Validation of a low-cost adjustable, handheld needle guide for spine interventions

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ABSTRACT

PURPOSE: MR-guided injections are safer for the patient and the physician than CT-guided interventions but require a significant amount of hand-eye coordination and mental registration by the physician. We propose a low-cost, adjustable, handheld guide to assist the operator in aligning the needle in the correct orientation for the injection.

METHODS: The operator adjusts the guide to the desired insertion angle as determined by an MRI image. Next, the operator aligns the guide in the image plane using the horizontal laser and level gradient. The needle is inserted into the sleeve of the guide and inserted into the patient. To evaluate the method, two operators inserted 5 needles in two facet joints of a lumbar spine phantom. Insertion points, final points and trajectory angles were compared to the projected needle trajectory using an electromagnetic tracking system.

RESULTS: On their first attempt, operators were able to insert the needle into the facet joint 85% of the time. On average, operators had an insertion point error of 2.92 ± 1.57 mm, a target point error of 3.39 ± 2.28 mm, and a trajectory error of 3.98 ± 2.09 degrees.

CONCLUSION: A low-cost, adjustable, handheld guide was developed to assist in correctly positioning a needle in MR-guided needle interventions. The guide is as accurate as other needle placement assistance mechanisms, including the biplane laser guides and image overlay devices when used in lumbar facet joint injections in phantoms.

KEYWORDS: MR-guided interventions, spinal injection, needle guidance, 3D printing

1. PURPOSE

Computerized tomography (CT) and fluoroscopy are traditionally used to guide physicians during injection procedures by providing an image of a patient’s internal structures which can be viewed on screen. Using mental registration and hand-eye coordination, physicians use CT imaging to accurately locate the entry point, and determine the trajectory and orientation on the patient before performing a free-hand insertion to the desired location [1]. All of this is done while attempting to minimize damage to surrounding tissues. Due to the possible human and systematic errors in the freehand technique, physicians may require several attempts to properly insert and guide the needle within a clinically acceptable range [2]. As the number of needle insertions increases, additional images must be acquired to confirm the needle’s position in the patient. For this reason, fluoroscopy is increasingly being used during injections, as it displays real-time cross-sectional images of relevant anatomy and facilitates freehand needle targeting [1].

Magnetic resonance (MR) imaging provides physicians with a more detailed scan of the bone, soft tissue and blood vessels compared with CT and fluoroscopy [3]. As in CT-guided needle interventions, the freehand technique is conventionally used with MR-guidance, requiring a physician to mentally align the patient’s anatomy to the image and insert the needle using precise hand-eye coordination [2]. Although the additional confirmation images only consist of a few MR image slices, this lengthens the procedure and increases costs [2]. Furthermore, patients may become irritated as they are moved in and out of the bore for continued needle insertions, increasing the pain experienced, and the damage to surrounding tissues [3]. However, MR is a safer imaging modality as both CT and fluoroscopy expose the patient and physician to dangerous ionizing radiation [4].

To reduce the length of the procedure and minimize patient discomfort, needle placement assistance mechanisms for CT-guided and MR-guided injections have been investigated. Laser navigation systems (LNS) in CT-guided needle interventions have been explored as devices to improve physician accuracy [5]. The SimpliCT™ LNS (NeoRad AS, Oslo, Norway) consists of a movable and rotatable laser unit mounted in front of the CT gantry [6]. The laser is aligned to point at the entry point on the skin at the desired angle of insertion [5]. The physician inserts the needle at the planned angle by maintaining the alignment of the laser beam at the distal end of the needle [6]. Laser navigation systems have been proven to increase the accuracy of the physician's needle placement and as a result, reduce the radiation dose to the operator and the patient [5].

Similar laser navigation systems have been investigated for MR-guided needle insertion procedures. A biplane laser guide uses the intersection of two calibrated laser planes to mark the intended needle trajectory on the patient [7]. The first laser line generator provides a laser plane parallel to the transverse imaging plane of the scanner. This line intersects the second laser line, generated at a given angle off the vertical sagittal imaging plane [7].

A 2D augmented reality image overlay device was also investigated as a needle placement assistance mechanism. This system displays transverse MR images on an LCD that are reflected back to the physician from a semi-transparent mirror [2]. The image appears to be floating in the correct location on the body of the patient. Furthermore, a mobile image overlay system was developed to improve clinical usability of the augmented reality device [8]. The system consists of an optically tracked frame that holds a tablet computer and a semi-transparent mirror. The system is optically tracked in real-time to accurately overlay the corresponding images at all times [8],[9].The biplane laser and image overlay devices have shown to produce significantly better accuracy and repeatability than the freehand technique [9]. However, for clinical implementation, the needle placement assistance mechanisms for MR-guided injections must be straightforward to setup, inexpensive and avoid lengthening the procedure [8].

