Version 03, February 2015 - 17 pages

Adolescent Idiopathic Scoliosis treated by posteromedial translation using Jazz sublaminar bands: results at minimum 1 year-follow-up

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White papers:

Part 1 – Results from Robert Debré Hospital

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Part 2 – Results from La Timone Hospital

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Introduction

The aim of surgical correction of adolescent idiopathic scoliosis (AIS) is to achieve a tridimensional correction of the deformity and to prevent progressive pathologic curvature in the unfused spine. As stressed by Winter et al.[1], 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 progression of the curves in the remaining unfused spine. In particular, restoring sufficient thoracic kyphosis should avoid inducing posterior sagittal imbalance and thus reduce the risk of progressive junctional kyphosis at the proximal extremity of the fused spine[2]. Correction of AIS has been reported with various systems. Since their description in 1995 by Suk et al.[3], 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 higher spinal implants charges (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[4, 5, 6].

In addition, the difficulty in thoracic screw placement has been recently emphasized in the concave dystrophic side of the deformity, within the periapical region, and at the upper thoracic spine[7, 8, 9]. Potential complications of thoracic pedicle screws include neurologic lesions, vascular injury, pleural tear, and increased radiation exposure during screw placement.

Since 2004, posteromedial translational correction and fusion using hybrid instrumentation with sublaminar bands has proved to achieve excellent 3D curve correction, with sagittal alignment restoration, while reducing operative time and radiation exposure[10, 11]. Recently, a novel sublaminar implant (Jazz, Implanet, Bordeaux, France) with a powerful dedicated reduction tool has been designed and developed for deformity surgery.

The purpose of this study was therefore to report our preliminary experience with the Jazz and assess the coronal and sagittal corrections obtained in AIS at minimum 1-year follow-up.

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 wires. The surface area of contact between the polyester band and a lamina is larger than that observed between a metallic wire and a 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 links the sublaminar band to the rod. The strength of the band-rod connection is equivalent to screw-rod connection, allowing conventional deformity correction maneuvers including translation, compression/ distraction, and *in situ* bending.

The Jazz polyester band contains a malleable metallic insert at one end to facilitate sublaminar insertion and two metallic square buckles 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 forceps. The tip of the band is then threaded through the Jazz connector next to the other end of the band. The free tip of the band is passed through the two square 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 forms an adjustable loop for the reduction tool. The buckles maintain the loop strongly, preventing any slippage of the band when tension is applied to the loop. Nevertheless, the buckles permit adjustment of the loop's length if necessary. Attention must be paid not to position the buckles 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 diameter, CoCr or Ti 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 connector of the Jazz is clipped on the rod using the dedicated tool, and the locking screw is loosely inserted to leave the band free to slip in the connector and to permit tension of the vertebrae toward the rod with the reduction tool. After any reduction maneuvers and optimal band tension is obtained, the Jazz is locked onto the rod with the screw. The loop of the band is removed from the reduction instrument and the excess band strands (including the malleable insert and the metal buckles) are cut and removed.

Materials and Methods (common for both centers)

Radiographic measurements

Low dose biplanar radiographs (EOS imaging, Paris, France) were obtained preoperatively, and at each visit as part of the routine work-up and follow-up[14]. 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.

The EOS system is a slot-scanning radiologic device consisting of two X-ray sources, allowing simultaneous acquisition of orthogonal images[15]. The sources are coupled to linear detectors that are based upon micromesh gaseous structure technology. The two source-detector pairs are positioned orthogonally, so the patient's anteroposterior and lateral images are generated line-by-line while the whole system is vertically translated. Scan time lasts from 6 to 10 seconds for a spine examination, depending on the patient's height.

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 appreciated 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, T1T12 and T4T12 thoracic kyphosis were measured, and lumbar lordosis was measured from the upper endplate of L1 to the upper endplate of S1.
As described by Vora et al.[16], the following ratios were determined:

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

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

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

With

PreCa = Preoperative erect Cobb angle

PoCa = Postoperative erect Cobb angle

SbCa = Supine bending Cobb angle

Statistical analysis

Paired-samples t tests were used to analyze differences between preoperative and postoperative curves. All statistical tests were 2-tailed, and a P value <0.05 was considered to be significant.

Part 1 – Robert Debré Hospital

Patients - Robert Debré Hospital

Following institutional review board approval, 20 patients operated for progressive AIS were prospectively included between December 2012 and July 2013. All patients were evaluated preoperatively, in the early postoperative period (within a week), at 3 months, and at 1-year postoperative. None of the patients had prior spinal surgery.

Operative procedures - Robert Debré Hospital

All patients underwent segmental posterior spinal correction and fusion using hybrid constructs, performed by one of the two senior surgeons. Fusion levels were selected following the same criteria during the entire study period[12]. 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 to L4), preferring monoaxial screws on the convex side and polyaxial screws on the concave side and at the lower instrumented level.

