

Original Research Article

Evaluation of correction rates for titanium-alloy and cobalt-chrome-alloy rods in adolescent idiopathic scoliosis

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ABSTRACT

Background: The customary treatment of AIS is spinal fusion with instrumentation using rigid rods. In parallel, agents such as, curve magnitude, points of fixation, level instrument selection, curve flexibility, kind of anchor rods used for patients and post-operative care are the main factors affecting the outcome of surgery.

Methods: A total 50 patients was included in the study. The control group, which included 31 patients treated with Ti rods, was compared with an experimental group of 19 patients treated with CCM rods. Correction surgery was performed through posterior approach using rod-rotation maneuver after inserting a pedicle screw in each vertebrae within the fusion. Six-millimeter CCM and six-millimeter Ti rods were used in experimental and control groups, respectively. Pre and postoperative indices of coronal alignment and sagittal alignment were measured.

Results: There was no statistical difference between the two groups for age, sex, Risser's stage, preoperative Cobb's angle, type and flexibility of curvature. The correction rate of thoracic curve was $71.4 \pm 10.2\%$ for the CCM group and $71.8 \pm 6.1\%$ for the Ti group. There were no statistical differences between the two groups for all coronal and sagittal factors ($p > 0.05$).

Conclusions: AIS cases with double curvature, there was no statistically significant difference between Ti and CCM rods for coronal and sagittal plane correction rates. The derivations from biomechanical studies do not translate into clinical situations.

Keywords: Adolescent idiopathic scoliosis, Correction surgery, Spinal implants, Titanium

INTRODUCTION

The goals of surgery for adolescent idiopathic scoliosis (AIS) are to correct the deformity and balance the curves with fusion of the least number of vertebral segments, so as to cause minimal short-term and long-term complications.¹ Various issues affect the ability of spine surgeons to achieve these goals, including patient-related factors and surgical factors such as type of device used, rod type, and technique used to achieve curve correction.²⁻⁶ Of these two considerations, surgical factors

can be controlled and thus are modifiable. The medical community has been striving to continuously improve the available instrumentation, so as to come up with better, safer, and stronger implants.

As spinal implants evolved, the pedicle screw-rod system has proven its efficiency due to a strong pull-out force and three-column fixation, and it has become accepted as the state-of-art technique for posterior spinal fixation.^{7,8} In recent years, titanium alloy (Ti) has become the most popular biomaterial used in pedicle screw-rod constructs.

The customary treatment of AIS is spinal fusion with instrumentation using rigid rods. In parallel, agents such as, curve magnitude, points of fixation, level instrument selection, curve flexibility, kind of anchor rods used for patients and post-operative care are the main factors affecting the outcome of surgery.⁹ Furthermore, correcting and preserving the ability of the rod is one of the most important factor in choosing the best alloy for this surgery. Titanium Ti6Al4V (Ti), stainless steel A316L (SS), and CrCoMoC (CrCo) are the most commonly used alloys of this surgery, each of them with different properties such as stiffness, radiologic features, postoperative complications, and effectiveness.^{10,11}

As the pursuit of the ideal biomaterial continues, use of cobalt-chrome-alloy (CCM) rods has been on the rise. CCM rods have the merits of both Ti and stainless steel rods, but CCM has higher rigidity than Ti and it is possible to use a lower-profile rod with similar strength. Other proposed advantages include relative resistance to infection and a radiological artifact size not significantly different from titanium.¹¹⁻¹³ However, the advantages of CCM over Ti have radiological artifact size not significantly different from titanium.¹¹⁻¹³ However, and the advantages of CCM over Ti have only been studied in biomechanical studies so far, with no clinical studies regarding the correction rates for AIS.

With this background, current study was designed to compare and analyze the efficacy of CCM and Ti rod systems on the correction rates of scoliotic curvature in patients with double-major AIS curves.

