Surgical management of moderate adolescent idiopathic scoliosis with a fusionless posterior dynamic deformity correction device: interim results with bridging 5–6 disc levels at 2 or more years of follow-up

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OBJECTIVE A posterior dynamic deformity correction (PDDC) system was used to correct adolescent idiopathic scoliosis (AIS) without fusion. The preliminary outcomes of bridging only 3–4 discs in patients with variable curve severity have previously been reported. This paper examines a subgroup of patients with the authors’ proposed current indications for this device who were also treated with a longer construct.

METHODS Inclusion criteria included a single AIS structural curve between 40° and 60°, curve flexibility ≤ 30°, PDDC spanning 5–6 levels, and minimum 2-year follow-up. A retrospective review was conducted and demographic and radiographic data were recorded. A successful outcome was defined as a curve magnitude of ≤ 30° at final follow-up. Any serious adverse events and reoperations were recorded.

RESULTS Twenty-two patients who met the inclusion criteria were operated on with the PDDC in 5 medical centers. There were 19 girls and 3 boys, aged 13–17 years, with Risser grades ≥ 2. Thirteen had Lenke type 1 curves and 9 had type 5 curves. The mean preoperative curve was 47° (range 40°–55°). At a minimum of 2 years’ follow-up, the mean major curve measured 25° (46% correction, p < 0.05). In 18 (82%) of 22 patients, the mean final Cobb angle measured ≤ 30° (range 15°–30°). Trunk shift was corrected by 1.5 cm (range 0.4–4.3 cm). The mean minor curve was reduced from 27° to 17° at final follow-up (35% correction, p < 0.05). For Lenke type 1 patterns, the mean 2D thoracic kyphosis was 24° preoperatively versus 27° at final follow-up (p < 0.05), and for Lenke type 5 curves, mean lumbar lordosis was 47° preoperatively versus 42° at final follow-up (p < 0.05). The mean preoperative Scoliosis Research Society-22 questionnaire score improved from 2.74 ± 0.3 at baseline to 4.31 ± 0.4 at 2 years after surgery (p < 0.0001). The mean preoperative self-image score and satisfaction scores improved from preoperative values, while other domain scores did not change significantly. Four patients (18%) underwent revision surgery because of nut loosening (n = 2), pedicle screw backup (n = 1), and ratchet malfunction (n = 1).

CONCLUSIONS In AIS patients with a single flexible major curve up to 60°, the fusionless PDDC device achieved a satisfactory result as 82% had residual curves ≤ 30°. These findings suggest that the PDDC device may serve as an alternative to spinal fusion in select patients.

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KEYWORDS fusionless posterior dynamic deformity correction; adolescent idiopathic scoliosis; AIS

ABBREVIATIONS AIS = adolescent idiopathic scoliosis; IMAST = International Meeting on Advanced Spine Techniques; PDDC = posterior dynamic deformity correction; SRS-22 = Scoliosis Research Society-22.


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A novel posterior dynamic deformity correction (PDDC) device (Apifix Ltd.) was developed to provide a less-invasive, fusionless means of correcting AIS curves and controlling the deformity over time. This device has a ratchet mechanism that allows unidirectional elongation of an expandable rod that is made of titanium alloy with amorphous diamond-like ceramic coating. The expandable rod, with polyaxial rings (eye joint) at its extremity, is anchored to the spine with 2 pedicle screws that are implanted around the apex of the main curve. This connection should deliver minimal moment to the screw-implant interface and is designed to resist mainly during compression loading. The ratchet mechanism enables both immediate intraoperative curve reduction and potential gradual postoperative curve correction by unidirectional implant elongation, which is driven by optional corrective spinal exercises performed by the patient. The implant has a control pin that can abort the ratchet mechanism and, if desired, put the device in a neutral mode or in a locked position to create a fusion-like rod (Fig. 1). In the current design, the total rod excursion is either 30 mm or 40 mm, depending on the predistraction rod length. Preclinical bench tests and biomechanical characteristics have previously been reported.

