Use of a novel corrective device for correction of deformities in adolescent idiopathic scoliosis

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Received: 10 March 2019 / Accepted: 30 April 2019 / Published online: 18 May 2019
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Abstract
Background Adolescent idiopathic scoliosis (AIS), with an incidence of 3%, is a common deformity. Correction of severe curvature of the deformity has attracted much investigation to achieve safe, reproducible results. We present our experience with a novel device for the correction of deformities across a spectrum of curve types, the rod link reducer. This system allows direct visualization of a mass derotation to achieve deformity correction.

Methods Prospective cohort study of patients with severe AIS treated in our institution during 2017 with major TL/L curves. Pre- and postoperative Cobb angles and coronal balance; operative time; and estimated blood loss, fusion levels, and screw density were recorded. Our results were split between those with a Lenke A/B classification and Lenke C, with a goal of correction of curve in the former and achieving good coronal balance with a preservation of distal motion segments in the latter.

Results There were 31 patients enrolled in our series. Within the Lenke A/B group, there were 18 patients, achieving a mean correction of 56% (SD 10%) and a correction of a mean coronal balance of 14.5 mm (SD 12.5 mm) of C7 from the CSVL to 10.9 mm (SD 10.6 mm). Our screw density was 1.3 screws (SD 0.1) per vertebrae fused. Our operative time was 185 min (SD 38 min). Average recorded blood loss was 721 ml (SD 289). In our Lenke C cohort, preoperative and postoperative mean Cobb angles (SD) were 73.3 (13.4) and 33.8 (11.9), respectively, with an average correction of 54% (SD 11%). The mean (SD) operative time was 03:35 (SD 00:35). Fusion levels were over a mean of 12.1 (SD 1.7) vertebrae, with a screw density of 1.3 (SD 0.1) per level. Mean intraoperative blood loss was 829 ml (SD 355). No patient received an allogenic blood transfusion. There were no adverse neurological events in this patient cohort.

Conclusions The link rod system allows for excellent correction of spinal deformity and a short operative time.

Keywords AIS · Novel device · Scoliosis

Introduction
Adolescent idiopathic scoliosis (AIS) is a three-dimensional spinal mal-alignment in the coronal, axial, and sagittal planes without a defined etiology [1]. Not all patients require surgery but in progressive curves, surgical intervention spinal fusion is recommended. The goal of surgery is to attain a well-balanced instrument spinal fusion. Over the last number of decades, several operative techniques have evolved to enable deformity correction with spinal balance.

Spinal instrumentation has advanced since Harrington published his pioneering work on the use of posterior rods in 1962. These rods were securing these with hooks and sublaminar wires [2]. The use of pedicle screws in posterior spinal fusion (PSF) is increasingly prevalent, with reports demonstrating greater correction and rigidity of correction over the more traditional hook wire constructs and greater pull-out strength in in vitro testing [3, 4]. The three-column fixation of the pedicle screw allows correction of the triplanar deformity in AIS, rather than medialization of the posterior elements attained with other techniques [5]. For larger curves, pedicle screws have allowed the surgeon to use a posterior-only approach, forgoing the need for an anterior release [6].

In concert with this, increased recognition of the importance of the sagittal plane has spurred the development of techniques in deformity correction, which can be used in isolation or in combination with each other. The early “flat back” techniques of Harrington have evolved through Cotrel–
Duboussé'ts rod rotation [7], distraction-compression [8], mass or focal vertebral derotation [1], in situ contouring [9], and cantilever reduction, all of which may be augmented with osteotomies of the posterior elements [10, 11]. With this increase in complexity comes additional risk and economic burden. There is a significant financial cost associated with the use of pedicle screws [12, 13] and osteotomies increase surgical time and result in increased blood loss [14].

The rising cost of healthcare is unsustainable and so today's surgeon needs to use techniques which can attain similar results with less. Interest in low-density constructs, allowing a reduction in surgical time and blood loss, is increasing [15–17]. We present our experiences with a novel reduction apparatus, the rod link reducer [18] in deformity correction, evaluating its effect on surgical time, blood loss, and correction.

