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ORIGINAL ARTICLE

Hypercomplex pedicle subtraction osteotomies: definition, early clinical and radiological results and complications

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Abstract

Purpose To describe hypercomplex pedicle subtraction osteotomies (HyC-PSO) for adult spine deformity with sagittal imbalance in terms of preoperative, intraoperative and postoperative outcomes and complications.

Methods From a prospective single centre database, patients undergoing PSO between January 2016 and May 2017 were reviewed. HyC-PSO were defined as those in patients with one of the following conditions: sagittal correction > 45° needed at a single level or at 1–3 consecutive vertebrae, more than 60° of total sagittal correction needed and PSO on segments of the spine with congenital deformities.

Results 22 patients were included, 14 had standard PSO (group A) and 8 had HyC-PSO (group B). Significant correction of lumbar lordosis (LL) and pelvic (PT) was noted in both groups ($p < 0.01$). Operative time was longer in HyC-PSO, 604 min compared to standard PSO, 478 min. A trend versus greater intraoperative blood loss (3837 vs 2285 ml) and greater intra-operative blood infusion (from cell saver plus homologous, 2306 vs 1280 ml) was recorded in HyC-PSO (ns). Patients in group B received significantly more blood units intra and postoperatively (8.25 vs 4.71 units, $p = 0.006$). Sagittal correction at the PSO level (54.7°—30° to 85°—vs 26.8°—8° to 39°—, $p = 0.000$) and total sagittal correction (64.5°—50 to 95°—vs 39.8°—20° to 51°—, $p = 0.000$) were greater in HyC-PSO. PROMs at the last available follow-up did not show significant differences between groups for any of the outcomes analyzed. Complications were similar in both groups.

Conclusion This is the first report on hypercomplex pedicle subtraction osteotomies. Hypercomplex PSO describes a subset of clinical scenarios with increased surgical effort that can be measured as longer surgical time and greater blood transfusion requirements. Successful correction of misalignment can be achieved in this specific group of patients, and clinical results and complications profile could be similar to standard PSO procedures.

Keywords Pedicle subtraction osteotomy · Adult spine deformity · Sagittal balance · Surgery · Complications · Congenital spine deformity · Prospective

Introduction

In the last decades, pedicle subtraction osteotomies (PSOs) have become popular in the management of severe rigid adult deformity [1].

PSOs are technically demanding procedures that provide powerful deformity correction but are associated with significant complications rate. Numerous studies have documented significant improvements in quality of life and function after surgery [2–4]. Sciubba et al. in a recent literature review reported an overall complication rate of 66%, 31.8% of major perioperative complications, 15% of minor preoperative complications and 18.7% of long-term complications [5]. Adults population, in contrast to younger age groups, typically suffer from more postoperative complications due to the presence of comorbidities [5]. The patients older than 50 years often have a multitude of systemic diseases, including cardiovascular diseases and diabetes [6]. Moreover, given their commodities and poor healing potential, elderly patients have a higher risk with reported complication rate of up to 80% [2, 7]. Ayhan et al. demonstrated that this high

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rate of complications has no or minimal effect on clinical outcome and that the greatest improvements in quality of life are seen to take place during the first 6 months after surgery, even in the presence of complications [8]. Though standard PSO procedures provide substantial correction in both the sagittal plane, ranging from 20° to 35°, a subset of patients will require substantially greater correction at a single level (due to the magnitude of the deformity or to the need to perform most of the correction at one single level—in case of complete fusion masses). Thus, variations to the PSO technique such as corner-PSO [9] have been described to provide increased correction, but this causes longer operating time and blood loss, suggesting that a subset of patients with higher complexity might exist.

For these reasons, adult deformity correction, especially when it includes PSO, is considered as highly complex surgery. In fact, for these procedures different authors have proposed team approaches in order to reduce the risk in a way that resembles how in the past six decades civil aviation has faced the problem of risk associated with complexity [10, 11].

However, there is a distinct group of procedures that are particularly challenging: PSO with large correction needed (correction > 45° at one level or up to three adjacent levels), large overall sagittal correction needed (more than 60° of total correction), and patients needing PSO at levels with congenital deformities or anatomical variations. In the senior authors' (PB, CL) experience, these patients need more complex than standard pedicle subtraction osteotomy procedures, and we have defined this subgroup as hypercomplex PSO (HyC-PSO).

