Development of notch-free, pre-bent rod applicable for posterior corrective surgery of thoracolumbar/lumbar adolescent idiopathic scoliosis

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INTRODUCTION: Adolescent idiopathic scoliosis (AIS) is a disorder that causes three-dimensional deformities of the pediatric spine. Lenke et al. suggested a classification of AIS with six curve types considering the lumbar spine modifier and thoracic kyphosis. The type 5 curve is defined as a structural thoracolumbar/lumbar curve, with nonstructural upper thoracic and main thoracic curves. Although the anterior approach remains useful for Lenke type 5 AIS, posterior spinal fusion with pedicle screw instrumentation is currently the standard technique with a relatively low complication rate. Although optimal rod contouring is essential for anatomical spinal correction, the rod contouring procedure highly depends on the surgeons' knowledge or experience. Additionally, the notches generated in rod contouring decrease the mechanical properties of the rod. We previously developed anatomically designed notch-free, pre-bent rods for patients with Lenke type 1 or 2 AIS, resulting in reduced intraoperative rod deformation and improved thoracic kyphosis after the correction [1.2]. However, this implantation system is not applicable to Lenke type 5 AIS. This study aimed to present optimum rod geometries to provide a pre-bent rod system for posterior spinal surgery in patients with Lenke type 5 AIS by classifying the rod shape before implantation.

METHODS: We included 20 consecutive patients with Lenke type 5 AIS (2 men and 18 women) who underwent posterior spinal fusion between 2021 and 2023 at our institutions. We investigated multiple parameters using preoperative and 2-week follow-up standing long-cassette posteroanterior, lateral radiographs and computed tomography (CT). In addition, the rod angles were also measured as indicators of rod deformation. The optimal shapes for the pre-cut and pre-bent rods were found as the following steps. First, papers with hand-traced outlines of 20 rods before implantation were scanned and converted to a JPEG file. Next, a computer-aided design (CAD) operator manually fit a sequence of circular arcs and straight lines to the outline images of each rod shape. Subsequently, the sequence of circular arcs and straight lines of the rod's outlines were exported and a center point cloud Pi of a rod $i \in R$,($R=\{1,2,\ldots,20\}$: a set of all rods) was generated. Differences between the center point clouds in each rod were evaluated using the iterative closest point (ICP) method with modification. Before the evaluation using the ICP method with modification, the point clouds were divided into four clusters based on rod length using hierarchical cluster analysis. In each cluster, the modified ICP method as follows are used (**Figure 1**). (a) The center points of rod i and j that are included in the valuation interval I^e (from the UIV to L3) are selected as P_i^e and P_j^e from the original center point clouds P_i and P_j. The point closest to a fixation point of L3 in P_i^e and P_j^e is selected as their starting point $p_{i,1}^e$ and $p_{j,1}^e$ respectively. (b) The points P_i^e and P_j^e are symmetrically copied w.r.t. their starting points $p_{i,1}^e$ and $p_{j,1}^e$. Then, P_i^e and P_j^e and their symmetrically copied points P'^e_i and P'^e_j are combined as Q_i and Q_j. Of the two point clouds Q_i and Q_j, the one with the longer length is selected as a target point cloud Q_t and the other as a source point cloud Q_s.(c) The source point cloud Q_s is best fitted to the target point cloud Q_t using the ICP method. (d) The final best fit alignment between the point cloud P_i and P_j was obtained by removing P'^e_i and P'^e_j from Q_s and Q_t at their best-fit position. As shown in **Figure 1 a**, a subset of the center point clouds that were included only in an evaluation interval I^e from the upper instrumented vertebra (UIV) to L3 were selected as targets of the alignment by the modified ICP, because L3 was fixed as the LIV. We used D_{rms} and D_{max} as evaluation indicator. D_{rms} is indicator as distance which the closet point pairs between rods are minimized and D_{max} as maximum gap between rods.

