

## Research Article

# The implant density does not change the correction rate of the main and the accompanying curves: A comparison between consecutive and intermittent pedicle screw constructs

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## ARTICLE INFO ABSTRACT

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**Objective:** The aim of this study was to evaluate the clinical outcomes and the coronal correction rate of the main and accompanying curves of adolescent idiopathic scoliosis (AIS) corrected with pedicle screws inserted consecutively or intermittently.

**Methods:** The prospectively collected data of 60 patients (8 men and 52 women; mean age: 14.6±2.5 years) who underwent corrective surgery for AIS between January 2010 and December 2015 were reviewed retrospectively. Two groups were constituted according to the pedicle screw construct type: consecutive pedicle screw construct (CPSC) and intermittent pedicle screw construct (IPSC) groups. The preoperative, early postoperative, and 24-month follow-up radiographs and the Scoliosis Research Society-22 (SRS-22) scores were reevaluated. The Cobb angle of the main and accompanying curves, the correction rate, and the flexibility of the curves were calculated.

**Results:** The mean preoperative Cobb angles were 57.03° and 57.46°, the mean postoperative Cobb angles were 14.93° and 14.4°, and the mean correction rates were 76.22% and 75.31% in IPSC and CPSC groups, respectively (p>0.05). The preoperative and postoperative accompanying curve magnitudes and correction rates were similar (p>0.05). These radiographic outcomes were also consistent with the SRS-22 scores.

**Conclusion:** Both the pedicle screw constructs had satisfactory outcomes following the surgery, which were confirmed by both the SRS-22 scores and radiographs taken perioperatively and at follow-ups. The IPSC and CPSC groups did not demonstrate a significant change in the correction rate of the main and minor or major accompanying structural and non-structural curves, and also in the SRS-22 scores.

**Level of Evidence:** Level III, Retrospective comparative study

After the introduction of the Harrington rod instrumentation in 1960, various procedures were suggested based on the concave distraction to the segmental realignment including rod rotation maneuver and segmental approximation via cantilever maneuvers with Cotrel-Dubouset instrumentation (1, 2). These constructs remained insufficient when compared to the biomechanically high-strength pedicle screws, first used by Boucher et al., which provided three-column fixation and three-dimensional

correction in scoliosis surgery (3-5). Pedicle screws, which are the state of the art in scoliosis surgery, provided better correction rates than hooks and wires (6). Pedicle screw implants are now the gold standard in the daily practice of spinal surgeons. These implants were inserted to the vertebrae for years unconsciously without any limitation until the question how much anchor sites should be filled with which anchor was first asked by Clements et al. (7). The correction ability of these constructs was very high,

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but the outcomes of these very rigid implants when inserted to a quite flexible spine of a child remain unknown. There is still no consensus on the optimum pedicle screw density needed for the desired rigidity to be provided to the solid fusion mass.

When the pedicle screws are inserted posteriorly, there are several drawbacks, such as impingement on the spinal cord and neural roots, major vascular and visceral injuries, and pleural violation. One of the most devastating cases would undoubtedly be a child with a simple adolescent idiopathic scoliosis (AIS) who suffered from a major complication secondary to a misplaced pedicle screw. Besides, because of the rise in cost with an increase in the number of implants and additional interventions secondary to complications of implant misplacement, spinal surgeons recently investigated whether similar outcomes can be gained with fewer anchors. Several comparisons were made previously evaluating the outcomes of pedicle screw constructs with different implant densities (5, 8, 9).

The purpose of this study was to evaluate the coronal correction rate of the main and accompanying curves of AIS with pedicle screws inserted bilaterally by posterior-only approach consecutively or intermittently, thus including only two types of construct designs. The hypothesis was that the postoperative radiographic and clinical outcomes evaluated by the Scoliosis Research Society-22 (SRS-22) scores were similar in these two different construct designs.