**Methods and materials**

**Institutional review board approval was obtained**

Our institution began using the rod link system in April 2017. We prospectively collected data on our AIS patient cohort undergoing correction and PSF from this time. This was a two-surgeon series, with two attending surgeons operating in each case where scheduling was allowed. All cases from April 2017 until April 2018 were included.

Indications for surgery were curves with a Cobb angle over 45°, progressive deformity, or progressive imbalance. All spines were classified as per the Lenke system [19]. Preoperative Cobb angles and coronal balance were recorded. A preoperative MRI scan to rule out any underlying pathology driving the scoliosis was performed for each patient.

**Surgical strategy and technique**

The surgical system used was the Globus Medical Creo system with a rod link reducer (Pennsylvania, USA). Deformity correction combined a cantilever reduction technique using the rod link reducer and mass vertebral derotation on the concave side using reduction towers.

Deformity correction was tailored to the lumbar modifier. Our surgical strategy for the A and B modifiers aimed to achieve maximum safe deformity correction. For those with significant lumbar curves, our surgical plan and targeted correction of the thoracic curve were based on the preoperative bending films, seeking to match the lumbar Cobb angle attained by the patient with a lateral bending radiographs.

We utilized a midline approach with subperiosteal exposure of the posterior elements. Pedicle screws were inserted free hand using the technique described by Kim et al. [20], with sensory and motor evoked potentials used throughout. Fluoroscopy was used intraoperatively to confirm the lowest instrumented vertebra after screw insertion and to check disc space balance after deformity correction.

Posterior instrumentation and fusion was performed for each case, with two posterior rods and local autograft. No anterior releases were performed. No thoracoplasties or Ponte osteotomies were performed. No bone allograft was used. For severe curves of greater than 60°, traction was applied, using a Gardner Wells Tongs and skin traction applied at the level of the pelvis. Sequential posterior facet release prior to pedicle screw insertion was performed at the thoracic spine. A low-density construct was preferred with a combination of uniaxial and polyaxial screw heads. Pre-op surgical planning informed fusion levels, with proximal fusion dictated by shoulder balance and distal level by lowest touched vertebral of the central sacral line.

**Pedicle screw placement**

Screw placement on the convex side of the curve created two deformity segments, proximal and distal. Each segment contained three pedicle screw anchor points. As many apical curve segments as possible were left free. The most distal and most proximal screw was poly axial and the remainder uniaxial. A temporary short rod was placed in the proximal and distal segments. The uniaxial screws allowed each short segment to be maximally corrected. These segments would employ a cantilever deformity correction technique with the rod link reducer. On the concave side, uniaxial screws were placed throughout the curve except at the LIV and UIV, where a polyaxial screw head was used. This allowed us to achieve maximum derotation.

**Deformity correction**

A cantilever correction technique of the deformity using the rod link reducer followed the sequence of axial derotation, coronal translation, and finally sagittal plane correction. Once the deformity is corrected, the rod link reducer was locked in place with a carbon fiber rod, and the shoulder balance is checked and adjusted using the lever arms as appropriate. The concave rod was now contoured with the desired amount of kyphosis for balance. We use a cobalt chrome rod as routine on this concave side. The rod is immediately locked proximally and distally to prevent further elevation of the concave shoulder and mass segmental derotation is performed using the reduction towers. Once the concave rod is in place, the rod link reducer is removed and a contoured titanium rod is inserted on the convex side, gaining further derotation through the differential bend. The sequence is illustrated in Fig. 1, demonstrating the rod link reducer holding the correction prior to the implantation of the contralateral rod and once the rod is in situ with reduction towers in place.
Type C curves

A modification to the above was utilized for the type C curves. Patients had selective thoracic fusions, with the goal of preserving as many motion segments as feasible with a concurrent stable construct with adequate correction.

Preoperative bending films demonstrated flexibility of the lumbar curve. The residual curve was noted. Our surgical aim was to give patients a balanced curve in the coronal plane, and so the residual thoracic coronal curve built into our construct matched the Cobb angle of the lumbar spine.

