

Accuracy Analysis of an Image-Guided System for Vertebroplasty Spinal Therapy based on Electromagnetic Tracking of Instruments

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ABSTRACT

Vertebroplasty is a minimally invasive procedure in which bone cement is pumped into a fractured vertebral body that has been weakened by osteoporosis, long-term steroid use, or cancer. In this therapy, a trocar (large bore hollow needle) is inserted through the pedicle of the vertebral body which is a narrow passage and requires great skill on the part of the physician to avoid going outside of the pathway. In clinical practice, this procedure is typically done using 2D X-ray fluoroscopy. To investigate the feasibility of providing 3D image guidance, we developed an image-guided system based on electromagnetic tracking and our open source software platform the Image-Guided Surgery Toolkit (IGSTK). The system includes path planning, interactive 3D navigation, and dynamic referencing. This paper will describe the system and our initial evaluation.

Keywords: image guidance, vertebroplasty, electromagnetic tracking

1. INTRODUCTION

Each year osteoporosis accounts for an estimated annual incidence of 700,000 fractures; of these, approximately 260,000 are vertebral compression fractures. Vertebroplasty is an increasingly popular medical procedure for treatment of this condition, with 14,152 cases reported in the U.S. in 2001 and case volume increasing to 24,558 in 2003(+73.5%).¹ In conventional vertebroplasty, 2D X-ray projection images are used to guide a trocar consisting of a solid stylete and hollow cannula through the pedicle and into the fractured vertebra. The vertebral body is then stabilized by injecting bone cement through the cannula. This is a difficult procedure to perform, since the trocar is inserted through a relatively narrow pedicle relying solely on 2D X-ray projection images. To gain an understanding of the underlying anatomical structures and the trocar's location physicians acquire many X-ray images. This exposes the patient to ionizing radiation and increases the physician's cumulative exposure. To overcome these drawbacks, we propose to use an image guidance system utilizing electromagnetic tracking, and a pre-operative cone-beam CT. This system replaces the intermittent use of 2D projection images with a dynamic 3D visualization of the anatomical structures and tracked instruments.

We have previously evaluated the use of image guidance for vertebroplasty.² In that work we used CT images and electromagnetic tracking to provide navigation information. Registration of image space to patient space was based on using three tracked needles as registration fiducials. The guidance system displayed the standard axial, sagittal, and coronal views, along with a three dimensional view. The system was successfully used by an experienced interventional radiologist to perform 14 needle insertions in seven vertebrae of an anthropomorphic phantom.

In this paper we describe a new open source version of this software which provides improved guidance using novel volume re-slicing views and a targeting view that are tailored for needle insertion procedures. We evaluate the fiducial localization accuracy when using needles as the registration fiducials and we evaluate the target registration error of our system using an anthropomorphic phantom.

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2. MATERIALS AND METHODS

We developed an image guidance system for vertebroplasty based on the Image-Guided Surgery Toolkit (IGSTK).³ IGSTK is an open source component based C++ software library which provides an open framework to allow researchers to develop customized image-guided applications with minimal effort. We used the following toolkit components: 1) tracker interface; 2) DICOM image reader; 3) paired-point registration; and 4) visualization components. The library utilizes a state machine architecture for robustness and includes detailed error logging. Our application's Graphical User Interface (GUI) was developed using the Fast Light Toolkit (FLTK), which is one of the GUI toolkits that are compatible with IGSTK.

The navigation system follows the common workflow in which the physician imports a volumetric image data set, plans the trocar insertion trajectory, registers the image data to the patient, and navigates to the target using tracked tools that are overlaid onto the image data.

All volumetric data was obtained in-situ using a cone-beam CT system, the Axiom Artis dFA (Siemens AG, Medical Solutions, Erlangen, Germany). Images are 256x256x221 with a 0.8mm isotropic spacing. The system is installed in the interventional radiology suite, and enables the acquisition of 3D images in-situ. The data is then directly downloaded to a DICOM server running on the navigation system's computer. The use of cone-beam CT does not change any aspect of the navigation system, as compared to the use of standard CT. What it does change is the procedure workflow, which is greatly improved, as there is no need to transport the patient to the CT suite and then back to the interventional suite. In turn this greatly effects the acceptance of such systems into clinical practice.⁴

Tracking was performed with the Aurora system (Northern Digital Inc., Waterloo, Canada). The tracked tools included two 22 gauge MagTrax needles (Traxtal Inc., Toronto, ON, Canada). These are five degree (5D) of freedom tools, with the needle pose known up to a rotation around the needle shaft. To perform the vertebroplasty we use a modified KyphX Osteo Introducer (Kyphon Inc., Sunnyvale, CA, USA), with an embedded 5D Aurora sensor coil. Figure 1(a) shows these components.

