




Pseudarthrosis in adult spine deformity surgery: risk factors and treatment options

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Abstract

Purpose Highlight risk factors for pseudarthrosis in long-segment spinal fusions, collect the approaches carried to address this complication.

Methods Patients with ASD and fusion of ≥ 4 levels with minimum follow-up (FU) of ≥ 2 years were included. Full-body X-rays were done preoperatively, < 3 months and ≥ 2 years. Oswestry disability index (ODI), Scoliosis Research Society-22 and SF36 assessed pre- and postoperatively. The relationship between demographic, surgical and radiological variables with the development of pseudarthrosis was evaluated.

Results Out of 524 patients included, 65 patients (12.4%) developed pseudarthrosis and 53 underwent revision surgery. Notably, 88% of pseudarthrosis cases are associated with fusion length (OR = 1.17, 95% CI = 1.05–1.292, $p = 0.004$), osteotomy requirement (OR = 0.28, 95% CI = 0.09–0.85, $p = 0.025$), pelvic fixation (OR = 0.34, 95% CI = 0.13–0.88, $p = 0.026$) and combined approaches (OR = 3.29, 95% CI = 1.09–9.91, $p = 0.034$). Sagittal alignment is not related to the rate of pseudarthrosis. Health related and quality of life scores were comparable at last FU between patients revised for pseudarthrosis and those that didn't require revision surgery (ODI = 28% no revision and 30% revision group).

Conclusions Pseudarthrosis is not related to malalignment, but with the surgical techniques employed for its treatment. Anterior approaches with anterior support decrease the rate by 30%, while long fusions, osteotomies and pelvic fixation increase its rate.

Keywords Spine · Deformity · Risk · Pseudarthrosis · Scoliosis · Alignment

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Introduction

Adult spinal deformity (ASD) is an increasingly burdening condition causing disability and pain. Surgical treatments to address this condition require neural decompression, reduction of the deformity and long spinal fusions [1, 2]. Although these procedures have a high rate of postoperative complications, most patients have good clinical outcomes [3–5]. Mechanical complications are the most commonly reported complications, with pseudarthrosis accounting for almost 25% of all revisions [4–6].

Pseudarthrosis in spinal surgery is generally described as any form of nonunion. Although surgical exploration is the gold standard for its diagnosis, a pseudarthrosis is usually detected by a late rod fracture (≥ 6 months) on plain films. CT-scanning may also be used as it is considered the most accurate imaging modality for determining union [7–12]. However, it is not used as a screening tool because of its expense and radiation risk.

The relevant risk factors for pseudarthrosis include smoking, osteoporosis, anatomic characteristics, number of levels fused and dural tears [6]. Biomechanical factors are also reported to play a major role, for example the lumbosacral junction, which is prone to nonunion, because of its high shear forces and mechanical loads. Long constructs are also associated with a higher risk of nonunion [9, 13]. In adult spinal deformity surgery (ASDS), the literature consistently demonstrates the importance of achieving sagittal alignment after ASDS in order to prevent mechanical complications [2, 14]. In addition, the long area of fusion in the presence of severe deformity also poses the challenge of collecting enough bone graft to allow fusion, necessitating the use of bone morphogenic proteins (BMP's) and bone substitutes [15]. More rigid instrumentations with double-rod constructs, cobalt chromium (CoCr) rods with higher diameter, combined approaches, interbody fusion, the use of domino connectors and the removal of all intervertebral disc (IVD) material have all been proposed to reduce the incidence of this complication [11, 16].

The purpose of the present paper was to determine the risk factors for pseudarthrosis in ASDS and to collect the treatment options and approaches used to address this complication.

Material and methods

A retrospective review of a multicenter collected database of ASDS involving 6 spine centers. Patients were collected from the KEOPS database from 1 January 2012 through to

31 December 2016 and data on all patients were abstracted from the electronic medical records. The inclusion criteria were patients over the age of 18 years operated for ASD with fusion of ≥ 4 levels and a minimum follow-up (FU) of ≥ 2 years. All patients had full-body X-rays performed preoperatively, < 3 months and ≥ 2 years after surgery. Patient-reported outcome measures (PROMs) were scored pre- and postoperatively including the Oswestry Disability Index (ODI), Scoliosis Research Society-22 (SRS-22) and Short Form 36 (SF-36). The minimal clinical difference was interpreted according to Carreon et al. and Sherif et al. [17, 18]. Pseudarthrosis was defined as rod fracture/s on plain films ≥ 6 months postoperatively. A CT-scan and/or SPECT-CT was done in some cases and centers to confirm the diagnosis and to plan the revision surgery.

