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Original Article

Vertebral templates combined with augmented reality technology for guidance of pedicle screw placement

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Abstract: Purpose: The aim of this study was to investigate whether vertebral templates can effectively complement augmented reality (AR) to improve the safety and accuracy of pedicle screw placement during spinal surgery. Methods: Three candidates were assigned to the Freehand group and three to the AR-Guided group. A total of 36 pedicle screws were placed. The AR group had reconstructed 3D models and preoperative planned trajectories from computed tomography (CT) data of the L1-L3 lumbar vertebrae, superimposed upon them on the real vertebrae models using Hololens2® to identify the vertebral templates, and then surgeons followed the trajectories to place the screws. The deviation of the screws from the preoperative planned trajectories was measured by Micron Tracker and the pedicle screws were evaluated by Gertzbein-Robbins Classification. Results: The mean linear deviation was 1.1±0.2 mm and 2.2±0.4 mm for the AR-Guide and Freehand groups, with the mean angular deviation of 1.8±0.3° and 2.6±0.7°, respectively. Both deviations were significantly different between the two groups (P<0.001). The accuracy ratio of screws in the AR-Guide group was 100%, compared to 72.2% in the Freehand group. Conclusion: The vertebral templates accompanied by AR technology to guide pedicel screw placement is an innovative technique that can significantly improve the safety and accuracy of the surgery.

Keywords: Vertebral templates, augmented reality, pedicle screw, Hololens2®, computed tomography, Gertzbein-Robbins classification

Introduction

Pedicle screw placement surgery is currently an important surgical procedure for the treatment of spinal disorders globally with the characteristics of short fixed segments, high fusion rate and good stability. The main indications for pedicle screw placement include: degenerative lumbar disc herniation with segmental lumbar instability, lumbar spondylolisthesis within grade I and II, discogenic lower back-pain and spinal neoplasia [1, 2]. The main contraindications include: elderly patients with severe cardiopulmonary disease, severe osteoporosis, significant scoliosis, and pedicel dysplasia. The benefits of the traditional pedicle screw placement technique have been well documented; however, the precise placement of pedicle screws is a major challenge for surgeons. Poorly placed pedicle screws can loosen, potentially causing serious complications such as nerve, vascular, and visceral damage, pedicle fracture, and cerebrospinal fluid leakage [3]. The traditional Freehand screw insertion method requires the surgeon to determine the screw placement points and screw trajectories by fully combining preoperative CT images with intraoperative observations of anatomical landmarks and bony markers. An assessment of the optimality of the screw trajectories is also a prerequisite for this surgery. The traditional method relies on the surgeon's ability to analyze spatial thinking and experience in surgical training, which can be deeply flawed. For this reason, malposition rates for freehand screw placement can be high, as high as 48% [4].

3D printing technology is an emerging digital technology that is being increasingly deployed in medical imaging, medical computer technology and additive manufacturing technology. The design of 3D-printable personalized verte-

