STATE OF THE ART REVIEW

Systematic review and meta-analysis for the impact of rod materials and sizes in the surgical treatment of adolescent idiopathic scoliosis

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Abstract
Purpose To assess surgical and safety outcomes associated with different rod materials and diameters in adolescent idiopathic scoliosis (AIS) surgery.
Methods A systematic literature review and meta-analysis evaluated the surgical management of AIS patients using pedicle screw fixation systems (i.e., posterior rods and pedicle screws) with rods of different materials and sizes. Postoperative surgical outcomes (e.g., kyphosis and coronal correction) and complications (i.e., hyper/hypo-lumbar lordosis, proximal junctional kyphosis, revisions, reoperations, and infections) were assessed. Random-effects models (REMs) pooled data for outcomes reported in ≥ 2 studies.
Results Among 75 studies evaluating AIS surgery using pedicle screw fixation systems, 46 described rod materials and/or diameters. Two studies directly comparing titanium (Ti) and cobalt–chromium (CoCr) rods found that CoCr rods provided significantly better postoperative kyphosis angle correction vs. Ti rods during a shorter follow-up (0–3 months, MD = − 2.98°, 95% CI − 5.79 to − 0.17°, p = 0.04), and longer follow-up (≥ 24 months, MD = − 3.99°, 95% CI − 6.98 to − 1.00, p = 0.009). Surgical infection varied from 2% (95% CI 1.0–3.0%) for 5.5 mm rods to 4% (95% CI 2.0–7.0%) for 6 mm rods. Reoperation rates were lower with 5.5 mm rods 1% (95% CI 0.0–3.0%) vs. 6 mm rods [6% (95% CI 2.0–9.0%); p = 0.04]. Differences in coronal angle, lumbar lordosis, proximal junctional kyphosis, revisions, and infections did not differ significantly (p > 0.05) among rods of different materials or diameters.
Conclusion For AIS, CoCr rods provided better correction of thoracic kyphosis compared to Ti rods. Patients with 5.5 mm rods had fewer reoperations vs. 6.0 and 6.35 mm diameter rods.
Level of evidence III.

Keywords Adolescent spine deformity · Surgery · Outcomes · Complications · Rods · Diameter · Material

Introduction
Adolescent idiopathic scoliosis (AIS) is the most common spinal deformity among the pediatric population, occurring in patients aged 10–18 years. Its idiopathic nature necessitates that defined causes of scoliosis (i.e., vertebral or neuromuscular disorders, and other syndromes) have been ruled out. The worldwide prevalence of AIS ranges from 0.47 to 12% and varies according to genetics, age, and gender [1–9]. AIS more commonly affects girls than boys, with a female to male ratio of 3.1–1.5 [1]. Moreover, the risk of AIS in girls increases more than boys with increasing age [10]. A higher prevalence of AIS has been reported in the African-American population (9.7%) compared to the Caucasian population (8.1%) [1].

AIS treatment depends on the severity of the curvature [10–13]. The objectives of surgery in adolescents with significant and/or progressive curvature include achieving a solid fusion and arresting curve progression, achieving permanent deformity correction, improving functional outcomes, improving physical appearance, and suppressing the development of problems in adulthood (i.e., back pain, degenerative changes, functional impairment, and cardiopulmonary compromise). Additional desirable characteristics include preventing surgical complications (e.g., neurological injury, dural tears, position-related complications, gastrointestinal complications, infections and wound

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complications, implant-related issues, pseudoarthrosis, curve progression, adding-on, and proximal junctional kyphosis [14]) while preserving as many mobile spine segments as possible.

There are multiple factors which contribute to the successful correction of AIS and to minimizing the complications brought about by the surgical treatment. Spinal fixation rods play an important role in the outcomes of spinal deformity surgery as they impact the success of the restoration of global alignment and balance. Hence, surgeons require rods that deliver optimal alignment and meet the needs of each individual patient. A better understanding of the clinical performance of various types of rods available for AIS would help healthcare providers and payers prioritize resource allocation and develop more effective and targeted interventions for the surgical treatment of AIS. The objectives of this study were to assess current evidence for the surgical and safety outcomes associated with rod materials and dimensions for the operative treatment of AIS.

Materials and methods

Study design and approach

The systematic literature review and meta-analysis was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [15]. Electronic searching of MEDLINE, Embase, KOSMET: Cosmetic Science, APA PsycInfo, and BIOSIS Previews was carried out on November 10, 2020 using the search terms: (spine* OR vertebra*) AND (fusion AND stabilization) AND (rods) AND (child* OR pediatric OR adolescent*). English-language studies published on or after January 1, 2010 evaluating AIS surgical management (patient age 10–18 years) using pedicle screw fixation systems (i.e., posterior rods and pedicle screws), including, but not limited to, ponte osteotomy, revision surgeries, and primary or secondary surgeries, were eligible. The focus of the systematic literature review and meta-analysis was to summarize published clinical evidence from studies conducted in human patients. Biomechanical ex vivo studies, animal studies, and cadaver studies were not included in the evaluations.

Outcome measures

Surgical outcomes included postoperative kyphosis and coronal correction. Postoperative complications included hyper/hypo-lumbar lordosis, proximal junctional kyphosis, revisions, reoperations, and infections.