The recorded patient-related characteristics included age, gender; BMI, current smoking status, comorbidities and prior spine fusion surgery. The recorded surgery-related variables included blood loss, surgical time, approach (anterior, posterior, combined), type of osteotomies performed (Smith-Peterson—SPO/pedicle subtraction—PSO), interbody cages (TLIF; ALIF; LLIF), number of levels fused (< 5 , < 10 , ≥ 10), the level of the most proximal (cranial to T5, cranial to T10, cranial to L1, L1 or caudal to L1) and most distal fusion (cranial to L4, L4, L5, S1 or iliac/S2 alar) rod material used (titanium alloy—TA or cobalt-chrome—CoCr), rod diameter (5.5, 6 or 6.35 mm) and revision surgery. The recorded radiological variables in both the coronal and sagittal plane were measured on the full-body weight-bearing X-rays and included coronal cobb, sagittal vertical axis—SVA, lumbar lordosis—LL, pelvic incidence—PI, pelvic tilt—PT, sacral slope—SS and lumbar lordosis index (LL/PI)—LLI [19].

Complications were defined as none, other and/or pseudarthrosis. The level of the pseudarthrosis was also collected (L1-L2, L2-L3, L3-L4, L4-L5, L5-S1 or more than one level). The revision approach used for the treatment of the pseudarthrosis, the time to re-intervention and the surgical technique were also collected. This study was approved (IRB GP-CE 2021–10) by the institutions of all 6 centers and all participants provided written consent.

Statistical analysis

The mean and standard deviation were calculated for continuous variables; number and percentage were calculated for categorical variables. An independent *t*-test was used for dependent variables that follow a normal distribution such as non-pseudarthrosis and pseudarthrosis. The equality of variances was assessed to determine the *p* value. If there was no equality of variances between the two groups, the *p* value was adjusted by Welch's correction. For independent variables, a Mann–Whitney U was used. To evaluate

the relationship between each variable and pseudarthrosis, a univariate logistic regression analysis was performed. Independent sample *t*-tests and chi-square analysis for continuous and categorical data were performed, respectively. All variables with univariate *p* values < 0.2 were taken as independent variables in the multiple logistic regression analysis, including radiographic parameters, to determine independent risk factors for pseudarthrosis and the odds ratio with the corresponding 95% confidence interval calculated (Table 1). A *p* value < 0.05 was considered to be statistically significant for the multivariate analysis. Statistical analysis

was performed using IBM SPSS Statistics software version 21.0 (IBM Armonk, NY).

Results

There were 524 patients included in this study. 76.5% were women, with a median FU of 2.9 years. From the 524 patients, 67.4% had posterior only approaches and 32.6% had staged surgeries involving a posterior approach

Table 1 Comparison of different variables in patients without complications and with pseudarthrosis

