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Hybrid Screw/Jazz Constructs In Degenerative Lumbar Scoliosis Surgery: Preliminary Results

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Introduction

The purpose of this study was to evaluate the safety and efficacy of a new polyester sub-laminar band-based hybrid construct used in the surgical treatment of adult degenerative lumbar scoliosis and to compare the early results of this technique to published clinical results of conventional all screw constructs.

Adult deformity surgery in older patients is becoming an increasingly common and requested procedure. Average life expectancy is rising with an increased expectation for extended quality of life. The global trend toward aging societies is well established, with large proportions of older people with disabilities. However, despite improved technical capabilities, complications remain a common occurrence and a significant concern in adult deformity surgery.

Although many reports exist in the literature, the cohorts analyzed are often heterogeneous and the actual prevalence of complications varies widely (1–20). Several published studies have reported a complication rate of greater than 40%. A meta-analysis published by Yadla *et al* (12) , who reviewed 3299 patients, found a 41.2% complication rate. In a recent multicenter retrospective series of 306 primary lumbar adult or degenerative scoliosis patients older than 50, Charosky *et al* (13) have shown an overall complication rate of 39%. Daubs *et al* (11), in their series of 46 complex adult deformity patients aged 60 years or older, presented a complication rate of 37%. In patients older than 70, Lonergan *et al* (18) reported 95% of patients experiencing a complication of some type.

Several risk factors have been identified through the literature: patient age (2–4,8,11), duration of the surgery and blood loss (11,15,19,20), ASA Physical Status, number of instrumented segments (8,13), fusion to the sacrum (7,11,13,21), pedicle subtraction

osteotomy (11,13), pelvic tilt above 26° (13) and comorbidities (9,10,13,17,19,20).

In this respect, osteoporosis is the most frequently associated comorbidity, affecting up to 50% of women older than 65. Chin *et al* (22) investigated a series of 759 South Korean patients requiring spine surgery and showed that 38% of these patients were osteoporotic (33% when kyphoplasties or vertebroplasties were excluded). Vertebral fractures after instrumentation, pseudarthroses and hardware failure secondary to poor fixation (screw pullout or loosening) in osteoporotic bone are the most common causes for mechanical failure.

Charosky *et al* (13) have reported a 19% rate of mechanical complications requiring reoperation. In a retrospective study of 38 patients older than 65 with five-level fusions, DeWald *et al* (10) reported that early complications were pedicle and compression fractures (13%) and late complications were pseudarthroses with instrumentation failure (11%), adjacent-level disc degeneration with herniation (4%), and progressive junctional kyphosis (26%) as a result of compression fractures in some instances. As a consequence of pseudarthroses, the instrumentation that is designed to provide temporary support during fusion experiences a longer than expected duration of stress and loading, thereby increasing the probability for failure. In this respect, Daubs *et al* (11) have observed a 19.5% reoperation rate due to pseudarthrosis. In a series of 29 patients (mean age 66), Burneikiene *et al* (14), have reported 35% hardware complications, 14% surgical technique related complications (28% of these complications requiring reoperation) and 17% pseudarthrosis, 60% of these pseudarthroses resulting in a hardware failure and subsequent reoperation. In a series of 89 patients published in 2009, Mok reported a lower reoperation rate (14%) due to mechanical failure (3.4% pseudarthroses, 5.6% adjacent segment problems, 4.4% implant

failures).

In order to reduce the risk of mechanical failure in patients demonstrating low bone quality, multiple techniques to improve fixation in the spine have been developed. These include increasing the number of instrumented segments, sublaminar wiring, cement augmentation of pedicle screw fixation, pediculolaminar hook fixation, conical screws, hydroxyapatite-coated screws, and new implant designs such as expandable screws (23).

To more evenly distribute the mechanical stresses at the bone/implant interface, increasing the length of the construct has been proposed. However, this method results in additional perioperative morbidity related to the increased time of surgery and blood loss and subsequent risk of complications (8,11,13,15).