Thoracic levels were instrumented with sublaminar Jazz on the concave side and 1 sublaminar Jazz at the apex on the convex side. The two upper thoracic levels, located at the proximal end of the construct, were bilaterally instrumented with autostable claws, made of angled supralaminar hooks and pedicle hooks (ZimmerSpine, Bordeaux, France). Two additional Jazz were usually placed bilaterally at the adjacent distal level, under the autostable claws, in order to reduce the pull-out forces and protect the proximal anchors.

In all cases, 5.5 diameter Co-Cr rods were used.

Correction was performed at the thoracic level using posteromedial translation, 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 on the autostable claws and the distal pedicle screws to level the proximal vertebra, the shoulders, and the lower instrumented vertebra. At the end of the correction maneuvers, a final revisiting on screw blockers and Jazz locking screws was performed as previously described[13].

In addition, thoracoplasty was performed when the patient and/or caregiver expressed concern over the prominence of the rib hump deformity.

Results - Robert Debré Hospital

Demographic data and curve classification

Twenty consecutive patients (17 girls and 3 boys) were included. Mean age at operation was 15.8 years (+/- 2). There were 16 Lenke 1, 4 Lenke 3 and 2 Lenke 5. The Cobb angle of the main curve averaged 57° ± 12, with a mean flexibility of 53% ± 15 (Table 1).

According to Lenke's sagittal classification, 2 patients were hypokyphotic (<10°), 18 were normokyphotic (10-40°) and none were hyperkyphotic (>40°). However, the mean T4T12 kyphosis only averaged 21° ± 10, with 9 patients (45%) having a thoracic kyphosis less than 20°.

Nine patients (45%) had a frontal imbalance (T1-CSVL > 20mm) preoperatively.

Procedures and curve corrections

The average operative time was 196 ± 45 minutes. Intraoperative blood loss was 232 ± 182 ml. The number of instrumented levels averaged 13.6 ± 0.8. The mean number of Jazz bands used for correction was 7.3 (5 to 12). Six patients (30%) underwent additional thoracoplasty for cosmetic concern.

Postoperative corrections obtained in the frontal and sagittal planes are reported in tables 1 and 2, respectively. An example of postoperative reduction is presented in figure 1 (frontal plane) and figure 3 (sagittal plane). All curves were significantly improved after surgery in the coronal plane ($p<0.0001$) (Figure 2). The mean Cincinnati index of the main curve was 1.63 ± 1.0. Shoulder and frontal tilts were not significantly modified by the procedure, but only 30% of the patients had a postoperative shoulders tilt greater than 5° at 3 month follow-up. The global coronal balance was not significantly altered after surgery, but spontaneously improved between the first postoperative visit and the 3-month follow-up ($p=0.001$). Only three patients (15%) had a coronal imbalance > 20 mm at latest examination, but one of them had a lower limb discrepancy greater than 3 cm explaining the radiological frontal imbalance.

Thoracic sagittal alignment was maintained or restored in all patients, with no hypokyphosis reported at 1-year follow-up (Figure 4). In patients whose initial thoracic kyphosis was less than 10°, the gain in T4T12 kyphosis averaged 19°. The SVA was not significantly impacted by surgery ($p=0.11$), but the global sagittal balance was shifted by more than 10 mm posteriorly in 50% of the patients and anteriorly in 18%. At latest follow-up, 6 patients (30%) were considered "unbalanced" in the sagittal plane (i.e 20 mm < SVA < -20 mm), although physiological values of this parameter remain unclear in the literature.

Complications

No intraoperative lamina fracture occurred, but at least one of the Jazz bands broke during correction in 10 cases (50%), without significant clinical consequence as the same band was reused during surgery to achieve the correction. In particular, no significant change in the monitored somatosensory/motor-evoked potentials was recorded either during insertion of the Jazz sublaminar band or during correction maneuvers in 19 out of the 20 patients (95%). A transient significant change in the evoked potentials was recorded in one patient during posteromedial translation, but the patient woke up with no neurological deficit. One patient (5%) underwent revision surgery on the 10th postoperative day for early surgical site infection, with satisfactory outcomes after one surgical debridement followed by 6 weeks of antibiotics (including 15 days parenteral).

Evolution of instrumented curves during the first postoperative year

An example of scoliosis evolution up to 1 year follow-up is presented in figure 5.

The mean loss of correction between the third postoperative month and 1-year follow-up averaged 2.7° ± 2.6 for the main thoracic curve, 4.3° ± 5.1 for the proximal thoracic and 2.6° ± 2.5 for the lumbar curve (Figure 2). Although the correction rates of each curves were significantly reduced between the postoperative period and latest follow-up (average 7%), the loss of correction in degrees of the main curve remained relatively small (average 5°), and close to the angle measurement reliability reported in the literature (12).