We hypothesized that HyC-PSO osteotomies are associated with higher surgical effort and complications rate than standard PSO but that are equally effective in restoration of sagittal balance and clinical and functional outcome.

The goal of this study is to describe hypercomplex PSO and to preliminary compare the preoperative, intraoperative and short-term postoperative characteristics, outcomes and complications of two concurrent cohorts of standard PSO and HyC-PSO.

Methods

An analysis of a prospective single centre prospective database was performed to review patients who underwent PSO from January 2016 to May 2017. Informed consent was obtained from all patients. All procedures were conducted according to Declaration of Helsinki.

Inclusion criteria were: patients undergoing PSO; age > 18. The reason for ineligibility was incomplete preoperative and postoperative clinical and radiological data.

Criteria to classify cases as HyC-PSO were:

1. correction > 45° at a one to three adjacent vertebrae,
2. greater than 60° of total sagittal correction needed
3. PSO on a spinal segment with congenital deformities.

Patients were divided into two groups: Group A that included standard PSO and Group B that included HyC-PSO.

Age, sex, body mass index (BMI), smoking status, comorbidities (diabetes, Parkinson Disease, rheumatic and ischemic heart disease), American Society of Anaesthesiologists score (ASA) of patients were collected preoperatively. The surgical strategy adopted (anterior and/or posterior surgical approach, type of interbody fusion technique, proximal and distal instrumented level, level of three column osteotomy) and surgical data (intraoperative blood loss, operative time) were analyzed. If the corrective strategy required two staged surgeries, the duration of each was added and the sum was considered as the total surgical time. Non-planned repeated surgery for complication management was not considered in the evaluation but was recorded as a complication. The number of blood transfusion units included intraoperative and postoperative transfusions.

Complications were divided into general intraoperative (death, anaesthesiological, cardiovascular, pulmonary thromboembolic and other complications), surgical intraoperative (radicular lesion, spinal cord injury, dural tear, vascular lesion, vertebral fracture and other) and postoperative complications. Postoperative complications were recorded as major and minor according to Glassman et al. [12] at 3 months and as long term at 6 and 12 months and last available follow-up (FU) according to Sciubba et al. [5]. Clinical status was analyzed with Visual Analog Scale (VAS) back and leg, Oswestry Disability index (ODI) and 36-item Short Form Health Survey (SF-36) preoperative and postoperative at 3, 6 and 12 months when available.

Spinopelvic parameters [Pelvic Incidence (PI), Pelvic Tilt (PT), Lumbar Lordosis (LL), and T4T12 Thoracic Kyphosis (TK)] were measured preoperative and postoperatively on standardized full-standing EOS X-rays [13, 14].

The degrees of total correction needed and achieved in sagittal plane and degrees of segmental correction at osteotomy level were calculated and measured. We considered segmental correction as the difference from preoperative to postoperative of the angle between the upper end plate of the vertebra above the osteotomy and the lower endplate of vertebra where the osteotomy was performed.

The amount of total segmental correction achieved was calculated as the difference between the preoperative and the postoperative sagittal cobb angle of the lordosis or kyphosis (depending on the area where the correction was performed, respectively the lumbar or the thoracic spine).

Categorical variables were expressed as number of cases or percentage. Continuous variables were reported as mean ± standard deviation (SD). The data have been analyzed using SPSS 21.0 software (SPSS Inc., Chicago, IL, USA). Due to small numbers, all the comparisons between continuous variables were performed with the two-tailed Mann–Whitney *U* non-parametric test for independent samples. Significance was set at $p < 0.05$.

Results

Thirty-nine patients ($n = 39$) underwent three column osteotomies by one of the two senior authors at a single center from January 2016 to May 2017. Twenty-two ($n = 22$) satisfied eligibility criteria.

Eight patients satisfied the HyC-PSO inclusion criteria and were assigned to group B. The remaining 14 patients had standard PSO and were assigned to group A.