The PDDC system was introduced for clinical use in 2012 with the aim to correct moderate Lenke type 1 or type 5 idiopathic curves without fusion. The preliminary outcomes of bridging 3–4 discs in patients with variable curve severity were reported at the 2018 International Meeting on Advanced Spine Techniques (IMAST). Analysis of the early experience with PDDC demonstrated major curve correction of 32% only. With further clinical experience it has been observed that utilization of longer PDDC constructs, spanning 5–6 disc levels, yielded better final curve correction. The learning curve with PDDC use, studied by comparing curve correction with short constructs to longer ones, was reported at the 2019 IMAST. By spanning more levels, 70% of the patients had a residual curve of less than 35° at 2 years’ follow-up. Following the recent FDA approval of the PDDC system and nearing the introduction of this new technology to the US, refined indications were formulated as follows: Lenke type 1 or type 5 curves up to 60° that reduce on lateral bending views to 30° or less and kyphosis of 50° or less. The purpose of this paper is to examine the outcomes after PDDC surgery spanning 5–6 levels for this subgroup of patients after a minimum 2-year follow-up.

**Methods**

We conducted a retrospective review of patients treated with PDDC with the following inclusion criteria: single AIS structural curve between 40° and 60°, curve flexibility ≤ 30°, PDDC surgery spanning 5–6 levels, and a minimum 2-year follow-up. A successful outcome was defined as a curve magnitude of ≤ 30° at final follow-up. Serious adverse events and reoperations were recorded.

**Surgical Technique**

The concave side of the spine was exposed through an incision 15 cm or greater around the apex of the curve, while the convexity of the spine was left unexposed. Two pedicle screws were inserted at the end vertebrae and connected by eye joints to the PDDC, spanning 5–6 disc spaces. Distraction during surgery was applied in concert with application of manual lateral corrective forces that allowed significant correction of the deformity. No fusion was performed. At approximately 2–3 weeks after surgery, the patients were directed to start 5 basic Schroth-like exercises with the goal to potentially enable further rod elongation through the ratchet mechanism. The patients were instructed to perform the exercises for 30 minutes daily and were continued for 3–6 months after surgery. No braces were used and no restrictions on physical activities were imposed on the adolescents.

**Patient Outcomes**

Patient demographic and radiographic data were evaluated. Patients completed the Scoliosis Research Society-22 (SRS-22) questionnaire preoperatively and at 24 months postoperatively. In addition, a numerical questionnaire (score range 1–5) regarding satisfaction with the procedure, would they choose it again, and would they recommend it to a friend, was administered at final follow-up.

**Statistical Evaluation**

The Wilcoxon signed-rank test for 2 means (paired observations) was applied for testing the statistical significance of the curve magnitude changes in the postoperative period from the pretreatment curve size. Data were analyzed using the SAS statistical program (version 9.3, SAS Institute).
Results

Twenty-two patients from 5 medical centers who met the inclusion criteria were identified (Table 1). These patients underwent surgery between June 2015 and December 2016. There were 19 girls and 3 boys, 13–17 years old, with Risser grades ≥ 2. Thirteen had Lenke type 1 curves and 9 had type 5 curves (Figs. 2 and 3). The mean preoperative curve was $47^\circ$ (range $40^\circ$–$55^\circ$). At a minimum of 2 years of follow-up, the mean final major curve angle measured $25^\circ$ (46% correction; $p < 0.05$). In 18 (82%) of 22 patients, the mean final Cobb angle measured $\leq 30^\circ$ (range $15^\circ$–$30^\circ$). Trunk shift was corrected by 1.5 cm (range $0.4$–$4.3$ cm). The mean minor curve was reduced from $27^\circ$ to $17^\circ$ at final follow-up ($35\%$ correction; $p < 0.05$). For Lenke type 1 patterns, mean 2D thoracic kyphosis was $24^\circ$ preoperatively versus $27^\circ$ at the final follow-up ($p < 0.05$), and for Lenke type 5 curves, the mean lumbar lordosis was $47^\circ$ preoperatively versus $42^\circ$ at the final follow-up ($p < 0.05$).