Study selection and quality assessment

Two reviewers independently applied inclusion/exclusion criteria to screen de-duplicated titles and abstracts. Potentially relevant citations were checked in a full-text screening. Disagreements were resolved through discussion and reasons for exclusion were recorded (Fig. 1). Included studies were critically appraised and ranked as low/good/high-quality evidence using the Evidence level and Quality Guide from Johns Hopkins Nursing Evidence-Based Practice [16, 17].

Evidence synthesis and statistical analysis

Qualitative and quantitative synthesis (using meta-analysis) were performed. Qualitative synthesis included summarizing individual studies and describing their results with respect to the relevant outcomes. Meta-analysis was performed for outcomes that were reported in ≥ 2 studies. For continuous outcome measures, inverse variance random effects models (REMs) estimated pooled mean differences (MDs). Pooled standardized mean differences (SMDs) were used for pain scores since the studies used different pain scales. Means and standard deviations (SDs) were extracted from individual studies or derived from medians with interquartile ranges or means with p values. For dichotomous outcomes, Mantel–Haenszel REMs estimated pooled risk ratios (RRs). For the pooled summary statistics for each outcome in the surgical and non-surgical intervention groups, inverse variance REMs were used. All effect sizes were reported with 95% confidence intervals (CI). The χ² test was used to test for statistical heterogeneity (α = 0.05) and heterogeneity was quantitatively evaluated using I² statistics. Statistical significance was set at p ≤ 0.05. RevMan version 5.4 was used for the evidence synthesis and statistical analysis.

Results

Study identification and selection

Among 75 studies meeting the inclusion criteria (Fig. 1), 46 described the rod material and diameter. Titanium alloy (Ti) rods were used in most studies (n = 32), followed by cobalt–chromium (CoCr; n = 16), and stainless steel (SS; n = 8). Rod diameter varied from 4.5 [18] to 6.5 mm [18]; however, the most common rod diameters were 5.5 mm [19, 20], 6.0 mm [21, 22], and 6.35 mm [23, 24]. Table 1 provides a description of the 75 included studies.
Meta-analyses

Impact of rod material

Surgical outcomes  *Kyphosis angle correction:* Two studies directly compared the use of Ti and CoCr rods and their effect on postoperative kyphosis angle correction over 0–3 months [21, 53] and ≥ 24 months [21, 53] (Fig. 2). The meta-analysis results revealed that CoCr rods provided significantly better postoperative kyphosis angle correction when compared to Ti rods, not only during a relatively shorter follow-up period (0–3 months, MD = − 2.98°, 95% CI − 5.79 to − 0.17°, \(p = 0.04\)), but also during a relatively longer follow-up period (≥ 24 months, MD = − 3.99°, 95% CI − 6.98° to − 1.00°, \(p = 0.009\)).

*Coronal angle correction:* Two studies compared the use of Ti and CoCr rods and their effect on postoperative coronal angle over ≥ 24 months (Supplemental Fig. S1) [21, 53]. The overall pooled MD between the two groups was 0.50° (95% CI − 2.15° to 3.15°) and was not statistically significant (\(p = 0.71\)). The indirect comparative analysis evaluating coronal angle correction included seven studies evaluating Ti rods [19, 28, 64, 68, 70, 72, 77] [pooled MD 73.69% (95% CI 68.05–79.32%)], three studies evaluating stainless steel rods [77–79] [pooled MD 71.91% (95% CI 63.63–80.19%)], and three studies evaluating CoCr rods [33, 47, 49] [pooled MD 64.88% (95% CI 59.57–70.19%)]. There were not statistically significant differences in percent change in coronal Cobb angle among the varying rod materials (\(\chi^2 = 5.35; p = 0.07\); Supplemental Fig. S2).

Postoperative complications  *Proximal junctional kyphosis:* The two direct comparative studies also presented the data on the risk of proximal junctional kyphosis stratified by rod material (Ti rods vs. CoCr rods; Supplemental Fig. S3) [21, 53]. The pooled risk ratio of proximal junctional kyphosis between the two groups showed no significant difference (RR = 1.28, 95% CI 0.30–5.54; \(p = 0.74\)). Two studies using Ti rods reported at least one case of PJK in AIS patients undergoing posterior spine deformity surgery (Supplemental Fig. S4) [21, 53]. The overall pooled proportion for PJK was 4% (95% CI 0.0–9.0%) in patients who utilized Ti rods. Three studies which used CoCr rods reported an overall pooled proportion of 3% (95% CI 0.0–6.0%) [21, 38, 53]. In the pooled indirect comparison, the test for subgroup difference showed no significant differences between rod materials (\(\chi^2 = 0.19; p = 0.67\)).

