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Comparison of two polyester sublaminar bands for the treatment of thoracic adolescent idiopathic scoliosis with CoCr rods: Jazz Band versus Universal Clamp

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Introduction

The goal of adolescent idiopathic scoliosis (AIS) surgery is to achieve a 3D correction of the deformity and to prevent progression of the unfused spine. Correction has been reported with numerous systems, but the most popular technique currently relies on pedicle screws, either combined with hooks in *hybrid constructs* or used alone in *all-screw constructs*. However, all-screw constructs have been associated with higher spinal implant costs (27.6% annually in United States), and in some cases with a significant decrease in thoracic kyphosis correction, a decrease not observed with hybrid constructs in matched patients [1,2,3]. In addition, potential complications of thoracic pedicle screws include neurologic lesions, vascular injury, pleural tear, and increased radiation exposure during screw placement.

The Lenke classification is now widely accepted and utilized by the majority of scoliosis surgeons worldwide. According to this system, Lenke 1 and 2 types correspond to thoracic curves (single or double, respectively) which are not only the most frequent, but also the most challenging ones, because they are often associated with a significant decrease of thoracic kyphosis.

While some authors advocate the use of larger diameter rods and/or screws to optimize the correction of thoracic sagittal misalignment using in situ maneuvers [4], several studies have recently emphasized the efficacy and safety of the posteromedial translation technique, even in large stiff curves, with no need for previous thoracoscopic anterior release [5].

As a matter of fact, thoracic sublaminar bands have been used in hybrid constructs for 10 years, with excellent long-lasting 3D curve correction and significant reduction of operative time and radiation exposure [6, 7]. In clinical practice, the reduction forces seem to be optimized when bands are used with rigid CoCr rods. Since 2013, a new sublaminar implant (Jazz™ Band, Implanet, Bordeaux, France) used with a powerful reduction tool, has been designed and implemented in our department. The purpose of this study is to compare the postoperative corrections obtained with two different sublaminar bands, using the same posteromedial translation technique, in a consecutive series of thoracic AIS treated with CoCr rods.

Materials and Methods

<u>Patients</u>

Following institutional review board approval, a consecutive series of 115 patients operated for progressive Lenke 1 or 2 AIS were prospectively included between November 2011 and January 2015. All patients were evaluated preoperatively, in the early postoperative period (within a week), and at latest follow-up. None of the patients had prior spinal surgery.

Operative procedures

All patients underwent segmental posterior spinal correction and fusion using hybrid constructs, performed by one of the two senior surgeons using 5.5mm CoCr rods. Fusion levels were selected following the same criteria during the entire study period[8]. During the posterior procedures, spinal cord function was monitored by means of somatosensory/motor-evoked potentials. Patients were treated by weekly injections of Erythropoietin (EPO) preoperatively, in order to reach a hemoglobin rate of 15 mg/dl. In all cases, pedicle screws were placed at the distal extremity of the curve (T12 or L1 to L4), where an anteromedial correction effect was expected.

Thoracic levels (T5 to T12) were instrumented with sublaminar bands placed on each vertebra on the concave side of the main curve, and with 1 sublaminar band at the apex on the convex side. The 2 upper thoracic levels, located at the proximal end of the construct, were bilaterally instrumented with either autostable claws (Zimmer Spine, Bordeaux, France) or with a combination of supralaminar angled hooks and sublaminar bands (Figures 1 and 2). Two additional bands were usually placed bilaterally at the adjacent distal level, under the proximal fixation, in order to reduce the pull-out forces and protect the proximal anchors from mechanical failure. Patients from group 1 were treated with Universal Clamp™ bands (Zimmer Spine, Bordeaux, France), while Jazz bands were used in group 2.