All the patients in group B needed more than 60° of total correction. In addition, three patients in the group needed a local correction of more than 45° at one to three consecutive segments. Another three patients satisfied the former two conditions and had congenital deformity at the site of PSO.

Figure 1 describes the study population, reasons for ineligibility and criteria of allocation to either of two groups.

The preoperative characteristics of groups A and B are presented in Tables 1, 2 and 3. Preoperatively groups were similar in terms of age, sex distribution, BMI, comorbidities, proportions of smokers, ASA score, ODI score, VAS pain

Table 1 Preoperative demographics and comorbidity

	Standard PSO (group A)	Hypercomplex PSO (group B)	Sig
n	14	8	
Male/female (*n*)	4/10	1/7	ns
Smokers	7.1%	0%	ns
Diabetes	7.1%	0%	ns
Parkinson's disease	0%	0%	ns
Rheumatic disease	0%	0%	ns
Heart disease	0%	12.5%	ns
Age	57.9 ± 12.9	55.0 ± 12.3	ns
BMI	25.7 ± 3.7	24.7 ± 4.3	ns
ASA1	7.1%	12.5%	ns
ASA2	50%	37.5%	ns
ASA3	42.9%	50%	ns
Follow-up (months)	7.9 ± 3.8	9.0 ± 4.24	ns

BMI body mass index, *ASA* American Society of Anesthesia risk category

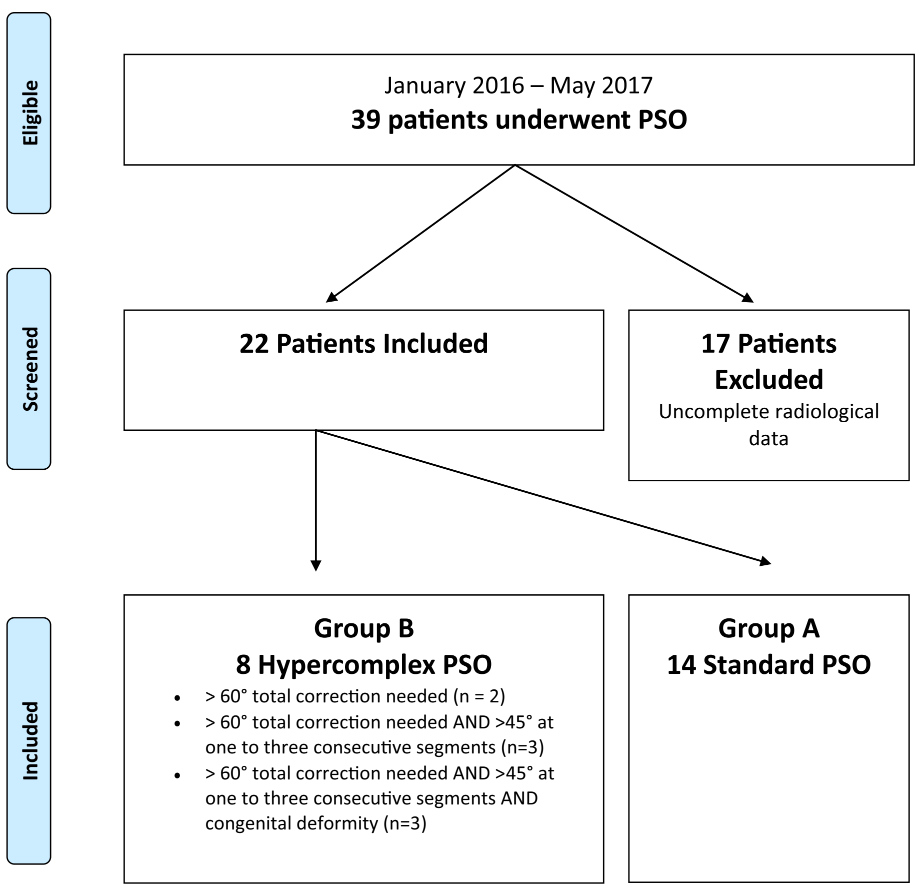

Fig. 1 Flowchart describing eligible patients, included patients and allocation to study groups

Table 2 Preoperative patient reported outcomes (PROMs)

