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Augmented Reality-assisted Epidural Needle Insertion: User Experience and Performance

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INTRODUCTION

The epidural injection is a medical intervention to inject therapeutics directly in the vicinity of the spinal cord and the nerves branching from it. Epidural needle insertion is a blind procedure that relies merely on the physician's tactile feedback. Nevertheless, tactile feedback can be polluted with needle-tissue friction and may vary from patient to patient. In order to achieve sub-millimetre accuracy, preempt neurological damage, and reduce the radiation exposure time for patients and physicians, new technologies have been used. Most recently, augmented reality (AR)-based methods have shown promising results in reducing the need for intraoperative X-ray imaging, especially in spine surgery. AR navigation is based on displaying images directly on a wearable device or screen visualizing surgical instruments and patients' anatomy. Combined with robotic precision, AR shows an excellent prospect for increasing accuracy for spinal injection similar to that of spine surgery [1]. Studies have shown that the AR navigation systems, when compared to the freehand methods, resulted in increased precision of pedicle screw placement without intraoperative fluoroscopy [1], [2] and decreased radiation [3]. Inspired by the recent developments in spine surgery, in this study we have studied the user experience who used our robot-assisted needle insertion system for epidural space localization and needle insertion. In addition, the accuracy and repeatability of augmented reality-assisted epidural needle insertion were compared to that of non-assisted robotic needle insertion. For user experience assessment, NASA Task Load Index (TLX) [4] was used and analyzed.

MATERIALS AND METHODS

Fig. 1 shows the needle insertion setup used in this study. For brevity, we have not provided details of the utilized needle insertion robotic system. The aim of the study was to evaluate the accuracy and repeatability of the AR-assisted system. To generate patient-specific 3D holograms that were projected to the physician's display, first, a patient-specific anatomical model was created based on a patient's lumbar CT scan using Mimics Medical (Materialise, Belgium) software. Afterward, the vertebral bones were extracted from the 3D model and were manufactured using the 3D printing technique. To generate multi-layered soft tissue covering the vertebrae,

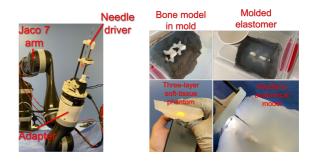


Fig. 1. Components of the epidural needle insertion setup and phantom spine.

a multi-level moulding technique was used using silicon elastomers (Ecoflex 00-30 and Ecoflex 00-10) as shown in Fig. 1(b). The seven-degree-of-freedom (7DoF) serial manipulator, and a custom-designed needle insertion endeffector. The needle was driven axially using a ballscrew mechanism with 50 μ m step accuracy. For AR model registration, two regions of the 3D printed spinal model (crest of the spinal processes of L4 and L5) were localized using an electromagnetic probe (Polhemus Viper, Polhemus, USA) and were registered to their corresponding regions on the 3D model through static 3D registration. The residual error of this static registration was 0.85 ± 0.33 mm. After model-to-phantom registration, the robotic arm's onboard VGA camera was used to register the arm with respect to a fiducial 2D marker (Vuforia). The center of the fiducial 2D marker was also registered with the electromagnetic tracker. This way, the arm's position with respect to the spine phantom was updated by the Vuforia Engine in the Unity environment. Also, the Unity environment was used to project the spine model onto the robotic arm's VGA camera.

For the experiments, a group of expert users (n=5) inserted a 19G epidural needle into the patient-specific model (L3-L4 and L4-L5 spaces) while looking at the augmented image feed from the arm's camera in Unity. Each subject repeated the task for five times with AR assistance (ROB+AR group). Also, the users repeated needle insertion without augmented reality assistance but with haptic feedback (ROB group). Haptic feedback was provided with a delta.3 haptic device with direct force reflection force rendering based on needle insertion force

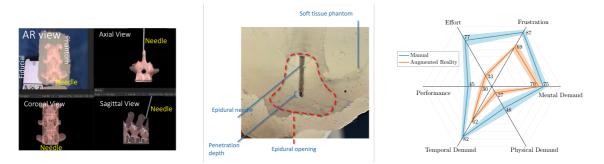


Fig. 2. Comparison of the sagittal and axial views of needle in spine model with virutal model, (b) internal view of the epidural space with needle tip penetration.

TABLE I NASA TLX metric weights

	Demand			Performance	Effort	Frustration
-	Mental	Physical	Temporal			
Weights	7	5	5	10	5	8
	A	ACCURAC	TABLE CY ASSESSM		TS	
		ror m)	Repeatabilit (mm)	y Succes (%)	s rate	T_c (sec)
ROB		4.3	1.8	7()	16 ± 4
	D :	0.0	0.77	10	0	7 + 2
ROB+A	K.	.03	0.77	10	0	/ ± 2

measured by an ATI Gamma force sensor installed on the robot's end-effector. The accuracy of needle insertion was quantified by measuring the needle position error and with/without assistance. The needle position error was assumed to be zero when it was 1mm into the epidural space. Moreover, the repeatability was quantified by measuring the standard deviation of the position error. To explore the usability of the system, participants were asked to complete the TLX questionnaire after the experiment. Mental, physical, and temporal demands, performance, frustration, and effort were asked on a scale of 0 to 100 with five increments for each setup. Based on the fact that the spinal needle insertion is a high-risk task to accomplish, we considered the metric weights provided in Table I for evaluation of the overall TLX score with AR assistance and without AR assistance groups. Afterwards, a statistical test was performed on the reported TLX outcomes to test significant differences between the two groups.

RESULTS AND DISCUSSION

 $\star T_c$: Time of completion.

★★: *p* < 0.05

Table II presents the results of the inspection of epidural space and manual needle penetration measurement after each needle insertion task. The ROB group showed an average needle position error (accuracy) of 4.3 mm while ROB+AR showed 1.03 mm (76% reduction). Also, the repeatability was 1.8mm in ROB and 0.77mm in ROB+AR group (57% reduction). In addition, the users had 100% success in localizing the epidural space on the

first try with AR and a 70% success rate without AR. Also, the time to completion of one needle insertion was 7±2s with assistance, while it was 16±4s without AR (56% reduction). The results of NASA TLX were statistically analyzed using a *t*-test with a confidence interval of 95% [5]. The results showed that the participants experienced significantly less temporal and physical demands, less effort and frustration, and perceived better success with the ROB+AR setup (p < 0.05). However, the mental demand did not show significant improvement (p = 0.29). The accuracy study results (Table II are also in agreement with the TLX findings about temporal demand (T_c), effort (success rate), and performance (accuracy and repeatability).

CONCLUSIONS

In this study, an augmented reality guided system was designed and tested for robotic epidural needle injection. Fiducial 2D markers and electromagnetic tracker-based static registration were used to register the hologram on a patient-specific 3D-printed model. The proposed system improved the accuracy, repeatability, and success rate of epidural needle insertion on an anatomical model. In addition, it reduced procedural time and was more effective from the users' perspective. In future studies, using optical tracking systems may increase the accuracy of the registered hologram leading to a sub-millimetre accuracy potentially.

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