The principles of our technique were as previously described. The most distal instrumented vertebra corresponded to the lowest touched vertebra.

Control of blood loss

Strategies to minimize the likelihood of blood transfusion were the use of cell salvage system, administration of 1 g of tranexamic acid, low-density pedicle screw constructs, and a dual attending surgeon operating strategy where scheduling was allowed.

Recording of results

Time of surgery was taken from the time recorded for knife to skin, until the recorded closure time.

At follow-up clinic, whole spine plain film x-rays were obtained and Cobb angle and coronal balance were recorded. Percent curve correction is reported for the major curve, calculated by \( \frac{\text{preoperative Cobb angle} - \text{postoperative Cobb angle}}{\text{preoperative Cobb angle}} \times 100 \).

Coronal balance was measured as the perpendicular line from the central sacral vertical line to the spinous process of C7. Preoperative and postoperative values were recorded. There is improvement shown over time post-initial operative correction, but for the purposes of this study, coronal balance at 3 weeks post operation is reported.

Results

There were 31 patients enrolled in our series. All were classified with AIS with no neurological drivers on MRI of the whole spine including brainstem, or on clinical examination. We have analyzed them separately based on either a Lenke A/B or C classification.

Within the Lenke A/B group, there were 18 patients, with a mean age of 13.9 years (SD 1.5). There was a 14:4 female to male ratio, with a mean thoracic curve of 67°. End vertebral and apex levels are shown in Table 1. A mean correction of 63% (SD 9.7%) was achieved in this group, with a correction of a mean coronal balance of 14.5 mm (SD 12.5 mm) of C7 from the CSVL to 10.9 mm (SD 10.6 mm). Low-density constructs were used throughout this group with a mean screw density of 1.3 screws (SD 0.1) per vertebrae fused. Our operative time was 185 min (SD 38 min) per procedure from recorded knife to skin until wound closure. Average recorded blood loss was 677 ml (SD 254), which is not inclusive of blood reinfused from the cell salvage device. No patient received an allogenic blood transfusion. There were no adverse neurological events in this patient cohort. An example of pre- and postoperative radiographs from this cohort is depicted in Fig. 2.
Table 1  Outcome measures across patient cohort, classified by curve type

