Orthopaedics & Traumatology: Surgery & Research 105 (2019) 1149–1155

Contents lists available at ScienceDirect

Orthopaedics & Traumatology: Surgery & Research

journal homepage: www.elsevier.com

Review article

Correction of adult spinal deformity with a minimally invasive fusionless bipolar construct: Preliminary results

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ARTICLE INFO

Article history:
Received 13 February 2018
Accepted 1st February 2019

Keywords:
Adult spinal deformity
Scoliosis
Percutaneous fixation
Fusionless spinal surgery
Spinal instrumentation

ABSTRACT

Introduction: Fusion in adult spinal deformity has a high rate of complications. Fusionless constructs in children and percutaneous fixation in adults are now being used routinely. The aim of this study was to evaluate the preliminary results of a minimally invasive fusionless surgical technique used to correct adult spinal deformity.

Materials and methods: Thirty-eight patients with an average age of 45 years (15–76) with major spinal deformity requiring extensive arthrodesis from the upper thoracic region to the pelvis were operated consecutively and followed prospectively. Two hooks were implanted at the top and two iliosacral screws at the bottom. Two large rods connected by dominos to two small rods joined the upper hooks to the lower screws. The surgical data (operative time and bleeding), the radiological findings (Cobb angle, sagittal parameters, C7-plumbline AP and lateral), the complication rate and the morbidity were evaluated at the last follow-up visit.

Results: The primary curvature was reduced by 40% from a mean of 58.5° (26–146) to 35.2° (3–109) ($p < 0.001$). A clear decrease in operating time (270min) and blood loss (50cc/level) were observed. The length of hospitalization averaged 18 days (6–66), including an 8–15 day long preoperative traction period for 11 patients. We found 7 infectious complications, 11 early mechanical complications and one case of paraplegia due to severe kyphoscoliosis.

Conclusion: The corrections obtained are comparable to those reported in the literature for standard constructs. Most patients had an uneventful postoperative course. The early complications observed led us to very carefully select the indications. Long-term follow-up is essential.

1. Introduction

The most commonly used surgical technique in major adult spinal deformity is open fusion. This technique requires full exposure of the operated spine and in adults has a high rate of complications, especially mechanical ones [1–4]. In addition, it has a long recovery period for patients that are increasingly older when operated.

Several observations and findings have led us to adopt an innovative surgical technique for treating adult spinal deformity.

First, using a graft increases the length of the surgery, increases blood loss and requires the entire spinal column to be exposed. Placing long, very rigid constructs with multiple implants causes stress peaks in certain areas: lumbosacral area, areas where rods are bent significantly, which is often necessary when a rod is being passed through several implants. Bone ankylosis is difficult to achieve because it must extend to the entire construct, without any continuity solution, in adults whose osteogenic potential is much less than in children (1.4% nonunion reported in children, 6.3% in adults) [5]. Moreover, even a continuous graft can become deformed, and in itself does not ensure a lasting result.

Also, fusionless spine surgery is now a standard procedure in adults: percutaneous fixation of vertebral fractures [6,7] or secondary tumors [8], flexible instrumentation to prevent the development of junctional syndrome in cases of degenerative disc disease [9–12].

Lastly, fusionless spine surgery is now a standard procedure for treating scoliosis in children when the child must be operated

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https://doi.org/10.1016/j.otsr.2019.02.015
1877-0568/