Correction was performed at thoracic levels using posteromedial translation, with several (3 or 4) reduction tools applied simultaneously, while derotation, compression/distraction and in situ contouring were used at lumbar levels. After an intraoperative radiograph, additional distraction or compression forces were applied as appropriate to level the proximal vertebra, the shoulders, and the lower instrumented vertebra[9]. At the end of the correction maneuvers, a final revisiting of screw blockers and band locking screws was performed as recommended[10]. In addition, thoracoplasty was performed if necessary at the end of the procedure when the patient and/or caregiver expressed a cosmetic concern over the prominence of the rib hump deformity.

Implant description

The Jazz is a novel implant consisting of three components: a woven polyester band, a titanium alloy connector, and a locking screw (Ti alloy).

The Jazz technique is similar to the Luque technique, but sublaminar polyester bands are used instead of sublaminar metallic wires. The surface area of contact between the polyester band and lamina is larger than that between wires and the lamina, permitting application of greater spinal deformity reduction forces without laminar fracture. The deformity reducing forces are applied progressively, step-wise at one or more spinal segments with a reduction tool. The connector couples the sublaminar band to the rod. The strength of the band-rod connection is similar to that of a screw-rod connection, allowing conventional deformity correction maneuvers such as in situ bending, and to a lesser degree compression/distraction.

The Jazz polyester band contains a malleable metallic insert at one end to facilitate sublaminar insertion and one metallic square buckle at the other end. After opening the yellow ligament both proximally and distally, the surgeon gives the malleable end of the band the desired shape, depending on the instrumentation level, 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 forcep. The tip of the band is then threaded back through the Jazz connector. The free tip of the band is passed through the square buckle on the other end of the band so that the band now forms an adjustable loop for the reduction tool. The buckle maintains the loop, preventing any slippage of the band when tension is applied. Nevertheless, the buckle permits adjustment of the loop's length, if necessary. Attention must be paid not to position the buckle next to the connection with the reduction tool. Optimal loop length averaged 20 to 25 cm.

Once all Jazz implants are placed along the spine and the pre-bent double-rod frame (5.5 mm CoCr rods, connected with 35mm closed connectors) is anchored to pedicle screws at the distal end of the construct, each Jazz is placed on the appropriate rod (concave rod at thoracic levels). The Jazz connector is then clipped on the rod using a dedicated tool, and the locking screw is loosely inserted to leave the band free to move and permit tensioning of the vertebrae toward the rod with the reduction tool. After reduction maneuvers and optimal band tension has been obtained, the Jazz is locked onto the rod with the screw, using the same dedicated tool to optimize connector-rod contact. The loop of the band is removed from the reduction instrument and the excess band (including the malleable insert and the metallic buckle) is cut and removed.

Differences between the Jazz Band and Universal Clamp

The Universal Clamp (UC) has been widely described in the literature[6, 7]. The Jazz connector is self stable and can be clipped on the rod without screw insertion. The UC is a hinge design that requires screw insertion to fix the connector onto the rod. Another particularity is the diameter of the locking screw, which is larger in the Jazz system, thus allowing a stronger locking couple before deleterious plastic deformation of the screw head (Figure 3). However, the main difference between the two systems is the reduction tool, which is stronger but requires a much longer loop for band connection (20cm vs 10cm, respectively, Figure 4).

Radiographic measurements

Low dose stereo radiographs (EOS imaging, Paris, France) were obtained preoperatively, and at each consecutive visit as part of the routine work-up and follow-up[11]. Patients were in the weight-bearing standing position, arms folded at 45° in order to avoid superposition with the spine. All images included the base of the skull and the upper third of the femurs.

Radiographic analysis included Cobb angle measurements of the major and minor curves, 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 iliolumbar angle (angle between the upper endplate of L4 and the distal sacroiliac joints). Curve flexibility was determined on the preoperative supine side bending films. Global coronal balance was measured as the distance between the center of T1 and the center sacral vertical line (CSVL), while global sagittal balance was analyzed by measuring the sagittal vertical axis distance (SVA, distance between a vertical line drawn from the center of C7 and the posterosuperior corner of the sacrum).

In addition, pelvic parameters, T1T12 and T4T12 thoracic kyphosis, and L1S1 lumbar lordosis were measured. According to Lenke's classification, patients were considered hypopkyphotic if the sagittal T4T12 Cobb angle was < 10°.