*Revision surgery:* Three studies using Ti rods reported revisions [53, 74, 82]. The overall pooled proportion for revision was 6% (95% CI 0.0–12.0%). Two studies using cobalt–chromium rods reported revision surgery with an overall pooled
Table 1  Characteristics of studies (n = 75) that fulfilled the inclusion criteria for the systematic review and meta-analysis

| Study | Study design | No. of patients | Gender | Patient Characteristics | Study groups (no. of patients) | Type of surgery | Mean age at surgery (years) | Follow-up Mean (SD), months |
|-------|--------------|-----------------|--------|-------------------------|-------------------------------|-----------------|----------------------------|-----------------------------|
| Machino et al. (2020) [25] | Cohort study | 67 | Male (n) | Female (n) | AIS | Posterior rods and pedicle screws | PLIF | 14.4 mean | NR |
| Kluck et al. (2020) [26] | Cohort study | 99 | NR | NR | AIS | Posterior rods and pedicle screws | NR | 14 ± 2 years | NR |
| Shen et al. (2020) [27] | Cohort study | 19 | 0 | 19 | AIS | Posterior rods and pedicle screws | PLIF | 15.6 ± 2.1 | NR |
| Miyazaki et al. (2020) [28] | Cohort study | 27 | NR | NR | AIS | Hypokyphotic normal–hyperkyphotic | PSF with double-rod rotation | NR | NR |
| Feeley et al. (2019) [29] | Cohort study | 31 | 8 | 23 | AIS | Lenke A/B Lenke C | PLIF | NR | NR |
| Chang et al. (2019) [30] | Cohort study | 28 | NR | NR | AIS | LIV L3 LIV L4 | PLIF | NR | NR |
| Violas et al. (2019) [31] | Case series | 23 | 5 | 19 | AIS | Posterior rods and pedicle screws | PLIF | 14.75 | 37 |
| Newton et al. (2018) [32] | Cohort study | 134 | 40 | 94 | AIS | Posterior rods and pedicle screws | PLIF | 14.7 ± 2 | NR |
| Lastikka et al. (2019) [33] | Cohort study | 90 | 20 | 70 | AIS | Circular rods Reinforced rods | PLIF | 15.6 ± 2.1 | NR |
| Mac-Thiong et al. (2019) [34] | Cohort study | 80 | 10 | 70 | AIS | Posterior rods and pedicle screws | PLIF | 14.5 ± 2.2 | NR |
| Uehara et al. (2019) [35] | Cohort study | 69 | 4 | 65 | AIS | Posterior rods and pedicle screws | PLIF | 14.8 ± 2.5 | NR |
| Zhang et al. (2018) [36] | Cohort study | 36 | 10 | 26 | AIS | Rod-link reducer (RLR) Traditional corrective techniques (TCT) | PLIF | NR | NR |
| Clément et al. (2019) [37] | Cohort study | 111 | NR | NR | AIS | Hypokyphosis Normokyphosis Simultaneous double-rod rotation technique (SDRRT) | PLIF | NR | NR |
| Miyazaki et al. (2019) [38] | Cohort study | 24 | 3 | 22 | AIS | Simultaneous double-rod rotation technique (SDRRT) + direct vertebral rotation (DVR) | PLIF | NR | NR |
| Study                      | Study design                      | No. of patients | Gender | Patient Characteristics | Study groups (no. of patients) | Type of surgery | Mean age at surgery (years) | Follow-up Mean (SD), months |
|---------------------------|-----------------------------------|-----------------|--------|-------------------------|--------------------------------|-----------------|-----------------------------|-------------------------------|
| Ilharreborde et al. (2018) [38] | Case series                       | 60              | 6      | 54                      | AIS                            | Posterior rods, pedicle screws, sublaminar bands, hooks | 15.4 ± 2          | 28.2 ± 4                     |
| Etemadifar et al. (2018) [19] | Randomized controlled trials (RCT) | 59              | 22     | 37                      | AIS                            | CoCr–Ti rods, Ti–Ti rods | 14.14 ± 1.41       | NR                           |
| Sabah et al. (2018) [21]    | Cohort study                      | 63              | 27     | 54                      | AIS                            | CoCr rod, Ti alloy TA6V rod (Ti) | 15 ± 2            | 42 ± 17                      |
| Sudo et al. (2018) [22]     | Case series                       | 39              | 0      | 39                      | AIS                            | Simultaneous double-rod rotation technique | NR               | NR                           |
| Ketenci et al. (2018) [39]  | Cohort study                      | 83              | NR     | NR                      | AIS                            | AIS group—T2 group, AIS group—T3 group, AIS group—T4 group, Control group | 15.1             | NR                           |
| Kaliya-Perumal et al. (2018) [40] | Cohort study                      | 88              | 10     | 78                      | AIS                            | Group 1: concave group, Group 2: convex group | 14.1 ± 2.2       | 47.7 ± 14.6                  |
| Faldini et al. (2018) [20]  | Case series                       | 36              | 4      | 32                      | AIS                            | Group A, Group B, Group C | 15.1 ± 1.8 years       | 24 (12–36)                  |
| Berger et al. (2018) [41]   | Case series                       | 30              | 5      | 25                      | AIS                            | Pedicle screw and rod system | 15               | NR                           |
| Seki et al. (2018) [42]     | Case series                       | 40              | 3      | 37                      | AIS                            | Lenke Type I, Lenke Type II, Lenke Type III or IV | 14.1 ± 3.1       | NR                           |
| Cheung et al. (2018) [43]   | Randomized controlled trials (RCT) | 23              | 6      | 17                      | AIS                            | CTA (control), SNT (intervention) | 15 ± 2.3          | NR                           |
| Allia et al. (2018) [44]    | Case series                       | 68              | 60     | 8                       | AIS                            | Group D+, Group D− | NR               | NR                           |
| Study                        | Study design | No. of patients | Gender | Patient Characteristics | Study groups (no. of patients) | Type of surgery | Mean age at surgery (years) | Follow-up Mean (SD), months |
|-----------------------------|--------------|----------------|--------|-------------------------|---------------------------------|-----------------|-----------------------------|-----------------------------|
| Luo et al. (2017) [45]      | Cohort study | 57             | 12     | 45 AIS                  | “Group 1 (postop TK ≥ 20°)” Group 2 (postop TK < 20°) | Posterior Posterior | 14.39 ± 1.82               | NR                         |