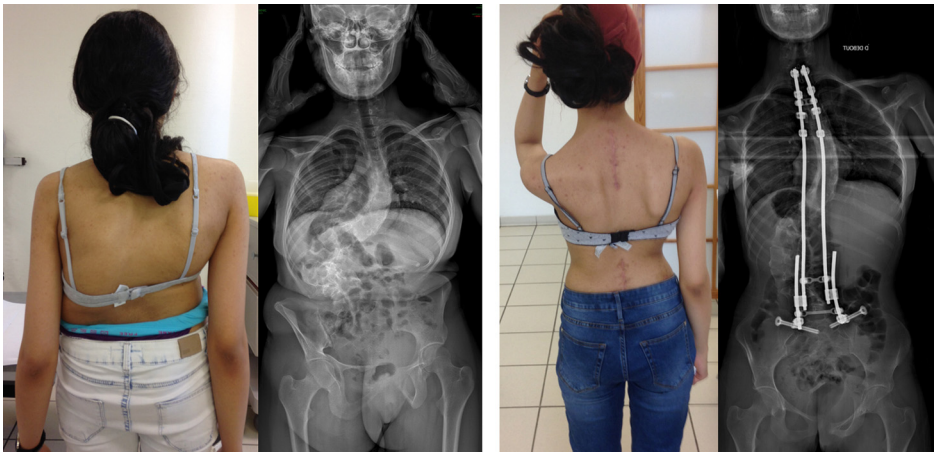

Fig. 1. Clinical findings and AP X-rays in the preoperative and postoperative period.

before the end of growth [13]. These solid, two-rod constructs are no longer protected by corsets since rod failure is much rarer given the more solid fixation. The bipolar constructs used no longer cross the apex of the curvature, which is difficult to access, but are limited to one approach and solid fixation at the extremities [13,14]. A recent study of the Growing Study Group [15] showed it was unnecessary to carry out an additional procedure to fuse the spine; they found the spine becomes stiffer with instrumentation alone and that adding a graft at the end of the growth period was not beneficial. This concurs with other observations that scoliosis is not better corrected with a final surgical fusion procedure [16]. Surgery for adult degenerative scoliosis can also be done without fusion [10,17–20]: some teams use metal or PEEK rods of variable stiffness. Recent techniques combining anterior grafting with a cage and a posterior percutaneous construct going beyond the fusion zone means that a large part of the instrumented spine does not receive a graft. Here again, the results are good with the goal of reducing the morbidity of this surgery.

Reducing the size of the incisions is an important focus: minimally invasive procedures have been described for scoliosis [14,21–26]. The desire to reduce the morbidity associated with surgical treatment of adult spinal deformity led us to develop a fusionless bipolar construct for these indications. The aim of this study was to report the preliminary results with this technique.

2. Material and methods

This was a prospective, single-center continuous study. The primary objective was to evaluate the correction achieved with metal instrumentation by a minimally invasive technique with bipolar construct and iliosacral screws (EUROS®), without graft-based fusion in adults. The secondary objectives were to evaluate the blood loss, operative time, length of postoperative stay, functional outcomes at the longest follow-up, complication rate and surgical revision rate. The study was approved by our institutional review board (IRB: 00001072).

2.1. Inclusion criteria

All patients with greater than 20° spinal deformity in the frontal or sagittal plane requiring extended correction of the superior thoracic spine down to the pelvis were included after providing informed consent. There were no limitations on the etiology of the deformity.

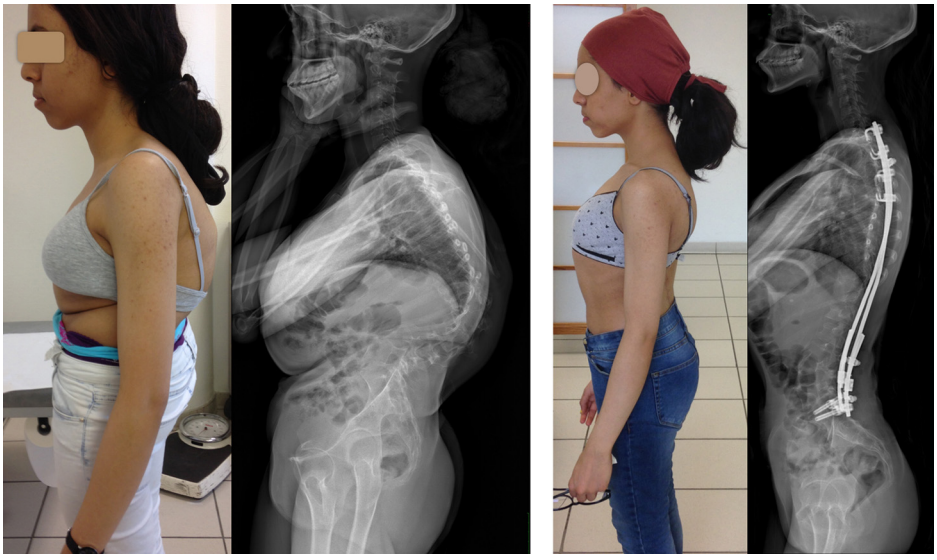

Fig. 2. Clinical findings and lateral X-rays in the preoperative and postoperative period.