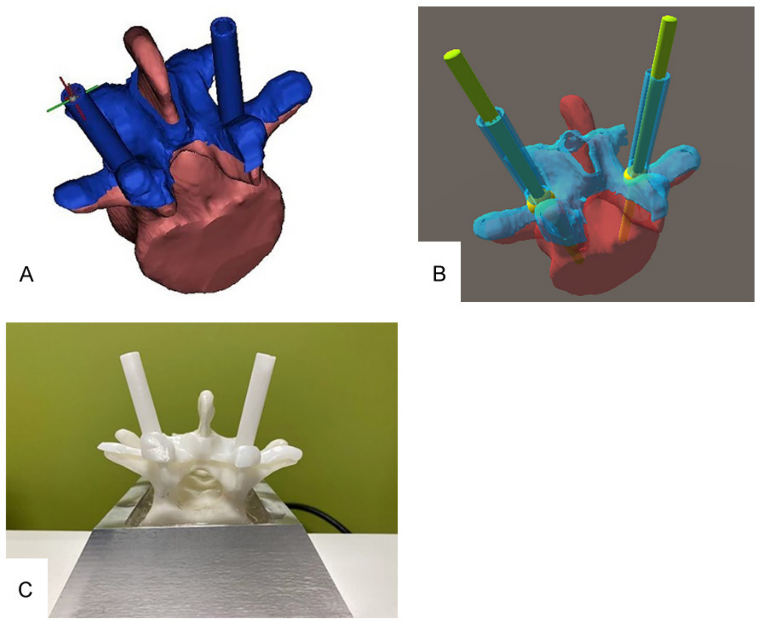


Figure 1. A. Virtual model after 3D reconstruction with CT data; the blue parts show the 3D spine guide model and the red parts represent the 3D vertebrae model. B. Preoperative planned trajectory designed with Unity based on medical imaging data; the yellow spheres indicate the screw placement points and the green cylinders show the trajectories. C. The vertebral guide after 3D-printing, which fits the surface structure of the vertebral body.

bral templates using preoperative medical imaging data can enable the surgeon to accurately fit the vertebral surface structure, locate the pedicle screw placement trajectories, shorten the operation time, and make the pedicle screw placement safer and more efficient, thus improving the quality and precision of the operation [5]. However, neurosurgeons today are still unable to envisage the depth of the vertebrae during the procedure and cannot guarantee the clinical fit of the screw templates to the vertebrae.

AR is a rapidly developing digital hologram technology that superimposes computer-generated 3D virtual image information with real-world objects with the help of optoelectronic display technology, navigation technology, and digital imaging technology to achieve 3D visualization effects [6]. HoloLens2®, a headset produced by Microsoft, is a technically mature augmented reality device that has gradually employed in the medical field [7].

In this study, personalized 3D printed vertebral templates were designed and AR technology was used to visualize the internal structure of the target vertebrae. The templates were also used to determine spatial positions of the relevant vertebrae, and guide the precise placement of pedicle screws.

Materials and methods

3D reconstruction of the vertebrae

3D reconstruction of medical images refers to the use of computer graphics and image processing techniques to process CT images and thus obtain 3D models of the original organs [8]. The reconstructed models were used to simulate clinical surgery on computer monitors and augmented reality devices. These models underpinned the surgical plan and enabled the surgeons to make accurate predictions of the surgical trajectory. In this study, the vertebrae were scanned with a thin-layer CT and the data exported to a medical imaging system as digital imaging and communications in medicine (DICOM) syntax, i.e., raw 2D image data. The data was imported into Materialise Mimics 21.0 software (Materialise NV, Belgium) for 3D reconstruction (**Figure 1A**). After reconstruction, the data was converted to standard subdivision language (STL) format for 3D printing. Preoperative planning was performed using the reconstructed model, and the entry point, direction, length, and diameter of the pedicle screws determined using the CT image data and anatomical features of the vertebrae (**Figure 2**). The preoperative planning data was used to create visible augmented reality scenes by using Mixed Reality Toolkit-Unity (MRTK-Unity) suite (Microsoft, USA) (**Figure 1B**).

Design of the vertebral templates

Computer Aided Design (CAD) and Computer Aided Manufacturing (CAM) were used to design individualized 3D templates for surgical application [9]. Based on the technical requirements of the surgical procedure, a reverse model identical to the vertebrae and sphenoid

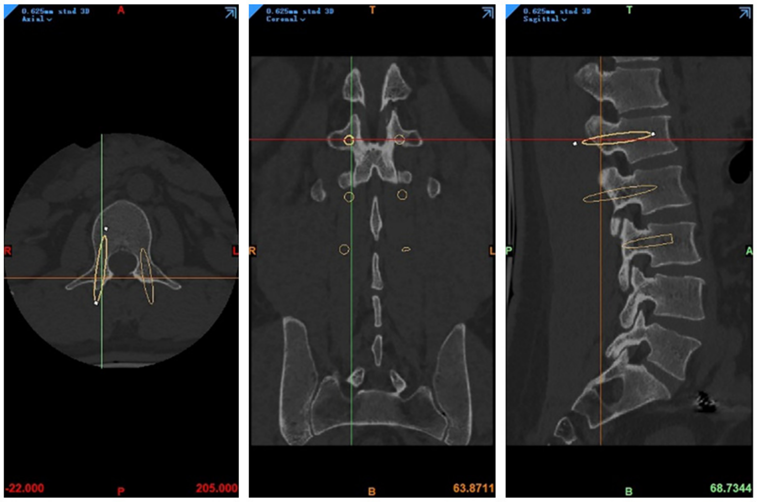


Figure 2. Preoperative planning of the entry point, direction, length, and diameter of the pedicle screws in Mimics 21.0 software. Figure from left to right shows axial, coronal and sagittal views respectively.