| Zifang et al. (2017) [46]   | Cohort study | 81             | 14     | 67 AIS                  | Convex-rod derotation group Concave-rod derotation group | Posterior Posterior | 15.0 ± 2.3 | 14.6 ± 2.2 | NR | NR |
| Ohrt-Nissen et al. (2017) [47] | Cohort study | 139            | 22     | 117 AIS                | Hybrid construct (HC) Standard construct (SC) Modified construct (MC) | Posterior midline approach Posterior midline approach Posterior midline approach | NR | NR |
| Faldini et al. (2017) [48]  | Case series  | 30             | 4      | 26 AIS                  | Combined DVR and vertebral translation | Posterior approach | 14.8 | 32.4 |
| Lamerain et al. (2017) [49] | Cohort study | 61             | 14     | 47 AIS                  | Group A: decreased thoracic lordosis Group B: normal (35–50 degrees) thoracic kyphosis | Posterior spinal fusion Posterior spinal fusion | 15.4 | 37.4 |
| Le et al. (2017a) [50]      | Cohort study | 42             | 5      | 37 AIS                  | CoCr SS Ti                        | Posterior approach | CoCr (n:35) 16.6 ± 4 | CoCr (n:35) 15.7 ± 2 | NR | NR |
| Chang et al. (2017) [51]    | Cohort study | 64             | NR     | NR AIS                  | AL3 (flexible) BL3 (rigid) | Posterior surgery Posterior surgery | 15 ± 1.9 (\(p=0.856\)) | 74.4 ± 44.4 (\(p=0.680\)) | 80.4 ± 51.6 (\(p=0.680\)) | NR | NR |
| Urbanski et al. (2017) [52] | Cohort study | Adolescents: 20 | 5      | 31 AIS Progressive adolescent and neglected adults idiopathic scoliosis | Posterior rods with all screw constructs | Posterior spinal fusion only PSF w/DVR | 15.6 ± 1.49 | 14.9 ± 1.58 | NR |
| Le Navéaux et al. (2017b) [50] | Case series  | 35             | 2      | 33 AIS                  | NR                              | Posterior instrumentation | 16 | NR |
| Angelliaume et al. (2017) [53] | Cohort study | 70             | 11     | 59 AIS (Lenke 1 and 2) Ti CoCr | NR | | Ti (n:35) 16.6 ± 4 | CoCr (n:35) 15.7 ± 2 | NR | NR |
| Lonner et al. (2017) [54]   | Case control study | 851 | 183 | 668 AIS | PJK+ PJK− | Posterior approach | 14.4 | NR |
| Study                     | Study design | No. of patients | Gender | Patient Characteristics | Study groups (no. of patients) | Type of surgery                                                                 | Mean age at surgery (years) | Follow-up Mean (SD), months |
|--------------------------|--------------|-----------------|--------|-------------------------|---------------------------------|---------------------------------------------------------------------------------|------------------------------|-------------------------------|
| Kim et al. (2017)        | Case control study | 106              | 10     | 96                      | AIS                             |  + DVR simple rod derotation w/o DVR Distal fusion, posterior approach          | 15                           | 37.2                          |
|                          |              |                  |        |                         |                                 | No DVR: 14.9                      | 14.9                          | 76.8                          |
| Panya-amornwat et al. (2017) | Cohort study  | 29              | 5      | 24                      | AIS                             | Simple rod derotation (SRD) DVR using VCM (VCM)                               | 14.8 ± 1.7                   | NR                           |
|                          |              |                  |        |                         |                                 | Posterior approach with rod derotation Posterior approach with direct vertebral rotation | 15.8 ± 1.8                   | NR                           |
| Sudo et al. (2016)       | Case series  | 64              | 7      | 57                      | AIS                             | TK < 15 TK > 15                                                                 | 14.8                         | NR                           |
| Kokabu et al. (2016)     | Cohort study | 49              | 1      | 48                      | AIS                             | Angle of rod deformation > 14                                                  | 15.5 ± 2.2                    | NR                           |
| Gehrchen et al. (2016)   | Cohort study | 129             | 24     | 105                     | AIS                             | Circular rods Beam-like rods                                                   | 16.5 ± 2.3                    | 34.4                         |
|                          |              |                  |        |                         |                                 | Posterior fusion with pedicle screw Posterior pedicle screw rod instrumentation | 30.3                         | NR                           |
| Huang et al. (2016)      | Cohort study | 39              | 9      | 30                      | AIS Lenke 5C                     | Simple rod derotation (SRD) Vertebral column manipulator (VCM)                 | 16.5 ± 3.3                    | NR                           |
|                          |              |                  |        |                         |                                 | Posterior pedicle screw rod instrumentation                                      | 15.8 ± 3.4                   | 30.3                         |
| Seki et al. (2016)       | Case series  | 30              | 2      | 28                      | AIS                             | Thoracic curve (Lenke 1 and 2) Thoracolumbar or lumbar (Lenke V)               | 14.1 ± 3.1                    | NR                           |
|                          |              |                  |        |                         |                                 | Rod reduction and differential rod contouring, followed by DVR using uniplanar screws | 15.8 ± 3.1                    | NR                           |
| Sudo et al. (2015)       | Case series  | 21              | 2      | 19                      | AIS Lenke 2                      | NR                                                                             | 15.8 ± 3.1                    | 32.4                         |
| Pankowski et al. (2016)  | Cohort study | 38              | 6      | 32                      | AIS                             | Posterior rods Pedicle screws                                                  | 15.8                         | NR                           |
Table 1 (continued)