## Materials and Methods

This is a retrospective evaluation of the data collected prospectively on patients who underwent deformity correction for AIS by posterior-only approach with a pedicle screw-only construct. The aim of the study was described, and informed consent was obtained from the parents of the patients prior to the inclusion. The data collection and the study were adhered to the tenets of the Declaration of Helsinki.

### Patients

Patients with a history of previous spine surgery, those suspected of having nonidiopathic scoliosis, and those who underwent procedures including any type of osteotomy or

other type of implants were not included in the study. The inclusion criteria were as follows: (1) diagnosis of AIS, (2) no accompanying disease, (3) no previous treatment with serial corrective Risser's plasters, halo-traction, or thoracolumbosacral orthosis, (4) age between 11 and 20 years at surgery, (5) curves <90 degree and >50% flexible (6) one-stage posterior-only approach with pedicle screws placed bilaterally, and (7) minimum follow-up of 24 months. The classification of the curves, decision on the need for surgery, and the determination of the upper and lower levels to be instrumented were made according to the Lenke Classification (10).

### Surgical technique

All the procedures were performed by the senior surgeon of the study (A.S.) in the same institute between January 2010 and December 2015 consecutively. Following the induction of general anesthesia, the anterior-posterior traction radiograph was obtained before positioning the patient in the prone position. No intervention was made to reduce the mean arterial blood pressure. The posterior approach was performed using a meticulous technique that prevented any arterial bleeding or venous leakage. After determining the end vertebrae of the curves using the Cobb method, the posterior elements of the predecided fusion levels were exposed by stripping the paraspinal muscles subperiosteally. The upper and lower instrumented levels were determined according to the preoperative bending and preoperative traction radiographs obtained under general anesthesia. After inserting the pedicle screws bilaterally with a free hand technique, and with screw sizes of 6 mm for the lower thoracic and lumbar region, 5 mm for the mid-thoracic region, and 4 mm for the upper thoracic region, a posterior-anterior radiograph was obtained to evaluate whether the screws were misplaced. First, the correcting rod, which was contoured manually to the normal sagittal profile of the instrumented segment, was inserted to the concave side and rotated 90 degree clockwise to correct the deformity. Fixation of the correcting rod to the most proximal pedicle screw by squeezing the locking cap was followed by the insertion of the stabilizing rod to the convex side of the pedicle screws. The correction of the deformity was performed with a direct vertebral rotation proximally to distally and locking the caps one by one. In all the procedures, 6-mm-diameter titanium-alloy rods and polyaxial screws were inserted. No transverse rod connector was placed. In situ benders were not used in any case. All the procedures were performed under continuous monitoring of sensorimotor and motor evoked potentials. Thoracoplasty was not added to any procedure. The trademark and model of the implants were invariable in all procedures: CD Horizon Legacy Spinal System (Medtronic, Sofamor Danek, Memphis, TN, USA).

### Data collection

An independent spine surgeon reviewed all the inpatient and outpatient medical records to collect data on patient

## HIGHLIGHTS

- The AIS deformity correction is satisfactory with intermittent pedicle screw constructions.
- Intermittent pedicle screw constructs are as efficient as consecutive screw constructs in AIS deformity correction.
- The compensatory curve correction, which is one of the main issues in AIS, is still favourable with intermittent pedicle screw constructs.

