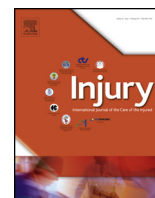




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Feasibility and accuracy of computer-assisted individual drill guide template for minimally invasive lumbar pedicle screw placement trajectory

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ABSTRACT

Objective: To discuss the feasibility and accuracy of a specific computer-assisted individual drill guide template (CIDGT) for minimally invasive lumbar pedicle screw placement trajectory (MI-LPT) through a bovine cadaveric experimental study.

Design: A 3-D reconstruction model, including lumbar vertebrae (L1–L5), was generated, and the optimal MI-LPTs were determined. A drill guide template with a surface made of the antitemplate of the vertebral surface, including the spinous process and the entry point vertebral surface, was created by reverse engineering and rapid prototyping techniques. Then, MI-LPTs were determined by the drill guide templates, and the trajectories made by K-wires were observed by postoperative CT scan.

Setting: General Hospital of Shenyang Military Area Command of Chinese PLA.

Results: In total, 150 K-wires for MI-LPTs were successfully inserted into L1–L5. The required mean time and fluoroscopy times between fixation of the template to the spinous process, entry point vertebral surface, and insertion of the K-wires for minimally invasive lumbar pedicle screw placement trajectories into each vertebra were 79.4 ± 15.0 s and 2.1 ± 0.8 times. There were no significant differences between the preoperative plan and postoperative assessment in the distance from the puncture to the midline and inclination angles according to the different levels ($P > 0.05$, respectively). The mean deviation between the preoperative plan and postoperative assessment in the distance from the puncture to the midline and inclination angles were 0.8 ± 0.5 mm and $0.9 \pm 0.5^\circ$, respectively.

Conclusions: The potential use of the novel CIDGT, which was based on the unique morphology of the lumbar vertebra to place minimally invasive lumbar pedicle screws, is promising and could prevent too much radiation exposure intraoperatively.

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Introduction

Selecting the correct pedicle screw placement trajectories and then inserting them properly within the pedicles to ensure the good anchoring and safe location of the pedicle screws is very important. Manual placement has a high rate of unplanned perforation of pedicle screws and causes a high risk of bone weakening or neurological deficit [1,2]. Several studies have shown

that image guidance navigation systems have good clinical results [3–5]. However, navigation systems have several disadvantages such as a longer duration for intraoperative registration and more workload during surgery. Finally, only a few large hospitals can bear the enormous costs of navigation or robot-based systems [6,7]. One way to overcome these shortcomings is the production of personalized templates by using reverse engineering and rapid prototyping techniques. Such methods have been introduced in several reports, but the personalized templates were applied only in traditional open spine surgeries and related cadaveric study [8–19]. The accuracy of a computer-assisted individual drill guide template (CIDGT) for pedicle screw insertion makes them highly desirable for open spinal surgeries [8–19]. However, the feasibility

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and accuracy of specific CIDGT for minimally invasive lumbar pedicle screw placement trajectory (MI-LPT) has not been investigated. The aim of this cadaveric experimental study was to discuss the feasibility of CIDGT by reverse engineering and rapid prototyping techniques for MI-LPT and then validate its accuracy.

Material and methods

Design of the CIDGT

The cadaver lumbar spines (L1–L5) were scanned through a spiral three-dimensional CT scan (GE, Light Speed 64-Row, USA) with 0.625-mm slice thickness and 0.35-mm resolution. We stored the images in DICOM format and transferred the images to a workstation running MIMICS 10.11 software (Materialise, Belgium). A 3-D vertebral model (L1–L5) was generated and exported in STL format. Next, we opened the 3-D vertebral model in a workstation running the UG imageware 12.0 (EDS Co., USA) for the optimal MI-LPT. The optimal MI-LPT was determined and established before surgery. The insertion point and angle of the screws trajectory can be confirmed, and then a drill template was constructed with a surface designed to be the inverse of the vertebral surface, including the spinous process and the entry point vertebral surface (Fig. 1). The 3-D reconstruction model, including lumbar vertebrae (L1–L5), was generated. The optimal MI-LPTs were determined. A drill guide template, which has a surface composed of the antitemplate of the vertebral surface, including the spinous process and the entry point vertebral surface, was created by reverse engineering and rapid prototyping techniques (Fig. 2).

