# Kyphoplasty Interventions using a Navigation System and C-arm CT data: First Clinical Results

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## ABSTRACT

This study evaluates new applications using a novel navigation system with electromagnetic (EM) tracking in clinical routine.

The navigation system (iGuide CAPPA, CAS innovations, Erlangen, Germany) consists of a PC with dedicated navigation software, the AURORA tracking system (NDI, Waterloo Ontario, Canada) and needles equipped with small coils in their tips for EM navigation. After patient positioning a 3D C-arm data set of the spine region of interest is acquired. The images are reconstructed and the 3D data set is directly transferred to the navigation system. Image loading and image to patient registration are performed automatically by the navigation system. For image acquisition a C-arm system with DynaCT option (AXIOM Artis, Siemens Healthcare, Forchheim, Germany) was used. As new clinical applications we performed kyphoplasty for reconstruction of collapsed vertebrae.

All interventions were carried out without any complication. After a single planning scan the radiologists were able to place the needle in the designated vertebra. During needle driving 2D imaging was performed just in a few cases for control reasons. The time between planning and final needle positioning was reduced in all cases compared to conventional methods. Moreover, the number of control scans could be markedly reduced. The deviation of the needle to the planned target was less than 2 mm.

The use of DynaCT images in combination with electromagnetic tracking-based navigation systems allows a precise needle positioning for kyphoplasty.

**Keywords:** Electromagnetic tracking, navigation system, interventional radiology, C-arm CT, minimally invasive image-guided interventions.

## 1. INTRODUCTION

Today CT-guided minimally invasive interventions on human subjects are established radiological procedures (such as percutaneous punctures, biopsies, pain therapy, vertebroplasties, and radio frequency ablations). Generally, the exact placement of the needle in the patient requires a great deal of experience and considerable skills. Admittedly, to ensure exact instrument placement and to introduce the tool along a preplanned path, frequent control scans are mandatory. This turns out to be an unwieldy procedure and adds up to an avoidable radiation exposure for patient, radiologist, and staff.

For vertebroplasty and kyphoplasty, in practice often two imaging systems are used in combination. A CT is best for needle placement, whereas fluoroscopy with a C-arm allows monitoring the cement propagation in the vertebra. Both systems together are often not available or need plenty of space in the CT room. A remedy is found by the AXIOM Artis

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system (Siemens Healthcare, Forchheim, Germany) with integrated C-arm CT option (DynaCT). Nevertheless, even with such a system it is difficult to place the needle without additional control scans.

Up to now, a number of different auxiliary needle positioning methods are applied such as laser targeting devices, navigation systems based on optical tracking, skin markers, frames and rails placed above the patient, or localization of the needles by pattern recognition in bi-plane fluoroscopy. Laser devices help the radiologist to meet the exact skin entry point. Nevertheless, they do not permit simultaneous real-time control of the needle feed in the patient. Optical tracking allows only needle tracking outside the patient and not inside. Likewise, all other tools outside the patient's body give a starting orientation for the needle feed. Nevertheless, needle bending is eventually not considered by any of them. The fluoroscopy-based methods have the drawback that X-ray radiation is continuously applied to the patient during the intervention.

Computer-assisted navigation systems provide real-time tracking by visualizing the instrument tip directly in the 3D data set. Various products for different clinical applications exist which are mainly based on optical tracking or electromagnetic (EM) tracking[1,2,3,4]. Multiple studies showed the advantages of computer-assisted navigation systems including validations of positioning precision as well as the clinical workflow. However, preparing the setup and initializing the components increase the intervention time in most cases, particularly if additional navigation hardware (e.g. reference frame, needle holder) is necessary. Finally, systematic inaccuracies such as needle bending and patient movement result in an insufficient precision of the whole navigation system.

In this study we investigated a novel navigation system with an EM tracking device using instruments (i.e. needles) with small coils in their tips for tracking. The EM navigation system is combined with a C-arm system with CT option. The C-arm system records a series of images and computes a CT-like 3D data set which is transferred to the navigation system and subsequently used to visualize the needle position in the patient[5]. The advantages of C-arm CT are discussed in a book chapter[6].

The aim of our work was to prove the accuracy and usability of the EM navigation system when applied to kyphoplasty. Kyphoplasty is besides vertebroplasty[7] a method to stabilize collapsed vertebrae. Balloon kyphoplasty consists of placing through a percutaneous posterior approach under radiological guidance into the fractured vertebra a balloon which is inflated with fluid and creates a cavity. This may restore part of the vertebral height loss due to the fracture. In addition, after balloon deflation, polymethylmetacrylate cement may be injected with low pressure into the created cavity. If balloon kyphoplasty is able to restore vertebral height of the fractured vertebra better than vertebroplasty is currently under discussion. The advantages of balloon kyphoplasty compared to vertebroplasty have been investigated in numerous studies. An overview is given by Taylor et al.[8].