root was created using Materialise Mimics 21.0 software (**Figure 1A**). Intrapedicular screw positioning and guide holes were designed according to the data from preoperative planning, and then integrated with the model to form the vertebral template. The template was then mounted on the surface of the corresponding vertebrae of the 3D reconstruction model (**Figure 1C**).

3D registration of spinal images

In the context of AR, changes in the position of the observer and observation angle should not compromise the view of the virtual vertebrae model. Therefore, the exact pose of the observer and the virtual vertebrae in the real environment must be declared. As soon as the observer's pose is obtained, the mapping system can be reconstructed based on the observer's real-time perspective, and the pose of the virtual vertebrae calculated to integrate the virtual model with the real-world view of the interactive object. This correlation is key to the coordinate mapping relationship between real and virtual space reflected in the 3D registration. An excellent 3D registration enables the virtual 3D vertebrae models to be accurately superimposed on the real vertebrae, thus improving the observer's understanding of the physiology and anatomy of the vertebrae [10].

Vuforia Engine (PTC, USA), the most widely used software development kit for AR applications for mobile devices, helps developers identify and track recognition targets in real scenes to create AR experiences where virtual objects and environments interact realistically [11]. In this study, 3D printed vertebral templates were used as recognition targets, and natural feature points of 3D printed vertebral templates from Vuforia Model Target Generator (MTG) utilized to complete 3D registration. MTG helped to determine whether the feature points detected by the vertebral templates were available or not, to merge the template views and set recognizable ranges for the Vuforia Engine database (**Figure 3**). Finally, HoloLens2® was used to match the feature points detected in real time to the template feature point data in the database, enabling identification and tracking of the vertebrae in the vertebral templates and visualization of the surgical trajectory and preoperative plan for screw entry points.

