Comparison of Stainless Steel and Titanium Alloy Instruments in Posterior Correction and Fusion Surgery for Adolescent Idiopathic Scoliosis-Prospective Cohort Study with Minimum 2-year Follow-Up

Eijiro Okada\textsuperscript{1,2} Kota Watanabe\textsuperscript{3} Naobumi Hosogane\textsuperscript{1} Yuta Shiono\textsuperscript{1} Yohei Takahashi\textsuperscript{1} Yuji Nishiwaki\textsuperscript{4} Kazuhiro Chiba\textsuperscript{1} Yoshiaki Toyama\textsuperscript{1} Morio Matsumoto\textsuperscript{1,*}

\textsuperscript{1}Department of Orthopaedic Surgery, Keio University, Tokyo 160-8582, Japan
\textsuperscript{2}Department of Orthopaedic Surgery, Saiseikai Central Hospital, Tokyo 108-0073, Japan
\textsuperscript{3}Department of Advanced Therapy for Spine and Spinal Cord Disorders, Keio University School of Medicine, Tokyo 160-8582, Japan
\textsuperscript{4}Department of Preventive Medicine and Public Health, Toho University, Tokyo 143-8540, Japan

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Abstract

This prospective study compares the radiographic and clinical results of posterior correction and fusion surgery for adolescent idiopathic scoliosis (AIS) using stainless steel and titanium alloy instruments. The subjects consisted of 65 AIS patients who underwent posterior correction and fusion surgeries using a 5.5-mm-diameter rod at a single institution. Of these, 27 patients were treated using stainless steel instruments (S group) and 38 were treated using titanium alloy instruments (T group). The mean age at the time of surgery was 14.4 ± 3.5 years. The radiographic findings, intra-operative time, estimated blood loss, perioperative complications, and SRS-22 (a patient questionnaire used in the clinical evaluation of idiopathic scoliosis outcomes) were examined. The mean preoperative Cobb angle of the major curve was 62.5 ± 17.2° in the S group and 57.8 ± 13.2° in the T group (p = 0.407). Postoperatively, the curves were corrected to 11.2 ± 10.5° and 10.3 ± 8.5° (p = 0.384), with mean correction rates of 83.4 ± 12.2% and 83.1 ± 11.6% (p = 0.940), respectively. At the final follow-up, although the mean correction loss was slightly larger in the S group (4.4 ± 5.2°) compared with that in the T group (2.3 ± 5.5°), the values were not significantly different (p = 0.118). The coronal balance and sagittal balance were also not significantly different between the two groups at the final follow-up. The function, pain, and mental health sub-scores and the total score for SRS-22 show a tendency for better outcomes in the T group; however, there were no significant differences between the two groups. Thus, there was no statistical difference in radiographical and clinical outcomes between AIS patients treated surgically using stainless steel instruments and those treated using titanium alloy instruments.

Keywords: Adolescent idiopathic scoliosis, Surgical treatment, Stainless steel, Titanium alloy, Material, Spinal instrumentation

1. Introduction

Stainless steel usually contains carbon, chromium, nickel, manganese, iron, and other minor components [1]. 316L stainless steel, a nonparamagnetic material also known as austenitic stainless steel, is the most commonly used material for orthopedic products. Many surgeons prefer stainless steel instrumentation for adolescent idiopathic scoliosis (AIS) correction surgery because it bends easily and can be used to obtain a physiological contour. Stainless steel also has sufficient strength and malleability to enable the effective correction of spinal deformities. However, it can produce unacceptable artifacts in computed tomography (CT) and magnetic resonance imaging (MRI) [2-5]. In addition, corrosion and metal sensitivity [6,7] are well-known...
disadvantages of stainless steel implants. Several arthroplasty reports have indicated that stainless steel implants can increase the serum chromium ion level [8-15], and patients with stainless steel spinal instrumentation are reported to have a high serum metal ion concentration [16].