The aim of performing kyphoplasty with navigation after a C-arm CT acquisition directly on an X-ray table is to place the needle precisely at a predefined location without the need of permanent control scans. The integrated EM navigation procedure is validated with respect to the conventional workflow under fluoroscopic guidance at a C-arm system.

## 2. MATERIAL AND METHODS

### 2.1 Navigation system

The navigation system consists of an EM tracking system (Aurora, NDI, Waterloo, Canada), a PC with touch screen as a user interface, dedicated navigation software (iGuide CAPPA, CAS innovations GmbH & Co. KG, Erlangen, Germany), and a patient plate with CT markers for image-to-patient registration. The Aurora system comprises a field generator producing an alternating EM field for operation in a volume of 50 cm x 50 cm x 50 cm. The complete iGuide CAPPA is mounted in a rack and can be thus easily placed near the patient table as required. A registration panel provides for image-to-patient registration. It comprises five CT markers with known HU values and known geometry thus enabling fully automatic detection by the integrated software. A six-degrees-of-freedom (6DoF) sensor unveils position and orientation of the registration panel to the EM tracking system.

An additional 6DoF motion sensor was developed to track patient motion. This sensor can be fixed to the skin of the patient using medical adhesive tape. Its position is monitored continuously (20 fps) by the tracking system. The motion sensor provides information about unintended patient motion. The system software will then indicate an alarm to warn the radiologist that further navigation might be impaired. Moreover, the motion sensor detects breathing agitation which the system software displays as a curve.

We developed different needle sets with diameters 11G, 14G, 18G and lengths 5 cm, 10 cm, 15 cm, and 20 cm, respectively. In order to track the tips of the needles in the EM field, small coils (about 0.8 mm diameter and 9 mm length) were imbedded in their tips. The type and the individual calibration data of each needle were stored in an EPROM in the cable connector of the device. This allows a very simple handling of the needles by just plugging them into the sensor interface unit. No further initialization or calibration is necessary. Each needle set consists of a stylet needle comprising the sensor and two trocars. This makes the needle sets very versatile. The trocars allow e.g. introduction of a biopsy gun, punctures, drainages, or radio-frequency ablation. For the specific applications vertebroplasty and kyphoplasty we developed a very rigid 11G needle (Fig. 1, this needle is not available in the USA, 510(k) pending.) which allows to forge it into the vertebra.

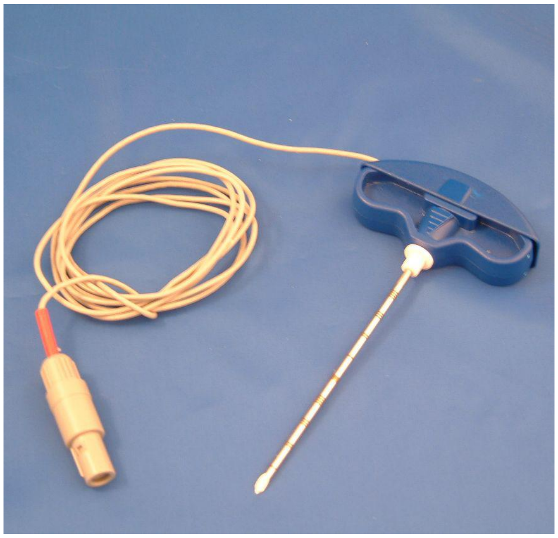

Fig. 1. Needle with 11G diameter and tracking sensor in its tip for vertebroplasty and kyphoplasty.

For image acquisition we used a 3D data set gained by a C-arm X-ray system with a C-arm CT option (AXIOM Artis dBA with DynaCT, Siemens AG Healthcare, Forchheim, Germany). The images were reconstructed on a workstation (Leonardo, Siemens AG Healthcare, Forchheim, Germany) and the 3D data subsequently transferred in DICOM format via LAN to the navigation system. Using DynaCT data proved to be convenient since patient treatment could be easily performed on the interventional table. Nevertheless, 3D data from other imaging modalities such as CT, MR, or 3D ultrasound could be used as well.