As described by Vora et al.[12], the following ratios were determined:

$$\text{Preoperative Flexibility } (\mathbf{PF}) \ (\textit{in \%}) = \frac{[\text{PreCa-SbCa}]}{\text{PreCa}}$$

$$\text{Postoperative Correction } (\mathbf{POC}) \ (\textit{in \%}) = \frac{[\text{PreCa-PoCa}]}{\text{PreCa}}$$

$$\text{Cincinnati Correction Index } (\mathbf{CCI}) = \frac{\text{POC}}{\text{PF}}$$

With

PreCa = Preoperative erect Cobb angle

PoCa = Postoperative erect Cobb angle

SbCa = Supine bending Cobb angle

Statistical analysis

Paired-samples Student's *t* tests were used to analyze differences between preoperative and postoperative curves, while unpaired *t* tests were used to compare the postoperative corrections between groups. All statistical tests were 2-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

Among the consecutive 115 Lenke 1 and 2 AIS patients included, 60 were treated with UC (group 1), and 55 with Jazz (group 2). Mean age at operation was 15.5 years (+/- 2), with no difference between groups. Demographic data of the cohort are summarized in Table 1. According to Lenke's sagittal classification, 17 patients were hypokyphotic (<10°). The only significant difference between groups was the length of the follow-up period, which was shorter in group 2, since the novel implant was only introduced in February 2013. However, all patients had a minimum 3-month follow-up, considered sufficient to evaluate the postoperative correction and assess early complication rates.

Procedures and early postoperative curve corrections

The average operative time was 185 ± 40 minutes and intraoperative blood loss was 245 ± 160 mL, without difference between groups. The number of sublaminar bands used for correction usually ranged between 7 and 8, without difference between groups (Table 1). Twenty patients (33%) underwent additional thoracoplasty in group 1 and 11 (20%) in group 2. Postoperative corrections obtained in the frontal and sagittal planes are reported in Tables 2, 3, 4 and 5. All curves were significantly improved after surgery in the coronal plane, without significant difference between groups (Table 6, Figure 5). No difference was found between groups when the preoperative flexibility was taken into account, with an early postoperative CCI of 1.8 in group 1, and 1.6 in group 2, consistent with the best values found in the literature for AIS, regardless of the correction technique. The mean loss of correction at follow-up averaged 5° in group 1 and 3° in group 2, but the difference did not reach significance. However, the follow-up was significantly shorter in group 2, and the stability of the correction at 2-years needs to be further evaluated in the Jazz group. In both groups, the global coronal balance was not significantly altered after surgery, but spontaneously improved between the first postoperative visit and the last follow-up ($p<0.001$).

Thoracic sagittal alignment was maintained or restored in all but 1 patient of the cohort, with, according to Lenke's criteria, only 1 hypokyphosis reported at follow-up in the UC group (Figure 6). Overall, no difference was found between groups regarding the average postoperative T1T12 and T4T12 kyphoses. The initial impact of surgery was an anterior shift of the SVA in both groups ($p<0.001$), but patients adapted during the follow-up period and their global sagittal alignment was finally back close to their initial position, even though they remained significantly more posterior ($p=0.01$).

The T4T12 kyphosis, which corresponded to instrumented levels in all cases, significantly increased in both groups during follow-up, mostly within the first 3 postoperative months (average 6° and 4°, respectively, p<0.001, Figure 7). This could be explained by (i) a plastic deformation of the construct, which is unlikely since rigid CoCr rods were used in all cases, (ii) a progressive loosening of the jaw-rod connection, complication that was never observed in our previous experience during revision procedures, or (iii) a gradual return to the initial balance (bone remodeling or biological structures creep). This finding will need to be further studied with in vitro studies, but did not have any clinical consequence in this series.

