Development of Scoliocorrector Fatma-UI to aid correction of adolescent idiopathic scoliosis in Indonesia

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ABSTRACT

Background: Adolescent idiopathic scoliosis (AIS) is a three-dimensional spine deformity and many techniques have been conducted to correct scoliosis. This study aims to develop a set of tools named Scoliocorrector Fatma-UI to aid in the correction of adolescent idiopathic scoliosis, to evaluate them in finite element analysis and biomechanical test, as well as to apply them in a real patient.

Methods: Needs, principles, and ways to achieve the needs of an ideal corrector of scoliosis were listed, and a design was developed. Finite element analysis was performed with static structural, no separation contact, automatic mesh, and a force of 800 N. The design was modified until it passed the finite element test, and the prototype was fabricated. The prototype was biomechanically tested using a universal testing machine. The modulus of elasticity of the tools was recorded. The pull was continued until the point of failure, and the response was recorded. After ethical clearance, the tools were applied to a 15-year-old girl with Lenke 1a- adolescent idiopathic scoliosis. Postoperatively, we measured the radiological profile (coronal, sagittal, and rotational) and neurological profile (motor-evoked potential, somatosensory evoked potential, and postoperative motor power).

Results: The correction tools consist of pulleys, wires, correction screws, correction houses, and pulling boards. In finite element analysis, the highest number of nodes and elements were found in the correction board, while the highest stress was in the wire. In biomechanical analysis, we found that the modulus elasticity of the correction tool is 95 613.24 ± 6 332.77 MPa. The failure point occurred at 800 Nm, at which point the wire was slowly detached from the correction screw. In clinical application, we found that the coronal and sagittal angles improved from 53 to 1 degree and 19 to 26 degrees. Axial rotation enhanced from 10 to 4 degrees. Motor-evoked and somatosensory-evoked potential were similar to baselines, and postoperative motor function was normal.

Conclusion: We have developed a set of correction tools that have been evaluated in finite element and biomechanical analysis and clinically applied to an actual patient.

INTRODUCTION

Adolescent idiopathic scoliosis (AIS) is a three-dimensional spine deformity characterized by lateral curvature of more than 10 degrees in adolescents aged 10–18 with an unknown cause. It remains a significant challenge in orthopedics due to its high incidence, high cost, and high risk.1–3 The incidence of AIS may reach as high as 13%.1 The cost of scoliosis treatment reached USD 177,000 and is increasing.2 The risks of AIS treatment include death (0.03%), neurological complications (1.5%), infection (3%), pseudoarthrosis (5%), and pedicle screw misplacement (15.8%).3

In AIS with a curve above 45°, surgery is necessary.4 Surgery aims to stop the curve's progression and achieve a three-dimensional deformity correction. Three-dimensional correction correlates with surgical outcome, pulmonary function, and cosmesis.5,6 Failure to achieve three-dimensional correction will result in a fixed sagittal imbalance syndrome.7

Among many techniques to correct scoliosis, postero medial translation is a technique that can achieve three-dimensional correction.10–15 However, postero medial translation requires a specific clamp and sublaminar polyester wire, which are unavailable in the Indonesian market.15 The sublaminar wire has a low failure load, an increased risk of neurological complications, and has been reported to cause mega-granuloma.15–17 Due to the posterior fixation point being more prominent than the rotational axis in scoliosis, the rotational correction of postero medial translation is also questioned.18

Since postero medial translation is subject to many limitations, especially in Indonesia, this study aimed to develop a set...
of correction tools called Scoliocorrector Fatma-UI to aid posteromedial translation of adolescent scoliosis. Other purposes of this study were to evaluate the developed tools in finite element analysis and biomechanical tests and apply them to actual patients.

METHODS
This study was conducted from January to May 2020. We listed the needs, the principles, and the way to achieve them and developed a design concept based on them. The concept was then developed into a computer-aided design using Solidworks® 2017. To determine the initial size of the design, we performed benchmarking on Waston's pedicle screws and Mizuho’s surgical table. Measurements were conducted using a Vernier digital caliper and a Dino-Lite digital microscope.

Finite element analysis
Finite element analysis was performed using ANSYS® 2020. The settings used were static structural, no separation contact, automatic mesh, and a force of 800 N. Stainless steel 316L (yield strength 690 MPa, ultimate strength 860 MPa, density 8000 kg/m³) were used as the material. The design was resized until it passed finite element analysis. The design was then exported to Ultimate Cura® 11, and slicing was performed to manufacture the design using CNC Milling Harford 1000x500x500 and Eccoca 1050x550x500. The prototype was assembled and biomechanically tested using the Universal Testing Machine (UTM) Tensilon RTF 2350.