## 2.2 Phantom study

Before starting the clinical evaluation, phantom studies were carried out to allow the radiologist to familiarize him or herself with the navigation system and to verify the precision which can be obtained under different circumstances. A Plexiglass phantom comprising 13 rods with spikes (Fig. 2a) and a wax phantom (Fig. 2b) with simulated lesions were used.

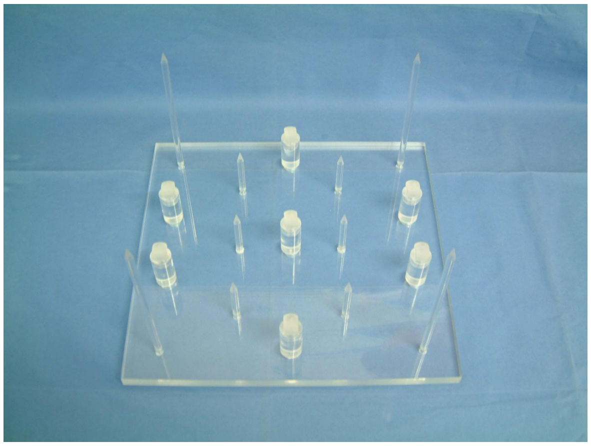

Fig. 2a. Plexiglass phantom comprising 13 rods

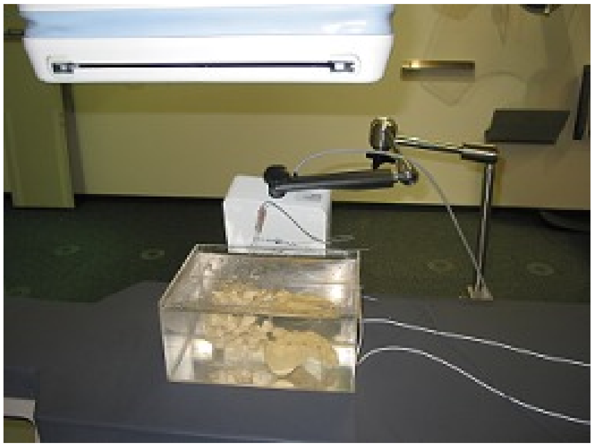

Fig. 2b. Wax phantom with simulated lesions

### 2.3 Clinical workflow

The workflow using a navigation system should be integrated into the established clinical workflow as far as possible. Especially the number of user interactions with the navigation system should be reduced to a minimum.

Different interventions like punctures, biopsies, discographies, periradicular therapies, radio-frequency ablations, and occlusions of arteries were performed in clinical routine. In this particular study we investigated the feasibility of balloon kyphoplasty.

During the clinical interventions (Fig. 3), the patients were placed supine or in lateral position on a vacuum mattress in most cases. However, for kyphoplasty the patients laid on the intervention table in prone position. The chest was placed on a cushion in a stable way. The arms could be put down on an arm rest. The registration panel bearing the CT markers and the reference sensor for EM tracking was positioned on the patient's back close to the vertebra to be treated (Fig. 4).

Fig. 3. Clinical kyphoplasty procedure. The radiologist feeds two needles with assistance of the navigation system to the vertebra to be reconstructed. The field generator (arrow) of the AURORA tracking system is mounted on a bracket.

After the scanning C-arm run, image reconstruction, and data transfer to the navigation system inside the OR, the radiologist planned the dedicated access path. Therefore, the target point was preset on the navigation monitor. Then the skin entry point was selected and tuned until the desired trajectory met the requirements, e.g. no vessels or other structures would become injured. It appeared that even complicated needle interventions (i.e. with a double oblique access, or close to delicate structures) were possible with great precision.

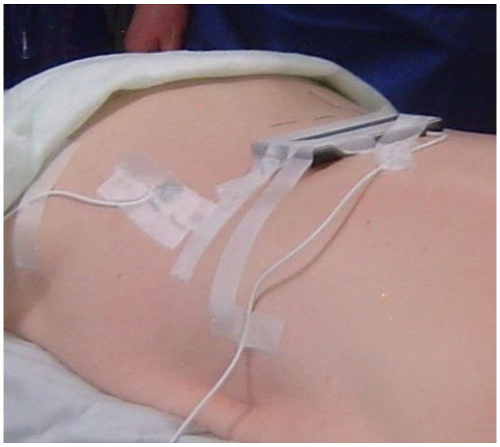

Fig. 4. Registration panel (upper right) and motion sensor (lower left) were fixed to the patient's back close to the skin entry point using medical adhesive tape.