Perioperative complications

No intraoperative lamina fracture occurred during the study period. No significant change in the monitored somatosensory/motor-evoked potentials was recorded either during insertion of the sublaminar band or during correction maneuvers in the entire cohort. The ease of insertion was considered similar between the 2 systems and no postoperative neurological deficit was reported. Eight patients (6.9%, 4 in group 1 and 4 in group 2) underwent revision surgery for early surgical site infection, with satisfactory outcomes after surgical debridement followed by 6 weeks of antibiotics (including 15 days parenteral). In addition, 17 patients (14.7%) (15 in group 1 and 2 in group 2) developed a radiological proximal junctional kyphosis (PJK) during follow-up, which was defined in this study by an increase of the T1T4 kyphosis (mostly uninstrumented) > 15° in comparison to preoperative values, but none presented clinical impairment. No case of pseudarthrosis was reported at follow-up and no patient required instrumentation revision during the study period.

Conclusion

Results of this comparative study confirm that posteromedial translation is an efficient technique to restore sagittal alignment in AIS using 5.5mm CoCr rods. Jazz bands offer a satisfactory alternative to other sublaminar implants for hybrid constructs[13], with excellent radiological outcomes, low morbidity, and reduced operative time and blood loss. Although many surgeons currently advocate the use of thoracic pedicle screws for optimal care in AIS[14], results of the present study show that Jazz sublaminar bands should be considered in hypokyphotic patients. The low density of implants (average 7 Jazz) required to obtain an efficient and long-lasting correction should also be taken into account in the global cost of AIS surgery, in comparison to all pedicle screw-constructs.

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Tables and Figures

Table 1: Demographic data of the cohort (N=115)

	group 1 (UC) N=60	group 2 (Jazz) N=55	p
Gender	9 boys / 51 girls	8 boys / 47 girls	ns
Curve distribution	8 Lenke 2 / 52 Lenke 1	9 Lenke 2 / 46 Lenke 1	ns
Preoperative main Cobb angle	56°±11°	55°±9°	ns
Preoperative flexibility	51%±21%	51%±18%	ns
Number of hypokyphotic patients	9/60 (15%)	8/55 (15%)	ns
Mean number of instrumented levels	13.6 ± 1	13.2 ± 1	ns
Mean number of sublaminar bands	7.3 ± 1	7.5 ± 1.6	ns
Mean follow-up	24 months	12 months	s

Table 2: Corrections in the coronal plane achieved with UC (group 1, N=60)

	Preop	Postop *(% correction)*	F-up *(% correction)*
Main curve	56°±11°	16°±9° *(72% ±12)*	21°±10° *(62.5% ±15)*
Cincinnati C. Index	---	1.8±1.6	1.6±1.5
Proximal curve	30°±8°	20°±8° *(32% ±22)*	22°±8° *(24% ±21)*
Distal curve	37°±9°	8°±6° *(78% ±14)*	10°±6° *(71% ±17)*
Iliolumbar angle	8°±6°	4°±3°	4°±3°
T1 tilt	6°±5°	7°±4°	7°±4°
Shoulder balance	3°±3°	4°±2°	3°±2°
Coronal balance (mm)	11±9	12±11	9±6

Table 3: Corrections in the sagittal plane achieved with UC (group 1, N=60)

	Preop	Postop	F-up
T1T12 kyphosis	32°±16°	33°±12°	45°±14°
T4T12 kyphosis	25°±17°	24°±10°	30°±11°
L1S1 lumbar lordosis	57°±12°	48°±11°	57°±11°
Number of patients with T4T12 kyphosis < 20°	24	24	12
Number of hypokyphotic patients (T4T12<10°)	9	1	1
Number of patients with thoracic lordosis	1	0	0
SVA (mm)	4±18	20±24	-1.4±20

Table 4: Corrections in the coronal plane achieved with Jazz bands (group 2, N=55)

