Use of the Universal Clamp in adolescent idiopathic scoliosis for deformity correction and as an adjunct to fusion: 2-year follow-up

Jérôme Sale de Gauzy · Jean-Luc Jouve ·
Franck Accadbled · Benjamin Blondel ·
Gérard Bollini

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Abstract

Purpose Among posterior surgical techniques for treating adolescent idiopathic scoliosis (AIS), hybrid constructs with pedicle-screw fixation in the lumbar spine and other anchors in the thoracic spine have been reported to provide to be of more physiological value in postoperative thoracic kyphosis than all-screw constructs. The Universal Clamp (UC) equipped with a soft sublaminar band is a relatively new thoracic anchor that can be used in hybrid constructs. A dedicated reduction tool that applies traction to the sublaminar band permits gentle translation of the thoracic curve to the precontoured fusion rods, which have been previously anchored distally by pedicle screws and proximally by hooks in a claw configuration. The aim of this study was to evaluate radiographic results of AIS treatment using UC hybrid constructs.

The device is FDA-approved (510K), but not for this indication (the device is approved by the FDA for adult deformity, but not for adolescent idiopathic scoliosis).

J. Sale de Gauzy · F. Accadbled
Pediatric Orthopedic Surgery, Hôpital des Enfants,
CHU de Toulouse, Toulouse, France

J.-L. Jouve · B. Blondel · G. Bollini
Pediatric Orthopedic Surgery, La Timone Children's Hospital,
Marseille, France

F. Accadbled (✉)
Service de Chirurgie Orthopédique et Traumatologique,
Hôpital des Enfants 330, avenue de Grande Bretagne,
31059 Toulouse Cedex 9, France
e-mail: faccadbled@wanadoo.fr

J.-L. Jouve
Service Orthopedic Surgery, La Timone Children's Hospital,
13385 Marseille Cedex 5, France

Methods This was a prospective case series in which 29 consecutive patients with Lenke type 1, 2 or 3 AIS operated on by two surgeons in two centers were followed for 24 months. Necessity for anterior release was an exclusion criterion.

Results A total of 5.4 ± 1.4 UCs were used per patient. The major thoracic curve was reduced from $55 \pm 7^\circ$ to $14 \pm 6^\circ$ at 1 month and $17 \pm 6^\circ$ at 24 months (correction 70%) without complications. In the patients who had less than 20° of T5–T12 kyphosis preoperatively, thoracic kyphosis improved from $14 \pm 4^\circ$ to $20 \pm 3^\circ$ at 3 months and $24 \pm 9^\circ$ at 24 months. In the other patients, preoperative thoracic kyphosis ($27^\circ \pm 6^\circ$) was unchanged by the operation.

Conclusion UC hybrid constructs appear to safely provide satisfying coronal correction while consistently improving thoracic kyphosis in patients who also have preoperative hypokyphosis. We hypothesize that diminution in thoracic kyphosis was consistently avoided due to the straightforward traction of the spine to the fusion rods into which the chosen kyphosis was contoured by the surgeon before applying the reduction tool to the sublaminar bands.

Keywords Adolescent idiopathic scoliosis · Universal Clamp · Thoracic kyphosis · Rod precontouring

Introduction

There is no consensus on the ideal posterior surgical technique for treating adolescent idiopathic scoliosis (AIS) [1–3]. Among posterior techniques, procedures using segmental pedicle screws are considered by some scoliosis surgeons as the current standard of excellence based upon

the deformity correction it provides in the coronal and axial planes [4–6]. Others prefer hybrid constructs with pedicle-screw fixation in the lumbar spine but not in the thoracic spine [7, 8]. Next to concerns they may have over misplaced pedicle screws [9–11], proponents of hybrid constructs report postoperative thoracic kyphosis to be of more physiological value to patients than all-screw constructs [7, 8], with little difference in coronal or axial correction [12]. A number of thoracic anchors can be used to replace the thoracic pedicle screws in hybrid constructs, including hooks, sublaminar wiring, intraspinal wiring and soft sublaminar bands [3, 13, 14].