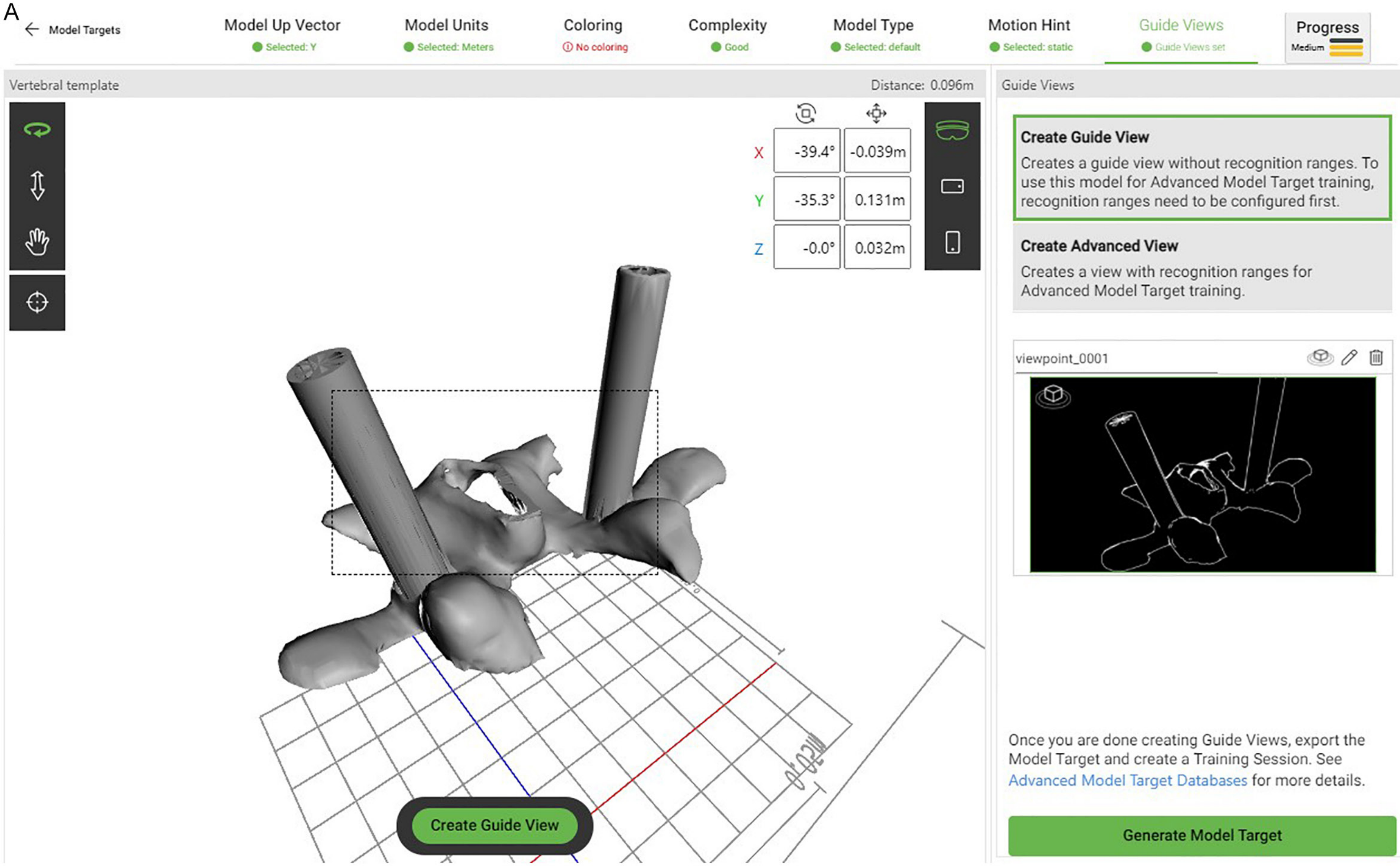
Experimental design

A segment of 2D CT images spinal images (L1-L3) was used as the experimental material. The 3D reconstructed and 3D printed vertebrae prototypes were used as the experimental models. Six inexperienced surgeons were divided into a Freehand group and an AR-Guide group, each group comprising 3 candidates (**Figure 4**). Both groups underwent training prior to the experiment. Eighteen pedicle screws were placed in three identical vertebrae models in each group, both groups placing a total of 36 pedicle screws.

Evaluation of pedicle screws

Technical accuracy analysis was performed by measuring the linear (mm) and angular (°) deviation of the real pedicle screw positions from the virtual pedicle screw planned trajectories. The spatial coordinate detector Micron Tracker (ClaroNav, Canada) was used for the analysis [12]. Micron Tracker is a repositioning system with sub-millimeter accuracy. Using this system, the location of the probe in space can be

A



Model Targets
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No coloring
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Distance: 0.096m
X -39.4° -0.039m
Y -35.3° 0.131m
Z -0.0° 0.032m
Create Guide View
Guide Views
Create Guide View
Creates a guide view without recognition ranges. To use this model for Advanced Model Target training, recognition ranges need to be configured first.
Create Advanced View
Creates a view with recognition ranges for Advanced Model Target training.
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Once you are done creating Guide Views, export the Model Target and create a Training Session. See Advanced Model Target Databases for more details.
Generate Model Target