The other main material used in spine surgery is titanium alloy. Titanium alloy has gained popularity as a biomaterial despite being less stiff than stainless steel [17]. The most popular titanium alloy, Ti-6Al-4V, has not been found to elicit any kind of allergic reaction, which is a concern with stainless steel implants. The advantages of titanium alloy over stainless steel include its extremely inert nature, high biocompatibility, high corrosion resistance, and apparent ability to be integrated with the surrounding bone [18]. Moreover, CT and MRI images obtained after the insertion of titanium have fewer artifacts and are of better quality for diagnosis than those taken after stainless steel insertion [2-5,19]. Patients who receive spinal deformity surgery in their youth are likely to live for decades and eventually undergo MRI of the spine. Considering the MRI compatibility of titanium alloy, the authors switched from using stainless steel implants to titanium alloy ones for scoliosis surgery after October 2007. However, some spine surgeons are concerned about the failure of spinal constructs, particularly those using titanium alloy implants for intra-operative rod contouring and corrective procedures using reduction devices, because the rods can be weakened if they are notched during surgery [20].

Thus, the best material to use in spinal deformity surgery is still up for debate. However, few reports have examined the differences in clinical outcomes of spinal deformity surgery according to the materials used [21,22]. The present study compares the radiographic and clinical results of posterior correction and fusion surgery for AIS between patients treated with stainless steel and those treated with titanium alloy instruments.

2. Materials and methods

This study was prospectively conducted at a single institution between 2005 and 2008. The inclusion criteria were as follows: 1) AIS patients treated using segmental pedicle screw fixation, 2) follow-up period of at least 2 years, 3) full set of preoperative, postoperative, and follow-up radiograms available, and 4) SRS-22 survey results obtained at follow-up. Of a total of 66 such patients, one patient treated with stainless steel was excluded because she developed a deep infection 13 months after the initial surgery that required the removal of the entire spinal instrument.

Thus, 65 patients who met the inclusion criteria were enrolled in the study. Of these, 27 underwent posterior correction and fusion surgery with stainless steel instruments (S group), and 38 received the same surgery using titanium alloy instruments (T group). 316LVM stainless steel instruments were used in patients who underwent correction surgery from January 2005 to October 2007, and titanium alloy Ti-6Al-4V instruments were used in those who underwent the surgery after October 2007. In both groups, rods with a 5.5-mm diameter were used. All the surgeries were performed by a single surgeon who had performed scoliosis surgery for over eight years. Pedicle screws were inserted at all fused segments using a free-hand pedicle screw placement technique. The concave rod placement was followed by rod rotational maneuvers, direct apical vertebral body rotational maneuvers, and in situ translational correction maneuvers by rod bending. Next, the convex rod, which is less severely bent than the concave rod, was placed using a cantilever technique. Finally, segmental compression and/or distraction were conducted via each screw. All patients underwent autologous bone grafting using the iliac crest and local bone.

The mean patient age at the time of surgery was 14.4 ± 3.5 years. The age distribution, preoperative Cobb angle of the main curve, gender, preoperative flexibility, and curve pattern, which was defined according to the Lenke classification system [23,24], were similar in the two groups, whereas the follow-up period for the S group was longer than that for the T group (34.7 months vs. 25.2 months) (Tables 1 and 2).

Table 1. Preoperative characteristics of stainless steel (S) and titanium alloy (T) groups.

<table>
<thead>
<tr>
<th></th>
<th>S group</th>
<th>T group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of cases</td>
<td>27</td>
<td>38</td>
</tr>
<tr>
<td>Mean age (years)</td>
<td>14.3 ± 3.4</td>
<td>14.4 ± 3.7</td>
</tr>
<tr>
<td>Mean follow-up time (months)</td>
<td>34.7 ± 5.5</td>
<td>25.2 ± 2.8</td>
</tr>
<tr>
<td>Mean Cobb angle of main curve</td>
<td>61.2 ± 17.2°</td>
<td>57.8 ± 13.4°</td>
</tr>
<tr>
<td>Preoperative flexibility (%)</td>
<td>52.2 ± 23.3%</td>
<td>49.6 ± 20.9%</td>
</tr>
<tr>
<td>Number of fused segments (number of patients)</td>
<td>9.5 ± 2.6</td>
<td>8.2 ± 3.1</td>
</tr>
</tbody>
</table>

Parentheses indicate range. Asterisks indicate statistical significance. N.S. = not significant.

Table 2. Preoperative curve patterns of stainless steel (S) and titanium alloy (T) groups.