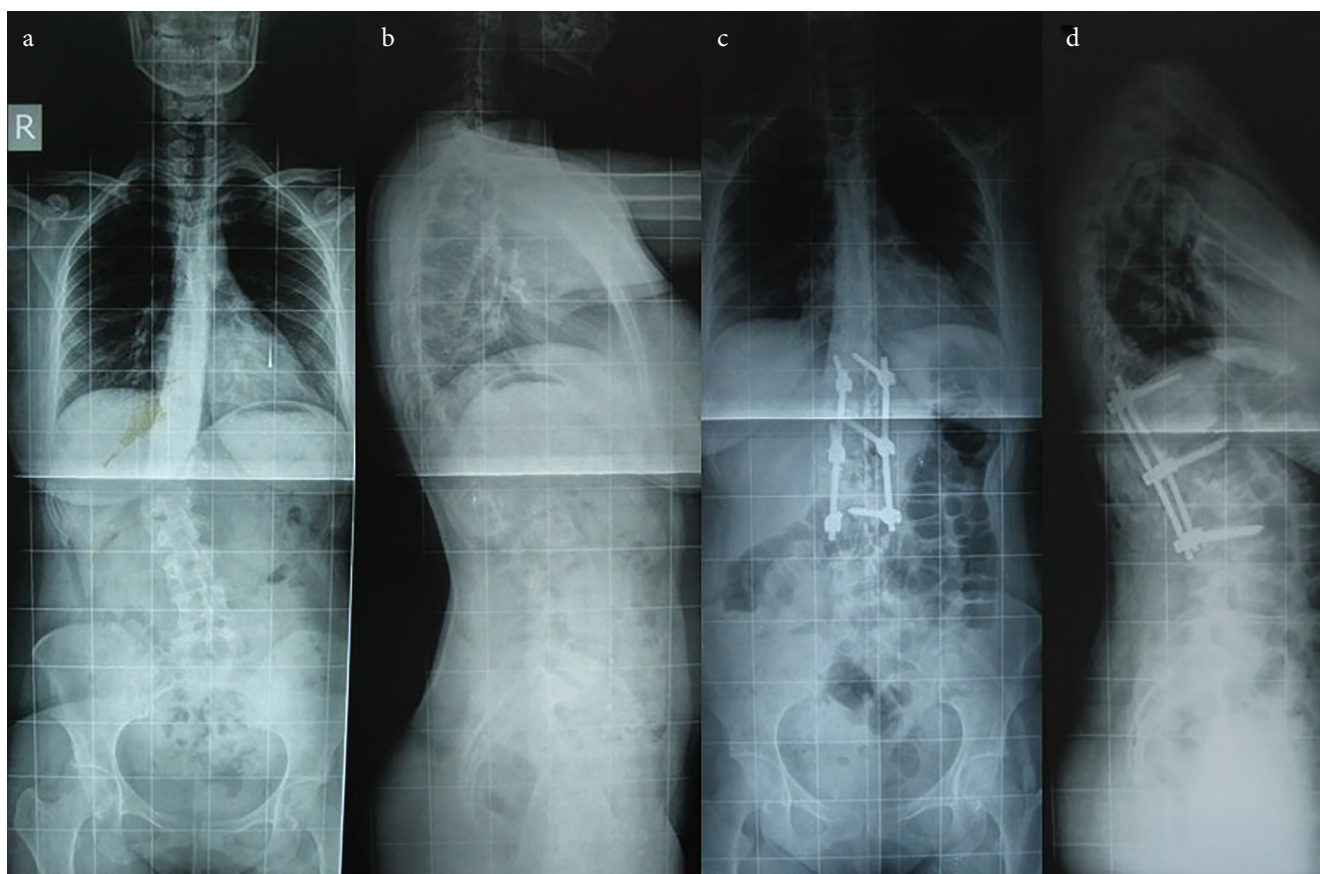
demographics; perioperative treatment; annotation of any medical and surgical-related complications; revision surgeries; follow-up findings; preoperative, postoperative, and follow-up SRS-22 scores; radiographs; preoperative, postoperative, and follow-up Cobb angle measurements of the upper thoracic, main thoracic, and thoracolumbar/lumbar curves; and the flexibility of the main curve. Radiographs included standing posterior-anterior and lateral films preoperatively, postoperatively, and at the 24-month follow-up, and right and left bending posterior-anterior films, longitudinal traction anterior-posterior films, and fulcrum posterior-anterior films preoperatively, all on 90×30 long cassettes. The main curve flexibility rate (%) was calculated as  $100 \times (\text{preoperative Cobb angle} - \text{bending Cobb angle}) / \text{preoperative Cobb angle}$ . The main curve correction rate was calculated as  $100 \times (\text{preoperative Cobb angle} - \text{postoperative Cobb angle}) / \text{preoperative Cobb angle}$ . The adapted Turkish version of the SRS-22 scores, which comprises 22 questions and covers five different domains (pain, function, self-image, mental health, and satisfaction), were gathered before surgery, after surgery, and at the 24-month follow-up (11).