| Age | Classification | Cobb angle | Apex | End vertebrae | Coronal balance (mm) | Number of screws | Fusion level | Fused vertebrae | Operative time | Intraoperative blood loss | Coronal balance | Screw density | Curve correction |
|-----|----------------|------------|------|---------------|----------------------|------------------|--------------|-----------------|---------------|--------------------------|----------------|---------------|------------------|
| 16  | 1C             | 62         | T9   | T7 T12        | 10                   | 13               | T3-T12       | 10              | 184           | 670                      | 13             | 1.3           | 55%              |
| 13  | 4C             | 85         | T7   | T5 T9         | 50                   | 21               | T3-L4        | 14              | 238           | 928                      | 20             | 1.5           | 53%              |
| 13  | 4C             | 97         | T8   | T5 T11        | 45                   | 15               | T3-L1        | 11              | 241           | 470                      | 10             | 1.4           | 33%              |
| 13  | 3C             | 66         | T7   | T6 T10        | 48                   | 19               | T3-L4        | 14              | 212           | 918                      | 15             | 1.4           | 55%              |
| 13  | 3C             | 90         | T8   | T5 T11        | 42                   | 21               | T3-L4        | 14              | 234           | 1010                     | 25             | 1.5           | 49%              |
| 13  | 1C             | 80         | T9   | T7 T11        | 0                    | 14               | T3-L1        | 11              | 159           | 340                      | 0              | 1.3           | 44%              |
| 20  | 3C             | 72         | T8   | T7 T10        | 10                   | 19               | T3-L4        | 14              | 218           | 1220                     | 0              | 1.4           | 39%              |
| 15  | 1C             | 78         | T8   | T5 T11        | 23                   | 16               | T3-L2        | 12              | 205           | 474                      | 27             | 1.3           | 68%              |
| 15  | 1C             | 85         | T9   | T6 T12        | 0                    | 13               | T3-L1        | 11              | 152           | 817                      | 0              | 1.2           | 53%              |
| 14  | 4C             | 82         | T9   | T6 T12        | 0                    | 16               | T3-L2        | 12              | 205           | 474                      | 27             | 1.3           | 68%              |
| 12  | 1C             | 64         | T8   | T6 T11        | 0                    | 13               | T4-L1        | 10              | 168           | 673                      | 40             | 1.3           | 56%              |
| 13  | 1C             | 88         | T8   | T6 T11        | 0                    | 14               | T3-T12       | 10              | 180           | 685                      | 30             | 1.4           | 67%              |
| 17  | 1C             | 62         | T8   | T5 T11        | 28                   | 12               | T3-T12       | 10              | 140           | 495                      | 26             | 1.2           | 42%              |
| Mean|                | 14.3       | 77.8 |               | 19.7               | 15.8             | 11.7         | 196           | 736           | 17.4                     | 1.3           | 53%           |                  |
| SD  |                | 1.6        | 20.5 |               | 20.5               | 3.2              | 1.7          | 34            | 253           | 12.6                     | 0.1           | 11%           |                  |
| 13  | 1A             | 69         | T9   | T6 T12        | 12                   | 18               | T2-L3        | 14              | 225           | 765                      | 0              | 1.3           | 67%              |
| 14  | 1B             | 87         | T9   | T7 T12        | 1                    | 17               | T2-L2        | 13              | 229           | 876                      | 0              | 1.3           | 60%              |
| 16  | 1B             | 53         | T9   | T6 T11        | 30                   | 12               | T3-T12       | 10              | 195           | 350                      | 10             | 1.2           | 60%              |
| 12  | 3B             | 57         | T11  | T9 L2         | 8                    | 15               | T4-L3        | 12              | 155           | 350                      | 14             | 1.3           | 60%              |
| 13  | 2A             | 82         | T8   | T6 T12        | 10                   | 14               | T3-L1        | 11              | 267           | 807                      | 31             | 1.3           | 51%              |
| 14  | 1B             | 59         | T8   | T6 T11        | 50                   | 15               | T3-L1        | 11              | 212           | 800                      | 10             | 1.4           | 51%              |
| 12  | 1B             | 90         | T9   | T7 T12        | 20                   | 18               | T2-L3        | 14              | 178           | 1300                     | 11             | 1.3           | 74%              |
| 17  | 1B             | 70         | T8   | T6 T11        | 7                    | 15               | T3-L2        | 12              | 229           | 1119                     | 0              | 1.3           | 59%              |
| 12  | 1A             | 62         | T8   | T6 T10        | 5                    | 13               | T3-L1        | 11              | 159           | 653                      | 5              | 1.2           | 68%              |
| 17  | 1B             | 65         | T8   | T6 T10        | 30                   | 12               | T4-T12       | 9               | 152           | 580                      | 30             | 1.3           | 46%              |
| 15  | 1A             | 74         | T8   | T5 T12        | 11                   | 13               | T4-L2        | 11              | 145           | 550                      | 0              | 1.2           | 81%              |
| 11  | 1B             | 65         | T8   | T5 T12        | 0                    | 14               | T3-L1        | 11              | 165           | 453                      | 14             | 1.3           | 69%              |
| 14  | 1B             | 74         | T8   | T6 T12        | 15                   | 15               | T3-L3        | 13              | 174           | 853                      | 10             | 1.2           | 81%              |
| 13  | 1B             | 67         | T8   | T6 T12        | 17                   | 16               | T2-L2        | 13              | 220           | 566                      | 0              | 1.2           | 72%              |
| 14  | 1B             | 62         | T8   | T6 T11        | 21                   | 14               | T3-T12       | 10              | 151           | 495                      | 18             | 1.4           | 66%              |
| 16  | 1A             | 58         | T8   | T5 T11        | 0                    | 14               | T3-L1        | 11              | 198           | 625                      | 0              | 1.3           | 62%              |
| 15  | 1A             | 57         | T9   | T7 T12        | 14                   | 15               | T4-L3        | 12              | 164           | 630                      | 28             | 1.3           | 63%              |
| 13  | 1B             | 55         | T7   | T5 T10        | 10                   | 12               | T3-T12       | 10              | 120           | 418                      | 15             | 1.2           | 56%              |
| Mean|                | 13.9       | 14.5 |               | 14.6               | 11.6             | 185          | 677           | 10.9          | 1.3                       | 64%            |               |                  |
| SD  |                | 1.5        | 12.5 |               | 1.9                | 1.4             | 38           | 255           | 10.6          | 0.1                       | 10%            |               |                  |
In our second subgroup, those with a Lenke C curve, there were 13 patients with a female to male ratio of 9:4 and a mean age of 14.3 years (SD 1.6). The mean thoracic Cobb angle in this group was 77.8° (SD 11.6) and a mean distance from C7 to the CSVL of 19.7 mm (SD 20.5). We achieved a mean correction of 53% (SD 11%) in the thoracic curve, aiming to achieve a balance between residual lumbar curves while preserving as many motion segments as possible. Fusion levels are shown in Table 1, with curve correction of the lumbar spine given in those who had a low lumbar fusion to L4. We maintained our practice of low-density constructs with a mean screw density of 1.3 (SD 0.1) per level fused. Operative time was 196 min (SD 290 min), with a mean blood loss of 736 ml (SD 253 ml). Post-op distance from C7 spinous process to CSVL was 17.4 mm (SD 12.6). No patient received an allogenic blood transfusion. There were no adverse neurological events in this patient cohort. One patient from this cohort had a deep wound infection at 4 weeks post operation, which required a washout.