<table>
<thead>
<tr>
<th></th>
<th>S group</th>
<th>T group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1 (number of patients)</td>
<td>11</td>
<td>14</td>
</tr>
<tr>
<td>Type 2</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Type 3</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Type 4</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Type 5</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>Type 6</td>
<td>0</td>
<td>4</td>
</tr>
</tbody>
</table>

The radiographic findings evaluated included the Cobb angle of the main curve, correction rate, global coronal and sagittal balance, and thoracic kyphosis. The clinical perioperative complications and results of SRS-22, a patient questionnaire used in the clinical evaluation of idiopathic scoliosis outcomes [25], at two years after surgery were also evaluated.

All the radiographic measurements were conducted according to the guidelines suggested by the Spinal Deformity Group [26]. All the statistical analyses were performed using Dr. SPSSII for Windows (SPSS Inc, Tokyo, Japan). The distribution of variables was determined as the mean, standard deviation (±), and range. Student’s t-test was used to compare the radiographic and clinical data between the S and T groups.
A p-value of less than 0.05 was considered statistically significant.

3. Results

The mean preoperative Cobb angle of the major curve was 61.2 ± 17.2° in the S group and 57.8 ± 13.2° in the T group (p = 0.340) (Fig. 1). Postoperatively, the curve was corrected to 10.0 ± 8.3° and 10.7 ± 8.9° (p = 0.744), with mean correction rates of 84.4 ± 11.0% and 83.1 ± 11.6% (p = 0.536), respectively (Fig. 2). No significant differences were found between the two groups. At the final follow-up, the mean Cobb angles were 13.8 ± 8.5° and 13.0 ± 9.8° (p = 0.724) in the S and T groups, respectively. Although the mean correction loss in the S group (3.8 ± 4.3°) was slightly larger than that in the T group (2.3 ± 5.5°), the difference was not significant (p = 0.226).

The mean preoperative thoracic kyphosis was 19.1 ± 13.3° in the S group, and 17.8 ± 10.7° in the T group (p = 0.657). The mean thoracic kyphosis at final follow-up was 20.2 ± 10.0° in the S group and 18.8 ± 8.1° in the T group (p = 0.534). The thoracic kyphosis at the follow-up tended to be larger in the S group, although the difference was not statistically significant. There was no significant difference in the mean global coronal or sagittal balance before surgery, immediately after surgery, or at follow-up (Figs. 3 and 4).

Postoperatively, a transient motor weakness in the lower limb developed in one patient in the S group. A superficial infection developed in one patient in the T group. No additional surgeries were conducted in the T group.

The sub-scores for function, pain, and mental health, and the total score of SRS-22 at the final follow-up tended to be superior in the T group, whereas self-image tended to be higher in the S group. However none of these differences reached statistical significance (Table 3).

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<table>
<thead>
<tr>
<th></th>
<th>S group</th>
<th>T group</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function</td>
<td>4.6 ± 0.4</td>
<td>4.5 ± 0.5</td>
<td>0.554</td>
</tr>
<tr>
<td>Pain</td>
<td>4.6 ± 0.5</td>
<td>4.4 ± 0.6</td>
<td>0.520</td>
</tr>
<tr>
<td>Self-Image</td>
<td>3.9 ± 0.8</td>
<td>4.1 ± 0.7</td>
<td>0.570</td>
</tr>
<tr>
<td>Mental Health</td>
<td>4.4 ± 0.5</td>
<td>4.1 ± 0.8</td>
<td>0.385</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>4.4 ± 0.6</td>
<td>4.2 ± 0.7</td>
<td>0.456</td>
</tr>
<tr>
<td>Total score</td>
<td>4.4 ± 0.4</td>
<td>4.3 ± 0.5</td>
<td>0.606</td>
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</table>
4. Discussion

Few studies have compared the radiographic and clinical outcomes of posterior correction surgery for AIS using stainless steel and titanium implants. Yoon et al. [21] investigated the postoperative outcomes (minimum of 2 years) for thoracic idiopathic scoliosis patients treated using a 4.0-mm-diameter stainless steel and a 4.75-mm-diameter titanium alloy single rod in the anterior thoracoscopic instrumentation, respectively. They concluded that the titanium alloy constructs resulted in better maintenance of the deformity correction at 2 years after surgery, with a lower incidence of instrumentation-related complications compared to the stainless steel constructs. However, the different rod diameters and the learning curve of the surgeon might have impacted the results of that study. Another study [27] compared the surgical results of operations using first-generation posterior stainless steel spinal segmental multihook instrumentation with those using newer titanium implants. Although they concluded that better results were seen in the titanium group, the results might have been affected by the construct type rather than the material.