	Preop	**Postop** *(% correction)*	**F-up** *(% correction)*
Main curve	55°±9°	17°±8° *(70% ±13)*	20°±9° *(63% ±15)*
Cincinnati C. Index	---	1.6±0.9	1.5±1
Proximal curve	31°±8°	21°±7° *(31% ±18)*	23°±8° *(24.5% ±20)*
Distal curve	32°±11°	8°±6° *(76% ±17)*	9°±7° *(73% ±20)*
Iliolumbar angle	9°±6°	4°±4°	5°±3°
T1 tilt	5°±4°	8°±4°	8°±5°
Shoulder balance	3°±2°	3°±2°	2°±2°
Coronal balance (mm)	13±12	10±9	10±7

Table 5: Corrections in the sagittal plane achieved with Jazz bands (group 2, N=55)

	Preop	**Postop**	**F-up**
T1T12 kyphosis	29°±15°	29°±9°	37°±11°
T4T12 kyphosis	21°±15°	21°±8°	25°±8°
L1S1 lumbar lordosis	55°±13°	44°±11°	53°±10°
Number of patients with T4T12 kyphosis < 20°	27	22	15
Number of hypokyphotic patients (T4T12<10°)	8	0	0
Number of patients with thoracic lordosis	4	0	0
SVA (mm)	5±24	19±31	-3.5±26

Table 6: Comparison between groups in the frontal plane

	UC	Jazz	p
Main curve POC	72% ±12	70% ±13	0.3
PO Cincinnati index	1.8±1.6	1.6±0.9	0.2
Main curve POC at F-up	62.5% ±15	63% ±15	0.7
Cincinnati index at F-up	1.6±1.5	1.5±1.0	0.2

PO: postoperative
POC: postoperative correction

Table 7: Comparison between groups in the sagittal plane

	UC	Jazz	p
T1T12 kyphosis preop	32°±16	29°±15	0.29
T4T12 kyphosis preop	25°±17	21°±15	0.19
T1T12 kyphosis postop	33°±12	29°±9	0.08
T4T12 kyphosis postop	24°±10	21°±8	0.16
T1T12 kyphosis at F-up	45°±14	37°±11	0.07
T4T12 kyphosis at F-up	30°±11	25°±8	0.09

Figure 1: preoperative and postoperative radiographs of a Lenke 1 AIS treated by hybrid construct with Jazz bands at thoracic levels and bivertebral autostable claws as proximal anchor (supralaminar angled hooks and double pedicular hook).

Figure 2: preoperative and postoperative radiographs of a Lenke 1 AIS treated by hybrid construct with Jazz bands at thoracic levels and supralaminar angled hooks secured by 2 adjacent Jazz as proximal anchor.