2.2. Exclusion criteria

Minors or patients who refused to participate were not included, nor were patients for whom the instrumentation did not extend to the pelvis.

2.3. Patients

Forty-eight patients were enrolled: 22 men and 26 women with a mean age of 44.8 years (15–76 years). The mean body mass index (BMI) of the enrolled patients was 21.9 (12–33). The patients were operated for various indications: 18 with cerebral palsy (CP), 21 with idiopathic scoliosis, 4 with degenerative scoliosis and 5 with deformity in the context of Parkinson's disease. These patients had a major spinal deformity with a mean primary curvature of 58.5° (26–146).

2.4. Surgical technique

First, patients with greater than 70° non-neurological scoliosis underwent a 15-day long traction treatment (day and night) using halo-gravity traction.

The first incision was made in the lower lumbar area and two transmuscular approaches were made in order to insert the iliosacral screws and their connectors. A second incision was made in the upper portion of the thoracic spine where hooks were implanted to act as two pediculolaminar clamps on either side. Cobalt-chrome rods were inserted under the fascia to join the upper hooks to the lower connectors with placement of a long rod and short rod joined by a domino. Rod curving, lever maneuver with lowering of rods in the lower connectors, distraction, compression and bending in situ were used to rebalance each patient's spine. The final construct was stabilized with three or four transverse linking devices. These devices were introduced in the standard manner from the upper portion and transmuscular to the lower portion to join the two approaches. No additional incisions were needed.

The iliosacral screws were implanted using a navigation system (O-Arm, Medtronic, Sofamor, Broomfield, CO). An X-ray image was taken with the O-Arm during the procedure to evaluate the balance and correction, allowing adjustments to be made as needed.

2.5. Analysis and data collection

Anonymized data were collected in the KEOPS database (SMAIO®, Lyon, France), including radiographic data obtained on whole-body EOS images with the patient standing when possible; otherwise, views of the entire spine were taken with the patient supine. The latter were also analyzed with the KEOPS software. The data were collected by an independent rater and the radiographs measured by an independent rater who had not participated in the surgical procedures.

2.6. Data collected

Standard demographic data were collected (age, sex, BMI) along with data related to the nature of the spine deformity and indication.

The following surgical data were collected: whether or not an associated release procedure was performed, operative time and blood loss were evaluated using the formula described by Rosencher et al. [27], the number of types of complications (infection, mechanical, neurological) along with any surgical revisions.

The usual preoperative and postoperative radiographic variables were measured: angle of primary curvature (Cobb angle for frontal deformity and kyphosis measured from the upper vertebra to the lower vertebra for predominant anterior imbalances), incidence and pelvic tilt, lumbar lordosis, thoracic kyphosis, spinal vertical angle (SVA), spinosacral angle (SSA), spinopelvic angle (SPA), frontal stability (plumb line from the midpoint of the C7 vertebral body, down to the sacrum–frontal offset).

Lastly, a functional evaluation was done postoperatively using the Algoplus scale (score 0 to 5) [28] for patients with verbal communication challenges (18 CP patients) and a visual analog scale (VAS 0 to 10) was used for the other 30 patients. At the last follow-up visit, a three-part outcome score (good, average, poor) was determined based on the intake of analgesics (occasional = 0, frequency = 1), the sagittal and frontal balance (relative to plumb line from the C7 vertebral body down to the sacrum in the frontal plane and to the posterior edge of the S1 endplate on a lateral view: less than 2cm = 0, more than 2cm = 1) and whether unresolved mechanical complications were present (= 1) or not (= 0). A "good result" was assigned when the sum of these three items was 0, an "average result" when the sum was equal to 1 and a "poor result" when the sum was equal to 2 or 3. When the patient had appropriate communication ability and the 6-month follow-up visit was reached, the SRS-30 score was used.