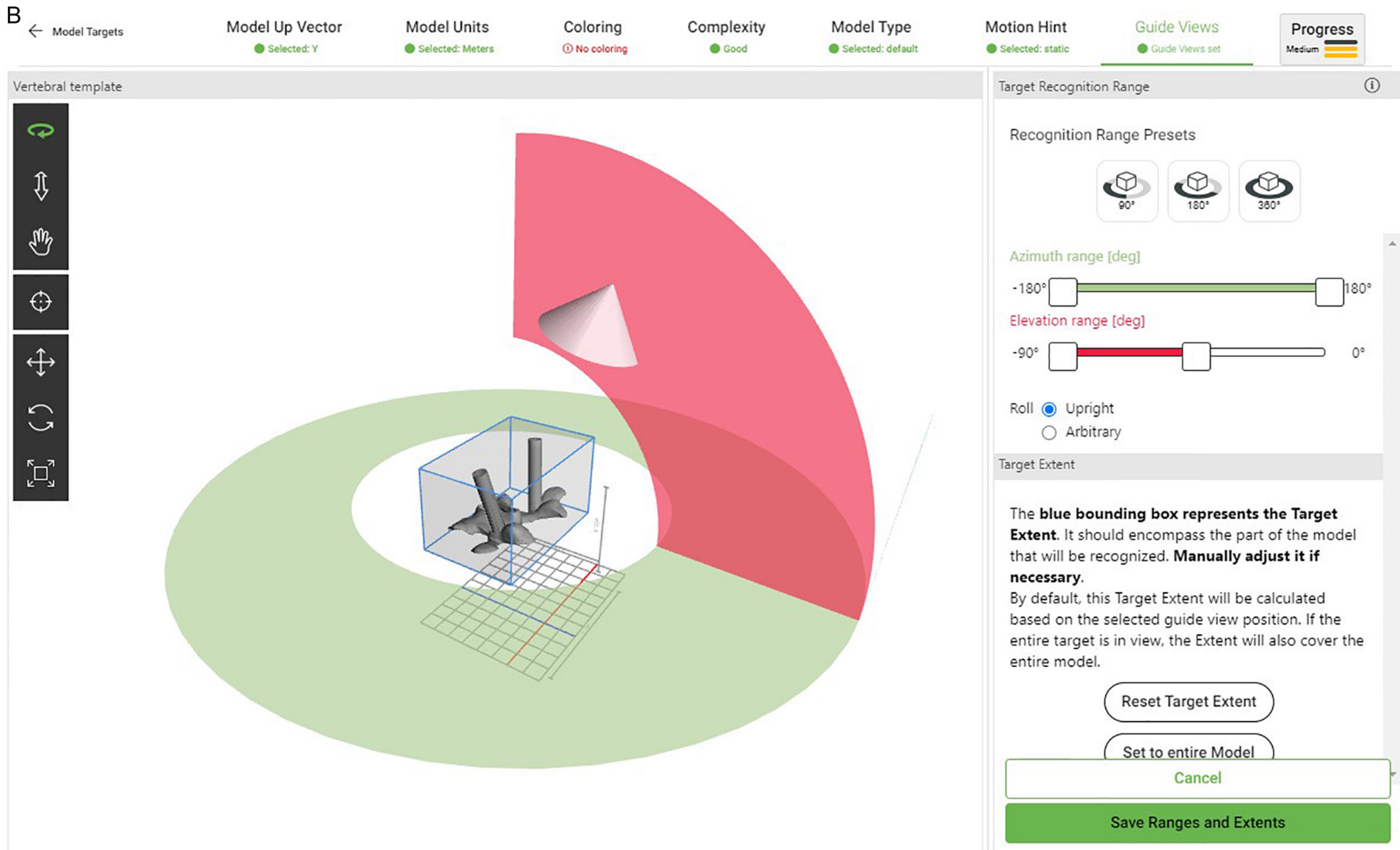

Figure 3. 3D registration with MTG. A. Acquisition of characteristic points on the surface of the vertebral guide. B. The identifiable range set in the vertical direction (red) and in the horizontal direction (green).