As the pursuit of the ideal biomaterial continues, use of cobalt-chrome-alloy (CCM) rods has been on the rise. CCM rods have the merits of both Ti and stainless steel rods, but CCM has higher rigidity than Ti making it possible to use a lower-profile rod with similar strength. Other proposed advantages include relatively low resistance to infection and radiological artifact not significantly different from titanium.¹⁴⁻¹⁶ However, the benefits of CCM over Ti have only been studied in vitro biomechanical studies so far, with rare clinical studies comparing their correction rates in vivo. With this present study was performed with an aim to compare the correction rates of Ti and CCM rod materials for the treatment of AIS curves.

METHODS

Present study was conducted at department of orthodontics, GMERS medical college, Vadnagar, Gujarat, for the duration of one year from August 2019 to July 2020. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Inclusion criteria for current study were; patients who are 11 to 17 years old, Risser grade 1 to 4, scoliosis

deformity with a double curve defined as Lenke type 6 which has thoracic and lumbar structure curve more than 30 degrees which also satisfying Suk's guidelines for fusion as a double major curve and a minimum follow-up period of 5 years.

Procedure

A single surgeon operated on all patients. The posterior midline approach, with instrumentation of mono-directional pedicle screws at each level and curve correction by rod-rotation maneuver, was used in all cases. Preoperative fusion level was determined based on Suk's guidelines.¹⁷ Proximal neutral vertebrae were determined as the proximal extent of the fusion, while the distal extent of the fusion level was decided as suggested by Suk and colleagues. A pedicle screw was inserted at each vertebral level on both the convex and concave sides. After insertion of pedicle screws, pre-contoured rods were attached to the screw heads. In the control group, 6-millimeter Ti-rod was used. In the experimental group, 6-millimeter CCM-rod was used. After making a construct of rod and pedicle screws on the concave and convex sides, rods on both sides were rotated simultaneously. Thoracoplasty was also performed in patients who had a significant rib deformity, which was defined as a preoperative hump height difference of more than 3 centimeters. After surgery, patients were monitored in an inpatient setting until they were stable.

To evaluate coronal balance pre and postoperatively, coronal Cobb angles, coronal balance first thoracic vertebral tilt (T1 angle), and clavicle angle (CA) were assessed.¹⁸ To evaluate sagittal balance pre- and postoperatively, spinal vertical axis (SVA) distance from the poster superior corner of the sacral endplate, thoracic kyphosis (TK), lumbar alignment (LA), and sacral slope were assessed.¹⁸ Normal values were based on the Korean sagittal profile as elaborated by Lee and colleagues.¹⁹ Additional evaluation of sagittal balance factors was performed using comparative analysis of trend-to-improvement tendency, SVA, TK, and the LA scoring system.²⁰

Statistical analysis

The recorded data was compiled and entered in a spreadsheet computer program (Microsoft excel 2007) and then exported to data editor page of SPSS version 15 (SPSS Inc., Chicago, Illinois, USA). For all tests, confidence level and level of significance were set at 95% and 5% respectively.

RESULTS

A total 50 patients was included in the study. The control group, which included 31 patients treated with Ti rods, was compared with an experimental group of 19 patients treated with CCM rods. Before the comparative analysis was started, matching was done for possible confounding

factors that could affect the correction rate. When preoperative age, sex, height, weight, body mass index, Risser stage, preoperative Cobb's angle, flexibility of major curve, curve type by King level, fusion level, and thoracoplasty were compared, there was no statistically

significant difference between the two groups (Table 1). Once these factors were matched, the changes in coronal and sagittal parameters were compared to obtain definitive results.

Table 1: Demographic information and surgical characteristics of the enrolled patients.

Factors	Control group (N=31)	Experimental group (N=19)	P value
Age (years)	13.9±1.7	13.1±2.1	0.20
Sex	Male (5), Female (26)	Male (0), Female (16)	0.51
Height	153.9±9.0	155.2±6.2	0.2
Weight	45.9±6.2	45.4±9.1	0.10
BMI	19.1±2.5	18.9±4.6	0.09
Preoperative Cobb angle (major curve)	60.1±13.3°	60.1±12.9°	0.24
Flexibility of curve (major curve)	29.8±11.1%	27.5±10.2%	0.39

Table 2: Pre and postoperative coronal balance evaluations of the control and experiment groups.