2.7. Statistical analysis

The statistical analysis was carried out with SPSS 18.0 software (IBM Corp., Armonk NY). The pre- and postoperative data were compared using Student's t-test after confirming the data were normally distributed using the Shapiro-Wilk test. The results were considered statistically significant when the p value was less than 0.05.

3. Results

3.1. Surgery

The average operative time was 270 minutes (180–420). The intraoperative blood loss averaged 845cc (171–2309) or 50cc per level. Of the 32 operated patients, 5 also underwent a laminectomy. Ten patients had previously undergone spine surgery: 4 cases of simple laminectomy, 2 cases of localized lumbar fusion, 3 cases of extended fusion and 1 patient with Pial arteriovenous fistula who had previous undergone three surgeries.

3.2. Functional outcomes

The mean length of hospital stay was 18 days (6–66). This hospital stay included the 8–15 days of preoperative traction in 11 patients. For the patients who underwent preoperative traction, the total length of hospital stay was 32 days (22–66), while it was 14 days (6–60) for the patients who did not undergo traction. This mean value is strongly impacted by the length of stay by the CP patients: 19.2 days (9–60). If we consider only the idiopathic scoliosis cases, the mean length of stay was 10.5 days (6–15).

The postoperative pain level on VAS (Day 1 to 3) was collected in 30 patients. The mean value was 3 (0–8). The Algoplus scale was used in 18 CP patients. The mean value was 2/5 (0–4).

The mean follow-up was 9 months (range 1–22). At the final follow-up visit, the result was deemed good in 37 cases, average in 8 cases and poor in 3 cases. The 6-month follow-up visit was reached for 27 patients, 19 of which had a degenerative or idiopathic indication. The SRS-30 score was recorded in 16 of these patients. It averaged 2.7 preoperatively and 3.6 at the 6-month follow-up.

3.3. Radiological outcomes

The angle of the primary curvature in the postoperative period was 36° (3–109) which was a mean correction of 40%. In the frontal

Table 1
Radiological data.

	Preoperative[a]	Postoperative[a]	Last follow-up[a]	p[b]
Sagittal				
Kyphosis	41 (24.7/1–132)	34.7 (11.6/7–65)	37.5 (18.1/7–88)	0.382
Lordosis	36.5 (19.9/− 10–67)	40.7 (14.7/12–82)	38.8 (13.9/17–78)	0.344
Incidence	53.5 (14.1/25–79)	54.8 (13.5/23–84)	55.5 (14.1/25–85)	0.03
Pelvic tilt	20.5 (10/0–39)	19.1 (9.7/1–39)	20.1 (10.8/2–43)	0.279
SVA (mm)	67.2 (66.4/− 58–306)	24.8 (38.3/− 52–125)	41.8 (38.5/− 37–129)	0.006
SSA	116.1 (18.3/73–151)	127.9 (12.5/108–167)	124.9 (12.5/92–155)	0.003
SPA	152.5 (17.3/111–190)	163.1 (14.5/139–197)	159.5 (16.4/135–195)	0.035
Frontal				
Cobb angle, primary curvature	58.5 (35.5/9–146)	35.2 (21.6/3–109)	37.9 (22.2/0–101)	< 0.001
Frontal offset (mm)	35 (32.8/4–157)	20 (17.3/0–95)	25.9 (22.8/0–96)	0.09

[a] Mean (SD/min–max).
[b] Comparison of preoperative data with data at last follow-up.

plane, the C7 offset was improved by an average of 9% (− 3% to 96%) going from 35 to 20mm. In the sagittal plane, the C7 offset (SVA) averaged 67mm preoperatively and 25mm postoperatively. The spinopelvic angle (SPA) was also improved, going from an average of 152° preoperatively to 163° postoperatively (Figs. 1 and 2).

All the radiological data are given in Table 1.

3.4. Complications and surgical revisions

There were no medical complications during the patients' hospital stay. The complications that occurred later on were placed in three categories: infection, mechanical, neurological. They are summarized in Table 2.

There were 7 surgical site infections (14.6%). This is a relatively high number, especially in the neurological indications since 5 patients had CP (27.7% for this subgroup of patients). The rate was 6.7% for the other indications. All patients who suffered an infection underwent surgical revision; all had a good outcome without hardware removal.