	Standard PSO (group A)		Hypercomplex PSO (group B)		Sig
n	14		8		
ODI	41.92	± 20.76	50.50	± 22.01	ns
VAS back	6.35	± 3.34	6.62	± 3.37	ns
VAS leg	5.42	± 3.43	4.87	± 3.64	ns
SF36 physical role functioning	14.28	± 32.09	6.25	± 11.57	ns
SF36 mental health	48.28	± 18.32	53.50	± 20.83	ns
SF36 social role functioning	36.60	± 27.06	45.31	± 29.07	ns
SF36 physical functioning	43.92	± 28.83	31.25	± 28.75	ns
SF36 vitality	40.71	± 17.95	34.37	± 11.78	ns
SF36 emotional role functioning	28.57	± 41.04	16.66	± 35.63	ns
SF36 general health perceptions	59.643	± 17.59	31.87	± 14.37	$p < 0.002$*
SF36 bodily pain	27.143	± 28.28	37.81	± 26.94	ns

Values are average ± standard deviation

ODI Oswestry Disability Index, *VAS back* Visual Analog Scale of back pain, *VAS leg* Visual Analog Scale of leg pain

*Mann–Whitney *U* test

Table 3 Preoperative spinopelvic parameters

	Standard PSO (group A)		Hypercomplex PSO (group B)		Sig
n	14		8		
PI	49.5°	± 13.8	52.7°	± 10.8	ns
PT	29.7°	± 11.7	31.8°	± 20.6	ns
LL	− 22.4°	± 21.6	− 22.5°	± 40.1	ns
TK	32.1°	± 14.7	63.1°	± 36.1	$p = 0.029$*
Correction needed	− 45.2°	± 9.0	− 81.5°	± 26.5	$p = 0.000$*

Correction needed: amount of correction planned in the sagittal plane

PI pelvic incidence, *PT* pelvic tilt, *LL* lumbar lordosis, *TK* thoracic kyphosis

*Mann–Whitney *U* test

score, and SF-36 scores. The only exception was the General Health domain of the SF-36 questionnaire, with significantly lower scores reported in group B (HyC-PSO).

Differences in preoperative spinopelvic parameters were found only in thoracic kyphosis and amount of correction needed (both significantly greater in group B—HyC-PSO), Table 3.

Intraoperative data

In group A (Standard PSO), 5 patients (35%) had an anterior fusion (2 patients XLIF, 3 patients hyperlordotic ALIF). In group B (HyC-PSO), 2 patients (25%) had an anterior approach (1 XLIF with anterior column release and 1 hyperlordotic ALIF). In all cases, the anterior fusion was performed in the same surgical session before the posterior procedure. No cases of posterior interbody cages (TLIF or PLIF) were recorded.

The operative time was longer in group B (HyC-PSO), 604 min compared to group A, 478 min. A trend versus greater intraoperative blood loss (3837 vs 2285 ml) and greater intraoperative blood infusion (from cell saver plus homologous, 2306 vs 1280 ml) was recorded in group B (HyC-PSO), though the differences did not reach statistical significance (Table 4). Patients in group B received significantly more blood units intra and postoperatively (8.25 vs 4.71 units, $p = 0.006$).

Postoperative outcomes

Postoperative pelvic incidence, pelvic tilt, and lumbar lordosis did not differ significantly between groups. Group B had significantly greater postoperative thoracic kyphosis (37.2 vs 52°, $p < 0.02$) (Table 4). Substantial correction was achieved in both groups, as demonstrated by a low value of pelvic tilt postoperatively (10.5° group A, 14.5° group B, ns).

The amount of sagittal correction at the PSO level (54.7°—30° to 85°—vs 26.8°—8° to 39°—, $p = 0.000$) and the total amount of sagittal correction (64.5°—50 to 95°—vs 39.8°—20° to 51°—, $p = 0.000$) were greater in group B.

Patient reported outcomes at the last available follow-up did not show significant differences between groups for any of the outcomes analyzed (Table 5).