The T4T12 and T1T12 kyphosis significantly increased during the postoperative year, mainly during the third postoperative month and latest follow-up (average 3° and 4°, respectively) (Figure 4).

One patient developed a radiological proximal junctional kyphosis during follow-up, without clinical impairment. Finally, one case of set screw loosening was observed on a monoaxial L4 screw, located at the distal end of a T2L4 construct, without loss of correction.

No case of pseudarthrosis was reported at 12-month follow-up and no patient required late revision.

Conclusion - Robert Debré Hospital

Results of this preliminary study confirm that posteromedial translation is an efficient technique to restore sagittal alignment in AIS. Jazz bands offer a satisfactory alternative to other sublaminar implants for hybrid constructs[17], with excellent radiological outcomes, low morbidity, and reduced operative time and blood loss. When CoCr rods are used for reduction, the average loss of correction in both frontal and sagittal planes ranges between 2 and 3° during the first postoperative year, which is consistent with previous reports in the literature with all-screw constructs[18]. Although many surgeons currently consider the use of

thoracic pedicle screws as optimal care in AIS[19], results of the present study show that Jazz sublaminar bands should be considered in hypokyphotic patients. The low density of implants required to obtain an efficient long-lasting correction (average 7 Jazz, 1.1 bands per instrumented level) should also be considered in the global cost of AIS surgery.

Tables and Figures – Robert Debré Hospital

	Preop	Postop	3 months	1 year
Main curve ***(Improvement %)***	57° ± 12°	14° ± 8° *(76% ± 10)*	16° ± 7° *(72% ± 10)*	19° ± 7° *(67% ± 10)*
Cincinnati C. Index	---	1.63 ± 1.00	1.51 ± 0.80	1.40 ± 0.72
Proximal curve ***(Improvement %)***	28° ± 9°	15° ± 5° *(46% ± 21)*	17° ± 6° *(40% ±23)*	20° ± 6° *(27% ±24)*
Distal curve ***(Improvement %)***	37° ± 14°	8° ± 8° *(81% ± 16)*	8° ± 9° *(81% ± 16)*	10° ± 8° *(72% ± 19)*
Iliolumbar angle	10° ± 6°	4° ± 4°	4° ± 3°	2° ± 2°
T1 tilt	5° ± 4°	5° ± 3°	5° ± 3°	5° ± 3°
Shoulder balance	3° ± 1°	4° ± 3°	3° ± 2°	2° ± 2°
Coronal balance (mm)	17 ± 14	17 ± 12	13 ± 10	9 ± 9

Table 1: Corrections in the coronal plane achieved with the Jazz hybrid constructs (N=20).

	Preop	Postop	3 months	1 year
T4-T12 kyphosis	21° ± 9°	22° ± 5°	24° ± 5°	28° ± 5°
T1-T12 kyphosis	27°± 12°	29° ± 9°	31° ± 7°	35° ± 9°
Lumbar lordosis	56° ± 11°	49° ± 9°	51° ± 7°	52° ± 11°
Number of patients with T4T12 kyphosis < 20°	9	8	3	0
Number of hypokyphotic patients (<=10°)	3	0	0	0

Table 2: Corrections in the sagittal plane achieved with the Jazz hybrid constructs (N=20).

Figure 1: Preoperative and postoperative anteroposterior radiographs of a 15 years old girl with Lenke 3 AIS, treated by posteromedial translation using 7 sublaminar Jazz.