Variable	No complications (<i>n</i> = 372) mean ± SD	Patients with pseudarthrosis (<i>n</i> = 65) mean ± SD	<i>p</i> value
BMI (kg. m-2)	25.54 ± 4.22	26.29 ± 3.75	0.26
Prior surgeries	0.34 ± 0.86	0.6 ± 0.84	0.04
Operative time (skin to skin)*	204.92 ± 90.66	245.98 ± 78.54	0.01
Peri-operative bleeding*	1094.59 ± 1030.73	1634.17 ± 1098.72	0.00
Number of fused levels*	10.14 ± 4.16	12.34 ± 4.15	0.00
Levels decompressed*	0.24 ± 0.67	0.11 ± 0.47	0.13
Number of inter-body fusions	0.59 ± 1.01	0.54 ± 0.97	0.62
ALIF*	0.38 ± 0.86	0.23 ± 0.66	0.15
TLIF*	0.21 ± 0.58	0.31 ± 0.68	0.21
Approach*			0.02
Combined	127 (34.4%)	13 (20%)	
Posterior	245 (65.6%)	52 (80%)	
Rod material*			0.01
Titanium	234 (63%)	36 (55%)	
CoCr	138 (37%)	29 (45%)	
Iliac fixation*			0.01
Yes	167 (45%)	51 (78%)	
No	205 (55%)	14 (22%)	
3 Column osteotomy*			0.04
Yes	126 (34%)	29 (45%)	
No	246 (66%)	36 (55%)	
Osteotomy*			0.037
Yes	145 (31.6%)	29 (44.6%)	
No	314 (68.4%)	36 (55.4%)	
Right rod diameter*			0.012
5.5 mm	294 (64.1%)	43 (66.2%)	
6.0 mm	136 (29.6%)	12(18.5%)	
6.35 mm	29 (6.3%)	10 (15.4%)	
Radiographic measures			
Preoperative lordosis*	44.73 ± 18	37.70 ± 16.82	0.003
Preoperative sacral slope *	31.77 ± 11.84	29.72 ± 11.22	0.190
Preoperative major curve cobb angle *	27.51 ± 21.07	35.02 ± 19.32	0.039
LDI 6-week follow-up*	43.81 ± 34.92	60.93 ± 24.79	0.000
Pelvic tilt variation*	- 2.08 ± 9.99	- 3.92 ± 13.05	0.184
Sacral slope variation*	2.84 ± 11.09	6.03 ± 11.91	0.032
Lordosis variation*	7.21 ± 17.87	14.33 ± 18.65	0.003

*Variables used as inputs in the logistic regression model (univariate *p* values < 0.2)

(instrumented correction and fusion) and an anterior approach with cages. No patient underwent isolated anterior surgery.

10 or more levels were fused in 32.3% of the patients ($n = 169$) and 41% ($n = 215$) had 5–9 levels fused. The level of the distal instrumentation was S1 in 33.2% and Iliac/S2 alar in 46.6%. The most upper instrumented vertebra was cranial to T5 in 23.9%, cranial to T10 in 28.4%, cranial to L1 in 26.7% and L1 or caudal to L1 in 21%. The rod material used was TA in 60.5%, CoCr in 38.2% or other in 1.4% of the cases. The rod diameter used was 5.5 mm in 64.3% of cases, 6.0 mm in 28.2% or 6.35 mm in 7.4%. A double-rod construct was used in 6.5% of the cases. Osteotomies were performed in 51.9% of the patients, 18.7% of which had a PSO and 32.2% Ponte/Smith-Petersen osteotomies.

Sixty-five of the 524 (12.4%) patients developed a pseudarthrosis during the FU period. The most frequent level affected by a pseudarthrosis was L5-S1 ($n = 20$) accounting for 30.8% of the cases, followed by more than one level involved (27.7%; $n = 18$), L4-L5 (20%; $n = 13$) and L3-L4 (10.8%; $n = 7$). Eighty-seven of the 524 patients developed other mechanical complications (16.6%), the most common of which was proximal junctional kyphosis.

Univariate analysis

Patients with a pseudarthrosis had a statistically significant higher number of fused levels (12.34 vs. 10.14, $p < 0.001$), higher blood loss (1634.2 ml vs. 1094.6 ml $p < 0.001$)

and operative time (246.0 min vs. 204.9 min $p = 0.006$) (Table 1). Rods used in 98.7% of the patients were TA and CoCr, 18% of the patients with TA rods had pseudarthrosis reported while it was only observed in 8.5% of the patients with CoCr rods. The rate of pseudarthrosis in relation to rod diameter was of 8.10% (6 mm), 25% (6.35 mm) and 12.5% (5.5 mm) and was statistically significant ($p = 0.012$).