Two groups were constituted according to the pedicle screw construct type: the consecutive pedicle screw construct

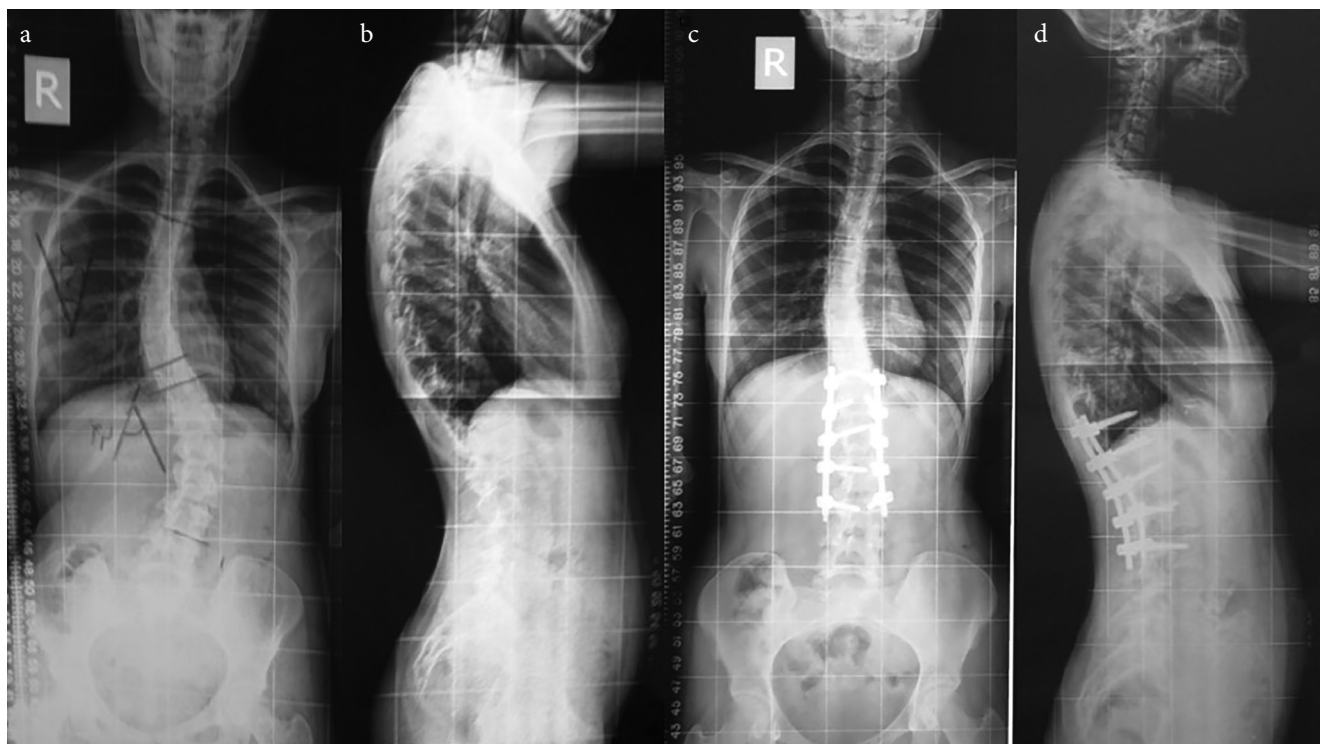
(CPSC) group, where the construct was implanted at all levels, and the intermittent pedicle screw construct (IPSC) group, where the construct was implanted intermittently (Figure 1, 2). All vertebrae with screw implantation had bilaterally inserted pedicle screws. The constructs with any pedicle in which instrumentation was planned, but was left uninstrumented, and intermittent pedicle screw constructs that had any segment instrumented consecutively (even number of vertebral levels in the fusion) were not included. The IPSC and CPSC groups were compared with each other in terms of age, gender distribution, the Cobb angles of the curves, correction rate, and SRS-22 scores preoperatively, postoperatively, and at the 24-month follow-up.