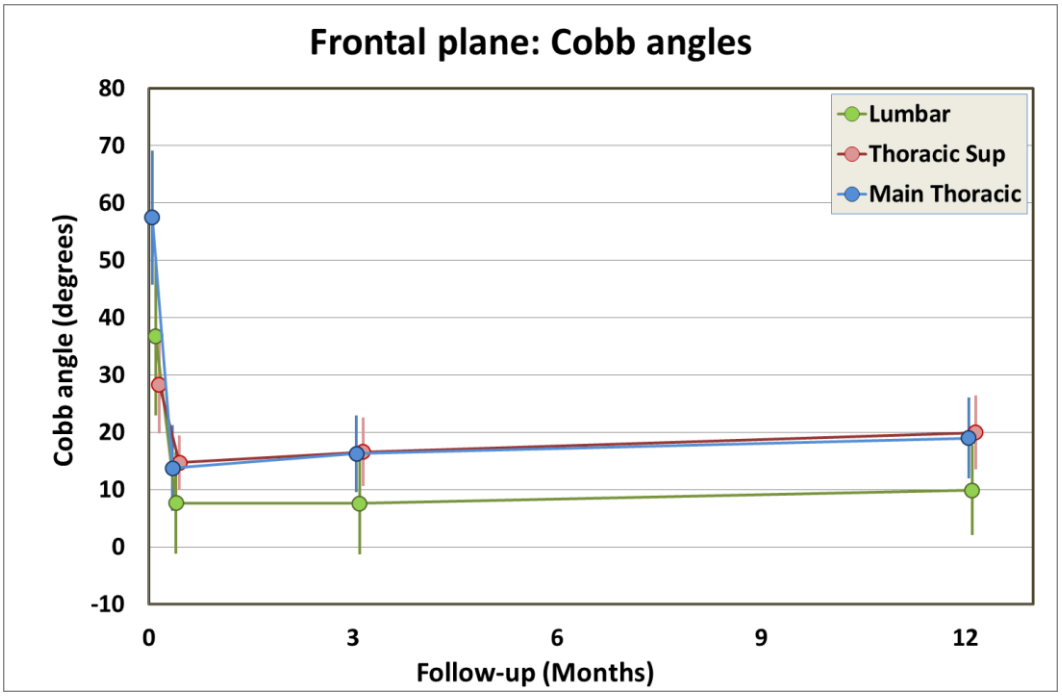

Figure 2: Evolution of the thoracic and lumbar curves.

Figure 3: Preoperative and postoperative mediolateral radiographs of the patient presented in figure 1.

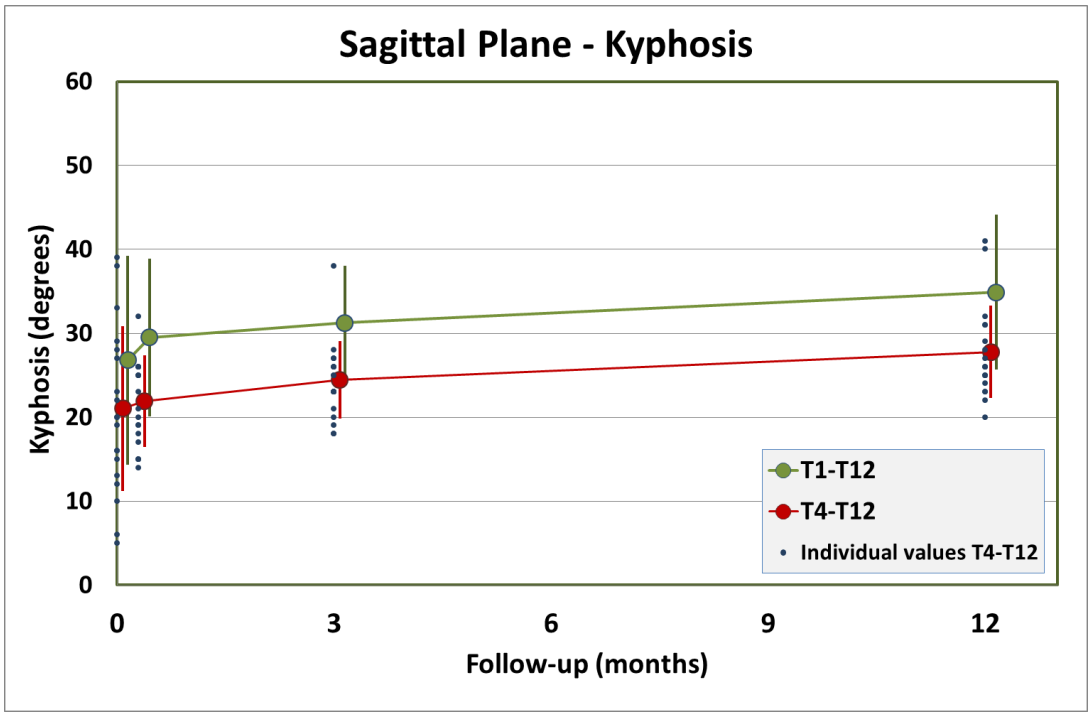

Figure 4: Kyphosis evolution (T4-T12 and T1-T12 measurements)