All experiments were performed using an anthropomorphic spine phantom comprised of a torso and vertebral column (Sawbones worldwide, Pacific Research Laboratories Inc., Vashon, Washington, USA). The spine was fixed in place inside the torso using urethane foam as shown in Figure 1(b). This was necessary as we have empirically found that the fixation provided by the phantom's structure is not sufficient for performing vertebroplasty. Without this additional fixation the vertebral body exhibited considerable motion, approximately 10mm, which is beyond the motion observed in clinical interventions.

We now describe our novel user interface followed by our needle based registration approach.

2.1 Graphical User Interface

To improve the quality of the image guidance we have designed a Graphical User Interface (GUI), that is tailored for needle based interventions. Preoperatively, we display the standard axial, sagittal, and coronal views. The physician manually identifies a target point on the vertebra and an entry point on the pedicle. The direction defined by these two points defines the desired path. Intraoperatively, once the patient is registered, we provide three re-sliced views, axial, off-axial and off-sagittal. The off-axial and off-sagittal views are re-slice planes that follow the needle axis. That is, these are axial and sagittal views that are tilted so that the needle shaft is in plane. This approach is based on our observations of current clinical practice for needle based biopsies under interventional CT. In these procedures the physician usually tries to align the needle to the fixed imaging plane. We provide similar views by aligning the imaging plane to the needle.

The re-slice plane is obtained as follows. Given the needle shaft direction, \mathbf{u} , and needle tip location \mathbf{p} , both in the image coordinate system, the off-axial re-slice plane is defined as:

$$\mathbf{n}^T(\mathbf{q} - \mathbf{p}) = 0$$

where $\mathbf{n} = \mathbf{u} \times \mathbf{x}$. Note that when $\mathbf{u} \times \mathbf{x} \simeq \mathbf{0}$ we set $\mathbf{n} \equiv \mathbf{z}$. The off-sagittal plane is obtained similarly. Figure 2 illustrates this concept.

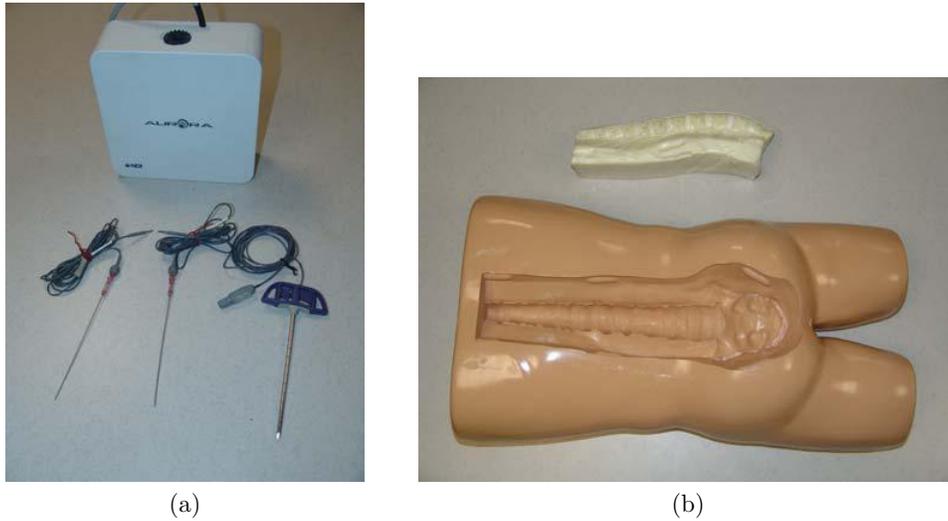


Figure 1. Hardware components used in the evaluation of the vertebroplasty image-guided navigation system: (a) Electromagnetic system field generator, tracked needles and vertebroplasty trocar, and (b) anthropomorphic phantom, torso and vertebral column.

