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ORIGINAL ARTICLE

Efficacy and safety of posteromedial translation for correction of thoracic curves in adolescent idiopathic scoliosis using a new connection to the spine: the Universal Clamp

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Abstract Correction of adolescent idiopathic scoliosis (AIS) has been reported with various systems. All-screw constructs are currently the most popular, but they have been associated with a significant decrease in thoracic kyphosis, with a potential risk of junctional kyphosis, not observed with hybrid constructs in the literature. In addition, it is important to weigh potential advantages of pedicle screw fixation against risks specific to its use. Because hybrid constructs are associated with a lower risk of complications and better sagittal correction than all-screw constructs, at present we use lumbar pedicle screws combined with a new sublaminar connection to the spine (Universal Clamps) at thoracic levels. The purpose of this study was to determine the efficacy and safety of the Universal Clamp (UC) posteromedial translation technique for correction of AIS. Seventy-five consecutive patients underwent posterior spinal fusion and hybrid instrumentation for progressive AIS. Correction was performed at the thoracic level using posteromedial translation. At the lumbar level, correction was performed using in situ contouring and compression/distractions maneuvers. A minimum 2-year follow-up was required. Medical data and radiographs were prospectively analyzed and compared using a paired *t* test. The average age at surgery was 15 years and 4 months (±19 months). The average number of levels fused was 12 ± 1.6. The mean follow-up was 30 ± 5 months. The average preoperative Cobb angle of the major curve was 60° ± 20°. The immediate postoperative major curve correction averaged 66 ± 13%. The average loss of correction of the major curve between the early postoperative assessment and latest follow-up was 3.5° ± 1.4°. The mean Cincinnati correction index was 1.7 ± 0.8 postoperatively, and 1.57 ± 1 at last follow up. The mean rotation of the apical vertebra was corrected from 23.3° ± 9° preoperatively to 7.3° ± 5° at last follow up (69% improvement, $P < 0.0001$). In the sagittal plane, the mean thoracic kyphosis improved from 23.8° ± 14.2° preoperatively to 32.3° ± 7.3° at last follow up. For the 68 patients who had a normokyphotic or a hypokyphotic sagittal modifier, thoracic kyphosis increased from 20.5° ± 9.9° to 31.8° ± 7.4°, corresponding to a mean kyphosis correction of 55% at last follow up. No intraoperative complication occurred and none of the patients developed proximal junctional kyphosis during the follow up. The principal limitation of the UC technique was the rate of proximal posterior prominence (14.6%), leading us to recommend the use of conventional claws at the upper extremity of the construct. The technique was safe, and reduced operative time, radiation exposure, and blood loss. While achieving correction of deformity in the coronal and axial planes equivalent to the best reported results of all-screw or previous hybrid constructs, the UC hybrid technique appears to provide superior correction in the sagittal plane. The excellent outcome in all three planes was maintained at 2 year follow up.

Keywords Adolescent idiopathic scoliosis · Sagittal balance · Correction · Instrumentation

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Introduction

The aim of surgical correction of adolescent idiopathic scoliosis (AIS) is to prevent curve progression by achieving strong spinal stabilization that leads to solid fusion with consistently low complication rates. As stressed by Winter et al. 40], we believe that it is important to consider not only frontal correction, but sagittal correction as well. The procedure should restore trunk height, while restoring sagittal and frontal balance to avoid the progression of the curves in the remaining nonfused spine. In particular, restoring sufficient thoracic kyphosis should reduce the risk of progressive junctional kyphosis at both extremities of the fused spine [40].

Correction of AIS has been reported with various systems. Since their description in 1995 by Suk et al. [32], thoracic pedicle screws have been widely used in the treatment of scoliosis, combined with hooks in hybrid constructs or used alone in all-screw constructs. However, all-screw constructs have been associated with a significant decrease in thoracic kyphosis, a decrease not observed with hybrid constructs in matched patients [20]. In a comparison of three types of constructs, Vora et al. [37] also reported that thoracic pedicle screws failed to enhance correction of Lenke 1 AIS, and that they had a lordosing effect on the thoracic spine.

Several studies have shown improved curve correction with screw-only and hybrid constructs as compared to hook constructs. Kim et al. [13] reported that all-screw constructs provided significantly better curve correction than all-hook constructs and improved pulmonary function values. Similarly, lumbar pedicle screws have been found to offer greater lumbar curve correction and better maintenance of correction than hook constructs [2]. To date, few authors have compared all-screw constructs with hybrid constructs [14]. Lowenstein et al. [20] observed a trend toward better correction of the main thoracic curve in all-screw versus hybrid hook-screw instrumentation but this trend was not significant.

In addition, it is important to weigh potential advantages of pedicle screw fixation against risks specific to its use. Upendra et al. [35] recently reported a 10% pedicle screw misplacement rate in scoliosis patients using an outcome-based classification. Potential complications of thoracic pedicle screw use include neurologic lesions, vascular injury, pleural tear, and increased radiation exposure during screw placement.

Because hybrid constructs are associated with a lower risk of complications and better sagittal correction; we consider constructs combining pedicle screw fixation with hooks or sublaminar wiring as the “gold standard” for treatment of AIS.

Posterior translational correction and fusion using hybrid instrumentation with sublaminar metal wire is known to achieve excellent curve correction, but spinal cord injuries and section of the lamina during deformity reduction have been reported with the use of metal wires or cables [34]. In 2003, we developed a novel sublaminar thoracic implant (the Universal Clamp, Abbott Spine, Bordeaux, France) that combines the initial stability of pedicle screws with the straightforwardness and correcting potential of Luque wiring, but with an increased surface of bony contact allowing higher reduction forces. Since 2004, in our spine unit, we have used hybrid constructs associating lumbar pedicle screws and Universal Clamps (UC) at thoracic levels.

The purpose of the present prospective study was to determine the efficacy and safety of the Universal Clamp posteromedial translation technique for correction of AIS.

Materials and methods

Implant description

The Universal Clamp is a novel implant used in place of sublaminar wiring, pedicle screws, or hooks to bind vertebrae to fusion rods in spinal osteosynthesis. The UC consists of three components, a woven polyester band (Dacron), a titanium alloy (or stainless steel) clamp, and a locking screw (Ti alloy or stainless steel) (Fig. 1).