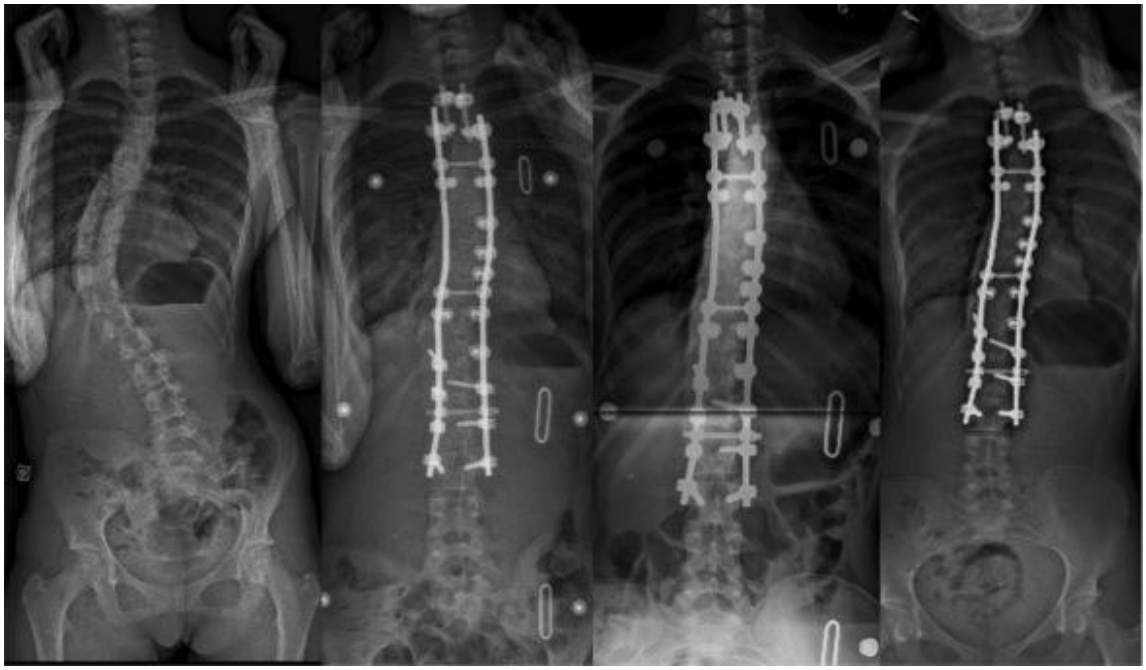

Figure 5: Preoperative, immediate postoperative, 3 month follow-up and 14 month follow-up posteroanterior radiographs showing the stability of the frontal correction obtained with sublaminar bands

Part 2 – La Timone Hospital

Operative procedures – La Timone Hospital

All patients underwent segmental posterior spinal correction and fusion using hybrid constructs, performed by two senior surgeons. During the posterior procedures, spinal cord function was monitored by means of somatosensory/motor-evoked potentials. In all cases, pedicle screws were placed at the distal extremity of the curve.

Thoracic levels were instrumented with sublaminar Jazz on the concave side. The 2 upper thoracic levels, located at the proximal end of the construct, were bilaterally instrumented with autostable hooks (Medtronic).

In all cases, 5.5 diameter Ti6Al4V rods were used.

Correction was performed at the thoracic level using posteromedial translation, while derotation, compression/distraction and in situ contouring were used on lumbar levels.

Results – La Timone Hospital

Demographic data and curve classification

Twenty-four patients (20 girls and 4 boys) were included. Mean age at operation was 15.1 years (+/-2). There were 17 Lenke 1, 1 Lenke 2, 4 Lenke 3 and 2 Lenke 6. The cobb angle of the main curve averaged 60.5° (+/- 13°), with a mean flexibility of 50% (+/- 22%) (Table 1).

According to Lenke's sagittal classification, 4 patients was hypokyphotic (< 10°), 18 were normokyphotic (10°-40°) and 2 were hyperkyphotic (>40°). However, the mean T4-T12 kyphosis averaged 22.3° (+/- 13°).

Six patients (25%) had a frontal imbalance (T1-CSVL > 20 mm) preoperatively, and 4 (17%) had a posterior SVA.

Procedures and curve corrections

The number of instrumented levels averaged 13.3 (+/-1). The mean number of Jazz bands used for correction was 6.85 (5 to 9).

Postoperative corrections obtained in the frontal and sagittal planes are reported in tables 3 and 4, respectively.

All curves were significantly improved after surgery in the coronal plane ($p < 0.0001$) (figures 6, 7 and 8). The mean Cincinnati Index of the main curve was 1.71 (+/-0.8). Correlation was found between the frontal cobb angle reduction and the preoperative flexibility ($r^2 = 0.7$).
Shoulder and frontal tilts were significantly modified by the procedure ($p = 0.0006$; $p = 0.0003$ respectively), two patients (8%) had a postoperative shoulder tilt greater than 5° at one year follow-up against five in preoperative (21%).

The global coronal balance improved after surgery (mean T1-CSVL shifted from 15.8 mm preoperatively to 7.5 mm at last follow-up) and was statistically significant at one year follow-up ($p = 0.005$). Only one patient (4%) had a coronal imbalance (> 20 mm) at one year follow-up.