The mean preoperative SRS-22 score changed from $2.74 \pm 0.3$ at baseline to $4.31 \pm 0.4$ at 2 years after surgery ($p < 0.0001$). The mean preoperative self-image score and satisfaction scores increased from preoperative values, while pain, activity, and mental health domain scores did not change significantly. Although statistically significant ($3.14 \pm 0.39$ vs $4.03 \pm 0.41$), the change in self-image score did not meet the minimum clinically important difference of 0.98.$^3$

Pooled results from the 3-question questionnaire (score range 1–5) were as follows: satisfaction with the procedure = 4.8/5, would they choose the procedure again = 4.8/5, and would they recommend it to a friend = 4.8/5.

Four patients (18%) underwent revision surgery because of nut loosening ($n = 2$), pedicle screw backup ($n = 1$), and ratchet malfunction ($n = 1$). In 3 patients the implant was retained without the need for fusion and in 1 patient it was removed without curve progression.

Discussion

Our preliminary experience with a novel and less-invasive PDDC spanning 3–4 disc spaces in moderate AIS showed that only a modest 32% curve correction was achieved.$^8$ This current study describes the clinical experience gained by using a longer construct that could enable better curve correction and stabilization of AIS without concomitant spinal fusion. The radiographic data obtained at 2–3 years of follow-up in a cohort of individuals with AIS supports the view that PDDC spanning 5–6 motion segments is a valid alternative to traditional instrumentation with fusion. Besides using a longer implant, flexible curves bending to ≤ $30^\circ$ were chosen and were considered to be crucial for procedural success. The main curves
were reduced by 46%, and curve reduction was maintained during the observation period of 2–3 years. In 18 of 22 patients (82% of the cohort) the final Cobb angle of the major curve did not exceed 30°. Keeping the major Cobb angle under 30° may enable future removal of the dynamic device without the danger of postremoval curve progression. Concomitantly, with reduction of the major curve, the secondary curves were also reduced by an average of 35%. The results obtained in flexible curves with instrumentation spanning 5–6 disc levels provided far better curve correction than was obtained with shorter constructs spanning only 3–4 disc levels. Surgery with longer constructs did not change the minor invasive nature of the procedure, ensuring very short hospitalization and recovery. The results obtained are comparable to those achieved with formal fusion without the need to sacrifice spinal motion and with a less-invasive nature, with the potential to ensure prompt recovery.

While Lenke type 1 curves were referred to surgery if the deformity exceeded 40°–45°, Lenke type 5 curves were operated on with a lower Cobb angle threshold because of the reported tendency of thoracolumbar curves...
above \(35^\circ\) to progress even after skeletal maturity,\(^{14}\) and also because of the marked trunk imbalance common in this type of deformity.\(^{18}\) Although 5 patients were Risser grade 4 at the time of surgery, they either had a progressive curve or were displeased with their body image. This technique enabled correction of the trunk shift as well as significant Cobb angle reduction. All participants reached skeletal maturity at the end of the follow-up period of this study; however, long-term follow-up is required to determine if there is any curve progression in the future. Longer-term follow-up will also better assess the possibility of a crankshaft phenomenon in younger skeletally immature patients. Initially, significant emphasis was put on activation of the ratchet mechanism and rod elongation by the performance of postoperative Schroth-like exercises. Per patient self-reporting, all patients who underwent operations were engaged in performing the exercises after surgery, resulting in rod lengthening in many. We have also observed that the ratchet can be activated by daily activities and not only by performing specific exercises. With the recent modified operative strategy in which maximal intraoperative correction is realized, the exercises contribute less to the final curve reduction, yet they may be important in reduction and control of the secondary curves. Nevertheless, in a few patients in the current series, \(2^\circ\)–\(5^\circ\) of additional curve correction was achieved following the Schroth-like exercises (Fig. 2). This generally occurred within the first 3–6 months postoperatively. We acknowledge that the primary goal of this device is to prevent the progression of scoliosis over time and that the potential for further correction over time through the ratcheting mechanism is still not fully known. With the current technique of maximizing intraoperative correction, the physical therapy exercises may not be as important as initially conceived and require further study.