The UC technique is similar to the Luque technique, but sublaminar polyester bands are used instead of sublaminar wiring. The surface area of contact between the polyester band and lamina is larger than that between wiring or cables and the lamina permitting application of greater spinal deformity reduction forces without laminar fracture. The deformity reducing forces are applied progressively,

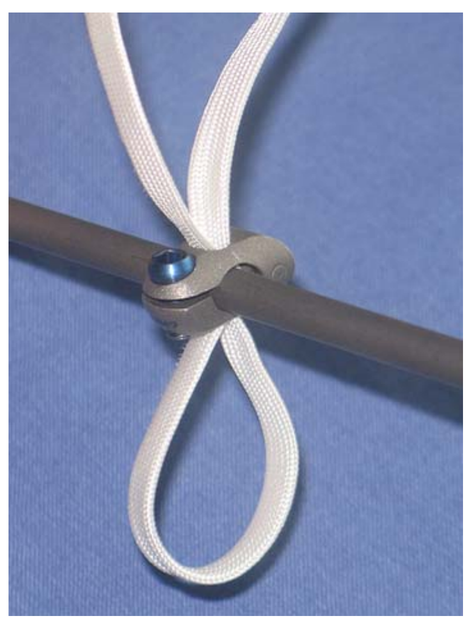


Fig. 1 The Universal Clamp

step-wise at one or more spinal segments with a reduction tool that is activated in the same simple manner as a rongeur. The clamp connects the sublaminar band to the rod. The strength of the band-rod connection is equivalent to screw-rod or hook-rod connections permitting conventional deformity correction maneuvers including translation, compression/distraction, and in situ bending.

The UC polyester band contains a malleable metallic insert at one end to facilitate sublaminar insertion and two metallic buckles at the other end. The surgeon gives the malleable end of the band a hook shape and inserts the soft polyester tip around the lamina between the bone and the dura and recovers the tip at the opposite side of the lamina with a small forceps. This maneuver requires experience in sublaminar wiring and is the most challenging part of the learning curve, which was not included in the current study.

The tip of the band is then threaded through the clamp next to the other end of the band. The free tip of the band is passed through the two buckles on the other end of the band. Then the free tip is passed over one buckle and back through the second buckle so that the band now forms an adjustable loop for the reduction tool. The buckles maintain the loop strongly, preventing any slippage of the band when traction is applied to the loop. Nevertheless, the buckles permit easy adjustment of the loop's length.

Once all Universal Clamp implants are placed along the spine and the prebent double-rod frame has been anchored to pedicle screws at the distal end of the construct, each UC is placed on the appropriate rod. The upper jaw of the clamp is closed over the rod.

The locking screw is loosely inserted to leave the band free to permit traction of the vertebrae toward the rod with the reduction tool (Figs. 2, 3). After any reduction maneuvers and once optimal band tension has been obtained, the clamp is locked onto the rod with the screw. The loop of band is removed from the reduction instrument and the excess band strands (including the malleable insert and the metal buckles) are cut and removed.

Fig. 2 The adjustable loop for the reduction tool after sublaminar placement of the band

Fig. 3 Universal Clamp-mediated traction of a vertebra toward the rod with the reduction tool

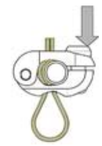
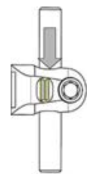
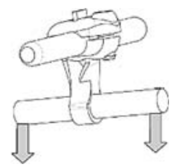
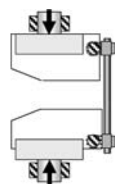
Polyester bands (polyethylene terephthalate, also known by the trade names Dacron and Trevira) have been extensively used over the last 30 years in orthopaedic surgery [15, 16, 31] and cardiovascular surgery [28] and its biocompatibility characteristics are well documented [15, 29]. The choice of this polyester band was based on its intrinsic strength to failure (strength to failure $\geq$1,400 N) and its low creep under static load (1.3% creep after 78 h under a static load of 300 N).

Pre-clinical mechanical tests

One of the initial concerns related to the design of this implant was that the insertion of a polyester band at the metallic interfaces of the clamp might interfere with the clamping capacity of the jaw onto the rod. This was not the case.

In addition, pre-clinical tests were performed in order to assess the ability of the implant to sustain the mechanical loads produced by both the reduction maneuvers and the long-term daily life activities of the patient. Table 1 provides the main results of the tests performed in independent certified laboratories.

Table 1 Results of preclinical tests

Type of test		Results	Mode of failure
Rotational grip test (static)		Torque to failure 4.4 ± 0.4 Nm	Sliding of the clamp
Axial grip test (static)		Stength to failure 1,400 ± 180 N	Sliding of the clamp
Tension test (startic)		Strength to failure 830 ± 70 N	Sliding or rupture of the band
Tension test (dynamic– 5 × 10^6 cycles)		Run-out value 270 N	At higher load: sliding of the band within the clamp
ASTM F-1717 corpectomy test for hooks. (dynamic −5.10^6 cycles)		Run out value 315 N	At higher load: failure of the band

Patients

Following institutional review board approval, data were prospectively collected in all patients with operative AIS in a single spinal unit. The patients operated between January 2004 and January 2006 were evaluated preoperatively, in the early postoperative period, 6 months and 1 year post-operatively, and at last follow up. The 15 first patients operated, considered as part of the learning curve of the technique, were not included. None of the patients had prior spinal surgery.

Operative procedures

All patients underwent posterior spinal fusion and instrumentation. During the posterior procedures, spinal cord function was monitored by means of somatosensory/motor-evoked potentials. Autotransfusion was performed with blood collected both preoperatively and intraoperatively.

Thoracic levels were instrumented with 3–7 (average, 5) sublaminar UC on the concave side and 1 sublaminar UC at the apex on the convex side. In all cases, pedicle screws were placed in two or more vertebrae at the distal extremity of the curve, where monoaxial screws were used on the convex side and polyaxial screws on the concave side. The vertebra at the proximal extremity of the curve was always instrumented either with UCs or conventional hook-claws. Correction was performed at the thoracic level using posteromedial translation and traction or compression as appropriate to level both the proximal vertebra and the distal vertebra. At the lumbar level, correction was performed using in situ contouring and compression/distractions maneuvers.