Real-time tracking system are used to assist physicians in image-guided procedures to align surgical tools for accurate placement into the target area. The ActiSight Needle Guidance System (ActiViews Ltd. Haifa Israel) is used in CT-guided needle interventions to visualize the needle and intra-body targets in real time [10]. A skin pad with fiducial points are identified on CT images to provide a frame of reference in which the coordinates of the target point can be located [10]. The fiducial points are optically tracked using a miniature video camera on the interventional tool, outside the body. The location of the needle tip is calibrated and the mapping of the known locations of the fiducial points from the CT images and video provides 6 degrees of freedom (DoF) information of the needle relative to the target [11]. Although the navigation system has been shown to improve the final location of the needle tip, it does not reduce the time of operation or radiation exposure to the physician or patient [10].

In previous studies, a handheld protractor guide with an angled sleeve was tested as a simple needle placement assistance mechanism [7]. In the freehand technique, the needle has 5 DoF, however the guide helps control 3 DoF. The physician must firmly slide the needle against the sleeve to control the needle's pitch and stop the insertion at the estimated target depth. The physician must also estimate the center of the guide to correctly align the guide with the MRI laser plane. The protractor guide was manufactured by hand, making it difficult to replicate quickly and accurately. We sought to design a guide that would serve as an inexpensive, adjustable, reproducible needle insertion technique for MR-guided needle interventions.

We propose a handheld, adjustable 3D-printed guide that will reduce physician error when performing MR-guided needle interventions. We present the design and methodology for use of a low-cost, adjustable handheld needle guide relative to clinical standard of care for MR-guided needle interventions. Quantitative analysis of operator performance using the needle guide is also provided to validate usability and effectiveness of the guide when used by trainees.

2. METHODS

2.1 Needle guide design

The needle guide was designed using Autodesk Fusion 360 (www.autodesk.com/fusion360), a program used to generate computer-aided designs (CAD). Two main components adjust the angle of insertion and help the operator properly orient the tool on the patient (Figure 1). The top of the needle guide features a 1 mm groove to reduce the rotation of the instrument when aligning the guide with the in-plane mounted laser. The guide holder contains a half-cylindrical slot for a 7 mm x 26 mm level gradient used to position the tool level with the insertion plane. The needle guide indicates insertion angles from

0 to 90 degrees, in 5 degree increments. The guide includes a sleeve which guides the needle at the desired trajectory, limiting its horizontal movements.

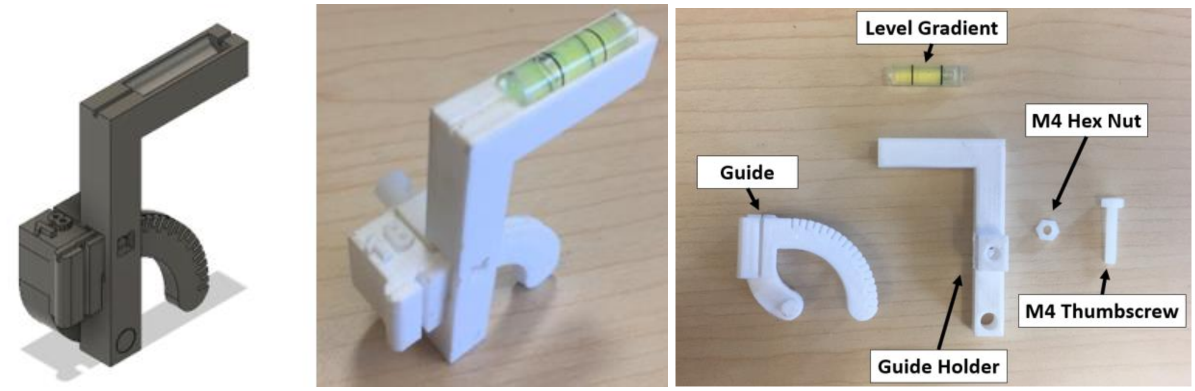

Figure 1. Autodesk Fusion model (left), 3D printed needle guide (center) and separated guide components (right).