Thoracic sagittal alignment was restored in all patients, with no hypokyphosis reported at last follow-up (figure 9, 10).
Mean T4-T12 kyphosis shifted from 22.3° preoperatively, to 33.3° at 1.5 month postoperatively, to 37.7° at one year postoperatively.
T4-T12 kyphosis was significantly restored in postoperative ($p = 1.75$ E-07) and at one year follow-up ($p = 2.5$ E-09). Even between 1.5 month and one year, this kyphosis continues to improve significantly ($p = 6$ E-05).

The lumbar lordosis was not significantly impacted by surgery ($p = 0.11$) at 1.5 month postoperatively, but it was restored significantly at one year follow-up ($p = 0.0001$).

The SVA was not significantly impacted by surgery ($p = 0.37$) at 1.5 month postoperatively, but it was restored significantly at one year follow-up ($p = 0.003$), the global sagittal balance was shifted by more than 15 mm posteriorly with a mean SVA at one year follow-up of -3.2 mm.

Complications

No intraoperative lamina fracture occurred, but at least one of the Jazz bands broke during correction in the first cases, without significant clinical consequence. The fracture of the band was explained in most of the cases by a conflict between the band and the stabilizing buckle, leading to a tear of the band after high tension forces were applied. This technical mistake was therefore corrected after the learning curve of the technique. No significant change in the monitored somatosensory/motor-evoked potentials was recorded either during insertion of the Jazz sublaminar band or during correction maneuvers.

One patient exhibited a non-significant loss of correction (2°) in the frontal plane between 1.5 month postoperatively and one year follow-up probably due to asymptomatic rupture of the proximal autostable hook clip which did not need revision surgery.

None of the patients developed neither proximal nor distal junctional kyphosis.

Conclusion - La Timone Hospital

Results of this preliminary study confirm that posteromedial translation is an efficient technique to restore sagittal alignment in AIS. Jazz bands offer a satisfactory alternative to other sublaminar implants for hybrid constructs, with excellent radiological outcomes, low morbidity, and **continous improvement in kyphosis correction between postoperative period and one year follow-up**.

Tables and Figures – La Timone Hospital

	Preop	Postop (1.5 month)	Postop (1 year)
Main curve *(Improvement %)*	60.5° ± 13° -	17.9° ± 9° *(71% ± 12)*	18.6° ± 10° *(70% ± 13)*
Cincinnati C. Index	-	1.71 ± 0.8	1.55 ± 0.75
T1 tilt	-0.5° ± 4°	2.6° ± 3.4°	3.2° ± 3.4°
Shoulder balance	-1.7° ± 4°	1.9° ± 2.2°	2.2° ± 2.6°
Coronal balance (mm)	15.8 ± 13.3	11.3 ± 7.7	7.5 ± 6.5

Table 3: Corrections in the coronal plane achieved with the Jazz hybrid constructs (N=24).

	Preop	Postop (1.5 month)	Postop (1 year)
T1T12 kyphosis	27.5° ± 12°	39.8° ± 10°	45.9° ± 10°
T4T12 kyphosis	22.3° ± 13°	33.3° ± 8°	37.7° ± 8°
Lumbar lordosis	50.2° ± 9°	53.1° ± 10°	57.7° ± 10°
% of patients with sagittal imbalance	38%	38%	33%
Sagittal balance (mm)	13.8 ± 24	9 ± 24	-3.2 ± 23

Table 4: Corrections in the sagittal plane achieved with the Jazz hybrid constructs (N=24).