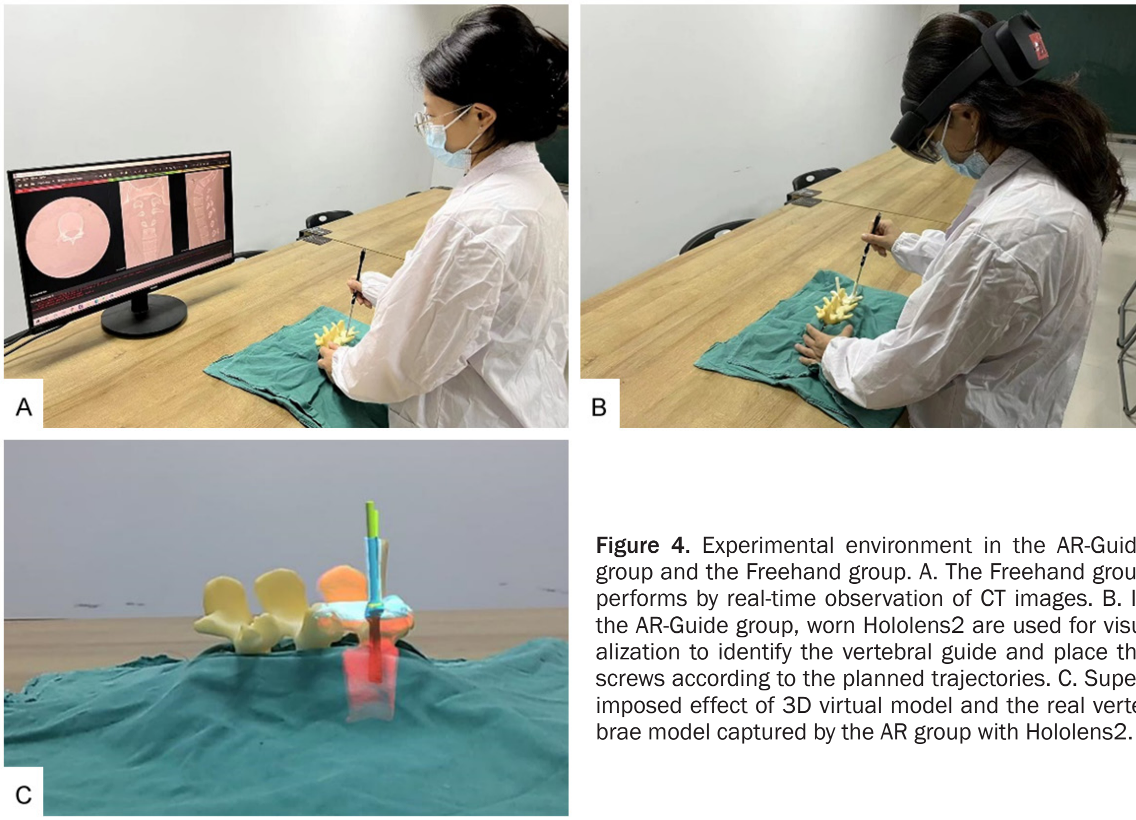

Figure 4. Experimental environment in the AR-Guide group and the Freehand group. A. The Freehand group performs by real-time observation of CT images. B. In the AR-Guide group, worn Hololens2 are used for visualization to identify the vertebral guide and place the screws according to the planned trajectories. C. Superimposed effect of 3D virtual model and the real vertebrae model captured by the AR group with Hololens2.

captured in real time, and a specific tool marker recognized and recorded. The tip of the Micron Tacker probe is placed at a marker point on the pedicle screw and each point is tested at least 20 times, saving the test results when the variance of its coordinates is 0.2 mm or less. The Gertzbein-Robbins classification, a common method for transpedicular screw evaluation, was used to assess the position of the pedicle screws and the degree of damage to the bone cortex [13]. The pedicle screws were graded according to the this classification system as follows: Grade A: screws do not penetrate the bone cortex; Grade B: screws penetrate the bone cortex ≤2 mm; Grade C: screws penetrate the bone cortex ≤4 mm; Grade D: screws penetrate the bone cortex ≤6 mm; Grade E: screws penetrate the bone cortex >6 mm. Grades A-B are clinically acceptable screw placement positions, while grades C-E are poor screw placement positions.

Statistical analysis

Experimental data was analyzed using SPSS 26.0. The following descriptors and parameters were computed: mean ± standard deviation, maximum value, minimum value, linear deviation of the screw placement points, and angular deviation of the screw placement trajectories from the preoperative planned trajectories. In addition, the independent sample t-test was used to compare the accuracy of the AR-Guide and the Freehand groups. $P<0.01$ indicated a statistically significant difference.