We have previously reported our 3-month postoperative results using hybrid constructs, including a recent system of thoracic spinal anchorage, the Universal Clamp (UC) [15]. In that series of 32 patients with Lenke type 1, 2 or 3 AIS operated on with no anterior release, UC hybrid instrumentation safely achieved $73 \pm 12\%$ correction, from $55 \pm 7^\circ$ to $14 \pm 9^\circ$. Among the 12 patients with low values of preoperative thoracic kyphosis, thoracic kyphosis was increased by an average of 9° at 3 months. In the 20 patients with more physiological values of preoperative thoracic kyphosis, there was no statistical difference in kyphosis after the operation. The purpose of this report was to evaluate the same group of patients to determine whether these good initial results were maintained at their 2-year follow-up visit.

Methods

Patients

Consecutive patients with Lenke type 1, 2 or 3 AIS were included in the study by two surgeons in two centers. Exclusion criteria were major lumbar curves, necessity for anterior release, congenital or neuromuscular scoliosis and spinal cord disorders visible on magnetic resonance imaging (MRI) scans.

The preoperative radiographic work-up included whole-spine erect posterior–anterior (PA), whole-spine erect lateral, and supine bending radiographs. Angular measurements were made in terms of Cobb angle by an independent observer with no intraobserver or interobserver verification. The following ratios were calculated:

- Preoperative flexibility (PF): $PF (\%) = [(\text{preoperative erect Cobb angle} - \text{supine bending Cobb angle}) / \text{preoperative erect Cobb angle}] \times 100$
- Postoperative correction: (POC) $POC (\%) = [(\text{preoperative erect Cobb angle} - \text{postoperative erect Cobb angle}) / \text{preoperative erect Cobb angle}] \times 100$
- Cincinnati correction index (CCI): $CCI = POC / PF$

Paired-samples *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.

Results

Thirty-two consecutive patients (28 girls, 4 boys) who did not have anterior release were included in the original study. Three of the original patients did not return for the follow-up visit at 2 years. Of these three patients, one has not returned since the 1-year visit, and one each was seen at the 3- and 4-year follow-up, respectively. These three patients were older than the initial cohort of 32 patients (mean age at operation 18 vs. 15 years, respectively) and experienced more change in thoracic kyphosis (mean 7° increase vs. 2° increase at 3 months, respectively), with little difference in the average 3-month coronal thoracic Cobb angle improvement (mean 39° vs. 41° , respectively) or percentage correction (mean 74 vs. 73%, respectively). Twenty-nine (27 girls, 2 boys; average age at operation 14.7 ± 1.6 years) patients were seen at the 2-year follow-up (90.6% follow-up). On average, 5.4 ± 1.4 UCs were used per patient in these 29 patients, and none of the original 32 patients required thoracoplasty.

The average preoperative value of the major thoracic curve of the present 29 patients was $55 \pm 7^\circ$ (range $42\text{--}70^\circ$). At the 1-month follow-up, the Cobb angle measured $14 \pm 6^\circ$ (range $6\text{--}30^\circ$), representing an average POC of $75 \pm 10\%$. At the 12-month follow-up, ($n = 28$ patients), the Cobb angle was $16 \pm 6^\circ$ (range $8\text{--}30^\circ$), and the average POC had slightly decreased to $71 \pm 12\%$. At the 24-month follow-up ($n = 29$ patients), the major thoracic Cobb angle was $17 \pm 6^\circ$ (range $5\text{--}28^\circ$), representing a POC of $70 \pm 10\%$. The average loss in POC was $3 \pm 5^\circ$ (range from a loss of 13° to a gain of 3° in correction) with respect to the Cobb angle at the 1-month follow-up. The course of the thoracic curve Cobb angles is illustrated in Fig. 1.