The secondary curves were spontaneously reduced concomitantly with major curve reduction, and the correction was maintained throughout the observation period. No “adding on” was observed during follow-up. Previous publications on selective thoracic instrumentation in Lenke type 1 curves have documented that the secondary curves undergo spontaneous correction, and that the correction is maintained in both short- and long-term follow-up for as long as 20 years.\(^{10,11}\)

A statistically significant change was noted in the sagittal profile of the spine after surgery. However, this change had no clinical significance. While the thoracic kyphosis was increased in patients with Lenke type 1 deformity, the lumbar lordosis was decreased in Lenke type 5 curves. As previously noted, this change, although statistically significant, had no clinical bearing as the sagittal vertical axis remained in the “normal” range.

The mean preoperative SRS-22 score improved significantly at final follow-up. In particular, the mean preoperative self-image score change was statistically significant, but it did not reach a level of clinical significance.\(^{3}\) Patient satisfaction assessed by a questionnaire showed a high satisfaction score (4.8/5). Patients were satisfied with their appearance as reflected in their response to their general satisfaction with the procedure, and the fact that they would recommend the procedure to a friend. In addition, there was also an improvement in the trunk shift by an average of 1.5 cm.

The PDDC device is intended to function as a dynamic implant, allowing motion approximating the natural spine mobility mitigating the occurrence of spontaneous fusion. The radiographs were specifically evaluated for the presence of spontaneous fusion and there was none seen. We realize that radiographic analysis is not 100% accurate for the assessment of fusion; however, CT evaluation poses the risk of additional radiation exposure, and surgical exploration is too invasive to be used routinely. During the reoperation procedures, no concave fusion was observed. Further study assessing the flexibility of instrumented segments would be of interest. The biomechanical properties of this device were investigated in vitro by Holewijn et al.\(^{9}\) They performed a biomechanical study on cadaveric thoracic spines in which they compared spinal motion with the dynamic device versus standard rigid pedicle screw fixation. In a cadaveric spine the ratchet device resulted in only a 40% decrease in range of motion in flexion/extension compared to a noninstrumented spine. There was only an 18% reduction in lateral bending, while the range of motion in axial rotation remained unaffected as compared to a noninstrumented spine. In comparison, a full pedicle screw instrumentation, similar to a spinal fusion, resulted in a significantly larger decrease in range of motion in flexion/extension (81% decrease), lateral bending (75% decrease), and axial rotation (71% decrease; \(p < 0.05\)). That study demonstrated that spinal range of motion was significantly less constrained by the PDDC device as compared to rigid pedicle screw-rod instrumentation.\(^{9}\) Therefore, the device should enable scoliosis correction with preservation of a more physiological spinal motion. Holewijn et al.\(^{9}\) also determined that adjacent spinal segment biomechanics were not significantly altered by this device and that these beneficial biomechanical characteristics can be attributed to the polyaxial connectors between the implant and screws. Therefore, the risk of implant failure is deemed low as implant loads in the absence of spinal fusion are expected to be minimal.

Posterior instrumentation and fusion significantly affect postoperative spinal motion and trunk mobility. The restriction is in flexion/extension lateral bending and axial rotation.\(^{6,19}\) One important advantage of the posterior dynamic deformity correction device is that the implant preserves spinal motion. The preservation of spinal motion in Lenke type 5 curves is a particularly important advantage of the PDDC because the standard surgical procedure mandates fusion of most of the lumbar motion segments. The preservation of spinal motion may prevent future occurrence of adjacent disc degeneration, pain, and the need for further surgical intervention.

Previous work compared the outcome in patients undergoing instrumentation with PDDC spanning 3–4 levels with a group of AIS patients, in which the major curve was reduced to \(35^\circ\) on bending views and in which a longer PDDC was used spanning more disc levels.\(^{5}\) It was found that only 42% of the short implant group achieved a correction to \(35^\circ\) or less, compared to the 70% success rate in the group with implants spanning 5–6 disc levels.