Complications

Two general cardiovascular intraoperative complications were reported, one in Group A (7.5%) and another in Group

Table 4 Intraoperative outcomes and postoperative spinopelvic parameters

	Standard PSO (group A)		Hypercomplex PSO (group B)		Sig
n	14		8		
Duration of surgery (min)	478.7	± 88.9	604.0	± 99.2	$p = 0.016$
Intraoperative blood loss (ml)	2285.7	± 1033.9	3837.5	± 2878.9	ns
Intraoperative blood infusion (ml)	1280.5	± 586.5	2306.2	± 2208.9	ns
Total transfusions (units)	4.71	± 2.55	8.25	± 2.86	$p = 0.006$*
PI	48.6°	± 13.8	49.0°	± 10.0	ns
PT	10.5°	± 8.2	14.5°	± 16.9	ns
LL	− 56.8°	± 14.2	− 51.3°	± 27.3	ns
TK	37.2°	± 13.3	52.0°	± 12.2	$p < 0.02$*
Sagittal correction at PSO level	− 26.8°	± 10.1	− 54.7°	± 16.2	$p = 0.000$*
Total sagittal correction	− 39.8°	± 10.3	− 64.5°	± 13.1	$p = 0.000$*

Correction needed: amount of correction planned in the sagittal plane

PI pelvic incidence, *PT* pelvic tilt, *LL* lumbar lordosis, *TK* thoracic kyphosis

*Mann–Whitney *U* test

Table 5 Postoperative patient reported outcomes (PROMs) at last available follow-up

	Standard PSO (group A)		Hypercomplex PSO (group B)		Sig*
n	14		8		
ODI	43.57	± 22.43	32.50	± 30.05	ns
VAS back	3.78	± 3.40	1.87	± 2.69	ns
VAS leg	4.42	± 3.43	2.50	± 3.29	ns
SF36 physical role functioning	17.85	± 33.17	46.87	± 41.05	ns
SF36 mental health	51.57	± 23.14	71.75	± 23.08	ns
SF36 social role functioning	41.96	± 33.82	60.93	± 34.99	ns
SF36 physical functioning	41.78	± 23.50	43.75	± 38.24	ns
SF36 vitality	42.14	± 25.01	58.12	± 25.62	ns
SF36 emotional role functioning	47.61	± 44.75	54.16	± 50.19	ns
SF36 general health perceptions	58.57	± 23.24	66.25	± 29.73	ns
SF36 bodily pain	38.03	± 32.33	62.81	± 31.63	ns

Values are average ± standard deviation

ODI Oswestry Disability Index, *VAS back* Visual Analog Scale of back pain, *VAS leg* Visual Analog Scale of leg pain

*Mann–Whitney *U* test

B (12.5%). In the standard-PSO group, 4 patients had 5 intraoperative surgical complications: 4 dural tears (28.6%) and 1 extension anterior tension band fracture of one vertebral body (caused by the corrective maneuvers). This patient was treated 1 week later by anterior approach, partial corpectomy and anterior structural support and graft with good final outcomes. In the HyC-PSO group, two intraoperative surgical complications were noted: 1 (12.5%) pleural lesion and 1 (12.5%) spinal cord compression with a paraplegic status detected after awakening from anesthesia that required immediate decompression and resulted in gradual resolution of symptoms in the postoperative period.

At 3-month follow-up, major complications had presented in six patients (42.9%) of group A (three patients with mild motor deficit and three patients with deep wound infection) and two patients (25%) of group B (both with mild motor deficit). Minor complications were recorded in six patients (42.9%) in group A (one wound dehiscence and two minor motor radiculopathy) and four patients (50%) in group B (one CSF fistula though no dural tear was noticed intraoperatively, one minor motor radiculopathy and two minor sensitive radiculopathies). By 3 months postoperatively, reoperation was needed in four patients in group A (28.6%) and two patients in group B (25%). No new complications were reported between 3 months and the end of this short-term follow-up.

Discussion

Though PSO is a complex procedure, the specific patient population described in this article as hypercomplex PSO (patients needing more than 45° of correction at a single level or short segment of the spine, needing overall more than 60° of sagittal correction and/or with congenital deformity at the site of PSO) has been hypothesized to require increased surgical effort and to encompass distinct challenges and risks.