When the reducibility on preoperative traction radiograph and supine bending films was less than 50% or thoracic kyphosis was less than 5°, anterior thoracoscopic release was performed first. The anterior release procedure included the apex of the deformity as well as the two discs above and two discs below the apex vertebra. No anterior bone graft was applied. Thoracoplasty was performed in patients with greater than 15° preoperative rib prominence on a scoliometer when the patient and/or caregiver expressed concern over the prominence of the rib hump deformity.

Radiographic measurements

Measurements were made on 36-in. long-cassette antero-posterior and lateral radiographs of the spine with the patient standing. All films were digitized then analyzed by the same investigator using the previously validated SpineBalance (Surgiview, Paris, France) software [26]. Radiographic analysis included Cobb angle measurements of the major and minor curves on the preoperative and early postoperative (within 3 months) radiographs, and at latest follow up. Curve flexibility was determined on the preoperative supine side bending films. Further parameters measured in the coronal plane were T1 tilt angle (angle between a horizontal line and the upper endplate of T1, the value of which is positive when the endplate leans to the right), shoulder balance (angle between the tangent to the superior edge of the clavicles and a horizontal line, the value of which is positive in patients whose left shoulder is higher than the right) and rotation at the apical vertebra according to Perdriolle [24, 38]. Global coronal balance was measured as the distance between the center of T1 and the center sacral vertical line (CSVL).

On lateral radiographs, overall sagittal balance was appreciated by measuring the T9 sagittal offset, i.e., the angle between a vertical line and the line between the center of the vertebral body of T9 and the center of the bicoxofemoral axis (Fig. 4). The values of T9 sagittal offset are negative when the angle opens on the posterior side of the T9 plumbline [36]. Thoracic kyphosis was measured from the upper endplate of T5 to the lower endplate of T12, and the lumbar lordosis was measured from the lower endplate of T12 to the upper endplate of S1.

Fig. 4 T9 sagittal offset

As described by Vora et al. [37], the following ratios were determined:

$$\text{Preoperative flexibility (PF) (\%)} = [(\text{preoperative erect Cobb angle} - \text{supine bending Cobb angle}) / \text{preoperative erect Cobb angle}] \times 100$$

$$\text{Postoperative correction (POC)(\%)} = [(\text{preoperative erect Cobb angle} - \text{postoperative erect Cobb angle}) / \text{preoperative erect Cobb angle}] \times 100$$

$$\text{Cincinnati correction index (CCI)} = \text{postoperative correction (POC)\%} / \text{preoperative flexibility (PF) \%}$$

$$\text{Kyphosis correction (KC)\%} = [(\text{postoperative kyphosis} - \text{preoperative kyphosis}) / \text{preoperative kyphosis}] \times 100$$

Statistical analysis

Paired-sample *t* tests were used to analyze differences between preoperative curves and postoperative curves. All statistical tests were two-tailed, and a P value <0.05 was considered to be significant. All statistical analyses were conducted using SPSS version 12.0 (SPSS Inc., Chicago, IL, USA).

Results

Demographic data and curve classification

Seventy-five patients with at least 2 years of postoperative follow-up were included. There were 59 female (79%) and 16 male (21%) patients. The average age at surgery was 15 years and 4 months (±19 months). According to the surgical classification of AIS by the Lenke et al. [19] system, there were 36 patients with Type 1 AIS (main thoracic, 48%), 23 with Type 2 (double thoracic, 30.5%), 6 with Type 3 (double major, 8%), 9 with Type 4 (triple major, 12%), and 1 with Type 6 (major thoracolumbar/lumbar and minor thoracic structural, 1.5%). Of the patients, 58 had a normokyphotic sagittal modifier (T5–T12, −10° to −40°), 7 had a hyperkyphotic sagittal modifier (T5–T12 >40°), and 10 had a hypokyphotic sagittal modifier (T5–T12 <10°).

Anterior release was performed in 23 patients (30.6%). The average number of levels fused was 12 ± 1.6. Mean follow-up was 30 ± 5 months.

Coronal and axial plane correction

The average preoperative Cobb angle of the major curve was 60° ± 20°. The mean flexibility of the major curve was 42 ± 13%. Immediate postoperative major curve correction averaged 66 ± 13% (Fig. 5). The reduction of the Cobb angle was significant ($P < 0.0001$). The average loss of correction of the major curve between the early postoperative assessment and latest follow-up was 3.5° ± 1.4°. No pseudarthrosis was noted. Coronal plane changes of the upper thoracic, main thoracic and lumbar curves are reported in Table 2.

The mean Cincinnati correction index was 1.7 ± 0.8 postoperatively, and 1.57 ± 1 at last follow up. Changes between preoperative and latest follow-up measurements for T1 tilt, shoulder tilt and global coronal balance are shown in Table 3.

The mean rotation of the apical vertebra was corrected from 23.3° ± 9° preoperatively to 7.3° ± 5° at last follow-up (69% improvement, $P < 0.0001$). Thoracoplasty was performed in 23 patients (30.6%).

Sagittal plane correction

As shown in Table 4, the mean thoracic kyphosis, which was 23.8° ± 14.2° preoperatively, was 32.3° ± 7.3° at last