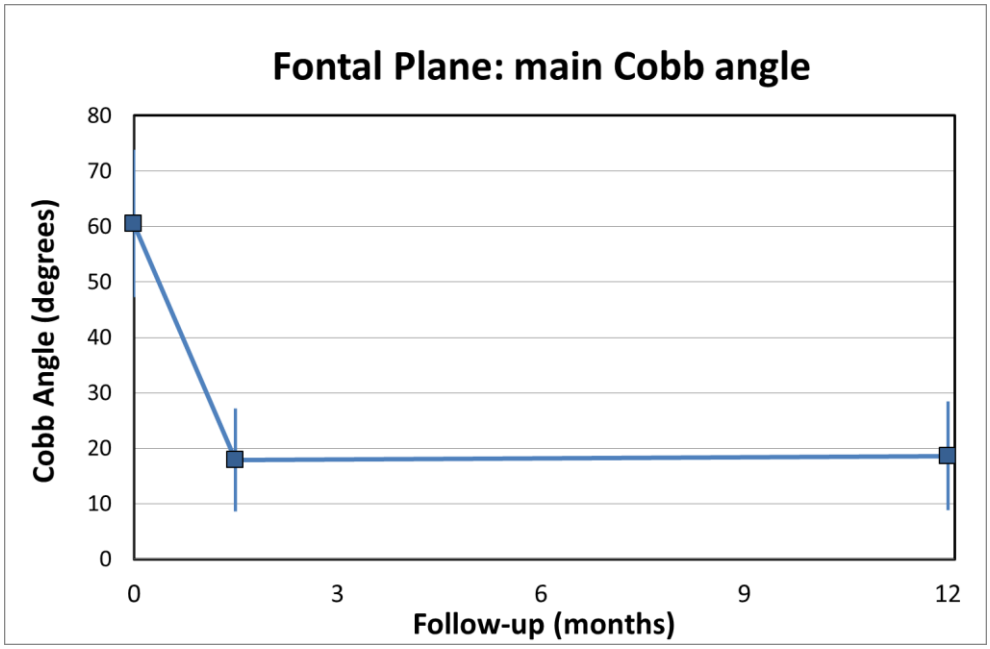

Figure 6: Evolution of the main thoracic curve.

Figure 7: Preoperative and postoperative anteroposterior radiographs of a 13 years old girl with Lenke 3 AIS, treated by posteromedial translation using 5 sublaminar Jazz.

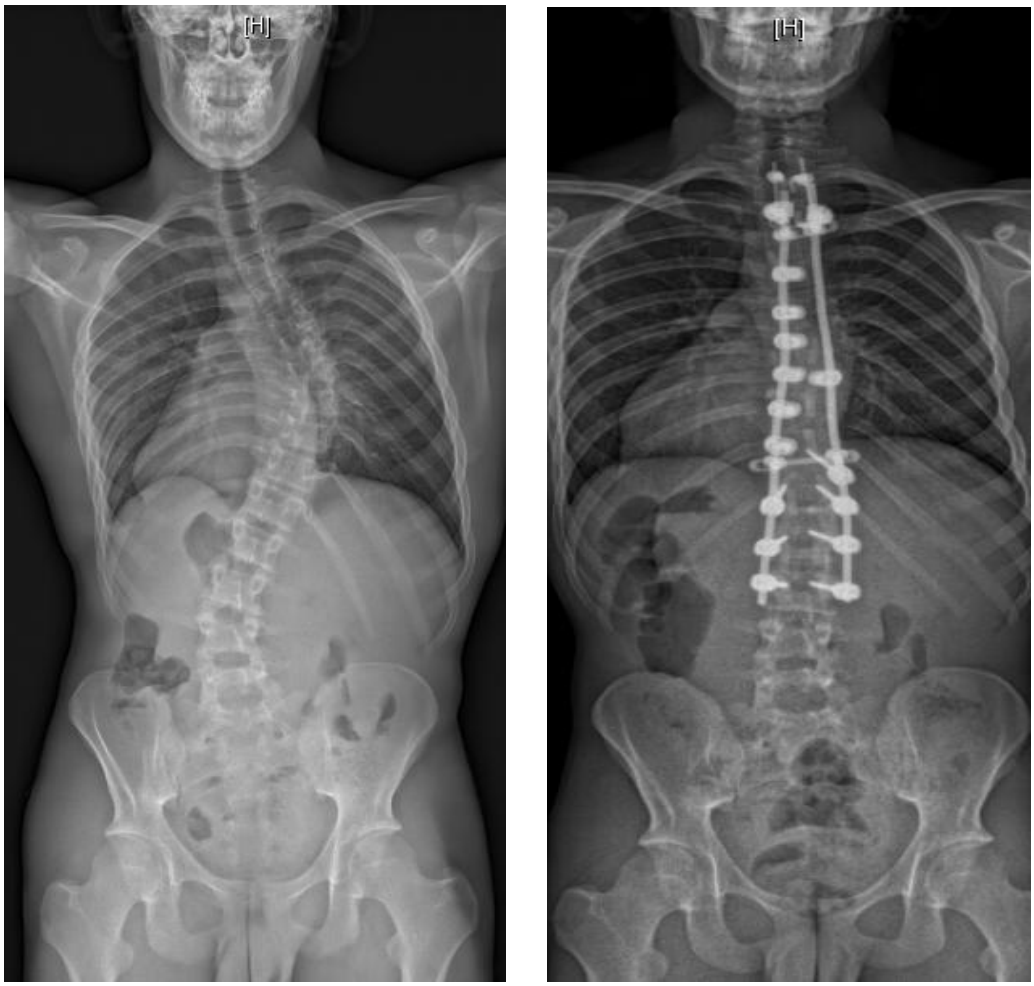

Figure 8: Preoperative and postoperative anteroposterior radiographs of an 18 years old boy with Lenke 1 AIS, treated by posteromedial translation using 7 sublaminar Jazz.