Regarding increasing the number of fixation points using hooks or wires, Tan *et al* (24), in an in-vitro study have shown that augmentation with laminar hooks, sublaminar wires, or calcium phosphate cement reduced pedicle screw motion and that the deleterious effect of low bone mineral density was offset by the addition of sublaminar wires.

However, the use of stainless steel wires has been associated with complications including wire breakage and neurological damage ranging from transient to permanent deficits. Neurological deficits seem to occur more often at the time of insertion and prior to securing the wire-rod construct. To address some of the short comings of thin metallic wires, new polymeric sublaminar fixation was proposed in the mid-80s (25). Specifically, these implants allowed easier placement, reduced the mechanical stresses at the lamina/band interface and offered smaller implant sizes (26). In a series of 30 patients, Takahata *et al* (27) compared flexible ultra-high molecular weight polyethylene tape to stainless steel wires in the treatment of adolescent idiopathic scoliosis. In an in-vitro biomechanical study, Hamasaki *et*

al (28) evaluated the potential of polyethylene tape for pedicle screw augmentation in the treatment of the osteoporotic lumbar spine. These authors have shown that a construct augmented with polyethylene tape provide firmer fixation of the screws and a stiffer pedicle screw/rod construct than the same construct without tape augmentation. In addition, due to a larger lamina/band interface, Murakami *et al* (29) have shown, in an in-vitro laminar cut-through test, that the cut-through force for polyethylene tape was higher than that of either a steel wire or cable. Furthermore, even when performing a decortication of the lamina, the decorticated lamina equipped with a PE band had a higher cut-through force compared to an intact lamina tested with either wires or cable.

Other authors have used new types of implants made of a polyethylene terephthalate (PET) band attached to the rod via a metallic jaw in the treatment of adolescent scoliosis (30,31) and in thoracolumbar spinal trauma (32).

In the treatment of adult deformity, the role of these implants is threefold: similarly to sublaminar wires and polyethylene tape, the PET band can be used to (i) secure the spine to the rod, (ii) protect adjacent screws; and (iii) reduce a spinal deformity, using a specific instrument, without overstressing the bone/screw interface.

Based on these concepts, a new PET band based implant, the Jazz system® (Implanet, Bordeaux, France), has been studied to treat degenerative scoliosis in old-aged patients.

Device

The Jazz System is part of a posterior spinal fixation system that is designed to provide a stable interface between spinal constructs and the rod. The Jazz System consists of the three components: a polyester (polyethylene-terephthalate) braid, a titanium alloy connector and a locking screw.

The multi-purpose 5.5 mm connector, shown in Figure 1, is made of Ti6Al4V titanium alloy. This connector is used to secure the spine to the rod through lamina, transverse or spinous processes from T1 to L5.

The connector is fixed to the rod by a conical locking screw (Figure 1 and 2).

Figure 1: Connector

The polyester (polyethylene-terephthalate) braided band, 4 mm in width and 700 mm in length, allows tightening of the device around the bony structures of the spine (Figure 2). The band has a malleable stainless steel strip attached at its tubular extremity. A stainless steel buckle is attached at the other end. The malleable strip is designed to facilitate passage of the polyester band around bony structures during implantation. The buckle is used to connect the tips of the braid in order to make a loop and to perform the tensioning of the

band, using a specific instrument. These stainless steel elements are removed after the device has been finally secured.

Figure 2: Polyester braided band

Surgical Technique

Patients were treated under general anesthesia in the prone position on a Mayfield spine table. A standard, open, posterior midline approach to the lumbar spine was made. Spine preparation was conventional: arthrectomy, trans- or interpedicular osteotomy was performed according to the patient's anatomy and pathology.

Canal preparation was performed at all levels on which a Jazz implant would be later implanted. In order to facilitate the polyester band insertion along the dural sac, the Ligamentum Flavum was resected above and below the lamina. When necessary, in order to avoid any interaction of the band with the Dura during the insertion, the cephalad part of the lamina was partially decorticated.