Preoperative bending films were not obtained in two of the patients. In the other 27, the PF of the main curve was $51 \pm 13\%$. Their average computed CCI was 1.56 ± 0.44 at 1 month, 1.51 ± 0.42 at 3 months, and 1.44 ± 0.39 at 24 months. As shown in Fig. 2, preoperative flexibility had almost no influence on the percentage of thoracic curve correction at 24 months [$r^2 = 0.11$, not significant (NS)]. Figure 3 shows the course of the lumbar curve Cobb angle from preoperative values to the 24-month follow-up. The final lumbar Cobb angle of $8 \pm 5^\circ$ corresponded to a correction of $72 \pm 20\%$ of the preoperative lumbar scoliotic curve ($36 \pm 15^\circ$).

Table 1 Nonexhaustive comparison of thoracic coronal correction and influence on kyphosis of various types of vertebral constructs in adolescent idiopathic scoliosis

Vertebral anchor	Reference	Number of patients	2-year scoliosis correction (%)	Preoperative thoracic kyphosis (°)	2-year T5–T12 kyphosis (°)	Change in thoracic kyphosis (°)
Universal Clamp (UC) hybrid	Present study	12	67.9 ± 6.0	26.8 ± 6.4	25.6 ± 9.8	−1.3
		16	71.5 ± 12.0	13.8° ± 3.7	23.7 ± 8.5	+9.9
	Total/average	28	70 ± 10	19.4° ± 8.2	24.5 ± 8.9	Gain of 5.1°
All pedicle screws with predominant use of rod derotation	Suk et al. 1999 [37]	17	65	8.1° ± 5.6	27.3 ± 11.3	+19
	Lee et al. 2004 [35]	17	78	16 ± 3	23 ± 4	+7
	Suk et al. 2005 [6]	203	69	18 ± 11	23 ± 8	+5
	Karatoprak et al. 2008 [34]	22	70	27.4	32.5	+5.1
	Lee et al. 2004 [35]	21	68	18 ± 3	23 ± 3	+5
	Lonner et al. 2009 [36]	17	64	22.7 ± 12.0	24.3 ± 13.7	+1.6
	Suk et al. 1999 [37]	17	61	27.3 ± 9.8	28.3 ± 13.7	+0.4
	Totals/weighted averages	314	68.6	18.8	24.3	Gain of 5.4°
All pedicle screws with less use of rod derotation	Potter et al. 2005 [32]	20	62	29.4 ± 2.8	25	−4.4
	Kim et al. 2006 [28]	29	65	26 ± 14	18 ± 8	−8
	Lehman et al. 2008 [29]	114	70	26.2 ± 13.1	16.3 ± 8.5	−9.9
	Cheng et al. 2005 [7]	25	63	28.0	15.7	−12.3
	Kim et al. 2004 [4]	26	70	30.6	17.1	−13.5
	Luhmann et al. 2005 [30]	11	59	34.3	17.0	−16.5
	Totals/weighted averages	225	67.3	27.6	17.4	Loss of 10.2°
All hooks	Suk et al. 1999 [37]	17	56	4.1 ± 8.6	14.5 ± 10.2	+10
	Remes et al. 2004 [41]	57	55	33	40	+7
	Takahashi et al. 1997 [42]	30	48	26 ± 13	32 ± 9	+6
	Boos et al. 2007 [43]	54	60	19.7	22.2	+2.5
	Sucato et al. 2008 [44]	132	55	8.6 ± 6.4	9.9 ± 7.1	+1.3
	Muschik et al. 2006 [45]	104	56	21 ± 14	22 ± 11	+1
	Pérez-Grueso et al. 2000 [46]	35	55	30.7 ± 12.3	29.7 ± 11.8	−1
	Kim et al. 2004[4]	26	42	27.3	25.9	−1.4
	Luhmann et al. 2005 [30]	36	43	28.2	24.4	−3.3
	Barr et al. 1997 [47]	19	58	27.6	21	−6.6
	Totals/weighted averages	510	54.0	20.5	22.1	Gain of 1.7
	Benli et al. 2001 [48]	24	55	22.0 ± 29.8	32.9	+11
Hook hybrids	Papin et al. 1999 [49]	30	36	32 ± 18	41 ± 13	+9
	Muschik et al. 1999 (T) ^a [50]	30	50	23 ± 12	19 ± 7	+3
	Muschik et al. 1999 (R) ^a [50]	39	59	19 ± 10	22 ± 9	0° change
	Ilharreborde et al. 2010 [13]	75	43	23.6 ± 13.8	22.1 ± 10.7	−1.5
	Kim et al. 2006 [28]	29	46	30 ± 14	28 ± 11	−2
	Di Silvestre et al. 2008 [51]	27	45	35.2	32.4	−2.8
	Barr et al. 1997 [47]	20	63	24.5	21.3	−3.2
	Luhmann et al. 2005 [30]	15	39	37.1	29.3	−7.9
	Totals/weighted averages	289	47.8	26.1	26.5	Gain of 0.7°
	Sucato et al. 2008 [44]	86	62	10.4 ± 8.1	13.2 ± 8.6	+2.8
Sublam wire hybrids	Karatoprak et al. 2008 [34]	26	68	27.6	29.6	+2
	Cheng et al. 2005 [7]	25	63	28.5	27.6	−0.9
	Totals/weighted averages	137	63.3	17.0	18.9	Gain of 2.0°