Results

Technical accuracy analysis

The accuracy analysis of screw placement showed that linear deviation ranged from 0.7 mm to 1.4 mm for the AR-Guide group and 1.6 mm to 2.9 mm for the Freehand group. Angular deviation ranged from 1.2° to 2.3° for the AR-Guide group and 1.9° to 4.2° for the Freehand group. The mean linear difference was 1.1±0.2 mm and 2.2±0.4 mm for the AR-Guide and Freehand groups, with the mean angular deviations at 1.8±0.3° and 2.6±0.7°, respectively. Both deviations were deemed to be significantly different ($P<0.001$) (**Figure 5**).

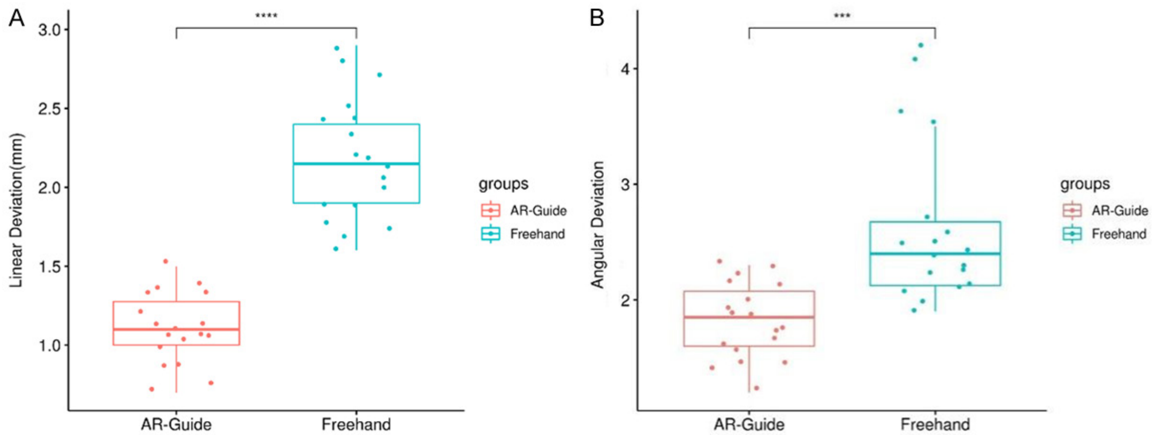

Figure 5. Comparison of deviations between position of the pedicle screw and the preoperative planned trajectory in the two groups. A. Linear deviation of the screw insertion point, ****P<0.0001. B. Angular deviation of pedicle screw placement trajectory, ***P<0.001.

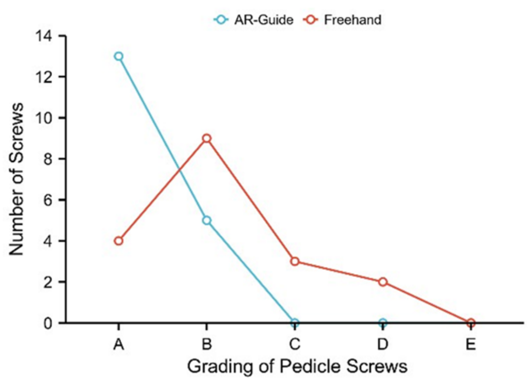

Figure 6. Grading of pedicle screws and grade's distribution.

Assessment of pedicle screw accuracy

Fourteen of the screws placed by the AR-Guide group and 6 of those placed by the Freehand group were classified as grade A. Nine of the screws placed by the latter were graded as grade B, and so were 5 of those placed by the former (**Figure 6**). These screws were deemed to be accurate and safe, while the remaining screws were considered unacceptable. The percentage of grade A and B screws was interpreted as the accuracy rate of pedicle screw placement, a staggering 100% for the AR-Guide group and 72.2% for the Freehand group.

Discussion

Pedicle screw placement is an important procedure in spinal surgery, evidenced by its crucial impact on the patient's prognosis. Misplacement or malpositioning of these screws can lead to serious complications. This study demonstrates that vertebral templates complemented by AR can effectively guide pedicle screw placement, significantly improving the safety and accuracy of screw placement. This is achieved by considerably reducing the linear deviation of the screw placement points and the angular deviation of the screw placement trajectories from the preoperative planned trajectories, a virtue that makes it superior to the freehand screw placement method.