| Study                  | Study design | No. of patients | Gender | Patient Characteristics | Study groups (no. of patients) | Type of surgery | Mean age at surgery (years) | Follow-up Mean (SD), months |
|------------------------|--------------|-----------------|--------|-------------------------|--------------------------------|-----------------|-----------------------------|-------------------------------|
| Liu et al. (2015) [64] | Cohort study | 77              | 21     | 56 AIS                  | Group A: low-stiffness rod with low density of screw placement <br>Group B: low-stiffness rod with high density of screw placement <br>Group C: high-stiffness rod with low density of screw placement <br>Group D: high-stiffness rod with high density of screw placement | Posterior surgery | 15.79 ± 3.21 | 16.56 ± 6.24 |
| Terai et al. (2015) [65] | Cohort study | 52              | 3      | 49 AIS                  | Group N: treated with the new technique using 6.35 mm diameter different-stiffness Ti rods <br>Group C: treated with conventional methods (correction started on the concave side) using 5.5 mm diameter Ti alloy rods | Posterior surgery | 16 | 18.8 |
| Tang et al. (2015) [66] | Cohort study | 81              | 6      | 75 AIS                  | DVBD: vertebral body derotation <br>SRD: simple rod derotation | Posterior surgery | 14.9 ± 1.8 | 15.1 ± 1.6 | 48 |
| Takahashi et al. (2014) [67] | Cohort study | 38              | 0      | 38 AIS                  | Ponte group <br>Control group | NR | 15.6 ± 2.0 | 14.4 ± 2.5 (p=0.122) | NR |
| Study                         | Study design | No. of patients | Gender | Patient Characteristics | Study groups (no. of patients) | Type of surgery | Mean age at surgery (years) | Follow-up Mean (SD), months |
|------------------------------|--------------|----------------|--------|-------------------------|--------------------------------|-----------------|-----------------------------|-----------------------------|
| Huang et al. (2014) [68]     | Cohort study | 93             | 14     | 79 AIS                  | CDH—Dubouset Horizon (CDH M10 system with a 6.35-mm rod (CDH M10 group) CDH M8 was used with a 5.5-mm rod (CDH M8 Group) | NR              | 15.6 ± 2.2                  | 63.5 ± 25.5               |
| Clément et al. (2014) [69]   | Case series  | 99             | NR     | NR AIS                  | Simultaneous translation on two rods (ST2R) | NR              | 14.8                        | NR                         |
| Sales et al. (2014) [70]     | Other        | 107            | NR     | NR AIS                  | Study 1—Mazda et al. Study 2—Jouve et al. Anterior release Posterior approach UC used without anterior approach | NR              | 15                          | NR                         |
| Cao et al. (2014) [71]       | Meta-analysis| 1615           | NR     | NR AIS                  | Hybrid construct pedicle screw Posterior rods and pedicle screws | NR              | 15                          | NR                         |
| Sudo et al. (2014) [72]      | Cohort study | 32             | 3      | 29 AIS                  | Lenke 1 thoracic AIS                | NR              | 15.0 ± 2.6                  | 42 ± 15                   |
| Lamerain et al. (2014) [73]  | Cohort study | 90             | 20     | 70 AIS                  | CoCr rods: 64 SS rods: 26 | NR              | 15.2                        | 30.6                       |
| Voleti et al. (2014) [74]    | Case series  | 3              | 1      | 2 AIS                   | Posterior rods and pedicle screws | NR              | NR                          | NR                         |
| Prince et al. (2014) [75]    | Cohort study | 352            | 70     | 281 AIS                 | 5.5 mm rod—screw only: 73 6.35 mm rod—screw only: 12 5.5 mm rod—hybrid: 90 6.35 mm rod—hybrid: 177 | Posterior       | 5.5 mm rod: 14.4 ± 1.8 6.35 mm rod: 14.1 ± 1.8 | NR                         |
| Di et al. (2013) [76]        | Case series  | 62             | 53     | 9 AIS                   | DR group Non-DR group | Posterior | NR                          | 3.7 years                 |
| Study                  | Study design | No. of patients | Gender | Patient Characteristics                                                                 | Study groups (no. of patients) | Type of surgery                          | Mean age at surgery (years) | Follow-up Mean (SD), months |
|------------------------|--------------|-----------------|--------|----------------------------------------------------------------------------------------|-------------------------------|------------------------------------------|-----------------------------|------------------------------|
| Okada et al. (2013)    | Cohort study | 65              | NR     | AIS patients treated using segmental pedicle screw fixation                             | SS: 27 (S group) Ti: 38 (T group) | Posterior correction and fusion surgery | 14.4 ± 3.5 years              | S GROUP: 34.7 ± 5.5         |
| Demura et al. (2013)   | Cohort study | 26              | 23     | AIS patients with thoracic curves (Lenke 1 and 2)                                       | NR                            | Posterior instrumentation and fusion     | 13.6 ± 1.5 years              | NR                           |
| Tsirikos et al. (2012) | Case series  | 212             | 24     | AIS                                                                                   | Group 1 bilateral segmental pedicle screw fixation Group 2 unilateral segmental pedicle screws | Posterior Posterior             | 14.8                        | 14.8                         | 3.5 years                    |
| Anekstein et al. (2012)| Case series  | 40              | 11     | AIS patients treated with posterior fusion using all-pedicle-screw construct with correction done through the convex side | NR                            | Posterior arthrodesis of the spine       | 15.2 years                   | 249 months                   |
| Larson et al. (2012)   | Cohort study | 28              | 1      | AIS                                                                                   | Selective fusion              | NR                                       | 14.3                        | 20 years                     |
| Clément et al. (2011)  | Cohort study | 62              | 8      | AIS                                                                                   | Simultaneous translation on two rods | PSF                                      | 14.8                        | 44                           |
| Khakinahad et al. (2012)| Case series  | 63              | 21     | Clinical charts and radiographs of patients with AIS who were 11–19 years of age at the time of surgery and had Lenke type 1 deformity corrected by a selective thoracic fusion (lowest instrumented vertebra of T12 or L1) and had a minimum 2-year follow-up were retrospectively reviewed | Posterior spinal fusion and instrumentation | Posterior                   | 15.8 ± 2.1                   | NR                           |
Table 1 (continued)