There were 11 mechanical complications in the early postoperative period: 1 case of upper hook pull-out, 5 cases of iliosacral screw disconnection, 2 cases of iliosacral screw cut-out and 3 cases of rod breakage. All of these complications led to surgical revision. There were no mechanical complications in the CP patients. The BMI in patients who suffered a mechanical complication was 25.2 versus 20.9 for those who did not.

There were two intraoperative complications: one neurological complication in a patient treated for major kyphoscoliosis who suffered paraplegia upon set-up. This extremely serious complication does not appear to be directly attributable to the method. The other complication was a dural breach occurring during placement of the reference frame needed for navigation.

In all, there were 17 surgical revisions in 14 patients; one patient required two revisions and one patient required three. Thus, the surgical revision rate was 29%.

4. Discussion

This study reports the preliminary results of an innovative surgical technique for major adult spinal deformity. We will discuss every aspect of these findings relative to the literature.

In terms of the correction obtained, the percentage improvement is slightly greater than recent published studies in this field (Table 3) [29–37]. However, it is difficult to compare our study to other studies because they solely focus on idiopathic scoliosis. In the context of the deformities in our patients, the primary goal is restoring overall balance. This goal was achieved, except for certain patients in which the correction was beyond the preoperative plan. These patients had a rigid spine deformity in kyphosis in the lumbar segment, requiring an osteotomy procedure, for which the combination with the type of fixation in this article should be discussed. These observations led us to refine the indications for this method: the best correction was achieved with the most physiological restoration of the profile in patients with a deformity in which the top is located in the thoracic or thoracolumbar region. In fact, the mean SPA correction achieved (10.5°) is evidence of the effectiveness of this technique for restoring sagittal balance.

Evaluating the blood loss allows us to estimate the morbidity related to various surgical techniques. This information is reported in certain studies with an average of 60 patients (19–132). The wide majority of these studies focused on idiopathic scoliosis in adolescents. The mean blood loss reported was 1585cc (738–2578), or 134cc (57–204) per level [38–48]. Our technique reduces by 67% the intraoperative blood loss when compared to published data (Table 4). In terms of operative time, Bourghli et al. recently reported a case series of transpedicular osteotomy of which the operative time averaged 270 minutes in the early cases (34 cases) for constructs involving an average of 11 vertebrae [49]. For our study, the constructs extended from T1 to the pelvis, which corresponds to constructs of more than 15 vertebrae for the same operative time. Relative to the length of the construct, the operative time is much less.

Table 2
Detail of complications by category.

Complications	Cerebral palsy ($n = 18$)	Other indications ($n = 30$)	Total ($n = 48$)
Neurological	1	0	1
Infection	5	2	7
Mechanical			11
Pull-out of superior hooks	0	1	1
Movement of iliosacral screw	0	2	2
Disassembly of lower connector	0	5	5
Rod breakage	0	3	3

Table 3
Correction reported in the main published comparable series.

Authors	Year	*n*	Type of curvature	Cobb angle correction (mean)
Kim et al. [28]	2006	58	Scoliosis (mean of 60°)	70%
Fang et al. [29]	2010	48	Scoliosis	74%
Hwang et al. [30]	2011	57	Scoliosis (< 90° and flexible > 20%)	69%
Yang et al. [31]	2011	58	Scoliosis (mean of 54°)	68%
Qiu et al. [32]	2011	48	Scoliosis	69%
Min et al. [33]	2013	48	Scoliosis	63%
Huang et al. [34]	2014	93	Scoliosis	60%
Shen et al. [35]	2015	28	Scoliosis (mean > 70°)	61%
Gecen et al. [36]	2016	38	Scoliosis (mean of 58°)	87%
Current study	2019	48	Scoliosis (mean of 58.5°)	40%

Table 4
Comparison of bleeding rates in main published series.