The interventionalist started to prepare kyphoplasty by carefully punching in the kyphoplasty needle. During the needle feed, the actual needle position was visualized on the screen of the navigation system. I.e. the interventionalist needed not to wait for a subsequent control scan, but could monitor the position of the needle in real-time. Generally, the radiologist trusted in the precision of the navigation system. Nevertheless, in the framework of this study the needle position was checked by fluoroscopy in some cases.

After placing the needle in the vertebra, the stylet was removed. The trocar remained on site and was used as guidance for the kyphoplasty inflation and injection set (Fig. 5a).

Since the registration panel was put on the patient's back, respiratory motion could not impair the navigation. Afterwards, the balloon was inserted, filled with contrast agent to inflate the vertebra, and subsequently removed. Then the cavity could be charged with cement (Fig. 5b).

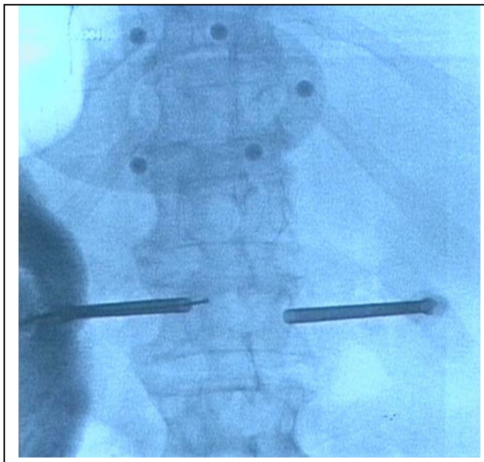

Fig. 5a. Two trocars for guiding the kyphoplasty needles in the vertebra to be treated.

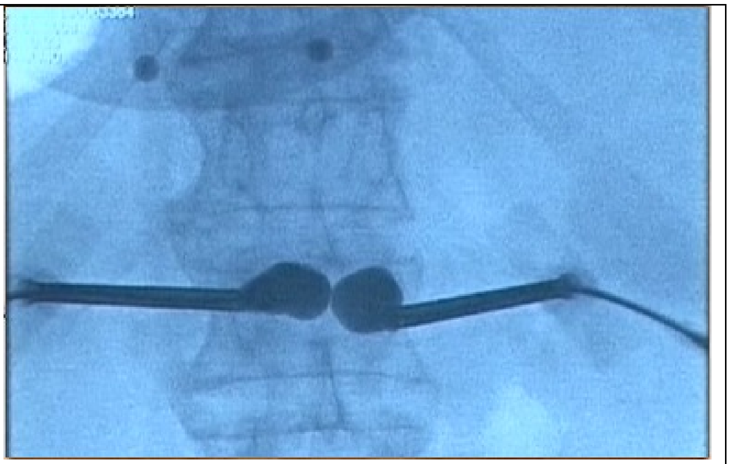

Fig. 5b. Kyphoplasty needles as in Fig. 5a, feeding cement into the vertebra.

## 3. RESULTS

### 3.1 Phantom study

The technical error was assessed at the Plexiglass phantom from some 900 measurements in total. The mean error was 1.2 mm ± 0.2 mm. Another 120 measurements were performed at the wax phantom. Here the mean error was nearly identical, i.e. 1.4 mm ± 0.3 mm. More details on the phantom studies will be published elsewhere.

### 3.2 Clinical evaluation

Kyphoplasties were carried out at the Institute of Neuroradiology, University Hospital Magdeburg, Germany in 25 patients. Besides the radiologist, an additional person was present to assist in operating the touch-screen panel of the navigation system.

Two needles were forged into the broken down vertebra which can be seen from screenshot in Fig. 6. Since a transversal and a sagittal view are presented simultaneously, the target can be reached easily even in case of a double oblique access. The whole procedure is carried out without applying additional radiation during the intervention.