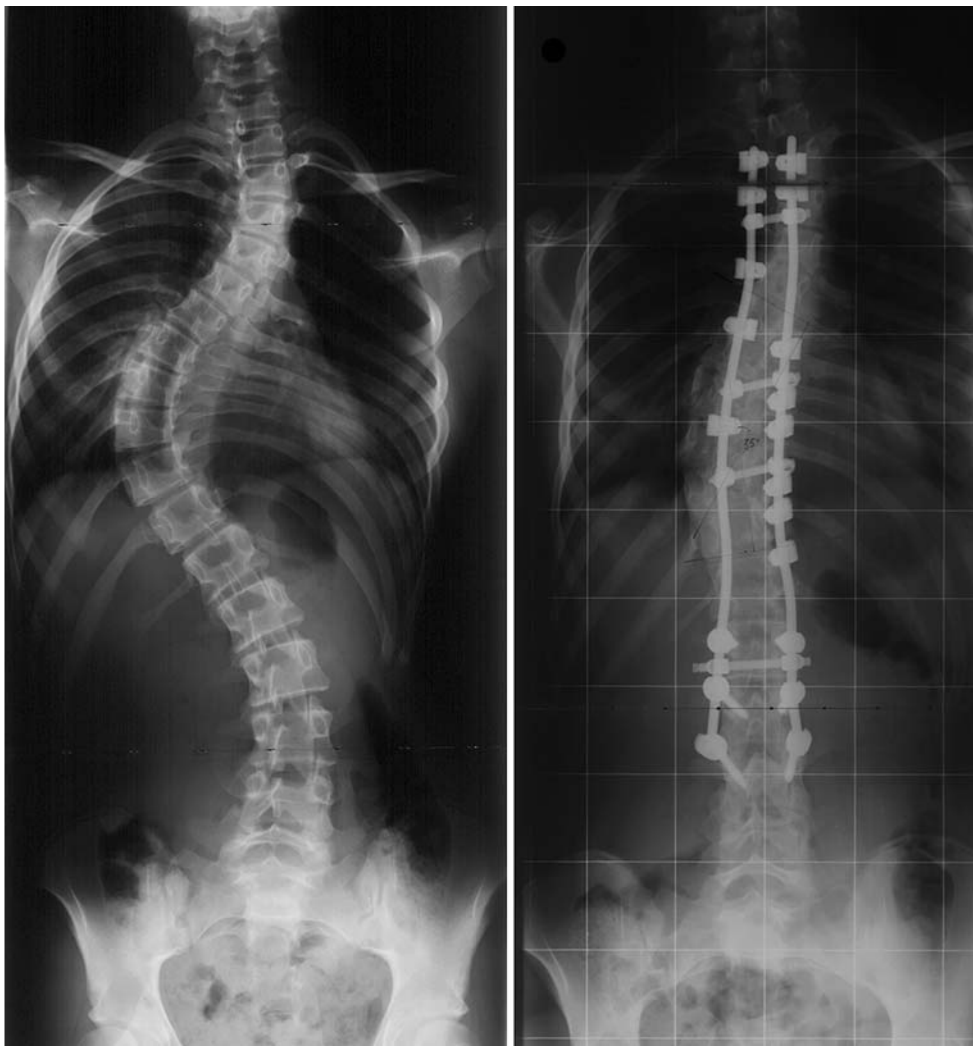


Fig. 5 Anteroposterior radiographs, preoperative and at 30 months postoperative, of a girl with Lenke type 2 scoliosis, operated at the age of 15 years. Six sublaminar UCs were used to instrument the concavity of the main thoracic curve. The posteromedial translation technique achieved a 65% correction of the major curve

Table 2 Changes between preoperative and latest follow-up Cobb angles of the curves ($N = 75$)

	Preoperative assessment (mean ± SD)	Latest follow-up assessment (mean ± SD) (correction %)	Cincinnati correction index (mean ± SD)	*P*
Upper thoracic curve (°)	29.1 (±15.5)	18.8 (±11) (36%)		<0.0001
Main thoracic curve (°)	60 (±20)	22.3 (±10.7) (63%)	1.57 (±1)	<0.0001
Lumbar curve (°)	38 (±13.7)	10.5 (±7.7) (72%)		<0.0001

SD standard deviation

Table 3 Changes between preoperative and latest follow-up coronal and axial parameters ($N = 75$)

Outcome measure	Preoperative assessment (mean ± SD)	Latest follow-up assessment (mean ± SD)	P
Coronal balance (T1 shift) (mm)	17.6 (±13.2)	13 (±11.5)	0.19
T1 tilt angle (°)	7.3 (±8)	3.7 (±2.6)	0.04
Shoulder balance (°)	3 (±2.6)	2.7 (±2.5)	0.63
Apical rotation (°)	23.3 (±8.8)	7.3 (±5.5)	<0.0001

SD standard deviation

Table 4 Changes between preoperative and latest follow-up sagittal parameters ($N = 75$)

Outcome measure	Preoperative assessment (mean ± SD)	Latest follow-up assessment (mean ± SD)	P
Thoracic kyphosis (°)	23.8 (±14.2)	32.3 (±7.3)	<0.0001
Lumbar lordosis (°)	46.5 (±14)	49.6 (±10.7)	0.091
T9 sagittal offset (°)	−7 (±5.7)	−7.8 (±4.8)	0.21

SD standard deviation

Table 5 Thoracic kyphosis correction according to the preoperative sagittal modifier ($N = 75$)

	Preoperative (mean ± SD)	Postoperative (mean ± SD)	Latest follow up (mean ± SD)
Hypokyphosis (T5–T12 <10°) $N = 10$	4.7° ± 3.8	29.4° ± 8.3 $P < 0.0001$	30.6° ± 6.6 $P < 0.0001$
Normokyphosis (T5–T12, −10° to −40°) $N = 58$	23.2° ± 7.8	29.7° ± 7.5 $P < 0.0001$	32° ± 7.5 $P < 0.0001$
Hyperkyphosis (T5–T12 >40°) $N = 7$	55.6° ± 9.2	36.4° ± 5.3 $P = 0.0001$	37.1° ± 4.9 $P = 0.001$

SD standard deviation

follow up ($P < 0.0001$). The changes in thoracic kyphosis according to the preoperative sagittal modifier are detailed in Table 5. For the 68 patients who had a normokyphotic or a hypokyphotic sagittal modifier, thoracic kyphosis increased from 20.5° ± 9.9° to 31.8° ± 7.4°, corresponding to a mean kyphosis correction of 55% at last follow up (Fig. 6). Among the seven patients with a hyperkyphotic sagittal modifier, the mean decrease in thoracic kyphosis was 17.7° ± 9°. Changes between preoperative and last follow-up measurements of lumbar lordosis and T9 sagittal offset are also shown in Table 4. Neither of these parameters was changed significantly.

Blood loss, operation time

The average operative time was 235 ± 35 min. Intraoperative blood loss was 840 ± 105 ml.