Only studies with 2-year results in coronal and sagittal planes published since 1995 were included. Those in which average preoperative thoracic kyphosis was >35.0° were excluded

^a T, Correction by translation; R, correction by rod rotation

Fig. 5 Preoperative view of one of the patients treated for Lenke type 3 adolescent idiopathic scoliosis (AIS)

Fig. 6 Lateral view of the same patient showing T5–T12 hypokyphosis (7°)

described by us in an earlier publication for the same cohort of patients [15]. The safety and efficacy of the initial report are confirmed by the 2-year follow-up data reported here.

In terms of safety, there were no complications directly involving the UC anchors between 3 months and 2 years. Mazda et al. reported on a group of 75 AIS patients who received hybrid constructs that included apical and peri-apical UCs and distal pedicle screws. Among their earliest patients, in whom UCs were also used at the most proximal vertebra included in the fusion, these authors reported proximal posterior prominence in 11 patients, leading them to recommend conventional claws at the upper extremity of the constructs. There were no other intermediate-term complications related to the use of the sublaminar UCs in their report [16]. Taking into account this recommendation to use conventional hook-claw devices at the proximal extremity of hybrid constructs, we recorded no intermediate-term UC-related complications. The promising intermediate-term safety results of sublaminar UCs are in contrast to the intermediate-term safety issues of sublaminar wiring [17–19]. La Rosa et al. also noted the safety of

UCs used in hybrid constructs with thoracic hooks and lumbar pedicle screws in a series of 15 patients with neurological scoliosis greater than 100° and an average follow-up of 3 years [20]. An apparent superiority in both intra-operative and intermediate-term safety of UCs compared to sublaminar wires has also been discussed by spinal surgeons who reported the use of UCs in the thoracic spine for traumatic vertebral lesions [21]. The latter authors confirmed the absence of implant-related MRI artifacts in the vertebral canal as well as the absence of epidural fibrosis next to the bands, either of which could have otherwise compromised early and intermediate postoperative safety. Even though severe neurological complications after surgical interventions for AIS are rare (none in the present series), it is important to use implants that do not preclude the use of MRI in case postoperative neurological complications do occur (Appendix).

The present 2-year findings confirm the efficacy reported initially in the same cohort of patients. With the UC hybrid constructs, the good correction (71%) of the main thoracic curve from a mean of 55° preoperatively to 16° at 1 year after the operation was only 4 percentage points less

Fig. 7 Two-year follow-up view showing the 60% correction achieved

than the mean immediate postoperative Cobb angle (14°). Moreover, there was no further loss of the achieved correction between 1 year and 2 years. This confirmed an earlier study by Ilharreborde et al., who reported an average initial thoracic main curve correction from 60° preoperatively to 20° (66% correction) in 75 AIS patients treated with UC hybrid constructs and a subsequent loss of only 2° (3%) at the 2-year follow-up [13]. In the series of 15 patients with more severe, neurological scoliosis $>100^\circ$, La Rosa et al. achieved a 70% initial reduction (from 107 to 32°) and lost only 7° of correction after an average follow-up of 3 years [20].