Factor	Control group (N=31)	Experimental group (N=19)	P value
Pre-operative Cobb angle			
Thoracic curve	60.3±13.9°	60.05±12.5°	0.10
Lumbar curve	48.9±12.4°	48.1±12.1°	0.2
Post-operative Cobb angle			
Thoracic curve	16.9±5.2°	17.5±5.4°	0.14
Lumbar curve	11.9±6.0°	14.1±6.5°	0.10
Preoperative clavicle angle	0.4±3.2°	0.8±2.1°	0.09
Postoperative clavicle angle	3.7±3.1°	3.1±1.6°	0.241
Pre-operative T1 tilt angle	1.4±8.4°	8.1±4.7°	0.198
Post-operative T1 tilt angle	5.3±7.4	5.6±6.0°	0.197

Table 3: Pre and postoperative sagittal balance evaluations of the control and experiment groups.

Factor	Control group (N=31)	Experimental group (N=19)	P value
Preoperative thoracic kyphosis	30.5±15.1°	31.1±13.3°	0.1
Postoperative thoracic kyphosis	26.8±7.2°	30.1±10.5°	0.08
Preoperative lumbar lordosis	51.8±12.1°	55.9±12.5°	0.07
Postoperative lumbar lordosis	47.8±9.2°	59.2±3.7°	< 0.001
Preoperative spinal vertical axis	17.2±23.1 mm	17.9±12.4 mm	0.14
Postoperative spinal vertical axis	17.5±33.21 mm	20.9±18.4 mm	0.24

The coronal balance data of the Ti and CCM groups are listed in Table 2. The change in Cobb's angle was measured as 42.1±12.0 degrees in the Ti group and 42.9±11.3 degrees in the CCM group. The correction rate of thoracic curve was 71.4±10.2% for the CCM group and 71.8±6.1% for the Ti group. The correction rate of thoracolumbar curve was 67.2±12.9% in the CCM group and 72.9±12.1% in the Ti group. There was no statistical difference in the correction rate for the thoracic and thoracolumbar curve between the Ti and CCM groups ($p \leq 0.05$). In addition, there was no statistical difference in pre and postoperative T1 and CA angles between the two groups (Table 2). The coronal balance (CB) correction rate after surgery was measured as

4.1±11.4mm in the CCM group and 1.9±12.4 mm in the Ti group. There was no statistical difference between the two groups ($p \leq 0.05$). Sagittal parameters between the groups were also similar, with no statistical significance (Table 3). In SVA, TK, and LA-scoring, there was also no statistical difference between the two groups ($p \leq 0.05$).

DISCUSSION

Pedicle screw construct and rod rotation is a commonly used technique for curve correction in AIS patients.¹⁻³ This technique involves rotation of pre-contoured rods stretched over pedicle screws with inner set screw. During this de-rotation maneuver, the amount of rotation

force applied to the rod should get transferred to the pedicle screws and then to the vertebral body to achieve ideal correction. Ideal correction can be achieved when there is no loss of force at the vertebral body–screw interface due to deformation of the rod. Therefore, it can be said that the stiffer the rod construct, the better the delivery of the corrective force and the better the correction. Rod stiffness is in turn related to the rod material properties, rod diameter, and manufacturing process.²¹ The stiffness of metals may be estimated by Young's modulus by this measure, wrought Co-Cr is approximately five times stiffer than titanium alloy. Stainless steel which has a Young's modulus about twice that of titanium is a balance between these two materials. With this background, our study was carried out with the hypothesis that CCM rods are stiffer than Ti rods, and thus can achieve better correction for scoliotic curvature.

For many years, CoCr has an extremely high particular strength and rigidity and it is generally used in gas turbines, dental implants and orthopaedic implants.^{22,23} CoCr rods have the ability to exert high corrective forces on the spine with relatively small amounts of rod deformation. This material also has the highest potential of plastic deformation in a highly rigid spine.^{24,25} In our experience, the group using CoCr-Ti rods revealed a notably greater increase in spinal kyphosis than Ti-Ti group.