### Statistical analysis

The frequency, mean, and standard deviation values were calculated by descriptive statistical methods. After confirming that the variables are homogeneous and normally distributed, the independent samples t-test was used to compare the groups. Dichotomous variables were assessed by Crosstabs and Pearson Chi-square test. For all comparisons, statistical significance was reported at  $p < 0.05$  (two tailed). Statistical analyses were performed using the Statistical Package for Social Sciences software version 21.0 (IBM Corp.; Armonk, NY, USA).



**Figure 1.** a-d. The preoperative (a- b) and postoperative (c, d) anterior-posterior and lateral radiographs of a 16-year-old female patient who underwent posterior instrumentation and fusion of T11-L3 vertebrae with pedicle screws inserted bilaterally and intermittently



**Figure 2.** a-d. The preoperative (a, b) and postoperative (c, d) anterior-posterior and lateral radiographs of a 16-year-old female patient who underwent posterior instrumentation and fusion of T11-L3 vertebrae with pedicle screws inserted bilaterally and consecutively

## Results

According to the Lenke classification, 24 patients had type 1 curves, six had type 2 curves, 14 had type 3 curves, six had type 4 curves, six had type 5 curves, and four had type 6 curves. The groups were not significantly different in terms of Lenke classification ( $p>0.05$ ). There were no preoperative complications and postoperative neurologic impairment in any of the patients. There was no thoracolumbar kyphosis postoperatively in both the IPSC and CPSC groups. All the pedicle screws were in the correct position in the pedicle tracts on postoperative posterior-anterior and lateral radiographs. Therefore, no patient required postoperative evaluation with computerized tomography. Sixty patients (8 men, 52 women), 30 in each group, who underwent posterior instrumentation and fusion with pedicle screws for AIS were enrolled in the study. The mean age was  $14.6\pm 2.5$  years. The mean age and sex distribution showed no significant difference between the groups ( $p>0.05$ ). The mean age; the mean preoperative, postoperative, and follow-up curve Cobb angles; the mean flexibility of the curves; and the mean correction rate did not reveal any significant difference between the groups ( $p>0.05$ ) (Table 1).

All the patients in the study significantly improved in terms of major curve correction, SRS-22 appearance scores, and SRS-22 total scores at early and late follow-ups after the sur-

gery ( $p=0$  for all comparisons) (Table 1, 2). The correction gained immediately after the surgery was still protected at the late follow-ups (76.22% and 75.21% for the IPSC and CPSC group, respectively) ( $p>0.05$ ). The IPSC and CPSC groups showed no significant difference in terms of preoperative SRS-22 appearance scores ( $2.92\pm 0.39$  and  $2.79\pm 0.54$ , respectively) and SRS-22 total scores ( $2.99\pm 0.47$  and  $2.9\pm 0.56$ , respectively). This consistency was also observed in the early and late postoperative follow-ups ( $p>0.05$ ) (Table 2). The changes in SRS-22 appearance scores between the groups also did not reach the minimum clinically important difference reported previously by Carreon et al. (12).

The mean correction rate of the accompanying minor curves was calculated in the same way as that of the major curve correction rate calculation. The consecutively inserted pedicle screws presented minimal further correction in the accompanying minor upper thoracic ( $44.41\pm 35.01$  vs  $39.86\pm 30.13$  for the IPSC and CPSC groups, respectively) and lumbar ( $68.19\pm 16.01$  vs  $73.51\pm 15.91$  for the IPSC and CPSC groups, respectively) structural and nonstructural curves. However, in the mid-thoracic region, the IPSC group revealed better correction rates ( $73.89\pm 20.09$  vs  $68.76\pm 24.63$  for the IPSC and CPSC groups, respectively). Nevertheless, these results did not represent any statistically significant difference ( $p>0.05$ ).