In a study contrasting the feasibility of a 2D X-Ray fluoroscopy guidance to that of an AR system, a 56% reduction in procedure time and 41.5% improvement in overall positioning accuracy were achieved by the AR system [14]. The findings of our study corroborate those reported by West and his colleagues. With AR technology, incessant checks between the monitor and the surgical area are unnecessary. A direct view of the spatial depth information and the preoperative planned trajectories of the vertebrae have been made possible by AR technology, easing the surgeon's workload and improving surgical accuracy.

Owing to the complexity of the spine's anatomy and limitations of the traditional freehand screw placement method, many surgeons and academics are exploring the benefits that AR technology can bring to this procedure. In an experimental study reported by Boyaci and his colleagues, 3D registration was performed using QR code recognition through a tablet personal computer (PC), and achieved a significant increase in the safety ratio of cervical pedicle screw fixation [15]. The augmented reality display device HoloLens2® was used in our study, facilitating the accurate superimposition of 3D reconstructed virtual vertebras on real vertebrae models, a feat that could not be achieved using mobile devices. As a head-mounted device, the user's hands are free, allowing him/her to perform an array of tasks. QR code recognition, the most common method of 3D registration, boasts the advantage of convenience, but is discredited by the need to keep the QR code flat, which is difficult to achieve on a complex operating table.

In a popular study, Gibby and his collagues used Hololens® and OpenSight® (Novarad, USA) application to view the virtual trajectory guides and CT images superimposed on the phantom in 2D and 3D [16]. Although the superimposition of 2D CT slices is uncommon, the visualization effect achieved by HoloLens® can be realized using this technique. The innovation of our study has a similar objective, that is to aid in 3D registration of AR by designing vertebral templates on the basis of CT data, reducing errors in the overlay of reality and virtual scene. However, we must bear in mind that the design and fabrication of vertebral templates undertaken in our study was quite time consuming, a notable problem. Furthermore, the fact that a vertebral template is rigid and thus can only be applied to the corresponding vertebrae also presents a drawback of this innovation.

There are limitations of this study that must be acknowledged. Firstly, the amount of raw data and experimental sample size were small, and the obtained measurement data might be unreliable. In addition, because the experiments were performed on a 3D printed model, one that is different from the clinical environment, the visualization quality and accuracy of the virtual models displayed in Hololens2® in the clinical studies are arguably defective. Further cadaveric or clinical experiments are thus needed for validation.

With continuing advancements in display and interaction technologies, intelligent technologies for medical image guided surgery will play a great role in tomorrow's operating room. Augmented reality with its fast recognition and real-time visualization technology can well compensate for the poor readability of CT and X-ray images. Interestingly, although the head-mounted AR device Hololens2® was not primarily designed for the medical field, its accuracy can meet the navigation requirements of most surgeries, thus improving the success rate of some difficult procedures. This technology also has great applicability to preoperative planning, simulated surgery training, and telemedicine. In pedicle screw placement surgery, AR technology also enables patients to visualize their body's lesions preoperatively, facilitating communication between surgeon and patient prior to surgery. Intraoperatively, this technology not only aids surgical navigation but can also be used to obtain other important information about the patient such as heart rate and blood loss and transmit it to the patient's monitory system in real time for the surgeon's reference. In future studies, we foresee the design of a robotic arm that acquires the set of spatial coordinate points of the preoperative planning trajectory captured by HoloLens2® through a communication protocol. The robotic arm will likely be able to operate the surgical instruments in such a way that it can reach these coordinate points automatically and complete the screw placement with the surgeon's confirmation.

Conclusion

The vertebral templates were well complemented by AR to guide pedicle screw placement. The significant improvements in safety and accuracy realized using AR-guided screw placement demonstrated its superiority to the freehand screw placement method. Although the current accuracy of the method meets the clinical requirements, further cadaveric and clinical trials are needed to verify the feasibility of the system.

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Disclosure of conflict of interest

None.

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