Complications

Intraoperative complications

No intraoperative complication occurred. In particular, no significant change in the monitored somatosensory/motor-evoked potentials was recorded during insertion of the UC sublaminar band. Furthermore, there was no modification of the monitored potentials and no lamina or UC broke during the posteromedial translation technique used for curve reduction.

Postoperative complications

One patient developed a transient superior mesenteric artery syndrome. She was treated with nasogastric decompression with no further sequela. There was no transient or permanent dysesthesia, paresthesia, or paraplegia. There were two cases of deep wound infection, treated by surgical debridement and antibiotherapy. None of the patients exhibited a clinically significant loss of the major curve correction during the follow up. However, posterior prominence of the proximal extremity of the instrumentation was observed in 11 patients (14.6%) associated with a mean loss of correction of 4° ± 1° in the proximal thoracic curve (Fig. 7). Of these 11 patients, 5 (7%) experienced disabling pain. All these 11 patients had their surgery during our first year of experience with the UC. None of the patients developed proximal junctional kyphosis.

Discussion

Correction of AIS has been reported with various systems over the last four decades, and the gold standard against which all systems have been measured has recently varied. The percent Cobb angle correction on anteroposterior radiographs has improved from roughly 40% achieved with Harrington rods, then around 55% with dual-rod multihook systems, to the current correction in the neighborhood of 65% obtained with dual-rod multiple pedicle screw constructs. Winter et al. [40] recently questioned what they qualified as an overzealous focus on the percent of frontal scoliosis correction at this time, asking whether a few more degrees of correction justified a construct that costs twice as much as a simple hook system and that increases the risk of damage to the spinal cord and aorta. We agree that there

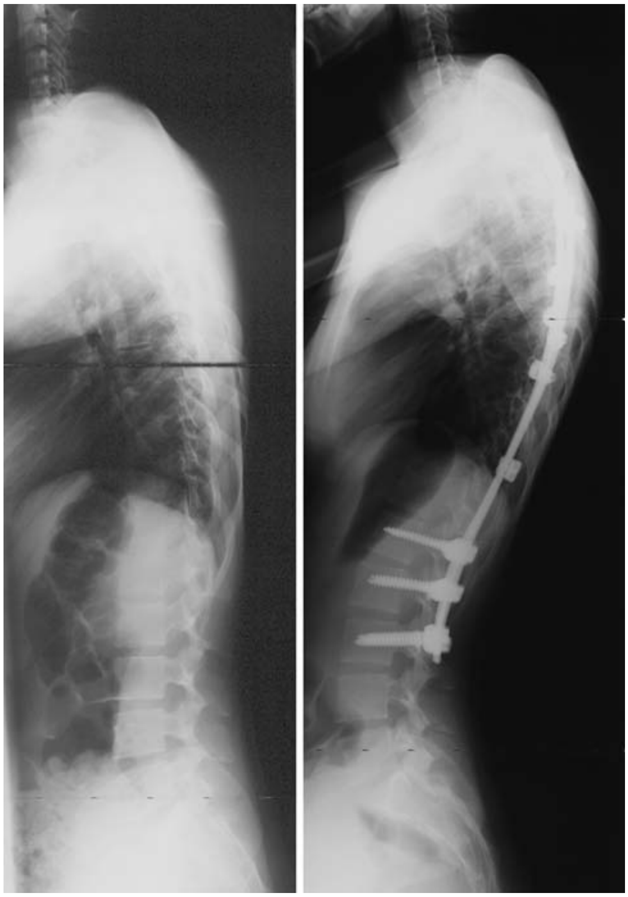


Fig. 6 Lateral radiographs, preoperative and at latest follow-up (26 months), of a girl with a Lenke type 1 curve, operated at the age of 16 years. Five sublaminar UCs were used to instrument the main thoracic curve. The thoracic kyphosis was 14° preoperatively, and was improved to 40° after the procedure

Fig. 7 Lateral radiographs, immediate postoperative and before the revision at 12 months postoperative, of a boy who had Lenke type 2 scoliosis, operated at 17 years of age. The thoracic kyphosis measured 10° preoperatively, and was corrected to 31° postoperatively. At 12 months postoperative, the patient presented neck pain and a cosmetic problem due to posterior prominence of the construct. A revision surgical procedure was performed

is overemphasis on achieving a few supplemental degrees of frontal correction and insufficient emphasis on the postoperative sagittal status of the spine. Since 2004, the present implant meets these specifications, achieving proper sagittal balance (55% of mean kyphosis correction) without sacrifice of correction in the frontal plane.

Coronal plane

In the frontal plane, the early Harrington system maintained a 28–30% mean average correction after 20 years of follow up [7]. Subsequent modifications in the Harrington technique achieved an average range of correction from 30 to 60% with a follow-up period of 48 months [39]. In 1982, Luque described his sublaminar wiring technique with which he reported 72% average final correction with 18 months follow up [21]. However, no long-term follow-up data were ever reported. The next major advance was the introduction in 1984 of Cotrel–Dubousset instrumentation [6]. This technique was the first posterior segmental instrumentation, using a dual-rod multiple-hook system placed on the laminae or pedicles. It obviated the need for postoperative external support and achieved a 46 to 57% average final correction after an average follow-up period of 35 months [9]. Burton et al. [4] even reported a 69% correction 40 months postoperatively in 102 patients with AIS treated with a CD-like instrumentation technique (Isola) described by Asher [1].

Under the impetus of recent work by orthopaedic surgeons at Inje University in Seoul [18, 33] and at Washington University in St Louis [3, 8, 14], the use of pedicle screws for the correction of AIS has progressed. All-pedicle screw systems achieve corrections as high as 65%, but are more expensive and appear to increase neurological and vascular risks with respect to hybrid constructs [40]. The rates of misplaced screws reach 10% in the hands of the best spine surgeons, largely due to the vertebral dystrophy observed in the concavity of scoliosis [35]. In a retrospective series reported by Senaran et al. [30] a hook replaced a planned pedicle screw that could not be safely inserted in 18% of the patients, primarily due to sclerotic, narrow pedicles with moderate rotation. In addition, results of comparative studies between all-screw systems and hybrid instrumentation remain controversial. Cheng et al. [5] recently compared a group with apical sublaminar wires and a group with thoracic pedicle screws, and found no significant difference regarding correction or fusion rate. These authors emphasized the safety and efficacy of the posteromedial translation technique used for reduction. Kim et al. [14] observed no difference in improvement of functional vital capacity between all-screw constructs and hybrid constructs.