Biomechanical analysis
For the biomechanical test, a specific jig (Figure 1) was developed to stimulate the fixation of the tools to a pedicle screw. The test was conducted ten times with a distance of 400 mm, a speed of 50 mm/minute, and 500 N of force. The modulus of elasticity of the tools was recorded. The pull was continued until the point of failure, and the response was recorded.

Clinical application
After ethical clearance, the tools were applied to a 15-year-old girl with Lenke 1a- adolescent idiopathic scoliosis (Figure 2). Her coronal and sagittal Cobb angles and rotational angles were 53, 19, and 10 degrees, respectively. Postoperatively, we measured the radiological profile (coronal, sagittal, and rotational) and the neurological profile (motor-evoked potential, somatosensory evoked potential, and postoperative motor power).

RESULTS
The needs, principles, methods, and selected methods are shown in Tables 1 and 2, while the computer-aided design is shown in Figure 2. The correction tools consist of a pulley, wire, correction screw, correction house, and pulling board. In finite element analysis, we found the highest number of nodes and elements in the correction board, while the highest stress was found in the wire. Stresses in the components were lower than the yield strength of stainless steel, so no design resizing was performed. Figure 3 shows the result of the biomechanical analysis, while Figure 4 shows the manufactured prototype.

In biomechanical analysis, we found that the modulus elasticity of the correction tool is 95 613.24 ± 6 332.77 MPa. The stress-strain curve is shown in Figure 5. The failure point occurred at 800 Nm, at which point the wire was slowly detached from the correction screw. In clinical application, we found that the coronal and sagittal angles improved from 53 to 1 degree and 19 to 26 degrees, respectively. The axial rotation improved from 10 to 4 degrees. The motor-evoked potential and somatosensory-evoked potential were similar to baselines, and postoperative motor function was normal.

DISCUSSION
Pedicle screws were used as fixation anchors for the spine in correction tools due to their high pullout strength. Pedicle screws have a higher pullout strength compared to hooks or wires and have been regarded as the gold standard for scoliosis surgery. To increase the failure load, we used at least three pedicle screws in the apical region. Multiple screws will allow force distribution, resulting in a higher failure load. The pedicle screws will span anteriorly to the vertebral body so that the axis of fixation will be anterior to the rotational axis in scoliosis. A more anterior fixation axis than a rotational axis is necessary for effective derotation.18

Wires were used as they allow longer translation distances compared to reduction screws and towers. The wires have a small dimension, thus allowing a better view of the surgical field. They are also easier to manufacture and disinfect than the rack and pinion system. The pulling board, correction screws, and correction houses allow adjustment of the pulling point. Adjusting the pulling point will result in a better pulling vector and a longer translation distance, thus allowing better coronal and sagittal correction. Correction screws allow incremental correction. Compared to other actuators, screws are simpler and easier to manufacture. A pulling board results in a more stable pulling point than a rod. Pulleys convert the vector of pull, and when arranged as moveable pulleys, they give a mechanical advantage. Compared to other systems, the mechanical advantage of a moveable pulley can be achieved without leveraging on the spine. The material
Table 1. Needs, principles, methods, and selected methods for correction tools