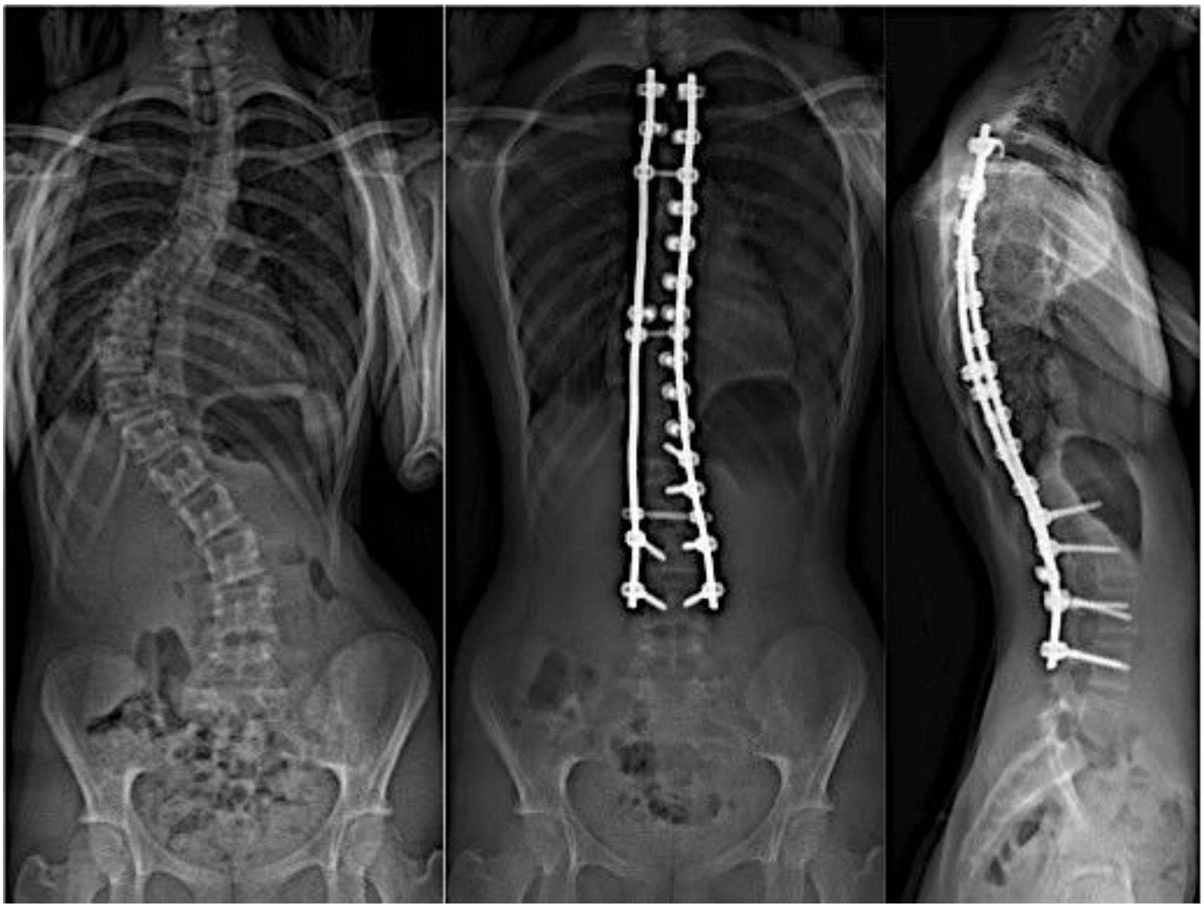
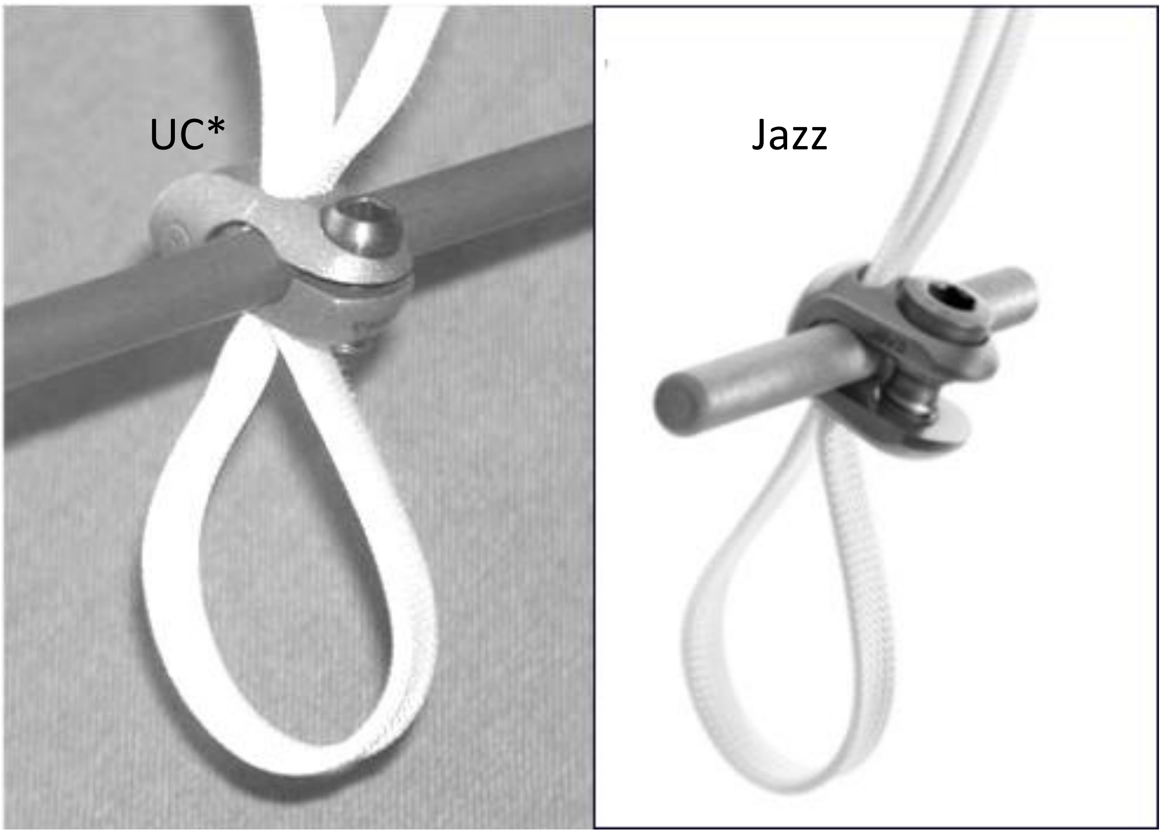