**Table 1.** Mean age; mean preoperative, postoperative, and follow-up curve Cobb angles, mean flexibility of the curves, and mean correction rate of the patients

	IPSC group	CPSC group	p
Mean age±SD	14.46±2.66	14.73±2.37	>0.05
Mean preoperative major curve Cobb angle±SD	57.03±13.75	57.46±12.38	>0.05
Mean major curve flexibility±SD	65.03±12.38	61.33±11.91	>0.05
Mean postoperative major curve Cobb angle±SD	14.93±14.02	14.4±7.67	>0.05
Mean follow-up major curve Cobb angle±SD	15.73±13.9	15±7.66	>0.05
The mean correction rate of the major curve±SD (%)	76.22±14.43	75.31±13.45	>0.05

CPSC: consecutive pedicle screw construct; IPSC: Intermittent pedicle screw construct; SD: standard deviation

**Table 2.** Mean and standard deviation values of the preoperative, early postoperative, and late postoperative 24-month follow-up SRS-22 total and appearance scores

	IPSC	CPSC	P value
The mean preoperative SRS-22 Total Score±SD	2.99±0.47	2.9±0.56	0>0.05
The mean preoperative SRS-22 appearance±SD	2.92±0.39	2.79±0.54	0>0.05
The mean early postoperative SRS-22 Total Score±SD	3.77±0.34	3.73±0.3	0>0.05
The mean early postoperative SRS-22 appearance±SD	3.69±0.4	3.61±0.4	0>0.05
The mean postoperative SRS-22 Total Score at 24-month follow-up±SD	4.28±0.29	4.32±0.29	0>0.05
The mean postoperative SRS-22 appearance at 24-month follow-up±SD	4.28±0.47	4.18±0.34	0>0.05

CPSC: consecutive pedicle screw construct; IPSC: Intermittent pedicle screw construct; SD: standard deviation; SRS-22: the Scoliosis Research Society-22

## Discussion

The study revealed that both the pedicle screw constructs, IPSC and CPSC, placed with a posterior-only approach for correction of AIS had satisfactory outcomes following the surgery. The correction gained immediately after the surgery was maintained at the late follow-ups. These outcomes were confirmed by both SRS-22 scores and the radiographs obtained perioperatively and at follow-ups. Comparison of the IPSC and CPSC groups did not demonstrate a statistically significant change in the SRS-22 scores and the correction rate of not only the main curves but also the minor and major accompanying structural and nonstructural curves.

The reason for constituting two groups as IPSC and CPSC, as described above, is to avoid the varying implant densities in patients as in the studies published previously (13-15). As it is difficult to determine which factor contributed to the outcomes when a difference was found between the groups and more than one variable was present, only two types of pedicle screw construct designs were included in the study. This avoided the difficulty in interpreting the data gathered by comparing the outcomes of the groups different from each other in terms of the vast number of parameters. This study serves a ground by comparing only two types of pedicle screw construct designs for the first time in the literature. Moreover, again first in the literature, this study demonstrat-

ed no unsatisfactory results with fewer screws regarding the accompanying curves of the main curve.

Contrary to expectations, the correction rate was better in the IPSC group (76.2% vs 75.3%), which may be due to the more flexible curves in this group than in the CPSC group (65% vs 61.3%). However, differences in the mean correction rate and flexibility between the groups were not statistically significant.

There is no consensus yet whether the implant density correlated with the improved outcomes. There are a few papers reporting better coronal correction of AIS with higher pedicle screw density (7, 15-20). However, only Ketenci et al. reported improved outcomes in the SRS-22 self-image domain (but with similar results in the total SRS-22 scores) (20). Similarly, the SRS-22 scores in the current study were not significantly different between the IPSC and CPSC groups. Furthermore, Larson et al. published a systematic review reporting no significantly improved outcome with higher implant density constructs (21). The literature also included papers advocating that no significant improvement could be gained with a higher pedicle screw density (4, 5, 9, 13, 22-24). All the studies that investigated the effects of implant density reported the outcomes of variable pedicle screw density constructs. Li et al. performed their study with study groups similar to those in the current study (25). They found no significant improvement in consecutive pedicle screw constructs both in the coronal and the sagittal planes.