Two to four screws were placed at each extremity of the construct. An additional screw was implanted at the apex of the convexity of the deformity. Titanium rods were then contoured using rod benders. One rod was placed in the screw heads of the concave side without

tightening. Then, several (from one to three) Jazz implants were clipped evenly onto the rod, the number of implants depending on the type and length of the deformity. For each implant, the polyester band was first inserted under the lamina using the malleable stainless steel strip and then slipped through the metallic connector. The locking screw of each connector was put in place without tightening and the buckle was used to close the band loop. After these preparation steps, using a specific reduction tool, sequential tension was applied on each band and the deformity was slowly reduced. The final thickness of the band in tension under the lamina is one millimeter.

Once the vertebrae were brought in contact with the metallic rod of the concave side and the screws on the convex side were aligned, the second rod was inserted in the screw heads. The two rods were then locked and the Jazz screw connectors were final tightened. The unused portions of the polyester bands were cut and, if necessary, transverse connectors were added to the construct.

When the correction of the deformity was important and/or the bone quality was inadequate due to a very low BMD, additional Jazz implants were added at the extremities of the construct to protect the screw fixation.

Intraoperative neurophysiological monitoring was performed systematically. In all cases, Cell Saver was used and prophylactic antibiotic treatment according to the recommendations of SFAR (French Society of Anesthesiology) was performed.

Patient Population

Following institutional review board approval, 21 consecutive patients operated in a single center for degenerative scoliosis between 2012 and 2013 were prospectively included and

followed for 15.8 ± 6.4 months (min 6, max 28). Preoperatively, and at each follow-up, all patients had a neurological assessment, full spine frontal and lateral x-rays and an ODI questionnaire was completed.

There were 18 females (86%) and 3 males (14%). The mean age at surgery was 68.2 ± 7.9 years (min 52, max 85).

All patients in this series were treated for lumbar and/or thoracolumbar junction pain. All patients exhibited a frontal lumbar deformation frequently associated with a sagittal disequilibrium (16 patients, 76%) and, in some cases, degenerative stenosis (8, 38%) or spondylolisthesis (2, 10%). Correction of frontal and sagittal deformities was always treated with a fusion construct; length was related to the deformity but also to surgical limitations due to the population age and poor bone quality necessitating limited surgery duration and blood loss. In addition to the construct, additional surgical steps were performed when other pathologies were present: laminectomies for lumbar stenosis in 4 cases or inter or transpedicular osteotomies (7) to correct the sagittal balance. In 4 of these 7 osteotomy cases, a TLIF cage was also added.

In term of physical status, 16 patients were rated as having a grade 2 (76%) and 4 as having a grade 3 (19%) ASA Physical Status. In addition, 15 patients (71%) demonstrated a T-score below or equal to -2.5.

Six patients (29%) had a reoperation secondary to a previous spine surgery.

Results

Mean operative time was 176 ± 43 minutes (min 90, max 240) and mean blood loss was 788 ± 444 ml (min 300, max 1700). On average, 7.4 ± 2.4 levels (min 4, max 14) were fused and 7 ± 1 screws and 4 ± 1 sub laminar implants were implanted per patient (Figures 3, 4).

Preoperative ODI was 52.5 ± 17.3 (min 16, max 82). At the last follow-up, all patients were doing well, the mean ODI was 31.2 ± 16.6 and significantly lower than the preoperative value ($p<0.001$). The mean ODI improvement between the preoperative evaluation and last follow-up was 21.4 ± 17.3.

The mean preoperative main Cobb angle was 23.6 ± 10.0 degrees, which was significantly reduced to 9.5 ± 4.8 degrees (54% improvement at the last follow-up, $p<0.0001$).

The C7 sagittal plumbline was 12.2 ± 8.0 cm preoperatively, which was reduced to 4.4 ± 8.5 cm at the last follow-up ($p<0.001$).

Intraoperative complications

No peri-operative complications were observed, including neurological complication related to the passage of the band, implant or lamina failure or implant loosening.

