the dose delivered during initial needle placement (mean DLP : 142.9 mGy.cm vs. 188.2 mGy.cm; p = 0.013). • Reduction of the duration from skin puncture to needle progression toward the target lesion (mean duration: 9 vs. 12 min respectively, p = 0.042 and of the dose delivered during this phase (mean DLP: 611.6 vs. 849.5 mGy.cm respectively p = 0.001). • Reduction of the total radiation dose delivered during the procedure (mean DLP: 1059 mGy.cm vs. 1481 mGy.cm; p< 0.0001).	3
Microwave ablation of hepatic tumor	34 patients	• Reduction of the single slice control scans for antenna positioning (mean 2.5 vs. 5.9; p<0.0001). • Reduction of the x-ray dose delivered during antenna placement (CTDI: 0.46 vs. 1.34 mGy/BMI; p<0.0001). • Improvement of antenna placement accuracy (mean total distance between the anticipated position of the antenna feed and the achieved position: 2.4 vs 3.9 mm; p = 0.0469).	4
Vertebroplasty	37 patients	• Reduction of the average duration per vertebrae treated (20 vs. 39 min; p<0.001). • Reduction of the Interventional Dose Length Product per vertebrae treated by a factor of 2.3 (153 vs. 353 mGy.cm; p<0.001).	5

Table 1: Summary of scientific evidence of the benefits of IMACTIS CT-Navigation in 3D guided procedures.

Cutting-edge CT-guided procedures made feasible by IMACTIS CT-Navigation

This section summarizes clinical publications that describe physicians' initial experience and feedback of IMACTIS CT-Navigation for cutting-edge guided procedures. The following results and conclusions are from single center studies conducted on small cohort of patients with respective methodological limitations. Consequently, the outcomes may only be applicable to their specific conditions and may not be generalizable or reproducible in your practice. Additional details for each study are included in the published papers referenced below.

Percutaneous pelvic bone cementoplasty

The initial experience of Boeken et al. on the use of an EM assistance for pelvic cementoplasty in 33 patients indicated that the EM navigation system was safe to use for pelvic bone cementoplasties, especially for less experienced radiologists, and did not compromise the benefits of such interventions in regard to duration or radiation exposure[6]. The high rate of successful sacroplasty interventions in the studied population suggests that the system was efficient in assisting the radiologist for extra-axial planes in challenging approaches.

Three limitations within this study were reported: the absence of a control group, no study of the level of difficulty of the planned intervention was performed and the radiologists' learning curve was not properly assessed.

Cutting-edge CT-guided procedures made feasible by IMACTIS CT-Navigation *(cont.)*

The "Eiffel Tower" technique: novel long-axis sacroplasty

Boeken et al. showed that the Eiffel Tower technique, a novel long-axis sacroplasty, was technically feasible across 12 patients treated and lead to satisfactory clinical results in 75% of the cases[7]. This technique relies upon the concept of injecting cement all along and through the lateral fractures while creating a solid horizontal landing zone. Despite the extreme angulations needed during such procedures, the use of Imactis allowed to successfully perform long-axis sacroplasties.

The authors reported the following limitations within their study: the absence of a comparative cohort and no long-term follow-up of the patients.

Cryoablation treatment of upper kidney pole lesions and adrenal metastases

Cryoablation is commonly used for patients with small, isolated metastatic lesions where systemic therapy alone may not be sufficient or for those who seek a less invasive alternative to surgery. The precision of this technique also makes it a suitable option for treating tumors in delicate or hard-to-reach areas, such as the adrenal glands and the upper pole of the kidney, where surrounding vital structures must be preserved. Because the accurate placement of the cryoprobes is crucial for the success of the treatment of adrenal metastases and upper kidney pole lesions, Michailidis et al. assessed the value of Imactis in guiding those procedures[8]. Among 31 patients treated (25 with upper pole kidney masses and 6 with adrenal metastases), all procedures were considered as technically successful, since the cryoprobes were accurately placed in the target lesions under CT guidance using the EM navigation system and without penetration of any other organs using an oblique trajectory. No major complications were reported, and local tumor control was achieved in all cases.

The limited size and diversity of the patient cohort and the absence of comparative cohort were reported as limitations of the study.

Percutaneous fixation by internal cemented screws

Percutaneous fixation by internal cemented screws (FICS) consists in inserting a screw across a fracture line or an osteolytic metastasis. This technique is mostly used for iliac bone, sacrum, posterior and superior columns of the acetabulum, superior pubic ramus, femoral neck, and hence often requires double obliquity with significant craniocaudal angulation which can be highly challenging under conventional CT guidance. Additionally, unlike soft tissues, changing the needle trajectory in the bone during the procedure is complex as soon as the entry point in the bone is obtained. A perfect accuracy can only be obtained if the needle is exactly on the right path once entering the bone. Moulin et al. experience over 76 screws inserted in 50 consecutive cancer patients treated by percutaneous FICS under Imactis guidance demonstrated a technical success (considered when a screw was correctly inserted through the fracture line or through the osteolytic metastasis) rate of 96% with average proximal, distal and angle deviation of 8.0 ± 4.5 mm, 7.5 ± 4.4 mm, and 5.4 ± 2°, respectively[9].

The lack of control group and the non-reporting of the clinical success were reported as limitations of the study.

Hepatic ablation of small US-Undetectable and difficult to access lesions

Ultrasound guidance is often preferred for hepatic tumor ablation because of its accessibility, the ability to monitor the probe placement in real time and the lack of exposure to radiation. However, some lesions are not visible on ultrasound, either due to a lack of contrast with the hepatic parenchyma, or because of the small size or depth of the lesion. While treatment could be performed under conventional CT guidance, out-of-plane trajectories are often necessary to avoid harming non-target structures complicating the procedure and resulting in higher radiation doses as well as a risk of inaccurate needle placement and incomplete treatment. Volpi et al. demonstrated over 27 lesions (14 hepatocellular carcinomas, 13 metastases, mean tumor size : 12 ± 5.7 mm) in 21 patients that Imactis guidance allowed to successfully (success rate: 100%; ablation probe correctly placed on the first pass in 96%) and safely (no complications related to the use of HFJV or Imactis) perform percutaneous liver ablation of lesions that cannot be seen on ultrasound and requiring out-of-plane CT access[10].

The authors reported the following limitations within their study: the limited number of patients, the retrospective design, the lack of control group and the short follow-up period.

Conclusion

IMACTIS CT-Navigation system is a versatile solution that can be used during various percutaneous interventions performed under 3D imaging (biopsies, tumor ablation, drainages, infiltrations, vertebroplasties…), on various organs, from standard to complex cases performed by novice or expert physicians, under local or general anesthesia. Instruments ranging from 25G to 11G are compatible with the system, allowing navigation for all instruments used during percutaneous interventions under computerized tomography imaging.

The solution provides real-time navigation of instruments in 3D images during percutaneous IR. It can be used for patient anatomy exploration, planning, needle insertion, needle position check, and provides benefits such as improved accuracy, fewer controls, reduced needle insertion time and access to high angulated out-of-plane paths.

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