The presence of an osteotomy was more significantly related to the occurrence of other complications (24.7%) than with pseudarthrosis (16%; $p < 0.001$). Patients with other complications had a higher preoperative ODI (51.8 vs. 46.1 vs. 44.9 $p = 0.009$), a lesser major curve Cobb angle (19.2° vs. 35.0° vs. 29.1° $p = 0.001$), a lower L4/S1 lordosis (25.9° vs. 30.9° vs. 29.6° $p = 0.001$) and had the highest number of prior spinal surgeries. There was no relation between pseudarthrosis and a worse preoperative clinical score (PROMs). However, patients with pseudarthrosis had a significant greater baseline Cobb angle (35.0° vs. 27.5° $p = 0.039$) and both the L1/S1 lordosis (44.7° vs. 37.7°) and LLI (0.8 vs. 0.6). The differences were statistically significant between the pseudarthrosis group vs no complications, but the SVA was comparable between the 2 groups. Patients that did not have reported complications had a significant lower preoperative PT (23.7° vs. 26.3 $p = 0.01$) (Table 2). From the pre-op to the 6 weeks radiographic study, patients who subsequently developed a pseudarthrosis were those that had the biggest correction of total lordosis (14.3° vs. 7.2°, $p = 0.003$) and sacral slope (6.0 vs. 2.84 $p = 0.03$).

Table 2 Comparison of clinical scores and radiographic variables in patients without complications and with pseudarthrosis

Clinical scores	Preoperative		<i>p</i> value	2-year follow-up		<i>p</i> value
	Patients without complications ($n = 372$) mean \pm SD	Patients with pseudarthrosis ($n = 65$) mean \pm SD		Patients without complications ($n = 372$) mean \pm SD	Patients with pseudarthrosis ($n = 65$) mean \pm SD	
ODI—Score (%)	44.92 \pm 16.62	46.11 \pm 14.33	0.01	27.09 \pm 18.86*	32.65 \pm 20.89*	0.31
SRS 22—SRS total score	2.55 \pm 0.62	2.53 \pm 0.59	0.98	3.56 \pm 0.79*	3.29 \pm 0.66*	0.33
SF 36—PCS	34.35 \pm 8.60	33.53 \pm 7.30	0.51	43.45 \pm 11.40*	39.61 \pm 8.37*	0.21
SF 36—MCS	40.23 \pm 11.65	40.02 \pm 11.39	0.95	43.76 \pm 14.01*	47.51 \pm 10.51*	0.4
<i>Radiographic measures</i>						
SVA	74.67 \pm 118.56	87.7 \pm 84.99	0.11	82.90 \pm 109.30*	83.61 \pm 120.33	0.68
Pelvic incidence	55.92 \pm 13.29	56.32 \pm 13.63	0.36	56.49 \pm 12.06	58.87 \pm 14.41	0.27
Sacral slope	31.77 \pm 11.84	29.72 \pm 11.77	0.190	33.24 \pm 10.39	33.16 \pm 10.01	0.95
Pelvic tilt	23.67 \pm 10.51	26.34 \pm 12.12	0.01	23.26 \pm 9.69	26.05 \pm 10.52	0.14
Lumbar lordosis (L1-S1)	44.73 \pm 18	37.7 \pm 16.82	0.003	50.96 \pm 13.30*	48.71 \pm 13.48*	0.47
Lumbar lordosis (L4-S1)	30.90 \pm 13.05	29.62 \pm 11.56	0.01	28.54 \pm 11.81	29.62 \pm 11.56	0.81
Major curve cobb angle	27.51 \pm 21.07	35.02 \pm 19.32	0.039	25.97 \pm 12.21	26.64 \pm 15.19*	0.24
Lumbar lordosis index	0.82 \pm 0.34	0.63 \pm 0.37	0.03	1.14 \pm 0.28*	0.80 \pm 0.25*	0.05

*Defines $p < 0.05$ comparing the preoperative and 2 years values

This lordosis gain also had a significantly greater loss to FU (16.8° vs. 13.5°, $p=0.037$).

Patients with iliac fixation (17.6% vs. 7.9%; $p=0.001$) and an osteotomy preformed (17% vs. 10% $p=0.037$) had a greater incidence of pseudarthrosis. Combined approaches had a lower percentage of pseudarthrosis (7.6% vs. 14.7% $p=0.02$).