A study by Larson et al. reported the potential annual cost saving of up to \$20 million (7%) in 5710 AIS patients by implanting fewer screws in the United States (26). In fact, intermittently placed pedicle screws decrease the cost much more significantly than they are thought. If we do not consider the upper and lower vertebrae, since they have to be instrumented to be upper and lower instrumented vertebrae by description both in IPSCs and CPSCs, the number of pedicle screws decreases significantly. In a construct including 11 levels of vertebrae in the fusion, if the upper and lower instrumented vertebrae are not counted, the numbers of pedicle screws would be 8 and 18 in an IPSC and CPSC, respectively, which translates to 55.6% fewer implants. Similarly, in a construct including five levels, the numbers would be two and six screws, which translates to 66.6% fewer implants.

Scoliotic curves that are more rigid during the preoperative assessments are likely corrected using more screws instinctively by the spine surgeons. Therefore, the current study included only the data of the patients with curves more than 50% flexible to prevent any potential misinterpretation. The outcomes of the IPSCs in rigid deformities cannot be estimated with these analyses. Quan et al. previously investigated this issue and found no worse outcome regarding the sagittal and coronal planes with and without considering the curve flexibility.

There are some disadvantages of using IPSCs. Suk et al. stated in their study that there may be a higher risk for screw pull-out and pedicle fracture (27). The authors have not met any of those aforementioned risks yet. However, the rigid curves are predisposing factors for such described complications. In the condition of a pedicle screw insufficiency, other adjacent pedicle screws may compensate for the defective screw in consecutively inserted constructs, while this compensation mechanism may fall short in intermittently inserted constructs.

### Limitations

All the data interpreted in the study were retrospectively evaluated from the prospectively collected data. The average operative time, intraoperative blood loss, and average total transfusion data were missing, which may have potential significant differences among the groups. The global coronal balance was not evaluated by measuring the distance between the C7 plumb line and the central sacral vertical line. The sagittal balance can also be compared between the groups by measuring the kyphosis angle and the distance from the C7 plumb line to the superior posterior endplate of the S1 vertebral body. The measurements on radiographs were not evaluated in terms of internal and between-subject consistency. However, these data were evaluated several times previously. The instrumented levels of the vertebral column were not constantly the same in all patients, which may also affect the outcomes. In our opinion, this was the most significant weakness of this study.

In conclusion, both pedicle screw constructs placed with a posterior-only approach whether intermittently or consecutively for the correction of AIS had satisfactory outcomes following the surgery. These outcomes were confirmed by both the SRS-22 scores and the radiographs obtained perioperatively and at follow-ups. The IPSC and CPSC groups did not demonstrate a statistically significant change in the correction rate of not only the main but also the minor or major accompanying structural and nonstructural curves, and also in the SRS-22 scores.

**Ethics Committee Approval:** Authors declared that the research was conducted according to the principles of the World Medical Association Declaration of Helsinki “Ethical Principles for Medical Research Involving Human Subjects”, (amended in October 2013).

**Informed Consent:** Written informed consent was obtained from the parents’ of the patients.

**Author Contributions:** Concept - A.S., E.A.; Design - A.S., E.A.; Supervision - A.S.; Re-sources - A.S., E.A.; Materials – M.A.S.; Data Collection and/or Processing - E.A., M.C., I.D., A.E.; Analysis and/or Interpretation - M.C.; Literature Search - M.C., İ.K.; Writing Manuscript - E.A., M.C.; Critical Review - A.S., M.C.

**Conflict of Interest:** The authors have no conflicts of interest to declare.

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