The intermediate-term results reported here on the corrective efficacy of the UC in the coronal plane are not inferior to results observed with other spinal anchors that have known safety issues [2, 22–27]. An initial average thoracic curve correction from 54° to 27° (50%) achieved in 75 AIS patients with hook hybrid constructs (before the development of the UC) was followed by a loss of 4° observed 2 years postoperatively [13]. In a series of 78

Fig. 8 The T5–T12 kyphosis had improved by $13\text{--}20^\circ$ at the 2-year follow-up

patients with either idiopathic or neurological scoliosis treated by segmental sublaminar wiring, Luque reported an average reduction from 69 to 20° (72% correction) followed by a 2% loss of correction (mean of $<2^\circ$) during the treatment period [23]. Kim et al. reported an average main curve correction from 63° preoperatively to 16° postoperatively (76%) in 26 AIS patients treated with segmental pedicle-screw instrumentation compared to a correction from 66 to 33° (50%) in 26 matched patients treated using hook instrumentation. At the 2-year follow-up, the loss of correction was 4° in the pedicle-screw group and 4° in the hook group [4]. The same team reported an average main curve decrease from 62 to 19° (70% correction) in 29 AIS patients with all-pedicle screw constructs and from 60 to 27° (56% correction) in a matched series of patients treated

with hybrid constructs that included hooks in the thoracic spine and pedicle screws distally. After 2 years, 3° of correction was lost in the pedicle-screw group and 6° of correction was lost in the hybrid group [28].

Among the present AIS patients who had normal values of thoracic kyphosis preoperatively, there was almost no change in average thoracic kyphosis at the follow-up visits. However, among the patients with low preoperative values of T5–T12 kyphosis, the average T5–T12 kyphosis increased by 6° at 3 months and continued to improve thereafter, attaining an increase of 10° at 2 years. This improvement in thoracic kyphosis confirms previous results on the use of the UC for both AIS and neurologic scoliosis [13, 16, 20], and contrasts with a large body of evidence suggesting that conventional all-pedicle screw constructs tend to worsen flatness of the thoracic spine in AIS [3, 4, 7, 8, 28–33] unless rod derotation is the predominant means used to correct coronal deformity (see Table 1) [6, 34–37]. Based upon a retrospective study of patients with Lenke type 1 AIS treated with all-pedicle screw instrumentation, Quan and Gibson recently concluded that the greater the coronal plane correction achieved with pedicle-screw constructs, the greater the loss of thoracic kyphosis [33]. The authors of a large multicenter analysis of patients with Lenke type 1 AIS surgically treated by a selective thoracic fusion have recommended techniques that lengthen the posterior column in order to maintain or increase thoracic kyphosis [31]. Among the techniques recommended to prevent diminution in thoracic kyphosis, the authors cited contouring kyphosis into the fusion rods. We believe that this is the key to the promising immediate and intermediate-term results observed in the sagittal plane with the UC compared to pedicle screws. Contouring more thoracic kyphosis into fusion rods may increase the difficulty of bringing thoracic pedicle screw heads to the rods, whereas traction of the spine to the fusion rods with the UC sublaminar bands and reduction tool remains just as straightforward regardless of the degree of kyphosis the surgeon decides to precontour into the rods. This also may explain why apical sublaminar wiring can provide significantly better thoracic kyphosis than conventional pedicle screws [7] and why certain pedicle screw systems with special translation-mediating screw heads can also improve hypokyphosis in AIS patients [38, 39].