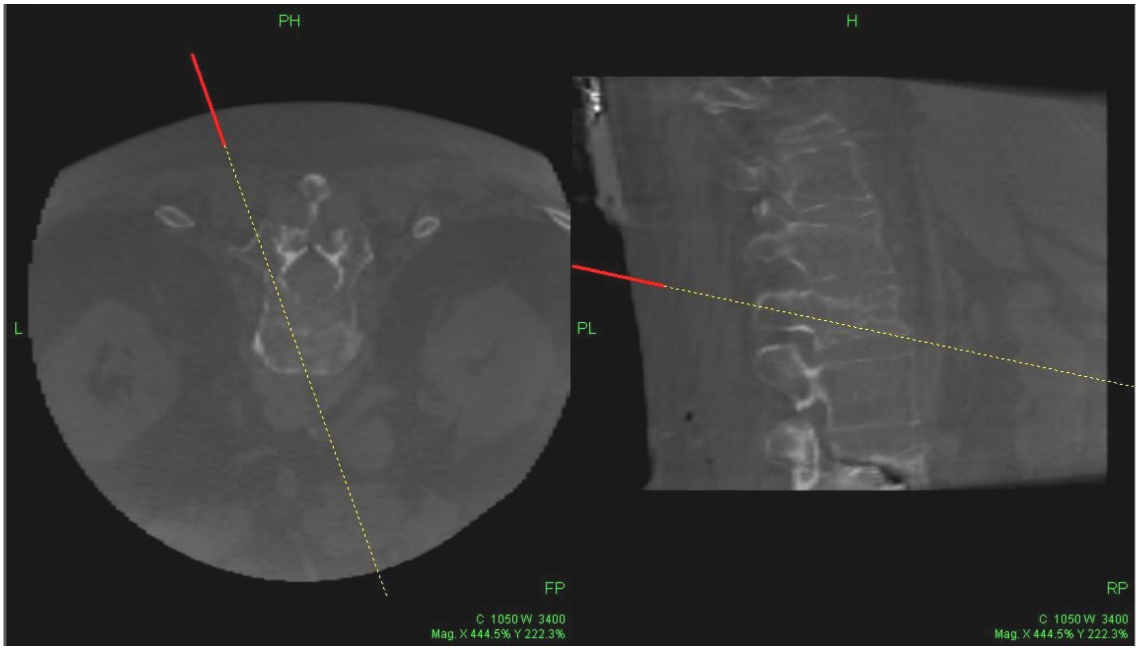

Fig. 6. Screenshot during introducing the kyphoplasty needle. The dotted line marks the extrapolation of the needle in forward direction. The left and the right part of the image show a transversal and a sagittal view of the spine, respectively. The needle target is the collapsed vertebra to be reconstructed.

The workflow was estimated by the radiologists as very user-friendly and intuitively. After 3D data transfer from the reconstruction workstation to the navigation system, data processing went on self-acting. Just one click on the touch-screen was required to verify that the data set was correctly assigned to this patient. Registration and needle identification were performed fully automatically in less than two seconds. All kyphoplasties showed a high degree of accuracy, the measured deviations of the needles from the desired positions were less than 2 mm. The kyphoplasties in this study were performed without any complications. In contrast to the conventional procedure, we were able to reduce the number of control scans and the time between planning and the final needle punching.

## 4. DISCUSSION

The workflow presented here proved to be a good solution for 3D imaging and needle placement. Especially C-arm CT (DynaCT) acquired directly on the interventional table allows immediate 3D imaging preceding needle placement. Moreover, fluoroscopy is also possible with the patient in the same position which is necessary to monitor the cement injection.

The integrated planning concept and the virtual trajectory of the needle in the data set allow a precise needle placement and give the radiologist a high degree of safety during the complete intervention.

Although there are optical tools such as laser crosshairs, only with the electromagnetic tracking-based navigation a real-time monitoring of the needle position in 3D is possible, avoiding frequent control scans.

The optical visualization on the monitor was estimated as very helpful by the clinicians. The navigation system is able to support the intervention by various views of the virtual needle. The MPRs are automatically chosen displaying the needle and the trajectory. Moreover, the deviation of the needle tip from the planned target is displayed. Using traditional fluoroscopy-based imaging, different views have to be selected manually and distances from a target cannot be determined directly. Therefore, this navigation system proved to be of great advantage.

The current setup seems to be still not optimal. Installation of the system and the field generator takes some 5 to 10 minutes which adds some delay into the clinical workflow. This is subject to further improvements in the system development. Especially the navigation procedure shall be displayed on a monitor of the imaging system.

The vertebroplasty needles proved to be useful. The needle sets with the stylet comprising the electromagnetic sensor and the trocar are very versatile. Besides kyphoplasty, e.g. radiofrequency ablation (RFA) in the vertebra could be easily carried out with such type of needle.

The results to be presented show the high potential of our EM navigation system in combination with the C-arm for application in kyphoplasty. Moreover, the navigation system (using other needles) is suitable in combination with CT scanners or other modalities delivering 3D data sets as well as for other minimally invasive interventions (e.g. biopsies, drainages, RF ablations in the liver). The accuracy of 1.4 mm ± 0.3 mm which we verified by phantom studies is outstandingly suited for kyphoplasty.

## 5. ACKNOWLEDGEMENTS

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