RESULTS: Although the preoperative thoracolumbar/ lumbar curve was 42.2°, postoperative radiographs improved to 5.9°. The UIV was selected as T9 in seven patients, T10 in 11 patients, and T11 in two patients, whereas the LIV was L3 in all patients. The proximal rod angle changed from 18.3° to 9.3° and the distal rod angle changed from 30.8° to 15.9°, indicating that both proximal and distal rod angles significantly decreased after the correction. The rods were classified into four clusters according to their length. (**Figure 2**). Without dividing the point clouds in the length-based cluster, the $D_{rms,}$ which is the overall difference between each point cloud, was < 5 mm in all clusters. The D_{rms} ranged from 0.21 to 1.91 mm, and the D_{max} ranged from 0.46 to 4.32 mm. The maximum Drms and Dmax between the best-fitted B-spline curvature and other point clouds in each cluster was 1.9 and 4.7 mm, respectively. Finally, the best-fitted curvature and STL images for the three-dimensional rods in each cluster are presented in **Figure 3**.

DISCUSSION: ICP method with modification was applied for identifying optimal rod shape for Lenke type 5 curve in this study. Our algorithm is modified in the point of best fitting between two rods at target point by making symmetry copied points from target point compared with ICP method in previous study. So that fixation points on two rods which are the target points of evaluation intervals are perfectly matched. In the present study, in the cluster analysis for length classification, 20 rods were divided into four clusters with intervals of < 25 mm. The D_{rms} was within 5 mm in each rod length-based cluster, indicating that it was possible for the point clouds of rod shape to converge to one best-fitted curve in each length-based cluster because the thoracic pre-bent rod was created based on a D_{rms} < 5 mm in each cluster in a previous study [1]. Furthermore, the maximum D_{rms} and D_{max} between the best-fitted B-spline curvature and other point clouds in each cluster was 1.9 and 4.7 mm, respectively. Previous thoracic pre-bent rods resulted in a good sagittal alignment without additional rod-bending, suggesting that four preset rod shapes with best-fitted B-spline curvature can be applied in the correction for patients with Lenke type 5 curve without additional rod-bending. Considering mechanical implant failure and correction loss, the material and fatigue life of rods are also essential to develop the pre-bent rod. In the current study, the rod angle of the convex side significantly decreased on proximal and distal curvature in the contoured rods. Although all correction surgeries were performed using cobalt chromium alloy rods, the titanium alloy rod can have a larger rod deformation that can influence postoperative outcomes. Furthermore, despite performing rod contouring prior to implantation in this series, the notch by intraoperative bending should be avoided from the viewpoint of the impact on the postoperative coronal and sagittal outcome due to rod deformation. Notch-free cobalt chromium alloy rods are optimum for the correction surgery for patients with Lenke type 5 curves.

SIGNIFICANCE: We identified four optimum rod shapes to develop pre-bent rods designed for corrective surgery for thoracolumbar/lumbar adolescent idiopathic scoliosis.

REFERENCES: 1. Kokabu, T.; Kanai, S.; Abe, Y. et al. Identification of optimized rod shapes to guide anatomical spinal reconstruction for ado-lescent thoracic idiopathic scoliosis. J Orthop Res 2018, 36, 3219-3224.2. Sudo, H.; Tachi, H.; Kokabu, T. et al. In vivo deformation of anatomically pre-bent rods in thoracic adolescent idiopathic scoliosis. Sci Rep 2021, 11, 12622.

Figure 1

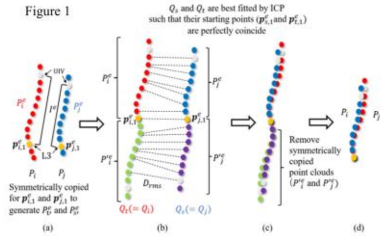

Figure 2

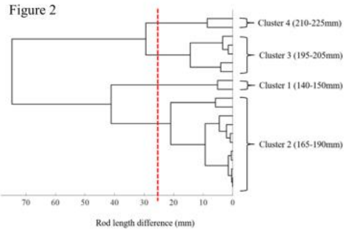

Figure 3