As shown in Table 1, the thoracic curve correction achieved and maintained in the AIS patients described here appears to be substantially higher than that reported for all-hook and hook hybrid techniques. The results in Table 1 also suggest that the sublaminar wire hybrid techniques, which resemble the UC hybrid technique, provide very satisfying deformity correction without lessening thoracic kyphosis. For various reasons, all-pedicle screw constructs

have begun to supplant all-hook, hook hybrid, and wire-hybrid techniques in many countries [5]. Regardless of the deformity-correcting method employed with all-screw constructs, the Cobb angle correction achieved is equivalent to that achieved with UC hybrid devices. The use of rod derotation alone to correct scoliosis is avoided in some units to prevent overcorrection [40]. However, as Table 1 shows, unless rod derotation is used with all-screw constructs, the latter tend to reduce thoracic kyphosis, which is in contrast to the substantial gain in thoracic kyphosis obtained when UC hybrids are used.

We did not report our results on apical vertebral derotation in this paper because they relate to the 2-year outcome on a series of patients for whom we have already reported the short-term results [15]. In that preliminary paper, only the coronal and sagittal corrections were reported. The primary objective of the present article was to show to what degree the immediate and 3-month postoperative results were maintained 2 years after the intervention. In our opinion, apical vertebral derotation is important—but difficult to obtain. Systematic preoperative and follow-up computed tomography scans were not performed in these children to avoid exposure to unnecessary radiation. We are currently studying the amount of derotation achieved in UC patients using the new EOS imaging system, which was not available at the time our patients underwent surgery. A sufficient number of patients have not yet undergone EOS imaging and derotation measurement for reliable conclusions to be drawn. This will be the objective of an upcoming report when this study is completed.

Conclusions

The present series of AIS patients treated with hybrid constructs that included proximal hook-claws, apical UCs, and distal pedicle screws was small. However, with data from the 2-year follow-up, it provides still more evidence that these hybrid constructs safely provide satisfying coronal Cobb angle correction while consistently improving thoracic kyphosis in the patients who also have preoperative hypokyphosis. The authors hypothesized that a diminution in thoracic kyphosis was consistently avoided due to the straightforward traction of the spine to the fusion rods into which the chosen kyphosis was contoured by the surgeon before the reduction tool was applied to the sublaminar bands.

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Conflict of interest None.

Appendix

Implant description

The Universal Clamp (Zimmer Spine, SAS, Bordeaux, France) has only three components, namely, 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 relies upon sublaminar polyester bands. The surface area of contact between the polyester band and lamina is larger than that of sublaminar wiring or cables. This permits application of greater spinal deformity reduction forces with less risk of bone fracture. Deformity correction is applied in a step-wise fashion at one or more spinal segments with a dedicated reduction tool. After conventional translation, compression, distraction, and in situ bending maneuvers, the set screw in the metallic jaw of each UC implant is tightened to prevent subsequent slippage of the band-rod connection along the fusion rod.

A malleable metallic insert in the leading tip of the polyester band facilitates sublaminar insertion (Fig. 2). Before sublaminar passage, that end of the band is slipped through slots on the hinge side of both metal jaws in a top-to-bottom direction. After sublaminar passage, the band leader is rethreaded (without introducing twists in the band) through the same slots in the jaws in the bottom-to-top direction next to the other end of the band, which has two metallic buckles at its extremity. The leader is then passed through both buckles in one direction and back through one buckle in the other direction to create an adjustable loop for the reduction tool on the top side of the jaws. Although the buckles maintain the loop strongly, preventing any slippage of the band when traction is applied to the loop, the loop can be easily shortened or lengthened as necessary to fit the reduction tool.

Operative technique

Briefly, two 5.5-mm titanium fusion rods joined by cross links were anchored to the distal vertebrae with pedicle screws and to the proximal vertebrae with self-retaining hook claws. Around the apex of the thoracic curve, sublaminar UCs were used in the concavity at three to six levels. One or two levels were also instrumented on the convex side. Pedicle screws were placed using the free-hand technique, and no intraoperative fluoroscopic guidance was necessary to implant the UCs or hook claws. The deformity was reduced in the proximal-to-distal direction. Autologous bone graft was collected from the resected spinous processes, and graft volume was augmented with a synthetic bone substitute (Biosorb; SBM, Lourdes, France).

Somatosensory and neurogenic evoked potentials were monitored in all patients during the operation.

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