Since pedicle screws have been shown to achieve better correction, translation, and horizontalization of the lumbar spine when compared with all-hook systems [10], we decided to use hybrid constructs with four to six pedicle screws in the lumbar extremity and UCs in the thoracic spine. In the lumbar spine, monoaxial screws were used on the side of the convexity in order to reduce the deformity and restore lordosis, while polyaxial screws were used on the side of the concavity to facilitate introduction of the rod on that side [17].

At thoracic levels, several sublaminar UCs were used on the concave side, and one UC was used at the apex on the convex side. The procedure always began by insertion of the pedicle screws in the lumbar spine, aiming to end the instrumentation at a stable and neutral vertebra. When the lower instrumented vertebra was horizontal and centered over the sacrum, the rods were locked on the pedicle screw base. During the second step of the reduction, two UCs were bound to the proximal instrumented vertebra, bilateral distraction was applied in order to lengthen the spine, and the proximal level was locked onto the rods. After obtaining these two fixed ending points (upper and lower instrumented vertebra), the main curve reduction was achieved by the progressive tightening of the concave UCs (three points bending), producing posteromedial translation of the spine toward the rods, which had been prebent in the sagittal plane.

The technique achieved a mean reduction of 66% (range 41–95%) in the frontal plane, which is equivalent to the best results published in the literature. It was safe since no modification of the potentials was recorded intraoperatively. As noted by Vora et al. [37] the only method to truly evaluate and compare the corrective ability of an implant is to take into account the flexibility of the scoliosis. They recommended using the Cincinnati correction index (CCI) to express the correction as a ratio of the preoperative flexibility. In the current series, immediate postoperative and latest follow-up CCI were, respectively, 1.7 and 1.57, better than CCI previously reported with all-screw constructs and confirming the efficacy of our technique [37]. These results are probably due to the increased surface of bony contact with the UC compared to previous sublaminar implants, thus reducing the stress on the bone and allowing increased reduction forces.

In addition, we avoided overcorrecting the major curve depending on the reducibility of the compensatory curves, and obtained a balanced fusion with the shoulders and T1 remaining level at latest follow up (Table 3).

The number of levels fused was relatively high in this study with respect to recent trends. This is explained by the fact that we avoid stopping the instrumentation at the thoracolumbar junction and we avoid performing selective thoracic fusion. These guidelines might result in a stiffer back, but it is our opinion that restoring physiological spinal balance in both the sagittal and frontal planes is the best guarantee against adjacent segment degeneration, even if a few more levels need to be included in the fusion.

The UC technique provided good rotational correction, with 69% improvement at the apical level. However, even though optimal “derotation” was achieved by translation to the rods, the vertical dystrophic ribs that had developed in the convexity in many patients led to a residual rib hump after the correction, prompting us to perform thoracoplasty in 23 patients. These findings are consistent with those of Hullin et al. [11], who reported no rib hump improvement in 68% of their patients with idiopathic scoliosis treated by segmental sublaminar wiring, and worsening or improvement of the rib hump in 17 and 15%, respectively.

Sagittal plane

Suk et al. [32] reported in 1995 that pedicle screw constructs gave a better correction of the (sagittal) hypokyphosis associated with the coronal deformity. However, Vora et al. [37] recently concluded from their multicenter comparative study that, contrary to popular belief, pedicle screw constructs further lordosed the thoracic spine. The latter authors reported 8% kyphosis correction in the hybrid group (combining pedicle screws and sublaminar wires) and a 42% loss of kyphosis in the all-screw group. Insufficient correction of thoracic kyphosis has been previously associated with an increased risk of proximal junctional kyphosis [12]. This can be explained by the anteroposterior force applied to introduce the rods in thoracic screws and the fact that kyphosing maneuvers at thoracic levels apply pull-out forces on the screws positioned at the apex of the deformity. The deformity reduction technique used with the UC, progressively translating the spine toward the rods prebent in the sagittal plane and linked with rigid transverse connectors, increased thoracic kyphosis by 11.2° in preoperatively normokyphotic or hypokyphotic patients (55% kyphosis correction). To the best of our knowledge, these results are higher than any previously reported in the literature for sagittal thoracic correction. Only seven of our patients had more than 40° of thoracic kyphosis preoperatively. In these patients as well, the technique corrected thoracic kyphosis, reducing it by an average of 18.5°. These findings are consistent with reports that hybrid constructs enhance sagittal correction, which might reduce the risk of subsequent proximal junctional kyphosis [12, 37]. T9 sagittal offset was not changed significantly by the procedure, but the mean preoperative value was already within physiological limits. That might reflect the need for another, more clinically relevant radiological parameter to assess overall sagittal spinal balance in patients with AIS.

The principal limitation of the UC technique was the rate of posterior prominence (14.6%) at the proximal extremity. Of these 11 patients, the five with disabling pain underwent revision. Slippage of one band inside the clamp was found at revision without band failure or lamina breakage. During the five revisions, the UCs at the proximal level were replaced by conventional claws. The cases of proximal prominence occurred during our first year of experience when fewer UCs were used to instrument the proximal levels of the construct where the highest shear forces are exerted. By precaution we now recommend using a conventional claw bilaterally at the proximal extremity, but this issue warrants further study.

Other aspects of the Universal Clamp

Among its advantages, the UC permits postoperative imaging without artifacts. Immediate CT scans or magnetic resonance imaging (MRI) are possible, especially convenient if transient neurological symptoms are observed after the procedure. In addition, the UC is a soft implant with less potential than wires or cables to push into the canal during the procedure, thus reducing the intraoperative neurological risk. This advantage might be even more critical during removal of the polyester bands versus removal of wires, in case of revision surgery [23]. The UC has a very low profile and is universal, which means that there is only one type of implant that is used to instrument any thoracic vertebra. The learning curve is very short and no fluoroscopy is needed at the levels instrumented by the UC, as opposed to recommendations by some authors of intraoperative fluoroscopy for screw placement [22]. As noted by Perisinakis et al. [25] fluoroscopically guided pedicle screw insertion adds radiation exposure to the physician and patient in addition to increasing operative duration and cost.