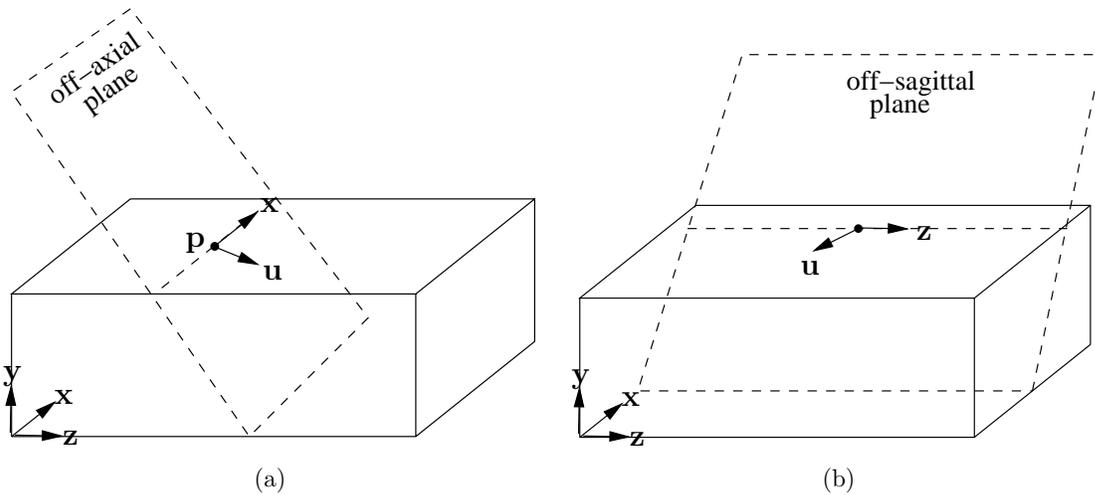


Figure 2. Off axis views: (a) tilting the axial (xy plane) and (b) tilting the sagittal (yz plane) so that the needle shaft is in the viewing plane.

Finally, we also provide a targeting view. The target is displayed as a green sphere, the needle tip as a red ring, and the needle hub as a yellow ring. To align the needle to the planned path the physician centers all three elements. Once the needle is aligned the physician advances the needle using a depth gage which displays the distance between the needle tip and the target. Figure 3 shows our GUI.

2.2 Registration method

To perform registration we use two MagTrax needles. The needles are inserted into the perispinal "musculature" lateral to the spinous process of the vertebra of interest. This is done percutaneously, minimizing trauma to the patient. Once the needles are firmly lodged they form a rigid body with the vertebra. In our system, this pair of needles serves a dual purpose. They are used as fiducials for registration, and once registration is performed the two 5D needles serve as a single 6D dynamic reference frame.

Our image to patient registration is similar to the approach presented in.⁵ It is based on the use of fiducial

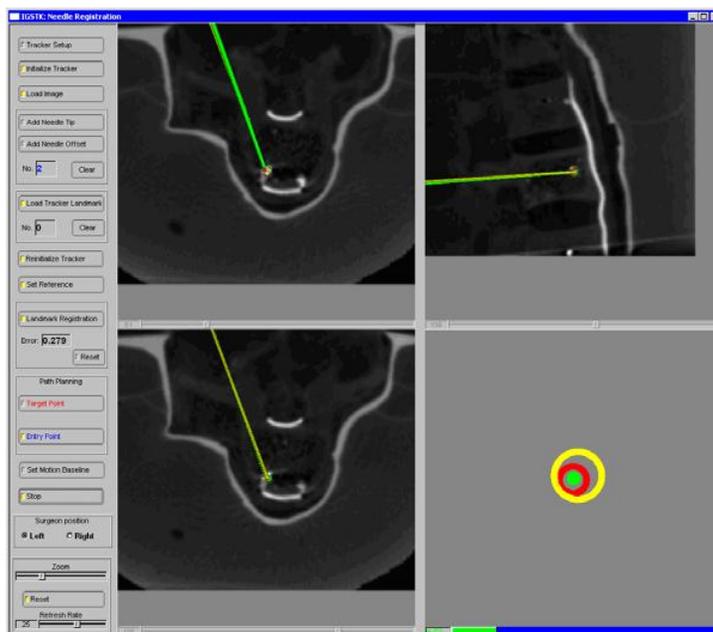


Figure 3. Graphical user interface for vertebroplasty guidance. Axial view (top-left), off-sagittal view (top-right), off-axial (bottom-left), and targeting view (bottom-right).

location and orientation. This enables us to use two fiducials instead of the three required for 3D/3D rigid registration when fiducial location is the only input.

We next describe our registration approach in detail.

First, the two needles are calibrated. The offset between the electromagnetic coil embedded in the needle shaft and the needle tip is estimated using pivot calibration.⁶ In our case, the sensor coil's main axis is aligned with the needle shaft, thus the offset to the needle tip is along a single axis.