Early and late complications

Three psychiatric complications (14%) were observed postoperatively that resolved spontaneously. One patient (5%) had an infection that was treated by lavage.

At the latest follow-up, 2 patients had died of causes unrelated to the surgery (lung cancer, myocardial infarction).

Four mechanical failures (19%) were observed: 2 (9.5%) vertebral fractures (T11) above the construct and 2 (9.5%) pull-outs of a caudal screw. The patients with vertebral fractures were not reoperated. The distal screw pull-outs were reoperated.

Finally, one patient was reoperated due a persistent pain at the level of an iliac screw that was removed.

Discussion

Intraoperative data and complications

On average, our series demonstrates a shorter surgery time (3h) and less blood loss (788ml) when compared to the literature (Table 1).

Obviously, these sublaminar polyester implants do not replace the commonly associated surgical procedures used for reduction and fusion with all screw constructs: arthrectomies, inter or transpedicular osteotomies. In our series, the percentage of patients with additional procedures is quite high (86%). In addition, the number of fused segments (mean: 7.4) is in the higher range of what has been reported in the literature. For this reason, both parameters cannot be responsible for the lower surgery time and blood loss observed in this study. In this respect, when adjusted for the number of fused levels, our series shows that the operating time and the blood loss per fused level is about 1/3 of the average of the mean values cited in Table 1.

One may hypothesize that (i) the lower number of implants used, (ii) the reduced number of bony screw wounds and (iii) the ease and speed of deformity reduction may explain in part the decreased the surgery duration and the limited associated blood loss observed in this study.

Blood loss, surgery duration and number of fused levels are in some way correlated (11,15,20), but blood loss appears to be one of the major factors influencing postoperative complications (15,20,24). Pellisé has shown in a large series of more than 200 patients (20)

that, for an Estimated Blood Loss >50 % (EBL given as % of an estimated blood volume of 75 ml/kg for men, 65 ml/kg for women), the risk of major complications was four-fold higher in patients with ASA grade II than in those with ASA grade I. In the present study, the average EBL expressed in the same unit was 18% ± 10% for patients with ASA grade II, with all values below 26% except one (45%), thus always lower than the 50% threshold described by Pellisé. Minimized blood loss and duration of surgery in this old-aged and fragile population is certainly of major importance when considering the postoperative results and complication rates. In addition, in these type of patients and using a hybrid screw/sublaminar band construct, blood loss and surgery time being significantly reduced; it would be conceivable to extend the number of fused segments in order to optimize the patient's sagittal balance without increasing the risk of later blood loss-related complications.

Table 1	**Comments**	**# of pat.**	**# of fused levels**		**Age**		**Blood loss (ml)**			**Op time (minutes)**		
			Mean	St-dev.	Mean	St-dev.	Mean	St-dev.	Mean/ fused levels	Mean	St-dev.	Mean/ fused levels
This series		21	7.7	2.4	68.2	7.9	788	444	102	176	41	23
Cho (15)		47	4.7	2.2	66.1	5.2	2106	1083	448	197	60	42
Daubs (11)	Patients over 60	46	9.1	3.2	66.8	6.2	2053	1339	226	605	213	66
Wu (16)		26	3.2	1.2	64.2	7.2	1678	829	524	300	64	94
Tang (19)	Patients with complications	21	4.2	0.8	66.8	5.5	1000	218	238	296	51	70
	Patients without complications	84	3.7	1.0	65.0	5.1	850	275	230	218	47	59
Pellise (20)		201	na	na	48.0	19.7	1546	1100	na	298	141	na
Lonergan (18)	Patients over 70	20	10.7	na	76.6	na	1500	na	140	480	na	45
total		445										
mean (literature)			5.9		64.8		1533		301	342		63
mean weighed by the number of patients (literature)			5.5		60.6		1577		296	327		61