Cadaveric experiment

Fifteen lumbar spines (L1–L5) came from fifteen bovines (24–36 months old, mean 29.3 months old; 750–900 kg, mean 837.3 kg) obtained from a regional slaughterhouse and examined through radiographs to exclude anomalies, tumour and osteoporosis. A bovine is a tetrapod. Its anatomical characteristics are different from that of a human. Additionally, the pedicles of the bovine spine were much thinner than the human spines. All pedicle screws will make a cortical perforation; thus, we did not insert pedicle screws into the pedicle to avoid the misjudgement about the cortical perforation. The purpose of the preliminary study is to gain first insights into the feasibility and accuracy of the CIDGT for minimally invasive pedicle screw placement. The length of the entry point to the middle line of the spinal process and insertion angle of the pedicle axis were measured for each pedicle. Then, K-

wires were inserted into bovine lumbar spines by CIDGTs according to the preoperative plan designed specifically for MI-LPT (Fig. 3). Fifteen bovine lumbar spines (L1–L5) had 150 K-wires inserted into them using the IDGT. We took notes of the surgical time and intraoperative fluoroscopy times, and then we assessed the position of the K-wires through postoperative CT. The procedure was approved by the ethics committee of the General Hospital of Shenyang Military Area Command of Chinese PLA. The study was fully compliant with the ARRIVE criteria [20].

Statistical processing

All statistical analyses were performed using SPSS 22.0 version (SPSS, Inc., Chicago, IL). The results are expressed as the mean values \pm standard deviations (SD). Statistical comparisons were performed using Fisher's exact test. A probability value of 0.05 or less than 0.05 was considered significant.

Results

Preoperative CT of fifteen bovine lumbar spines (L1–L5) in axial plane was captured for each vertebra. The entry points and trajectories of the screws were preoperatively planned and designed specifically for minimally invasive pedicle screw placement. In the 15 cadaveric specimens, 150 MI-LPTs were determined by a preoperative CT scan and the trajectories made by K-wires were observed by a postoperative CT scan. All the K-wires were inserted in the pedicles. There was no evidence of cortical perforation. The best fit for positioning the CIDGT was easily found manually during the operation through lateral radiograph. In total, 150 K-wires for MI-LPTs were successfully inserted into L1–L5. The required mean time and fluoroscopy times between fixation of the template to the spinous process, entry point vertebral surface, and insertion of the K-wires for minimally invasive lumbar pedicle screw placement trajectories into each vertebra were 79.4 ± 15.0 s and 2.1 ± 0.8 times. There were no significant differences between the preoperative plan and postoperative assessment in the distance from the puncture to the midline and inclination angles according to the different levels ($P > 0.05$) (Tables 1 and 2). The mean deviation between the preoperative plan and postoperative assessment in the distance from the puncture to the midline and inclination angles were 0.8 ± 0.5 mm and $0.9 \pm 0.5^\circ$, respectively.

Discussion

Various techniques have been explored for lumbar pedicle screw placement. Traditional techniques of intraoperative spinal

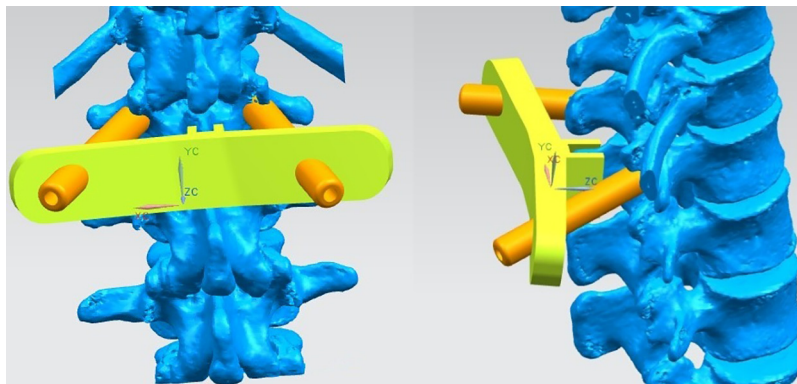


Fig. 1. CIDGT was a drill guide template which was constructed with a surface designed to be the inverse of the vertebral surface, including the spinous process and the entry point vertebral surface. The template includes the clamping unit, which can be used to clamp the spinous process, and the puncture unit, which can be used to provide preoperatively planned trajectory for the K-wires through the drill hole.

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