The present prospective study provides several findings of clinical relevance in orthopedic surgical practice. First, the radiographic and clinical outcomes for AIS patients who underwent posterior correction surgery using titanium alloy instruments were almost the same as those using stainless steel at the minimum 2-year follow-up. Second, instrumentation failure was not observed in the surgical treatments for AIS, regardless of the material used.

Although the follow-up periods in this study were relatively short, the correction rates and correction losses between the two groups were similar. Kim et al. [28] compared the 2-year postoperative results of posterior correction and fusion for AIS with segmental pedicle screw instrumentation versus hybrid constructs. In that study, the mean correction loss in the coronal plane was 3° in the pedicle screw group and 6° in the hybrid group at the 2-year follow-up; however, the authors did not comment on the type of material used for the spinal instrumentation. Oto et al. [29] investigated 24 patients with AIS who underwent surgery using titanium alloy instrumentation and reported a mean correction loss of 3.5° at the 2-year follow-up. Our results agree with those of previous studies that used a similar kind of instrumentation to achieve and maintain the correction in AIS. A larger correction loss in the T group was expected because the elastic moduli for titanium alloys are about half those of stainless steels [30]. However, a larger correction loss was actually seen in the S group in this study.

Stainless steel implants are stiffer than titanium alloy implants of equal design and size [31]. Furthermore, Lindsey et al. reported that contoured titanium constructs demonstrated a significantly lower fatigue life than that of contoured stainless steel constructs [32]. Nevertheless, in situ contour techniques were applied in our series. In addition, the sensitivity of titanium alloy to being notched, which can result in rod breakage, is a cause for concern; however, no instrumentation failure was seen in this study.

There is some evidence that titanium alloy is resistant to infection [22,27,33-36]. Chang and Merritt [36] conducted an in vitro experiment using Staphylococcus epidermidis, and found that about 4 times more bacteria adhered to stainless steel than to titanium; they also found a higher rate of infection with a stainless steel segment in vivo. Di Silvestre et al. investigated 540 patients with AIS and reported that titanium alloy instrumentation resulted in fewer late post-operative infections compared to those for stainless steel [33]. In our series, there was no deep infection in either group, and only one superficial infection, in the S group, was observed. Therefore, our results do not offer insight into the role of the implant on the development of deep infection.

One limitation to the present study is that, although it was conducted in a prospective fashion, it was not randomized, and the difference in the inclusion period between the two groups (earlier for the S group) may have affected the outcomes due to the learning curve of the surgeon. In addition, all the AIS patients were included as subjects in this study, regardless of characteristics such as sex or curve pattern. Thus, the curve pattern was not assigned equally between the two groups. Another limitation is that the follow-up period was longer for the S group. In addition, since the T group consisted of more recent patients, the surgeon’s learning curve may have impacted the results of this study. Another limitation is the relatively small number of subjects enrolled in this study, which may have caused beta errors, i.e., a failure to detect differences between the two groups. In addition, the small number of subjects may explain why rare complications, such as instrumentation failure and deep infection, were not seen during the follow-up.

Despite these limitations, this is the first comparative study of patients treated using stainless steel and titanium alloy implants, respectively. Our findings indicate that the difference in materials used for spinal instrumentation does not have a significant impact on the radiographic and clinical outcomes in patients with AIS.

5. Conclusions

This prospective study compared the radiographic and clinical results of posterior correction and fusion surgery using stainless steel and titanium alloy instruments, respectively, in 65 patients with AIS. There was no statistical difference in the radiographic or clinical outcomes between patients treated using stainless steel and those treated using titanium alloy instruments. It can be concluded that the clinical results of AIS patients who were surgically treated with stainless steel and titanium alloy implants, respectively, were equivalent. Thus, the choice of implant material for posterior correction surgery in AIS patients remains the preference of the surgeon.

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Surgery for Adolescent Idiopathic Scoliosis

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References