Authors	Year	*n*	Mean age	Drug given	Bleeding (cc)	Number of levels	Blood loss per level
Letts et al. [37]	1998	30	14		2359	15	163
Neilipovitz et al. [38]	2001	40	14	TXA	2578	15	178
Cole et al. [39]	2003	44	13	TXA	738	13	57
Pineda et al. [40]	2004	36	14	TXA	1554	12	129
Sethna et al. [41]	2005	44	14	TXA	1658	13	123
Tayyab et al. [42]	2008	82	44	Aprotinin	1719	11	157
Joseph et al. [43]	2008	19	17		875	8	109
Xu et al. [45]	2012	40	19	TXA	2338	13	180
Khurana et al. [44]	2012	73	26	TXA/Aprotinin	788	11	73
Verma et al. [46]	2014	125	15	TXA	1833	9	204
Choi et al. [47]	2017	132	55	TXA	1002	10	105
Current study	2019	48	46		758	17	44

TXA: tranexamic acid.

A major goal of this study was evaluating the intraoperative and postoperative complications. They occurred on various levels. On the neurological front, given the rarity of the events and the small sample size in this study, it is not possible to conclude whether there is a significant difference relative to standard techniques. On the infection front, the rate of surgical site infections was relatively high. But it is difficult to compare the infection rate in our study with that of published studies; in fact, in large adult scoliosis studies, this rate varies between 1.5% and 5.2% [4,50,3,1]. If we consider only the non-neurological deformity cases, the infection rate in our study was 6.7%. Thus, our study has two populations of patients at higher risk of infections: 10.4% rate in Parkinson patients according to Bouyer et al. [51], while there were no infections in these patients in our study. CP patients with a spinal deformity also have a high infection risk with rates ranging from 4.2% to 20% [52–56]. In our study, the infection rate in CP patients was high, but reducing the size of the incision leaves us hopeful this rate will be reduced, as will morbidity (bleeding and operative time) in a larger study.

The mechanical complications are certainly those generating the most discussion. We divide them into two groups for analysis: first, there were three instances of rod breakage. Standard spinal fusion techniques are not immune to this type of complication: Charosky et al. report that this complication – which is evidence of nonunion – can reach 50% [50]. In our study, these cases of rod breakage led to relatively simple rod change from a technical viewpoint, with reuse of one or both incisions, which does not require complete exposure of the spinal column. They are not the primary type of mechanical complication. Another type of noteworthy complication was that of the fixation at the ends of the construct. This occurred in 16.7% of cases in our study. It consisted of either pull-out of the superior fixation or cut-out of the iliosacral screw, or disconnection of the component joining the iliosacral screw with the rod. The latter hardware-related problem is currently being investigated by the manufacturer to improve the system. In terms of the bone fixation at the ends of the construct, several authors have reported high mechanical complication rates when the fixation includes the pelvis, and have shown this rate to be lower when there is good hold at the pelvis [57,58]. The implants must be inserted meticulously to limit this risk [59]. As an example, surgical navigation greatly increases the safety of the iliosacral screw implantation, ensuring optimal trajectory and hold. In summary, we want to emphasize that CP patients had no mechanical complications and that a higher BMI appears to contribute to the occurrence of complications.

Our study has obvious limitations. These are very early findings on a small group of patients. However, we believe it is important to disclose these preliminary results because our experience has led us to be very careful about the indications: vertebral ankylosis, given the complete absence of reduction of the deformity, appears to be a limitation of this technique, sometimes requiring transpedicular osteotomy. In addition, the population of patients included in this first cohort is heterogeneous and the nature of the results leads us to believe this technique will find its place in certain specific indications (CP, Camptocormia) as opposed to other indications (rigid deformity in an overweight patient) leading obviously to an unacceptable mechanical complication rate.

5. Conclusion

The bipolar fusionless construct in adult spine surgery is a promising technique for treating certain deformities in adults. The technique allows surgeons to make corrections equal to conventional surgical techniques in less time and with less blood loss compared to published studies. The early complications observed led us to very carefully select the indications. Long-term follow-up of this cohort is essential for evaluating the added benefit of this technique and its exact indications.

Disclosure of interest

Dr L Miladi, who is a scientific expert with Euros®.
The other authors declare that they have no competing interest.

Funding

None.

Contributions

Wolff: procedures, protocol, writing.
Habboubi: data collection.
Sebaaly: data collection, statistics.
Moreau: procedures.
Miladi: development of the surgical technique.
Riouallon: procedures, protocol, writing.

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