| Study                          | Study design  | No. of patients | Gender | Patient Characteristics | Study groups (no. of patients) | Type of surgery | Mean age at surgery (years) | Follow-up Mean (SD), months |
|-------------------------------|---------------|-----------------|--------|-------------------------|--------------------------------|-----------------|----------------------------|-----------------------------|
| Qiu et al. (2011) [18]        | Cohort study  | 48              | NR     | NR                       | AIS                            | VCA technique  | Group A: 15.2±4.8           |                             |
|                              |               |                 | Male (n) | Female (n)      | Derotation maneuver           | NR             | Group B: 16.1±5.5           | 16.8                        |
| Abul-Kasim et al. (2011) [24] | Cohort study  | 116             | 22     | 94                      | AIS                            | Derotation maneuver | 15.9±2.8 years           |                             |
| Mladenov et al. (2011) [84]   | Cohort study  | 30              | NR     | NR                       | AIS                            | Simple rod rotation technique (SRR) | 14.65 (range 3.8)      | 32.2 (15.6)               |
| Canavese et al. (2011) [85]   | Case series   | 32              | 3      | 29                      | AIS                            | Posterior fusion with the multisegmented hook and screw instrumentation | 14.6±1.4          | 72.0±16.7                 |
| Clément et al. (2011) [82]    | Case series   | 24              | 2      | 22                      | AIS patients with hypokyphosis (T4–T12<20°) | AIS with hypokyphosis | 14.6                  | 49.2 (24–89)              |
| Dalal et al. (2011) [86]      | Cohort study  | 210             | 48     | 162                     | Adolescent idiopathic thoracic scoliosis | Uniplanar screw group Polyaxial screw group | 15                    | NR                         |
| Study                  | Study design | No. of patients | Gender | Study groups (no. of patients) | Type of surgery | Mean age at surgery (years) | Follow-up Mean (SD), months |
|-----------------------|--------------|----------------|--------|--------------------------------|-----------------|----------------------------|-----------------------------|
| Lamartina et al. (2011) [87] | Cohort study | 36             | 8      | Screw group: all screw construct | Hybrid group: pedicle screws and hooks | 19                         | NR                          |
|                       |              |                | 28     |                                |                 |                            |                             |
| Lavelle et al. (2016) [88] | Cohort study | 22             | NR     | AIS                            | Posterior only Cotrel–Dubousset instrumentation | 35 (age at follow-up)    | 240                         |
|                       |              |                |        |                                |                 |                            |                             |
| Miyanji et al. (2018) [89] | Cohort study | 161            | 31     | AIS                            | PSIF group      | PSIF: 15.3 ± 2.0           | 2                           |
|                       |              |                | 130    |                                |                 |                            |                             |
| Li et al. (2018) [90] | Cohort study | 77             | 9      | AIS                            | Posterior selective fusion | Posterior | PSF: 14.7 ± 2.2 (p = 0.844) | PSF: 80.4 ± 15.2 (p = 0.002) |
|                       |              |                | 68     |                                |                 |                            |                             |
| Geck et al. (2013) [91] | Cohort study | 42             | NR     | AIS                            | Posterior spinal fusion | PSF            | NR                          | NR                          |
|                       |              |                |        |                                |                 |                            |                             |