An example of pre- and postoperative radiographs from this cohort is depicted in Fig. 3.

Discussion

There has been a veritable explosion in options for treating the AIS population [21]. Our study aims to present our results with one of the new generation of systems for scoliosis.
correction. This is the first prospective study examining early results with the rod link system. Our results demonstrate a good correction relative to the published literature, with a short operative time and no requirements for allogenic blood transfusion. Our constructs were all low density, with screws concentrated on the concave side of the curve. Our population cohort had a diverse range of curve patterns, all of which were treated with the same system.

Scoliosis has a prevalence of between 1 and 3% [22, 23]. Although surgical intervention is controversial in terms of absolute necessity, it reliably improves curvature, prevents progression, and improves self-image [23]. Our unit’s primary goal is prevention of progression, with secondary goals of correction of deformity in three planes, and coronal balancing. The natural history of progressive scoliosis is of decreased thoracic volume [24], with increased rates of degenerative intravertebral disc disease and low back pain in those with severe curves compared with those who undergo surgical procedures [25]. These long-term effects are not without conflicting evidence [23], with many studies showing no significant effects from mooted cardiopulmonary compromise or disability levels.

All deformities were classified with the Lenke classification system, a comprehensive radiographic classification system of coronal plane deformities [19]. Rotational alignment is not accounted for within this system, and indeed the quantification of deformities in this plane is difficult with use of plain film radiography. Numerous techniques exist but have been found to be inaccurate and difficult to utilize [26].

The definition of low-density pedicle screw constructs is somewhat unclear [15] but we have taken it to be less than 1.5 based on a prior multicenter study from Larson et al. (2014) [27]. Since the broad adoption of pedicle screw only implants amongst orthopedic surgeons, there has been an increased economic cost, much to do with the cost of screws themselves [28]. An economic evaluation from 2016 by Larson et al. suggests a 4–7% saving

![Fig. 3 Pre- and postoperative x-ray films of a Lenke C curve. With our goal of preserving lumber motion segments, we achieved a balanced correction rather than seeking long fusion with maximum correction](image-url)
based on reducing number of screws inserted, as well as the decreased likelihood of rehospitalization or revision surgery secondary to misplaced screws [15].