This preliminary comparison of two small groups of patients undergoing standard vs hypercomplex PSO confirms that the two categories seem to have different surgical requirements (as expressed by significant differences in total amount of planned correction). The hypothesized increased surgical challenge is congruent with the finding of increased surgical time, and greater number of transfused blood units and a non significant (but clinically relevant) trend to greater intraoperative blood loss and intraoperative blood infusion.

From a technical point of view, the authors perception is that the magnitude of correction needed (especially when large corrections are needed at a single level), along with complex local anatomy (as in the case of congenital deformities), are the key factors increasing the technical difficulty and the surgical effort. The example in Fig. 2 illustrates the challenge in this case needing the largest correction in the series.

Interestingly, we were not able to show baseline significant differences in the sagittal spinopelvic parameters (with the only exception of a trend to greater pelvic tilt and a significantly greater thoracic kyphosis in the HyC-PSO group). Similarly, we were not able to identify substantial significant differences in the baseline PROMs (except for a worse general health perception in the HyC-PSO group). It is not possible with the numbers available to explain whether the absence of baseline differences was due to heterogeneity within the groups, to small sample size or to real lack of relevant baseline clinical differences. Similarly, no significant differences in PROMs were found postoperatively at the last follow-up between the series. Limitations of our study are a non-homogeneous length of follow-up and short follow-up time. Previous studies suggest that the improvements of clinical status are gradual and take place in the first year after surgery [8].

Patients in both groups had positive change both in spinopelvic alignment and in PROMs, though the aim of the study and the design (mainly the numbers available) precluded formal comparison between pre- and postoperative status.

Of note is the finding that both groups (despite the technical challenge of the HyC-PSO group) gained satisfactory alignment (as shown by the average PI-LL mismatch, with magnitude of LL higher than the magnitude of PI in both groups after treatment and by the low final pelvic tilt in both groups, suggesting reversal of most compensatory mechanisms for residual misalignment).

We hypothesized that increased technical challenge would translate into higher complication rate in the hypercomplex PSO group compared to standard PSO. We found that high complication rates, but with the numbers available, were not able to identify an increased complication risk in the hypercomplex PSO group. The literature has shown that general and surgical complications are increased with patient's age and with type of surgery [15] (higher complication rates in vertebral column resection than in pedicle subtraction osteotomy and higher in both than in posterior column osteotomy or adult deformity surgery without osteotomies). Data are missing regarding the effect of higher technical