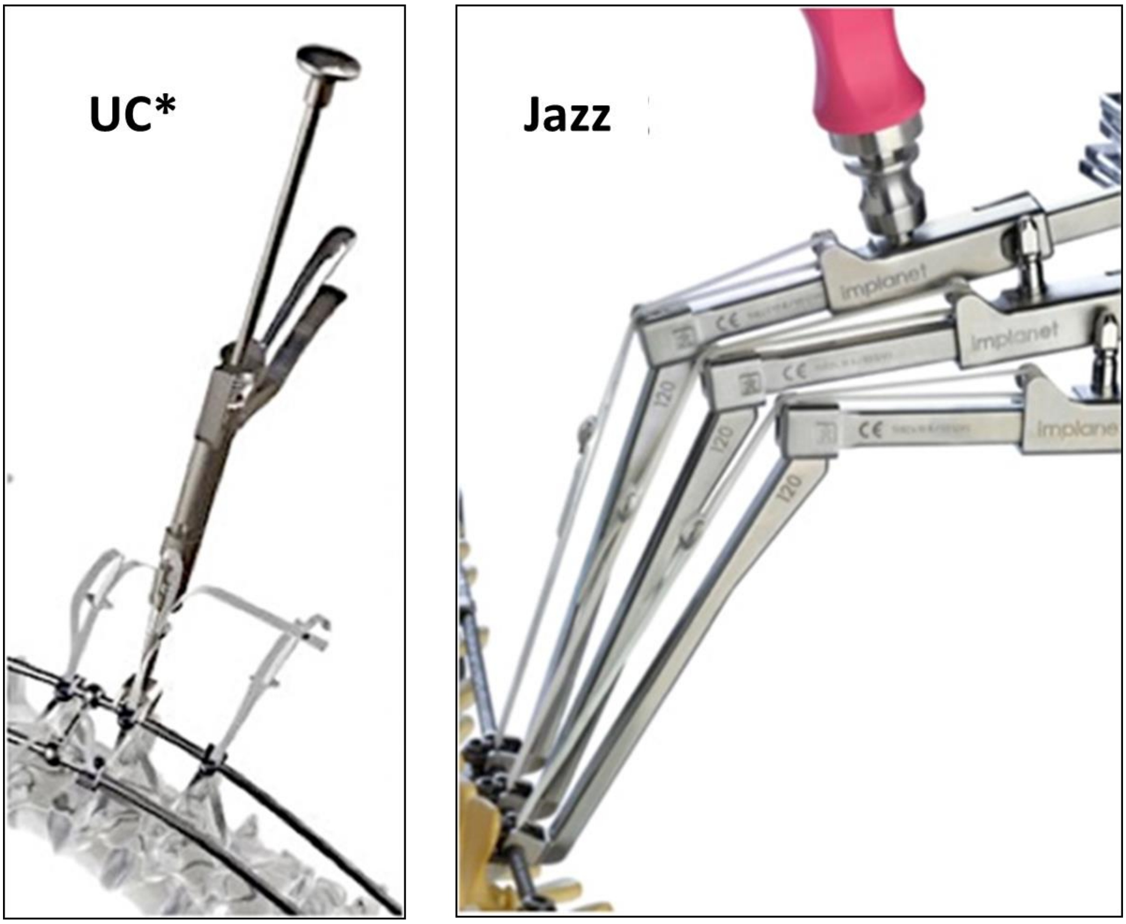