Then the needles are inserted percutaneously and a cone-beam CT data set is acquired. The physician manually identifies the needle tip and a point on the needle shaft in the 3D image. This defines the shaft direction \mathbf{u} in the image coordinate system. We then obtain a virtual fiducial point on the needle shaft at a distance of 20mm from the needle tip. Thus, each needle provides us with two points. The choice of a 20mm offset from the needle tip is based on the physical characteristics of our needles. The needle shaft is only locally rigid with respect to the sensor coil. As our sensors are embedded approximately 10mm from the needle tip, we define our virtual point 10mm in the opposite direction from the needle tip. This 20mm segment around the sensor coil does behave as a rigid body.

Finally, we position the electromagnetic field generator next to the patient, read the sensors' locations and orientations and compute the locations of the two needle tips and two virtual points. Rigid registration is then computed automatically using these four points as input to a quaternion based analytic solution.⁷ Figure 4 illustrates the registration point identification in image space and in physical space.

3. EXPERIMENTAL RESULTS

Given that our navigation system uses an electromagnetic tracking system we first need to assess its accuracy in the specific interventional environment. We have previously found that accuracy is highly dependent upon the interventional environment.⁸ In that study we also evaluated the Aurora system in the interventional radiology environment. We concluded that the system's accuracy is sufficient for our procedure, with a median positional

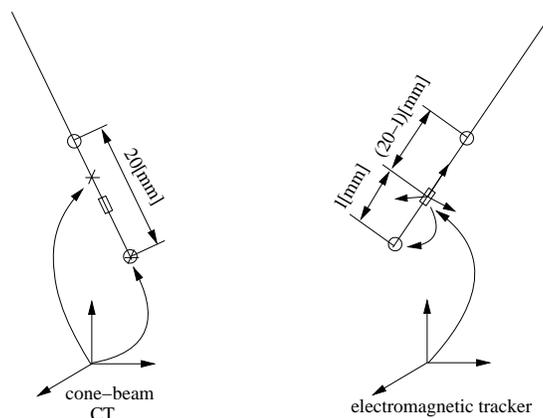


Figure 4. In image space, left coordinate system, the user manually identifies needle tip and needle shaft (x marks) and the registration points (circles) are computed. In physical space, right coordinate system, the location of the sensor coil is obtained and the registration points (circles) are computed using the offset l obtained via pivot calibration.

	data set 1		data set 2	
	tip ($\sigma_x, \sigma_y, \sigma_z$)	shaft ($\sigma_x, \sigma_y, \sigma_z$)	tip ($\sigma_x, \sigma_y, \sigma_z$)	shaft ($\sigma_x, \sigma_y, \sigma_z$)
needle 1	(0.29, 0.75, 0.24)	(0.5, 0.82, 0.39)	(0.39, 1, 0.39)	(0.48, 1.1, 0.97)
needle 2	(0.3, 1.2, 0.61)	(0.87, 1.3, 0.74)	(0.43, 0.83, 0.4)	(0.54, 0.87, 0.55)

Table 1. Standard deviations for fiducial localization, as identified by three operators. The fiducials are the needle tip, and a virtual fiducial located $20mm$ away from the tip on the needle shaft. All measurements are in millimeters.

error of $0.53mm$ and standard deviation of $0.43mm$. This accuracy was obtained when the C-arm based cone-beam CT system was away from its imaging position, which is the setup in which our navigation system is used.

An important aspect of any image guidance system that uses fiducials is the fiducial localization. In our application, we are using tracked fiducials, which enable automatic fiducial localization in physical space. In image space we manually identify the fiducials in the image. In our case the needle tip is well defined, but the point on the needle shaft is a virtual fiducial and is expected to have a higher localization variability. It should be noted that the localization of the virtual fiducial is dependent on the localization of the needle shaft and needle tip. That is, if the needle shaft's true location is identified the virtual fiducial localization will have the same variability as the needle tip localization.

To assess the variability of fiducial localization in the images we performed the following experiment. The MagTrax needles were inserted into the phantom next to the vertebra of interest and a cone-beam CT data set was acquired. We acquired two such data sets. We then analyzed the possible localization variability by having three engineers localize the fiducials (four needle points) ten times in each of the images.

While the needle tip is well defined, the virtual fiducial on the needle shaft is indirectly identified by the operator by marking a point on the needle shaft. We thus expected that the variability in the virtual fiducial localization would be greater than needle tip localization. When analyzing the data we observed that the variability in virtual fiducial localization is comparable to needle tip localization, albeit with a slightly greater variability. Table 1 summarizes this experiment.

The complete system was then evaluated using the anthropomorphic phantom described above. To provide well defined targets we embedded $2mm$ steel ball bearings into the vertebral column in clinically viable locations that correspond to valid trocar positions. The system was then used to perform navigated vertebroplasty. Figure 5(a) shows our experimental setup.