Although there is no direct system of tension measurement among the instruments, on the side of the tensioning device there are marks that indicate when the maximum recommended tension of 500 N has been attained. In practice, tension applied on the UC is subjectively evaluated by the surgeon. For experienced surgeons, the learning curve for use of the UC, including application of appropriate tension, is short. In our experience, the operative time with the UC averaged 235 min, a mean reduction of 50 min as compared to our previous constructs using a multihook system (SCS, Eurosurgical, 62217 Beaurains, France).

Limits of the study

There are several weaknesses in this study. Because all the procedures were performed by a single surgeon, who promotes the technique, the results need to be confirmed in a multicenter study. In addition, the follow-up period was short (30 months), even though it is now accepted that loss of correction after fusion in AIS primarily occurs during the first postoperative year and that results of spine surgery can be reliably evaluated radiologically after a minimum follow-up of 2 years [27].

No functional score was used to evaluate patient outcomes, since no SRS score has been validated to date in the authors' native language.

In conclusion, the principal limitation of the UC technique was the rate of proximal posterior prominence (14.6%), leading us to recommend the use of conventional claws at the upper extremity of the construct. The technique was safe, and reduced operative time, radiation exposure, and blood loss. While achieving correction of deformity in the coronal and axial planes equivalent to the best reported results of all-screw or previous hybrid constructs, the UC hybrid technique appears to provide superior correction in the sagittal plane. The excellent outcome in all the three planes was maintained at the 2-year follow up.

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References

1. Asher MA (1997) Isola spinal instrumentation system for scoliosis. In: Bridwell KH, DeWald RL (eds) The textbook of spinal surgery. Lippincott-Raven, Philadelphia, pp 596–606
2. Barr SJ, Schuette AM, Emans JB (1997) Lumbar pedicle screws versus hooks. Results in double major curves in adolescent idiopathic scoliosis. Spine 22:1369–1379. doi:10.1097/00007632-199706150-00016
3. Bess RS, Lenke LG, Bridwell KH, Cheh G, Mandel S, Sides B (2007) Comparison of thoracic pedicle screw to hook instrumentation for the treatment of adult spinal deformity. Spine 32:555–561. doi:10.1097/01.brs.0000256445.31653.0e
4. Burton DC, Asher MA, Lai SM (1999) The selection of fusion levels using torsional correction techniques in the surgical