The sleeve was designed in multiple different widths for different gauges of needles commonly used in spinal interventions. The needle gauge to be used with a given guide is indicated by the number on the top of the guide. The needle can easily be removed from the guide by moving the guide perpendicularly from the inserted needle. The guide holder contains a slot to view the insertion angle as well as to place an M4 hex nut and M4 thumbscrew. The thumbscrew is tightened to secure the adjusted insertion angle.

2.2 Experimental Set Up

Two perpendicular lasers, mounted on an aluminum frame, were aligned before each facet joint injection, one in the plane of the selected image slice, and the intersection indicating the insertion point. The positioning of both the needle and the spine phantom was determined using an electromagnetic (EM) tracking system. This system consisted of a laptop computer, Ascension TrakSTAR, EM field generator and the two EM trackers attached to the needle and spine phantom (Figure 2). Needle tip position relative to the spine phantom was displayed in real-time on the laptop computer.

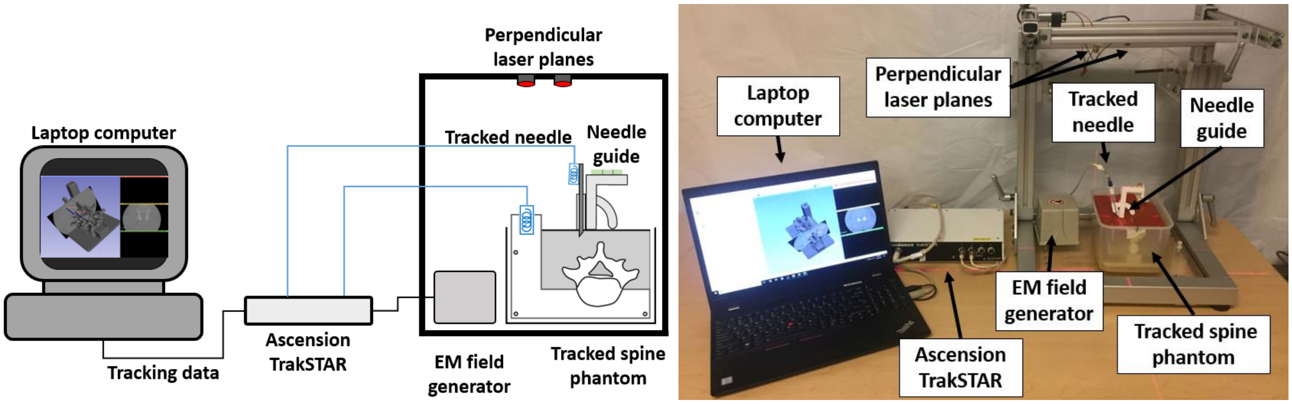

Figure 2. *Left:* Schematic diagram of the electromagnetic tracking system, *Right:* The electromagnetic tracking system.

2.3 Validation Study

Two facet joints were selected from the lumbar spine phantom for needle insertions. Using a CT image slice of the model, a target point and insertion point for each facet joint was marked in 3D Slicer (www.slicer.org), an open-source application platform for medical image analysis and image guided interventions. A software extension was developed that displayed the insertion angle and projected needle trajectory.