To evaluate the accuracy of our system and the possible procedure variability we had a second year medical student, a fellow, and an attending physician each perform five navigated interventions. An intervention was

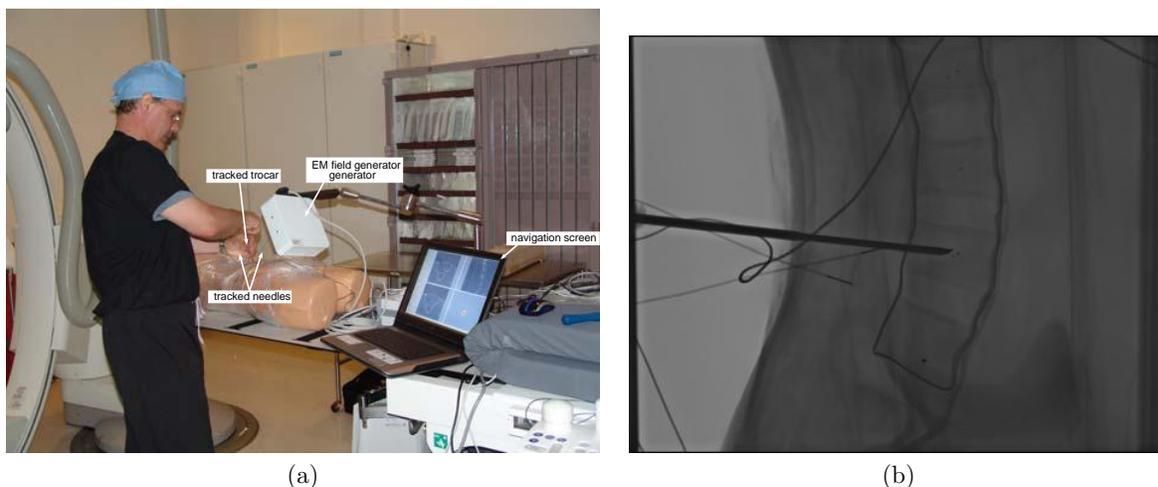


Figure 5. In-vitro experimental setup in the interventional radiology suite, and a lateral projection image acquired after successful navigation which shows the trocar inside the pedicle with its tip near the target ball bearing.

Experiment	student	fellow	attending
1	1.3	0.94	0.6
2	1.44	0.96	1.47
3	2.28	1.2	1.6
4	2.36	1.53	1.63
5	2.62	1.75	1.66
mean(std)	2.0(0.59)	1.28(0.36)	1.39 (0.45)

Table 2. Accuracy results for in-vitro navigated vertebroplasty procedure. Distances were measured between trocar tip and embedded ball bearing using cone-beam CT images. All measurements are in millimeters.

judged as a success if the trocar was completely inside the pedicle, otherwise it was considered a failure. Figure 5(b) shows a lateral image used for qualitative evaluation. We then quantitatively evaluated the accuracy of a successful intervention as the distance between the trocar tip and the target ball bearing center. This distance was measured using a confirmation cone-beam CT scan after each trocar insertion.

All procedures in this experiment were performed successfully by all participants. That is, the trocar did not breach the pedicle. Not surprisingly, the difference between the medical student and practicing physicians was reflected by the accuracy results. The fellow and attending exhibit similar accuracy with the medical student being less accurate. Table 2 summarizes this experiment.

4. DISCUSSION AND CONCLUSIONS

We have described an image-guided navigation system based on cone-beam CT and electromagnetic tracking. This system provides a fully integrated in-situ navigation solution for vertebroplasty, with 3D image acquisition seamlessly integrated with the navigation system. The software is based on the open source Image-Guided Surgery Toolkit (IGSTK).⁹

We evaluated the variability of fiducial localization in the 3D images. This was primarily motivated by the fact that our fiducials are needles and that we use a virtual point on the needle shaft that is indirectly identified by the user. From analyzing the variability of three engineers performing this task we conclude that the localization variability is on the order of $1mm$ which is on the same scale as our voxel sizes ($0.8mm^3$).

We then evaluated the accuracy of our system using an anthropomorphic phantom. Three medical professionals with different skill levels (student, fellow, attending), performed the procedure five times. All procedures were deemed successful with the trocar inserted through the pedicle without breaching it. The variability due to skill

level was reflected by the distance between the trocar tip and planned target point, with the more experienced operators being more accurate.

To improve these results, a semi-automatic method for needle localization is needed, removing the dependence of fiducial localization on the human operator. The next level of system validation should then be done on cadavers.

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