treatment of idiopathic scoliosis. Spine 24:1728–1739. doi:10.1097/00007632-199908150-00015
5. Cheng I, Kim Y, Gupta MC, Bridwell KH, Hurford RK, Lee SS, Theerajunyaporn T, Lenke LG (2005) Apical sublaminar wires versus pedicle screws—which provides better results for surgical correction of adolescent idiopathic scoliosis? Spine 30:2104–2112. doi:10.1097/01.brs.0000179261.70845.b7
6. Cotrel Y, Dubousset J (1984) A new technique for segmental spinal osteosynthesis using the posterior approach. Rev Chir Orthop Repar Appar Mot 70:489–494
7. Dickson JH (1973) An eleven-year clinical investigation of Harrington instrumentation. A preliminary report on 578 cases. Clin Orthop Relat Res 113–130
8. Dobbs MB, Lenke LG, Kim YJ, Kamath G, Peelle MW, Bridwell KH (2006) Selective posterior thoracic fusions for adolescent idiopathic scoliosis: comparison of hooks versus pedicle screws. Spine 31:2400–2404. doi:10.1097/01.brs.0000240212.31241.8e
9. Fitch RD, Turi M, Bowman BE, Hardaker WT (1990) Comparison of Cotrel–Dubousset and Harrington rod instrumentations in idiopathic scoliosis. J Pediatr Orthop 10:44–47
10. Hamill CL, Lenke LG, Bridwell KH, Chapman MP, Blanke K, Baldus C (1996) The use of pedicle screw fixation to improve correction in the lumbar spine of patients with idiopathic scoliosis. Is it warranted? Spine 21:1241–1249. doi:10.1097/00007632-199605150-00020
11. Hullin MG, McMaster MJ, Draper ER, Duff ES (1991) The effect of Luque segmental sublaminar instrumentation on the rib hump in idiopathic scoliosis. Spine 16:402–408. doi:10.1097/00007632-199104000-00002
12. Kim YJ, Lenke LG, Bridwell KH, Kim J, Cho SK, Cheh G, Yoon J (2007) Proximal junctional kyphosis in adolescent idiopathic scoliosis after 3 different types of posterior segmental spinal instrumentation and fusions: incidence and risk factor analysis of 410 cases. Spine 32:2731–2738. doi:10.1097/BRS.0b013e318074c3ce
13. Kim YJ, Lenke LG, Cho SK, Bridwell KH, Sides B, Blanke K (2004) Comparative analysis of pedicle screw versus hook instrumentation in posterior spinal fusion of adolescent idiopathic scoliosis. Spine 29:2040–2048. doi:10.1097/01.brs.0000138268.12324.1a
14. Kim YJ, Lenke LG, Kim J, Bridwell KH, Cho SK, Cheh G, Sides B (2006) Comparative analysis of pedicle screw versus hybrid instrumentation in posterior spinal fusion of adolescent idiopathic scoliosis. Spine 31:291–298. doi:10.1097/01.brs.0000197865.20803.d4
15. Kock HJ, Sturmer KM, Letsch R, Schmit-Neuerburg KP (1994) Interface and biocompatibility of polyethylene terephthalate knee ligament prostheses. A histological and ultrastructural device retrieval analysis in failed synthetic implants used for surgical repair of anterior cruciate ligaments. Arch Orthop Trauma Surg 114:1–7. doi:10.1007/BF00454727
16. Konno S, Kikuchi S (2000) Prospective study of surgical treatment of degenerative spondylolisthesis: comparison between decompression alone and decompression with graf system stabilization. Spine 25:1533–1537. doi:10.1097/00007632-200006150-00012
17. Kuklo TR, Potter BK, Polly DW Jr, Lenke LG (2005) Monaxial versus multiaxial thoracic pedicle screws in the correction of adolescent idiopathic scoliosis. Spine 30:2113–2120. doi:10.1097/01.brs.0000179260.73267.f4
18. Lee SM, Suk SI, Chung ER (2004) Direct vertebral rotation: a new technique of three-dimensional deformity correction with segmental pedicle screw fixation in adolescent idiopathic scoliosis. Spine 29:343–349. doi:10.1097/01.BRS.0000109991.88149.19
19. Lenke LG, Betz RR, Harms J, Bridwell KH, Clements DH, Lowe TG, Blanke K (2001) Adolescent idiopathic scoliosis: a new classification to determine extent of spinal arthrodesis. J Bone Joint Surg Am 83-A:1169–1181
20. Lowenstein JE, Matsumoto H, Vitale MG, Weidenbaum M, Gomez JA, Lee FY, Hyman JE, Roye DP Jr (2007) Coronal and sagittal plane correction in adolescent idiopathic scoliosis: a comparison between all pedicle screw versus hybrid thoracic hook lumbar screw constructs. Spine 32:448–452. doi:10.1097/01.brs.0000255030.78293.fd
21. Luque ER (1982) Segmental spinal instrumentation for correction of scoliosis. Clin Orthop Relat Res 192–198
22. Mac-Thiong JM, Labelle H, Rooze M, Feipel V, Aubin CE (2003) Evaluation of a transpedicular drill guide for pedicle screw placement in the thoracic spine. Eur Spine J 12:542–547. doi:10.1007/s00586-003-0549-4
23. Nicastro JF, Hartjen CA, Traina J, Lancaster JM (1986) Intraspinal pathways taken by sublaminar wires during removal. An experimental study. J Bone Joint Surg Am 68:1206–1209
24. Perdriolle R (1979) La scoliose. Son étude tridimensionnelle. Maloine, Paris
25. Perisinakis K, Theocharopoulos N, Damilakis J, Katonis P, Papadokostakis G, Hadjipavlou A, Gourtsoyiannis N (2004) Estimation of patient dose and associated radiogenic risks from fluoroscopically guided pedicle screw insertion. Spine 29:1555–1560. doi:10.1097/01.BRS.0000131214.57597.21
26. Rajnics P, Pomero V, Templier A, Lavaste F, Illes T (2001) Computer-assisted assessment of spinal sagittal plane radiographs. J Spinal Disord 14:135–142. doi:10.1097/00002517-200104000-00008
27. Remes V, Helenius I, Schlenzka D, Yrjonen T, Ylikoski M, Poussa M (2004) Cotrel–Dubousset (CD) or Universal Spine System (USS) instrumentation in adolescent idiopathic scoliosis (AIS): comparison of midterm clinical, functional, and radiologic outcomes. Spine 29:2024–2030. doi:10.1097/01.brs.0000138408.64907.dc
28. Sawyer PN, Stanczewski B, Hoskin GP, Sophie Z, Stillman RM, Turner RJ, Hoffman HL Jr (1979) In vitro and in vivo evaluations of dacron velour and knit prostheses. J Biomed Mater Res 13:937–956. doi:10.1002/jbm.820130611
29. Seitz H, Marlovits S, Schwendenwein I, Muller E, Vecsei V (1998) Biocompatibility of polyethylene terephthalate (Trevira hochfest) augmentation device in repair of the anterior cruciate ligament. Biomaterials 19:189–196. doi:10.1016/S0142-9612(97)00201-9
30. Senaran H, Shah SA, Gabos PG, Littleton AG, Neiss G, Guille JT (2008) Difficult thoracic pedicle screw placement in adolescent idiopathic scoliosis. J Spinal Disord Tech 21:187–191. doi:10.1097/BSD.0b013e318073cc1d
31. Senegas J, Vital JM, Pointillart V, Mangione P (2007) Long-term actuarial survivorship analysis of an interspinous stabilization system. Eur Spine J 16:1279–1287. doi:10.1007/s00586-007-0359-1
32. Suk SI, Lee CK, Kim WJ, Chung YJ, Park YB (1995) Segmental pedicle screw fixation in the treatment of thoracic idiopathic scoliosis. Spine 20:1399–1405. doi:10.1097/00007632-199506000-00012
33. Suk SI, Lee SM, Chung ER, Kim JH, Kim SS (2005) Selective thoracic fusion with segmental pedicle screw fixation in the treatment of thoracic idiopathic scoliosis: more than 5-year follow-up. Spine 30:1602–1609. doi:10.1097/01.brs.0000169452.50705.61
34. Takahata M, Ito M, Abumi K, Kotani Y, Sudo H, Ohshima S, Minami A (2007) Comparison of novel ultra-high molecular weight polyethylene tape versus conventional metal wire for

sublaminar segmental fixation in the treatment of adolescent idiopathic scoliosis. J Spinal Disord Tech 20:449–455. doi:10.1097/BSD.0b013e318030d30e
35. Upendra BN, Meena D, Chowdhury B, Ahmad A, Jayaswal A (2008) Outcome-based classification for assessment of thoracic pedicular screw placement. Spine 33:384–390
36. Vialle R, Levassor N, Rillardon L, Templier A, Skalli W, Guigui P (2005) Radiographic analysis of the sagittal alignment and balance of the spine in asymptomatic subjects. J Bone Joint Surg Am 87:260–267. doi:10.2106/JBJS.D.02043
37. Vora V, Crawford A, Babekhir N, Boachie-Adjei O, Lenke L, Peskin M, Charles G, Kim Y (2007) A pedicle screw construct gives an enhanced posterior correction of adolescent idiopathic scoliosis when compared with other constructs: myth or reality. Spine 32:1869–1874. doi:10.1097/BRS.0b013e318108b912
38. Weiss HR (1995) Measurement of vertebral rotation: perdriolle versus raimondi. Eur Spine J 4:34–38. doi:10.1007/BF00298416
39. Willers U, Hedlund R, Aaro S, Normelli H, Westman L (1993) Long-term results of Harrington instrumentation in idiopathic scoliosis. Spine 18:713–717. doi:10.1097/00007632-199305000-00007
40. Winter RB, Lonstein JE, Denis F (2007) How much correction is enough? Spine 32:2641–2643