The ultra long-term consequences of having a spinal
implant across several disc levels without fusion is unknown at present. The main concern is future screw or implant fracture, or screw loosening. The standard practice of treating patients with AIS is spinal fusion, which is expected to last the lifetime of the individual. Based on the work performed by Rohlmann et al., we know that the metal construct of a fusion system is under significant loads after bone fusion is achieved; however, as a portion of the load is relieved by the bone fusion, these loads are below the level that leads to system failure. The uniqueness of the PDDC system is its polyaxial joints that do not transfer moments to the screw-bone interface and let the spine take a significant portion of the loads. If the remaining loads are below the level that leads to system failure, then the long-term survival of this system should be similar to that of fusion constructs. Preclinical bench testing of the PDDC system showed that the system was able to hold 700 N for 10 million cycles; this value is significantly higher than the values with a standard fusion system. Therefore, the rate of implant failure is predicted to be extremely low. The ultimate goal of the system is to reduce the curve to a point that system removal after several years of serving as an internal brace would not result in curve recurrence or progression. Surgical intervention with the system in patients with low Risser grades (0–1) with curve reduction to 25° or lower may enable safe removal of the implant after skeletal maturity. Additional work and longer follow-up are required to assess the ability of this novel system to achieve this long-term goal.

Four severe adverse events were encountered in the present series. In 2 instances nut loosening occurred in the early postoperative course. Nut loosening was attributed to insufficient torque while tightening the nuts. As a result, currently, more torque is applied during nut tightening. In 1 case, ratchet malfunction allowing rod shortening occurred 3 years after surgery. The residual curve did not progress after removal of the implant without further action. The implant was retained in 3 of 4 patients undergoing revision surgery.

The limitations of our study were the small cohort and the retrospective outcomes evaluation. Nevertheless, the radiographic and patient outcomes are encouraging.

Conclusions

In AIS patients with a single flexible major curve up to 60°, the fusionless PDDC device achieved a satisfactory result as 82% had residual curves ≤ 30°. These findings suggest that the PDDC device may serve as an alternative to spinal fusion in select patients.

References


Disclosures

Dr. Floman is a co-founder of ApiFix. Dr. El-Hawary reports being a consultant for Medtronic Canada, DePuy Synthes Spine, ApiFix Ltd., Globus Medical, and Wishbone Medical, and holding stock options in ApiFix Ltd. and Wishbone Medical. Dr. Millgram reports having direct stock ownership in ApiFix. Dr. Lonner reports being a consultant to DePuy Synthes, Ethicon, Zimmer Biomet, and ApiFix; having direct stock ownership in Spine Search and Paradigm Spine; serving on the Scientific Advisory Board, Speaker’s Bureau, and receiving royalties from DePuy Synthes for the development of the Expedium Plus Implant System; serving as a Scientific Advisory Board Member for ApiFix; serving on the Board of Directors of Spine Search and the Setting Scoliosis Straight Foundation; and serving on the Speaker’s Bureau for K2M. Dr. Betz reports being a consultant for ApiFix, DePuy Synthes Spine, Globus Medical, SpineGuard, and Wishbone Medical; having stock options in Abyrx, ApiFix, Electrocore, Medovex, Orthobond, SpineGuard, and Wishbone Medical; receiving royalties from DePuy Synthes Spine, Globus Medical, SpineGuard, and Thieme Medical Publishers; serving on the Speakers Bureau for DePuy Synthes Spine and Globus Medical; and having a child who is employed by DePuy Synthes Spine.

Author Contributions

Conception and design: Floman. Acquisition of data: Floman, Millgram. Analysis and interpretation of data: all authors. Drafting the article: Floman, El-Hawary, Lonner, Betz. Critically revising the article: all authors. Reviewed submitted version of manuscript: Floman, El-Hawary, Millgram, Lonner. Approved the final version of the manuscript on behalf of all authors: Floman.

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