We show an excellent ability to achieve correction with low-density construct of 64% in spines with a Lenke lumbar modifier of A or B. We would expect that this correction will hold based on previous studies which demonstrate maintenance of 94.5–98% over 5 years [16, 29, 30]. The average coronal deviation from center in our study was 12.7 mm (SD 11.56), which we would project to improve further with time. Wei et al. (2017) demonstrated an improvement in coronal balance over 5 years post-scoliosis corrective surgery from an initial postoperative value of 13.1 mm (SD6.4) to 11.5 mm (SD11.5) [16]. For our Lenke C cohort, our goal was balance in the coronal plane, with a goal of matching the residual lumbar curve on bending films to our correction of the thoracic spine, and maintaining as many vertebral motion segments distally as feasible. We improved our coronal balance acutely to a degree, as seen in Table 1, and, as previously stated, we would expect the coronal balance to continue to normalize as patients adjust to the new decreased magnitude of thoracic curvature.

Our blood loss (excluding cell salvage) was an average of 794 ml (SD 313 ml). Our allogenic blood transfusion rate was 0%. Previous studies have established that the posterior spinal fusion operation does place patients at high risk for requiring a transfusion, with an analysis in 2015 by Minhas et al. showing 36.3% of their cohort between 2012 and 2013 on the National Surgical Quality Improvement Program pediatric database requiring a transfusion of over 300 ml [31]. Our protocol for surgery was designed to minimize blood loss, including use of tranexamic acid [32], dual attending operating strategy [33], and the use of a low-density construct, with an aim to minimize fusion levels in the lumbar spine. Thomson et al. (2014) demonstrated quite eloquently that number of screws and levels fused are independent predictors of estimated blood loss [34].

Lehman et al. (2007) found that there is a 10% incidence of pedicle wall breach with screws placed free hand. Of these, the majority (82%) were lateral breaches [35]. One of the potential drawbacks of using the rod link system is the high stress placed on the anchor screws during correction with the short temporary rods. Diligent intraoperative assessment of pedicle wall integrity was performed for all levels, with additional screw insertion performed if a breach was found. A screw was not inserted where a breach was caused. Work by Parent et al. (2008) on cadaveric bone showed an average tolerance of 12 Nm of the vertebrae to torquing forces [36]. This is likely higher in the adolescent population of our patient group, but certainly something to be mindful of when performing correction with the cantilevered handle technique. In our series, we had one intraoperative decrease in magnitude of spinal cord monitoring after insertion of the concave rod. The decrease was in the order of 20% from baseline. We released the rod and reduced the amount of deformity correction and signals returned to baseline at the end of the procedure. There was no postoperative neurological deficit.

Rotational deformity within scoliosis is somewhat of a calculative quagmire. The plain radiograph landmarks used, be they the spinous process for the Cobb method or the pedicle shadows used with the Nash and Moe or Perdriolle methods, are often somewhat hypoplastic or dysplastic, thus rendering inaccurate estimates of rotation [26]. While CT has been demonstrated as a more accurate measure of rotation [37], the increased radiation exposure to establish this rotation for little clinical value was not felt to be warranted in our patient group. This does lead to a limitation of being unable to quantify the rotational correction achieved by the rod link system.

Other limitations acknowledged in this paper are the prospective cohort design, and that the use of a dual surgeon strategy may cause some skewing of results in terms of operative time and blood loss. We also record our experiences with this system, rather than offering a comparison with more traditional correction techniques. Our follow-up time for this cohort of patients was between 6 and 18 months, and we recognize to adequately assess technologies for long-term complications, a longer follow-up period is warranted. Our goal in this paper is to describe our intraoperative and immediate postoperative experiences with this novel corrective device.

In conclusion, we demonstrated that the rod link reducer is a safe, efficient, and economic addition to deformity correction and fusion surgery in adolescent idiopathic scoliosis.

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Compliance with ethical standards

Conflict of interest Two authors report grants from Globus Medical outside the submitted work, as contributors to the Research Fund at our institution. Globus Medical manufactured the Link Rod System. Other authors have no disclosures to make.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Institutional Review Board approval was obtained before initiation of this study.

Informed consent Not required. Only general non-identifiable data on a series of patients is included in this work.
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