In this population, peri-operative screw pull-out or construct failure is always a cause of concern and protecting the screws from high mechanical loads during the reduction of the deformity is of prime importance. The sublaminar polyester implant and its reduction tool allowed safe and effective reduction without peri or early postoperative mechanical complications. As the reduction maneuvers were performed by bringing the deformed spine toward the rods while the rods were already in place in the screw heads, rather than forcing the rods toward the screw heads, the risk of screw pull-out during the reduction was certainly reduced and may explain the absence of perioperative mechanical failures observed in this series. In addition, in this study, reduction loads directly applied to the lamina did not induce any peri or post-operative lamina fracture. Coe *et al* (33) has demonstrated in a biomechanical study that pull-out load to failure was not correlated to bone mineral density when the mechanical loads were directly applied to the lamina, while in contrast, it was highly correlated when the loads were applied to pedicular screws. In this respect, some of the high risk patients evaluated herein would have been excluded if an all screw construct-based surgical procedure had been required.

Immediate postoperative complications (3, 14%)

Three immediate complications (14%) have been reported. All these complications were psychiatric and resolved spontaneously. This relatively high percentage can be explained by the numerous comorbidities encountered in these three patients: the first patient was severely underweight (BMI=16), with a history of previous osteoporotic fractures and treatment for psychosis. The second patient, demonstrating a psychiatric collapse, was obese (BMI=33), and osteoporotic with a preexisting psychiatric condition. Finally, the third patient demonstrated self-limiting space-time disorientation. This patient was 81 year-old,

very fragile and demonstrated severe osteoporosis.

Early postoperative complications (4, 20%)

- One wound infection (5%) was reported in this series and was successfully treated with an incision, debridement and antibiotic therapy.

This infection rate was well within the range of the data (4% to 9%) reported in the literature (11,13,15–18) and indicates that the use of sublaminar polyester bands did not seem to be a source of an increased infection rate.

- Two vertebral fractures above the construct (T11) have been documented (10%). Both patients had psychiatric complications postoperatively as described above (cases 1 and 3). Both patients were severely osteoporotic, a comorbidity that may be the main cause for these fractures. However, in the two cases, in order to reduce the duration of the surgery that would have resulted in an increased blood loss and risk of complications, it was decided to shorten the construct. It is clear, retrospectively, that a longer construct insuring a more optimal sagittal balance should have been used to reduce the risk of vertebral fractures. These fractures did not progress and did not require additional surgery. These 2 patients are doing well at the last follow-up (16 and 24 months).

- One mechanical failure of the caudal part of the construct (5%) was reoperated 3 months after the index surgery. This patient had only 2 sacral screws and 2 Jazz to insure the distal stability of the construct. To assume that these four implants alone could insure mechanical stability of the construct was overly optimistic. The construct was extended and iliac screws were added. The patient is doing well 8 months after the surgery with an ODI of 16. This is the only case in which a part of a construct failed while the screws were protected by Jazz

implants.

Late complications (2, 10%)

- One mechanical failure of the caudal part of the construct (5%) occurred 10 months after the first surgery. Once again, this patient belonged to the group demonstrating an early psychiatric complication (case 2). Although the numerous comorbidities (obesity, psychiatric history and osteoporosis) may be responsible in part of the failure, one may suspect that the insufficient kyphosis correction performed in such a heavy patient may have also contributed to this late complication. In addition, this patient was operated in the early phase of the product learning curve, and protection of sacral screws with polyester bands was not performed.
- One reoperation was performed for a painful iliac screw that was replaced (5%).

Overall, 9 complications occurred in 6 patients (29%). These complications required 4 reoperations (19%), 2 of which (10%) were related to mechanical failures.

These values have to be put into perspective and be compared to similar series from the literature in which:

- percentage of overall complications ranged from 30% to 68% (10,11,13,15,18,20),
- rate of overall reoperations ranged from 15% to 33% (11,15,17)
- rate of reoperation for mechanical failures ranged from 13% to 26% (11,13,17).