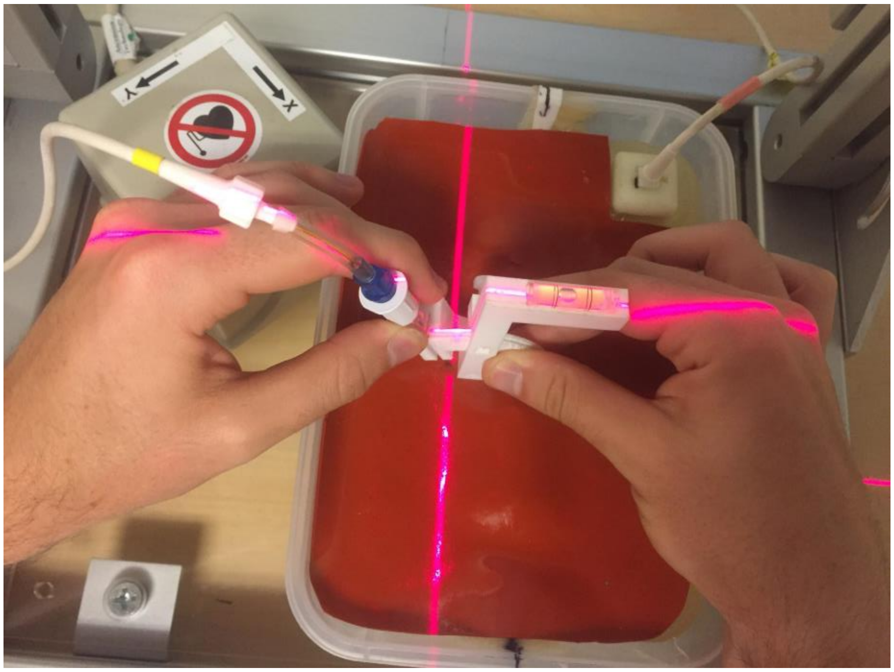

Figure 3. Operator inserting needle after aligning the guide with perpendicular laser planes.

Operators adjusted the angle of the guide to match the angle of insertion calculated by the 3D Slicer extension. While keeping the level gradient steady, the groove of the guide was aligned with the laser plane (Figure 3). The needle was placed in the needle sleeve and the position of the guide was adjusted. Once the laser plane, level gradient and insertion point were aligned, the operator attempted to place a needle in the facet joint. In total, twenty insertions were performed, ten in each facet joint. Operators were given one insertion attempt per trial.

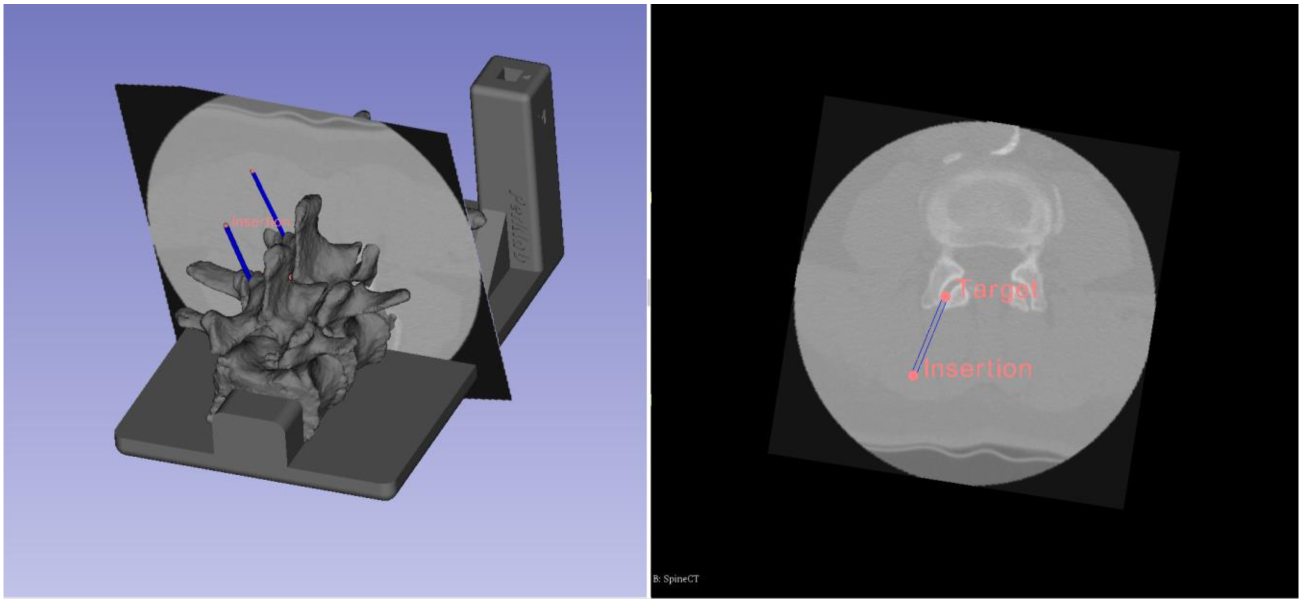

Figure 4. 3D Slicer Extension used for data collection and analysis: *Left:* Spine phantom model with MR image scan and planned needle trajectory, *Right:* MR scan with planned needle insertion point, target point and trajectory.

To validate the needle guide, the insertion position and final needle tip position were recorded in the 3D Slicer extension (Figure 4). The operator's insertion, target and angle were compared with the planned needle trajectory. The total, in-plane and out-of-plane error was analyzed. The insertion was considered successful if the needle tip was placed inside the target facet joint.

3. RESULTS

On their first attempt, operators were able to successfully insert the needle into the facet joint using the guide 85% of the time. The in-plane, out-of-plane and total error between the planned and projected insertion points, final points and trajectory angles was calculated (Table 1). On average, the operator's insertions had an in-plane target error of 2.49 ± 1.99 mm and in-plane angle errors of 2.31 ± 1.69 degrees.