AIS adolescent idiopathic scoliosis; CDH Cotrel–Dubousset Horizon; CoCr cobalt–chromium; CTA conventional titanium alloy; DR direct vertebral rotation group; DVBD direct vertebral body derotation; DVD direct vertebral derotation; DVR direct vertebral rotation; HC hybrid construct; LIV lowest instrumented vertebra; MC modified construct; PJK proximal junctional kyphosis; PLIF posterior lumbar interbody fusion; PSF posterior spinal fusion; PSIF posterior spinal instrumentation and fusion; RCT randomized controlled trial; RLR rod-link reducer; SC standard construct; SDRRT simultaneous double-rod rotation technique; SNT superelastic shape-memory alloy; SRD simple rod derotation; SRR simple rod rotation technique; SS stainless steel; ST simultaneous translation; TCT traditional corrective techniques; Ti titanium; TK thoracic kyphosis; UC universal clamp; VCA vertebral coplanar alignment; VCM vertebral column manipulator
One study reporting revision surgery used stainless steel rods [73]. In the pooled indirect comparison, no significant differences between rod materials were observed (Chi² = 0.65, p = 0.72; Supplemental Fig. S5).

Reoperation: Four studies using CoCr rods reported reoperation in AIS patients who underwent spine deformity surgery (Supplemental Fig. S6) [38, 49, 59, 72]. The overall pooled reoperation rate was 2% (95% CI: 0.0–3.0%) for CoCr rods. Only one study using stainless steel and another study using Ti rods reported reoperation rates [82]. Thus, the test for subgroup difference could not be performed due to the small number of studies.

Infection. Four studies using titanium rods reported postoperative infections in AIS surgery with pedicle screw fixation systems (Supplemental Fig. S7) [21, 70, 77, 79]. The overall pooled proportion of postoperative infection was 2% (95% CI: 0.0–3.0%) with titanium rods. Six studies using cobalt chromium rods reported postoperative infection with a pooled proportion of 4% (95% CI: 2.0–6.0%) [20, 21, 38, 48, 49, 73], while two studies using stainless steel rods reported a pooled infection rate of 8% (95% CI: 0.0–18.0%) [73, 77]. In the pooled indirect comparison, the test for subgroup difference showed no significant differences among rod materials (Chi² = 4.17, p = 0.12).

Impact of rod diameter

Surgical outcomes Kyphosis angle correction: No studies directly compared the impact of rod diameter on postoperative kyphosis angle. Three studies utilized 6 mm posterior rods for AIS surgery and reported corresponding change in the kyphosis angle [21, 22, 82]. The pooled MD in change in kyphosis angle with 6 mm rods was 13.69° (95% CI: 8.54°–18.84°). Similarly, three eligible studies utilizing 5.5 mm rods reported corresponding change in kyphosis angle were also analyzed [26, 52, 67]. Our analysis revealed a pooled MD of 10.05° (95% CI 8.53°–11.57°) in kyphosis angle. Further, when subgroups were analyzed, the test for subgroup difference showed no significant differences in kyphosis angle change between rods of 5.5 and 6 mm diameters, respectively (Chi² = 1.77; p = 0.18) (Supplemental Fig. S8).

Coronal Angle Correction: Two studies reported on 5.5 mm and 6.35 mm rods and directly compared their effect on postoperative coronal angle at 6- to 12-month follow-up period (Supplemental Fig. S9) [60, 64]. Our analysis showed no statistically significant difference between postoperative coronal angles among the two groups (MD = 1.63, 95% CI: −0.35° to 3.61°, p = 0.11). Further, no significant heterogeneity was observed among the studies (I² = 0%, p = 0.96). Three studies directly compared the use of 5.5 mm and 6.35 mm rods and their effect on percent change in coronal angle at follow-up period 6–12 months [60, 64, 75]. The pooled MD showed no significant difference between change in coronal angle of the two groups (MD = 2.81%; 95% CI: −5.94 to 11.57%; p = 0.53; Supplemental Fig. S10).

Three studies that utilized 6.35 mm rods reported percent change in the coronal Cobb angle of AIS patients who underwent spine deformity surgery with pedicle screw fixation systems (Supplemental Fig. S11) [60, 64, 75]. The pooled MD was 69.80% (95% CI 56.43–83.17%). Thirteen studies that used 5.5-mm diameter rods reported relatively
higher percent change in the coronal cobb with a pooled MD of 73.01% (95% CI 69.61–76.42%) [19, 32, 35, 46, 47, 60, 64, 70, 75, 77, 78, 86]. On the other hand, three studies which used 6-mm rods reported similar percent change in the coronal cobb angle with a pooled MD of 67.65% (95% CI: 60.88–74.42%) [22, 33, 49]. The test for subgroup difference showed no significant difference in the results among varying rod diameters (Chi² = 2.02, p = 0.36).

Postoperative complications

Revision surgery: Two studies which used 6-mm diameter rods reported having at least one case of revision surgery in AIS patients who underwent spine deformity surgery with pedicle screw fixation systems (Supplemental Fig. S12) [73, 82]. The overall pooled proportion for revision surgery was 6% (95% CI 2.0–9.0%) in patients who utilized 6-mm diameter rods. One study with at least one case of revision surgery used 6.35-mm diameter rods [74]. Test for subgroup difference was not done due to the small number of studies.