<table>
<thead>
<tr>
<th>Need</th>
<th>Principle</th>
<th>Methods</th>
<th>Selected method</th>
</tr>
</thead>
<tbody>
<tr>
<td>High failure load</td>
<td>Strong vertebral fixation</td>
<td>Pedicle screw</td>
<td>Pedicle screw</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hook</td>
<td></td>
</tr>
<tr>
<td>Better coronal correction</td>
<td>Multiple fixation points</td>
<td>Multiple pedicle screws</td>
<td>Multiple pedicle screws</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Multiple hooks</td>
<td></td>
</tr>
<tr>
<td>Better rotational correction</td>
<td>Longer translation distance</td>
<td>Wire/band</td>
<td>Wire</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reduction screw</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reduction tower</td>
<td></td>
</tr>
<tr>
<td>Better sagittal correction</td>
<td>Adjustable pulling vector based on a normal sagittal contour</td>
<td>Pull from the contoured rod</td>
<td>Pull from the adjustable point</td>
</tr>
<tr>
<td>A lower force is needed.</td>
<td>Mechanical advantage</td>
<td>Lever</td>
<td>Moveable pulley</td>
</tr>
<tr>
<td>Optimal pull vector</td>
<td>Adjustable pulling vector</td>
<td>Pull from the adjustable point.</td>
<td>Pull from the adjustable point.</td>
</tr>
<tr>
<td>Controlled correction</td>
<td>Incremental correction</td>
<td>Adjustable locking system</td>
<td>Screw thread</td>
</tr>
<tr>
<td>Responsive</td>
<td>High accuracy</td>
<td>Manual correction</td>
<td>Manual correction</td>
</tr>
<tr>
<td>Avoidance of sublaminar fixation</td>
<td>Other fixation methods</td>
<td>Pedicle screw</td>
<td>Pedicle screw</td>
</tr>
<tr>
<td>Low neurological injury risk</td>
<td>Spinal cord shunning</td>
<td>Direction of pull away from the spinal cord</td>
<td>Direction of pull away from the spinal cord</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rack and pinion system</td>
<td></td>
</tr>
<tr>
<td>No foreign body reaction</td>
<td>No additional implant</td>
<td>Removable tool after correction is achieved.</td>
<td>Removable tool after correction is achieved.</td>
</tr>
<tr>
<td>Cheaper</td>
<td>Cheap material</td>
<td>Stainless steel or iron</td>
<td>Stainless-steel</td>
</tr>
<tr>
<td>Simple</td>
<td>Simple design</td>
<td>Simple mechanical system</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Small size</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Easy to manufacture</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Easy for sterilization</td>
<td></td>
<td></td>
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</tbody>
</table>

Table 2. Nodes, elements, and stress of correction tools

<table>
<thead>
<tr>
<th>Component</th>
<th>Nodes number</th>
<th>Elements number</th>
<th>Stress (MPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correction board</td>
<td>115 807</td>
<td>60 450</td>
<td>126.5</td>
</tr>
<tr>
<td>Correction screw</td>
<td>69 388</td>
<td>40 757</td>
<td>31.2</td>
</tr>
<tr>
<td>Correction house</td>
<td>13 100</td>
<td>7 286</td>
<td>92.1</td>
</tr>
<tr>
<td>Wire</td>
<td>68 305</td>
<td>33 430</td>
<td>252</td>
</tr>
</tbody>
</table>

used for the correction tools is stainless steel. Stainless steel is high-strength, corrosion-resistant, low-maintenance, and more economical.\(^\text{19}\) It is also one of the most commonly used alloys for spinal implants.\(^\text{20-21}\) To lower the risk of neurological deficits, the direction of correction is away from the spinal cord. We avoid the derotation maneuver as it lever the pedicle screw toward the spinal cord. Correction was performed manually rather than using power tools. The stress of correction tools is lower than the yield and ultimate strength of stainless steel 316L, meaning that the correction tools can hold the correction force without any failure. The modulus elasticity of the wire is also less than the modulus elasticity of stainless steel 316L.\(^\text{22}\) According to Hooke law, the correction tools are elastic and will return to their original shape when the force is removed.\(^\text{23,24}\) In both finite element and biomechanical analysis, we used a higher force than the actual force used in a clinical setting. In a clinical setting, the pullout of the screw occurs at 400 Nm, implicating that the pullout of the screw will happen even before the tools fail. At the point of failure, the detachment of wire occurs slowly and can be observed with the naked eye, thus being safe for the patient. In the initial clinical application, we found that
the correction tools satisfy radiological outcomes comparable to other correction techniques, are safe, and give a good functional outcome.25–27  

Our study is subjected to several limitations. This clinical application is done on only one patient, and further evaluation with more subjects should be done. The finding should also be confirmed further in a randomized controlled clinical trial. The ease of application, as well as the cost analysis, should also be evaluated.  

CONCLUSIONS  

We have developed a set of correction tools evaluated in finite element and biomechanical analysis and clinically applied to an actual patient. The correction tools will be named Scoliocorrector Fatma-UI.  

CONFLICT OF INTEREST  
The author reports no conflicts of interest in this work.  

ETHICAL CONSIDERATION  
This study has received ethical clearance from the Ethical Committee of Medical Faculty Universitas Indonesia with number KET-615/UN2.F1/ETIK/PPM.00.02/2020.  

FUNDING  
None.

REFERENCES  
Figure 4. Free Body Diagram. The correction board is the static component to withstand any forces.

Figure 5. Finite element analysis of correction tools.