Table 1. Total, in-plane and out-of-plane error using needle guide.

Metric	Total	In-Plane	Out-of-Plane
Insertion Distance to Plan (mm)	2.92 ± 1.57	2.21 ± 1.31	1.55 ± 1.44
Target Distance to Plan (mm)	3.39 ± 2.28	2.49 ± 1.99	2.07 ± 1.71
Angle to Plan (degrees)	3.98 ± 2.09	2.31 ± 1.69	3.09 ± 1.98

4. DISCUSSION

A low-cost, adjustable, handheld guide was developed to assist physicians in accurately positioning a needle in MR-guided needle interventions on their first attempt. Injections performed with the aid of the needle guide resulted in less in-plane positioning and smaller angle error than the traditional freehand technique (Table 2). As determined in Fischer's study, the traditional freehand technique had an average in-plane position error of 5.27 ± 5.56 mm and in-plane angle error of 4.07 ± 4.11 degrees based on 30 insertions in an abdominal phantom [2]. In the same study, insertions with the biplane laser technique and image overlay technique produced similar results to the needle guide. Percutaneous biopsies were performed using the SimpliCT™ and ActiSight needle guidance systems on 24 and 20 patients, respectively [12], [13].

Table 2. Comparison of in-plane position and angle errors in needle guidance techniques.

Needle Guidance Techniques	Needle Tip Position Error (mm)	Angle Error (degrees)
3D-Printed Handheld Guide	2.49 ± 1.99	2.31 ± 1.69
Laser Navigation System- SimpliCT™ [13]	-	1.3 ± 0.7
Bi-Plane Laser Guide [2]	2.90 ± 2.62	2.02 ± 2.22
Augmented Reality- Image Overlay [2]	2.00 ± 1.70	2.41 ± 2.27
ActiSight Needle Guidance System [12]	2.3 ± 3.9	-
Freehand [2]	5.27 ± 5.56	4.07 ± 4.11

In facet joint injections in phantoms, the handheld guide produced results as accurate as the image overlay and biplane laser guide in abdominal phantoms. Furthermore, the in-plane position accuracy of the guide is comparable to the accuracy of the ActiSight needle guidance system in biopsy interventions. The guide was less accurate than the SimpliCT™ navigation system as it produced a larger average in-plane angle error.

The CAD model of the guide can easily be adjusted for different injection procedures and is an inexpensive assistance mechanism. The guide can be 3D printed and be ready for sterilization in less than an hour. The guide holder is estimated to cost $0.83 whereas the guide costs $0.75 to 3D print using acrylonitrile butadiene styrene (ABS). This material is impact resistant and can be sterilized for clinical procedures [14].

The method was evaluated by analyzing the performance of two trainees inserting 5 needles in 2 facet joints of a lumbar spine phantom. The insertion points, final points and trajectory angles were compared to the planned needle trajectory. Analyzing the performance of more trainees would better assess the usability and effectiveness of the guide. In addition, trained physicians familiar with spinal interventions, specifically facet joint injections should test the usability and usefulness of the guide.

In the future, the handheld guide should be evaluated as a learning tool for medical trainees when learning how to perform percutaneous spinal interventions. The learning curve for these needle insertions should be evaluated with and without the guide. It should be investigated if the guide is a faster route to clinical competence in image-guided needle interventions. Furthermore, the accuracy of freehand insertions performed by novices trained with the guide should be compared with experts at the procedure.

5. CONCLUSION

A handheld adjustable needle guide was developed to reduce the extent of hand-eye coordination and mental registration required by a physician in MRI-guided needle interventions. The guide is as accurate as the biplane laser guides and image overlay devices when used in lumbar facet joint injections in phantoms. The CAD model of the guide can be adjusted for different injection procedures as an inexpensive assistance mechanism.

ACKNOWLEDGEMENTS

Financial support was received from the SEAMO Educational Innovation and Research Fund. This work was financially supported as a Collaborative Health Research Project (CHRP #127797), a joint initiative between the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Canadian Institutes of Health Research (CIHR). Zachary M. C. Baum was supported by the Alexander Graham Bell Canada Graduate Scholarship from the Natural Sciences and Engineering Research Council of Canada (NSERC). Gabor Fichtinger is supported as a Cancer Care Ontario Research Chair in Cancer Imaging.

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