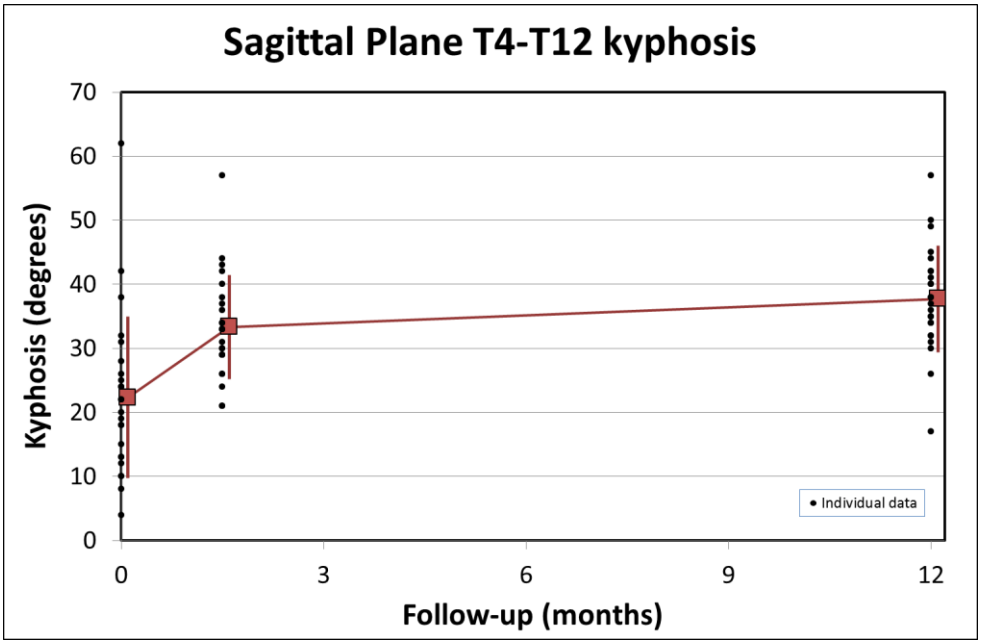

Figure 9: Kyphosis evolution (T4-T12)

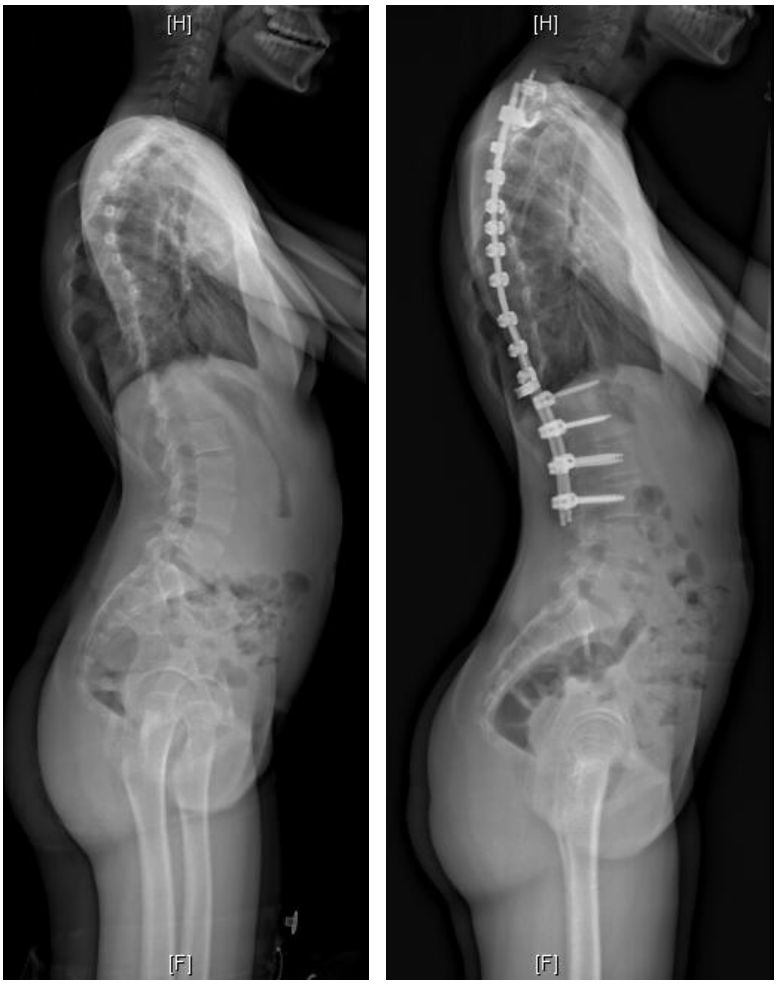

Figure 10: Preoperative and postoperative lateral radiographs of a 13 years old girl with Lenke 2 AIS, showing the restoration of the spinal sagittal alignment, with correction of the preoperative anterior imbalance.

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