A study by Hwang et al showed maintenance of coronal and sagittal plane correction between 2 and 5 year follow up using screw constructs in AIS.²⁵ Our data confirms the capability of the whole-pedicle screw construct to prevent deformity improvement while maintaining balance in kyphotic patients. Furthermore, different studies in recent years have shown that efficiency of pedicle screws for achieving acceptable sagittal alignment in translation technique. In this correction technique, the importance of rod mechanical property should be steeply considered. In this term, by pedicle screw, the spine should be brought to the pre-contoured rods. It has been presented that CrCo rods have the ability of main curve correction and preventing sagittal change from deviations due to its balance between stiffness and flexibility.²⁶⁻³⁰

Many studies compared effect of cobalt-chrome-alloy and Ti on correction rates in AIS surgery.¹⁵⁻²⁰ Etemadifar et al reported that cobalt chromium-titanium (Co-Ti) rods were more effective than Ti only rods.³⁰ However, their study used polyaxial pedicle screws which is less effective in transferring correction force to vertebral body due to freedom of head to body, and there was mixed use of relatively small-sized (5.5 mm) cobalt chromium and titanium on concave and convex side each.

The pre and post-operative TK values were also statistically similar between the Ti and CCM groups (Table 3). There was no statistical difference in values for SVA, TK, or LA scoring between the Ti and CCM groups ($p \leq 0.05$). The results reported above contradict

the findings of a recently published study by Lamarein et al wherein CCM rods were found to produce higher correction rates in the frontal plane when compared to stainless steel rods of the same diameter.²⁹ In the CCM group, the correction was 63.75% and 68% for the main and secondary curves. In SS group, the correction was 53.35% and 51.45% for the main and secondary curves. Statistical analysis showed improved correction rates in patients treated with CCM rods for the main ($p=0.0001$) and secondary ($p=0.0003$) curves. The study was limited by the fact that the degree of correction can be improved in response to the learning curve, which could explain the improved results seen in more recent patients, most of whom were treated with CCM rods. Also, the study population was inhomogeneous in that it included all six types of Lenke curves.

Experimental and clinical studies based on the effect of different rod diameters (and resultant different stiffness) for the correction of scoliotic curves have also not been able to conclusively establish the effect of rod rigidity on magnitude of curve correction.⁴⁻⁸ Lamartina et al analyzed the correction rate in AIS patients using a pedicle screw or hybrid system that employed hook and screw concomitantly and reported the correction rate to be better with the hybrid system, owing to the use of thicker rods.⁴ However, this study was limited by the fact that it did not exclusively study pedicle screw constructs and also was not supported by a concrete statistical analysis. Prince et al analyzed the radiographic outcomes of patients who underwent scoliosis surgery using different rod diameters constructs by posterior approach.²⁰ The authors reported similar correction rates in the coronal and sagittal planes despite the differences in diameter. Abul-Kasim et al reported a study of AIS patients treated with de-rotation maneuver and direct vertebral rotation via pedicle screw instrumentation.²⁶ This study showed that a larger rod diameter had a positive impact on the deformity in the sagittal and axial planes. Thus, studies based on rod diameters in AIS patients have reported conflicting evidence on the effect of rod diameter and hence rod stiffness on correction rates of curves.

Limitations

Limitations of current study were; the study was not randomized, which would have provided more reliable information about the effect of rod stiffness on correction rates in AIS patients. The study population was also relatively small. Although adequate for statistical analysis, achieving homogeneity of the enrolled patients in terms of a single curve type was not possible for such a small study cohort. Despite these limitations, we feel our study is relevant given the optimal rod stiffness to correct scoliotic curves has yet to be determined.

CONCLUSION

AIS cases with double curvature (King type 1 and type 2), there was no statistically significant difference

between Ti and CCM rods for coronal and sagittal plane correction rates. The derivations from biomechanical studies do not translate into clinical situations. Large-scale randomized controlled multicentric prospective clinical trials are needed to definitively establish the superior efficacy of any particular metal alloy for spinal deformity correction.

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