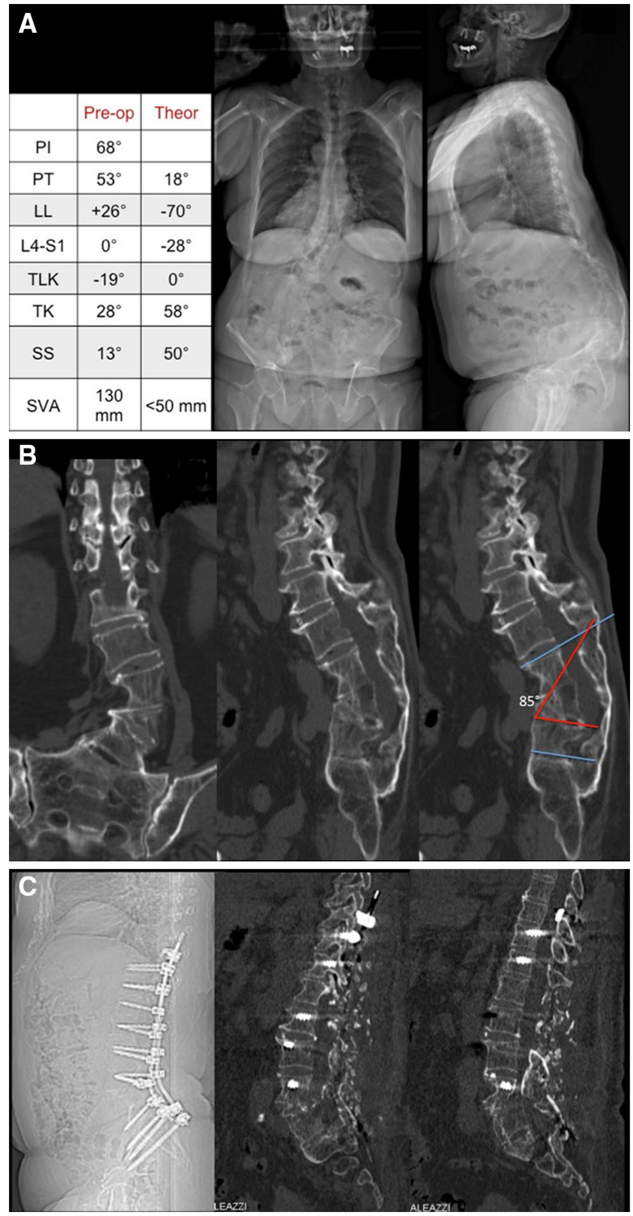

Fig. 2 Hypercomplex PSO case. The patient is a 70 year-old lady with L2-sacrum posterior fusion for congenital deformity 30 years earlier. She presents with progressive, unbearable back pain and difficulty to maintain the standing position. **a** EOS films and table with spinopelvic parameters. **b** Coronal and sagittal CT scan showing the fusion mass and the complex coronal and sagittal deformity. The lumbar sagittal alignment is shown with blue lines. The planned osteotomy of 85° at a single point (including 2 consecutive pairs of pedicles) is shown in red. **c** CT scan showing the correction with satisfactory alignment

complexity within one of the anatomical types of correction. A difference could have been missed by our study due to the small sample size.

Surgical technique variations have been proposed to reduce complication rates associated with three-column osteotomies [16, 17]. Though these techniques can be used in a growing number of patients with sagittal deformity, some complex scenarios such as most of the cases defined as hypercomplex PSO still need at the present time management through three column osteotomies to achieve proper sagittal alignment and clinical outcomes.

The main strength of this study is to have described the entity of hypercomplex PSO, a distinct type of clinical scenarios that require higher surgical effort than standard PSO and to have (despite the small numbers available) provided a proof of the increased surgical challenge (measured as increased surgical time, magnitude of correction, need of transfusions and trend to clinically relevant greater blood loss) in a prospective study.

Still, this study has substantial limitations. Seventeen of the 39 eligible patients did not have complete preoperative and postoperative radiographs or clinical data and thus were not available for analysis. This could have caused selection bias. The numbers available were small and the follow-up period was not long enough to describe every possible complication. The criteria to classify cases as standard or hypercomplex PSO were chosen by discussion and agreement among the research team, mainly based on the experience of the senior authors. Heterogeneity among cases is substantial, and could be a further source of bias. Though these data suggest that the entity of hypercomplex PSO is likely to be real, this study must be considered a narrative evaluation of two proposed different degrees of complexity in three-column osteotomy. Future investigations, in the form of multicenter prospective studies, with precise definitions of types and degrees of deformity, age groups, comorbidities, surgical team experience and case-load, outcomes end-points and sufficiently long follow-up, could confirm, change or reject this definition of HyC-PSO. Some of the questions arised in this study are still unsolved. Whether hypercomplex PSO procedures can achieve similar clinical results as standard PSO and whether the incidence and type of complications are different can be answered by future studies with greater samples.

This is to our knowledge the first report on hypercomplex pedicle subtraction osteotomies, their classification criteria and their technical challenges. Hypercomplex PSO describes a subset of clinical scenarios with increased surgical effort that can be measured as increased surgical time and blood transfusion. Successful correction of misalignment can be achieved in this specific group of patients, and clinical results and complications profile could be similar to standard PSO procedures.

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Compliance with ethical standards

Conflict of interest This study used equipment funded by "The Italian Ministry of Health (Bando Conto Capitale 2014-2015)". Pedro Berjano received honorarium for surgeons' education activities from Nuvasive, Medacta, DepuySynthes and his department received unrestricted research grants from Nuvasive, Medacta, DepuySynthes and K2M. Marco Damilano received honorarium for surgeons' education activities from Nuvasive. Claudio Lamartina received honorarium for surgeons' education activities from Nuvasive, Medacta, DepuySynthes and K2M and his department received unrestricted research grants from Nuvasive, Medacta, DepuySynthes and K2M. No other disclosures by the rest of authors.

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