In term of mechanical failure, postoperative mechanical loads applied to the screw/bone interface in patients demonstrating low vertebral bone quality are responsible for long term screw loosening and mechanical failures of the construct. The addition of polyester bands to the construct in the vicinity of screws that are at risk of being subjected to high cyclic

mechanical loading is certainly the reason for the low rate of pull-out of the screws protected with a Jazz (1 case, 5%), and appears to confirm the results obtained by Hamasaki *et al* (28) in their in-vitro biomechanical study. In addition, there was no failure of a polyester sublaminar band.

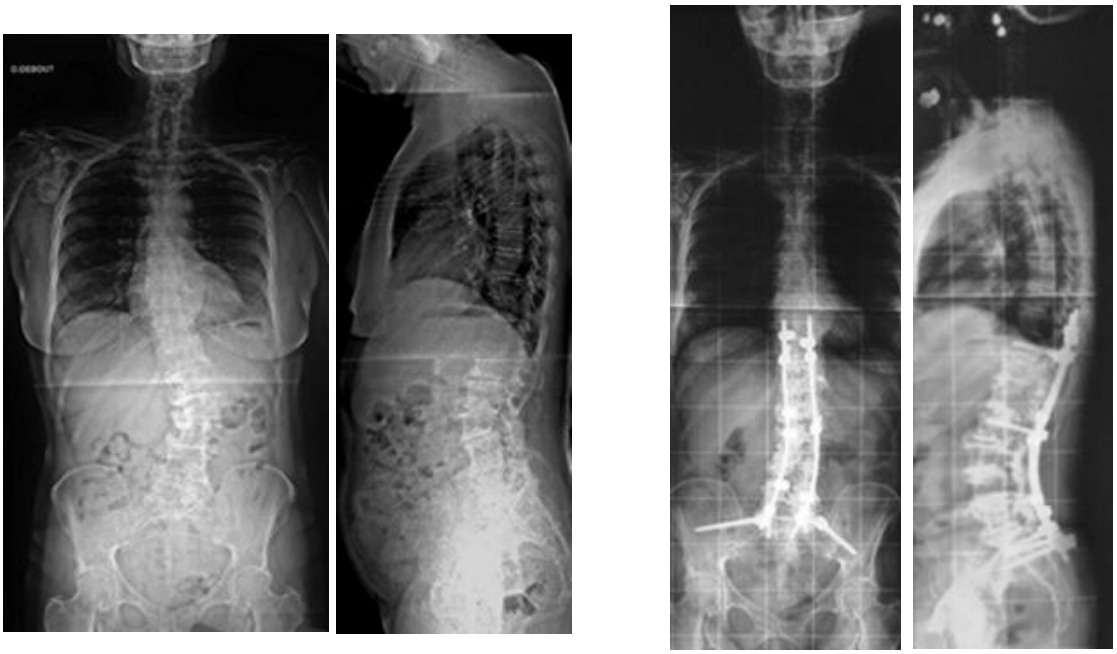
Conclusion

Morbidity is a major factor affecting the results of degenerative spinal deformity surgery. Parameters such as surgery duration, blood loss, number of fused levels, associated osteotomies, patient's age and comorbidities are the main factors influencing the rate of complications associated with this type of surgery.

In this limited series of old aged and fragile patients, Jazz / screw hybrid constructs have shown their efficacy in reducing spinal deformities while significantly reducing the duration of surgery, blood loss and the number of implants. This may explain the relatively low complication rate encountered to date.

This preliminary study, which continues, has several limitations: the number of patients is low and the mean follow-up is only 16 months. In addition, the true rate of late mechanical failures related to pseudarthroses cannot be fully evaluated at this follow-up and will require a longer-term follow up.