Reoperation: Three studies utilizing 5.5 mm rods reported having at least one case of reoperation in pediatric patients who underwent spine deformity surgery (Fig. 3) [20, 38, 59]. The overall pooled proportion for reoperation surgery was 1% (95% CI 0.0–3.0%) in patients who utilized 5.5 mm diameter rods. Two studies which used 6-mm diameter rods reported having at least one case of reoperation with an overall pooled proportion of 6% (95% CI 2.0–9.0%) [73, 82]. Test for subgroup difference showed a significant difference in proportion of reoperation between the two rod diameters, with the 6 mm diameter rod having a higher propensity for reoperation (Chi² = 4.39, p = 0.040; Fig. 3).

Infection: Three studies which used 6-mm diameter rods reported having at least one case of postoperative infection in AIS patients who underwent spine deformity surgery with pedicle screw fixation systems (Supplemental Fig. S13) [21, 49, 73]. The overall pooled proportion for infection was 4% (95% CI 2.0–7.0%) in patients who utilized 6-mm diameter rods. Six studies which used 5.5-mm diameter rods reported having at least one case of infection with an overall pooled proportion of 2% (95% CI 1.0–3.0%) [20, 38, 48, 70, 77, 79]. Test for subgroup difference showed no significant differences between rod diameters (Chi² = 2.69, p = 0.10).

Discussion

The choice of rod used for the correction of scoliosis is an important consideration in the treatment of AIS. There is substantial force exerted in AIS correction and contoured rods must be able to withstand deformation. Composition and design of the spinal rod must strike a complex balance: the rod must be flexible enough for the surgeon to bend in the desired curve, have a high enough bending yield strength that the rod maintains the bent-in-curve throughout the procedure, and have a high enough fatigue strength that it does not fracture during the therapeutic lifetime of the implant (6–24 months for a solid fusion). The rod’s ability to resist deformation or fracture brought about by contouring will depend on the material used and the diameter and shape of the rod. There have been significant changes in the types of rods and the materials used for rods over the years. Initially,
Harrington rods consisted of stainless steel (SS). Present day rod constructs are more likely to consist of either Ti or CoCr.

This systematic review and meta-analysis identified 75 studies evaluating the surgical management of AIS using pedicle screw fixation systems; among which 46 studies described rod material and diameter. Study findings showed that CoCr rods provided better correction of thoracic kyphotic angle compared to Ti rods, not only during a relatively shorter follow-up period (0–3 months), but also during a relatively longer follow-up period (≥ 24 months) (p < 0.05). Differences in coronal angle, lumbar lordosis, proximal junctional kyphosis, revisions, and infections did not statistically significantly differ among rods of different materials or diameters. Overall, surgical treatment in patients with AIS using pedicle screw fixation systems had low complication and reoperation rates. Infections varied from 2% for patients receiving 5.5 mm rods to 4% for 6 mm rods (p > 0.05). Reoperation rates varied from 1% for 5.5 mm to 6% for 6-mm diameter rods and were significantly lower with 5.5 mm rods (p = 0.04).

There is a need for improved rod yield strength that will help maintain kyphosis and reduce intra and postoperative loss of correction [92]. Within the evolution of pediatric spinal deformity corrections, surgical technique has evolved to allow for higher degrees of derotation. As surgeons attempt these more aggressive techniques, they have begun observing an inability of the rod to maintain the kyphosis they have bent into the rod [47, 50, 92]. This “flattening” of the curve is most often observed during the high load correction maneuvers in stiff severe curves [50, 93]. There is a need for a rod material with a high yield strength to maintain the kyphosis correction that does not require a large diameter.

Biomechanical properties of spinal rods are typically differentiated by yield strength and stiffness. Generally, Ti is characterized by high yield strength but a lower stiffness, and CoCr is characterized by a very high stiffness and low yield strength [94]. However, the potential impact of rod material properties observed in the laboratory setting are not easily extrapolated to the clinical reality [94]. The clinical performance of spinal rods is susceptible to a complicated interplay of patient, surgeon, and environmental factors [95, 96]. It is possible the answer lies in other combinations of stiffness and bending yield strength. Thus, the focus of this systematic literature review and meta-analysis was to summarize published clinical evidence from studies conducted in actual human patients. Biomechanical ex vivo studies, animal studies, and cadaver studies were not included in the evaluations. Additional high-quality clinical studies comparing biomechanical differences among rod constructs are needed [94].

As expected, when pooling observational (real-world) data [97–99], the main limitation of the current study is the heterogeneity of the patient populations evaluated, the surgical techniques and technologies employed, and the definitions of outcomes used. The current study was conducted in line with recommendations available in the literature for the use of real-world evidence in meta-analyses [100]. Since Q was significant and I² was > 50%, it was appropriate to use the random-effects model (REM) to calculate pooled summary estimates. The range of I² values observed in the current study (0–98%) is not inconsistent with the range of those observed in other meta-analyses of observational data.

Conclusion

CoCr rods provided better correction of AIS thoracic kyphosis compared to Ti. Surgical AIS treatment using pedicle screw fixation systems had low complication and reoperation rates. Patients with 5.5 mm rods required fewer reoperations compared to patients with 6.0/6.35 mm rods. There is a need for rod materials that provide improved rod strength and bending yield strength in a smaller profile that will help maintain kyphosis and reduce intra- and postoperative loss of kyphosis correction.

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Declarations

Conflict of interest DB, AM, MM, and SW are employees of Johnson & Johnson.

Ethical approval Not required as it is a systematic review and meta-analysis of previously published data.

Informed consent Not required as it is a systematic review and meta-analysis of previously published data.

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