Figure 3: Comparison between Universal Clamp and Jazz bands.



*From Ref 6

Figure 4: Comparison of the tensioning tools of the UC and Jazz systems.



*From Ref 6

Figure 5: Cobb angle measurements of the main thoracic curve.

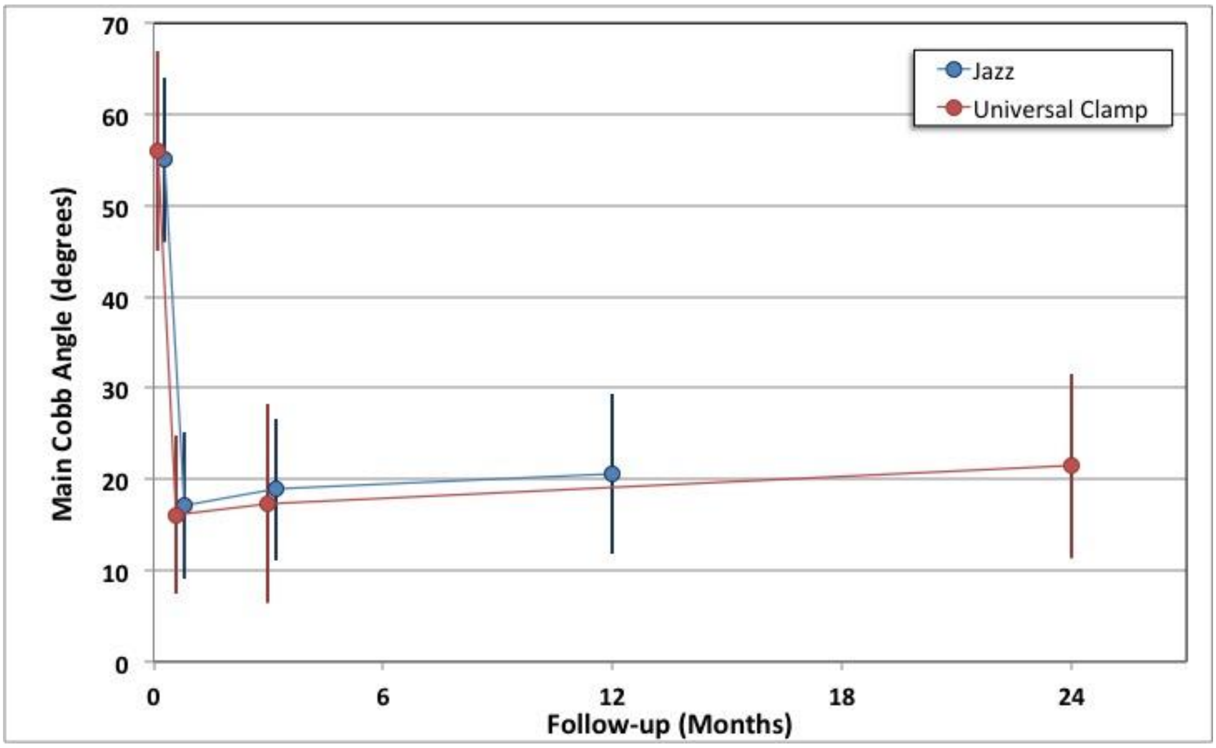


Figure 6: Example of a hypokyphotic Lenke 1 AIS, with a restored sagittal alignment postoperatively.

Figure 7: Sagittal T4T12 kyphosis measurements.