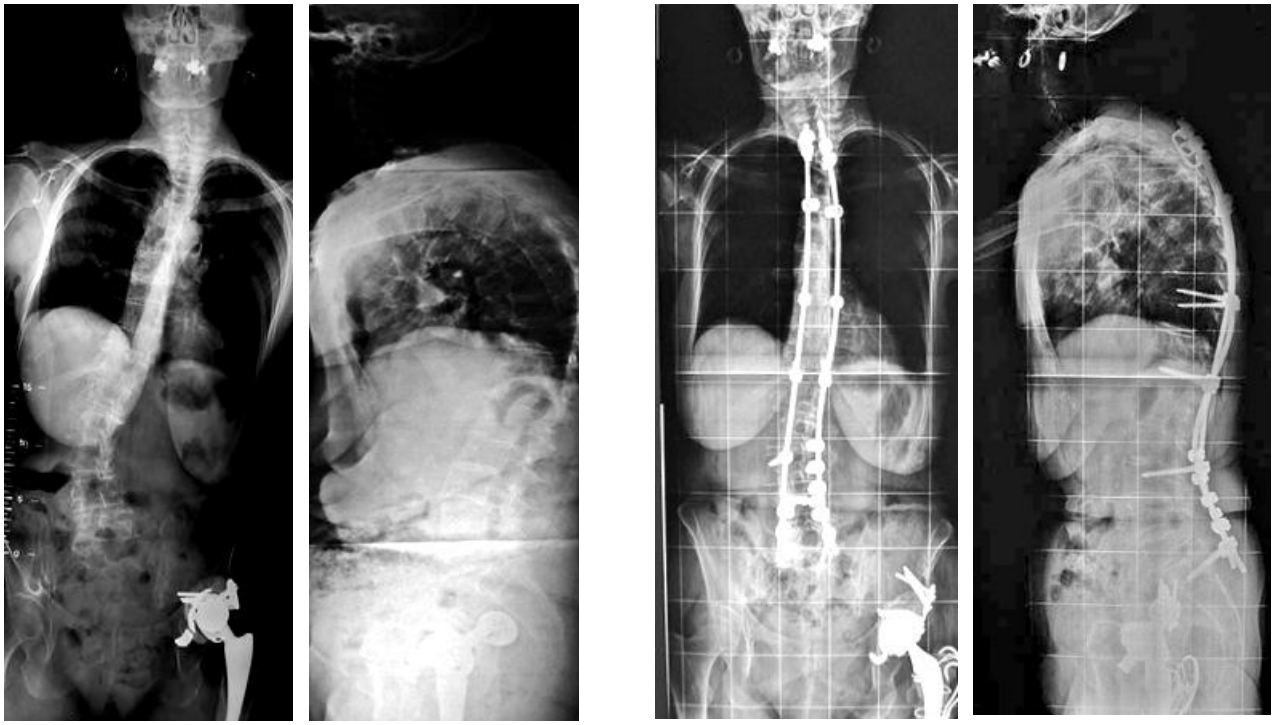
However, this study has validated the short term safety and efficacy of polyester sublaminar band-based hybrid constructs in degenerative deformity surgery.



Preoperative X-rays **8 Month Follow-up**

Figure 3

This 68 year old female patient was seen in medical consultation for chronic lumbar pain and progressing frontal disequilibrium (preoperative ODI= 38, Cobb angle= 28 degrees and C7 sagittal plumbline = 3.9 cm. At 8 months follow-up, the patient was doing well (ODI= 14) with a 16 degree Cobb angle and C7 sagittal offset= 0.5 cm. No radiological evolution was observed.



Preoperative X-rays **8 Month Follow-up**

Figure 4

This 72 year old osteoporotic female patient was seen in medical consultation with a progressive frontal and sagittal deformity (preoperative Cobb angle: 29 degrees). During the medical examination, the spine was found very stiff and the deformity was irreducible. In addition, this patient had total hip prosthesis on the left side that was loose but asymptomatic.

A T5-S1 arthrodesis was performed. Two Jazz were added at the upper part of the construct and 5 Jazz were implanted in the lumbar part of the construct to protect the distal screws from pull-out. No problem was reported in the immediate follow-up. 45 days after the surgery, the patient developed left lower limb pain directly related to the loosening of the hip prosthesis. Four months later the hip prosthesis was reoperated and the pain was relieved. At 8 month follow-up, the patient was doing well with a 5 degree Cobb angle and no radiological evolution was observed.

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