Multivariate analysis

The multivariate analysis revealed significant independent risk factors for pseudarthrosis. Notably 88.2% of cases could be explained by 4 predictive factors: the fusion length, an osteotomy, pelvic fixation and combined approaches (Table 3). The longer the fusion length, the higher the risk of having a pseudarthrosis (OR = 1.17, 95% CI = 1.05–1.292, $p=0.004$). Combined approaches reduce the risk of having a pseudarthrosis (OR = 3.29, 95% CI = 1.09–9.91, $p=0.034$) and the presence of iliac fixation (OR = 0.34, 95% CI = 0.13–0.88, $p=0.026$) or a three-column osteotomy (OR = 0.28, 95% CI = 0.09–0.85, $p=0.025$)

each are responsible for 3 times the risk of developing a pseudarthrosis.

Revision surgery

Fifty-three patients from the 65 patients with a pseudarthrosis underwent revision surgery. The median time to revision was 19 months. Revision surgery was combined in 41.5% ($n=22$) of cases, posterior only in 43.4% ($n=23$) and iliac autograft was used in 81%. Iliac/autologous bone graft was used in 43 patients and 4 had BMP used. Interbody fusion was performed in 29 cases (ALIF—2 cases, TLIF—5 cases, and ALIF + posterior approach—22 cases). In 18 cases, the approach undertaken was rod exchange without interbody fusion, and in seven cases of revision supplementary osteotomies were undertaken to improve the deformity correction (3 SPO and 4 PSO). In only 6 cases the fusion length was extended and in all other cases the upper and lower instrumented vertebra remained the same. At final FU, HRQL scores were comparable between patients revised

Table 3 Independent risk factors for pseudarthrosis according to the multivariate logistic regression analysis

Variables	Odds ratio	95% CI (lower limit)	95% CI (upper limit)	<i>p</i> value
<i>Significant variables</i>				
Number of posterior instrumented levels (ref = ?)	1.17	1.05	1.29	0.004
Surgical approach (ref = posterior only)	3.29	1.09	9.91	0.034
Iliac fixation (ref = No)	0.34	0.13	0.88	0.026
3 Column osteotomy (ref = No)	0.28	0.09	0.85	0.025
<i>Insignificant variables</i>				
Preoperative major curve Cobb angle				0.206
Preoperative lordosis (top of L1S1)				0.819
Preoperative SS				0.867
Preoperative RPV				0.891
Preoperative RLL				0.090
Operative time (min)				0.590
Operative blood loss (cc)				0.246
Number of decompressions				0.554
ALIFS				0.445
TLIF				0.582
LLIF				0.216
Osteotomy				0.583
Postoperative PT				0.551
Postoperative sacral slope				0.660
Postoperative L1S1				0.974
Postoperative RPV				0.831
Postoperative RLL				0.665
Distal fixation type				0.163
Rod material				0.366
Rod diameter				0.922

CI confidence interval

for pseudarthrosis and those never revised (ODI = 28% no revision and 30% revision group).

Discussion

To our knowledge, this is the first multicenter study to comprehensively assess the factors involved in the development of pseudarthrosis post ASDS. Our results suggest that long fusions, osteotomies, and pelvic fixation increase the overall rate of pseudarthrosis, while combined anterior and posterior procedures confer a lowest risk. (Fig. 1). These results support the role of mechanical instability in the genesis of pseudarthrosis [16, 20, 21]. Merrill and colleagues observed that patients with ASDS treated with dual-rod constructs had a greater incidence of lumbosacral pseudarthrosis than with multi-rod constructs [16]. In a biomechanical study by Charosky and colleagues performed with the goal of analysing the biomechanical instability after a PSO, the relevance of rotational instability strongly increased by disc degeneration was observed and the addition of anterior support to the disc below the osteotomy effectively reduced the stress on the rods [20].



Fig. 1 Long constructs, pelvic fixation and PSO without anterior support concentrate all the risk factors for pseudarthrosis occurrence

Our data also show that patients that developed a pseudarthrosis were those that had the biggest correction of total lordosis, thus the possibility of rod fragility fractures due to excessive bending should also be considered. However, our study found that sagittal malalignment does not directly influence the rate of pseudarthrosis in ASDS. The latest literature is in favor of the importance of the systematic increase in stability in the presence of long constructs and PSO's either by increasing rod diameter, the use of 3 or 4 rod constructs in the area with the highest risk of pseudarthrosis and the preference of CoCr and patient specific rods (Fig. 2)

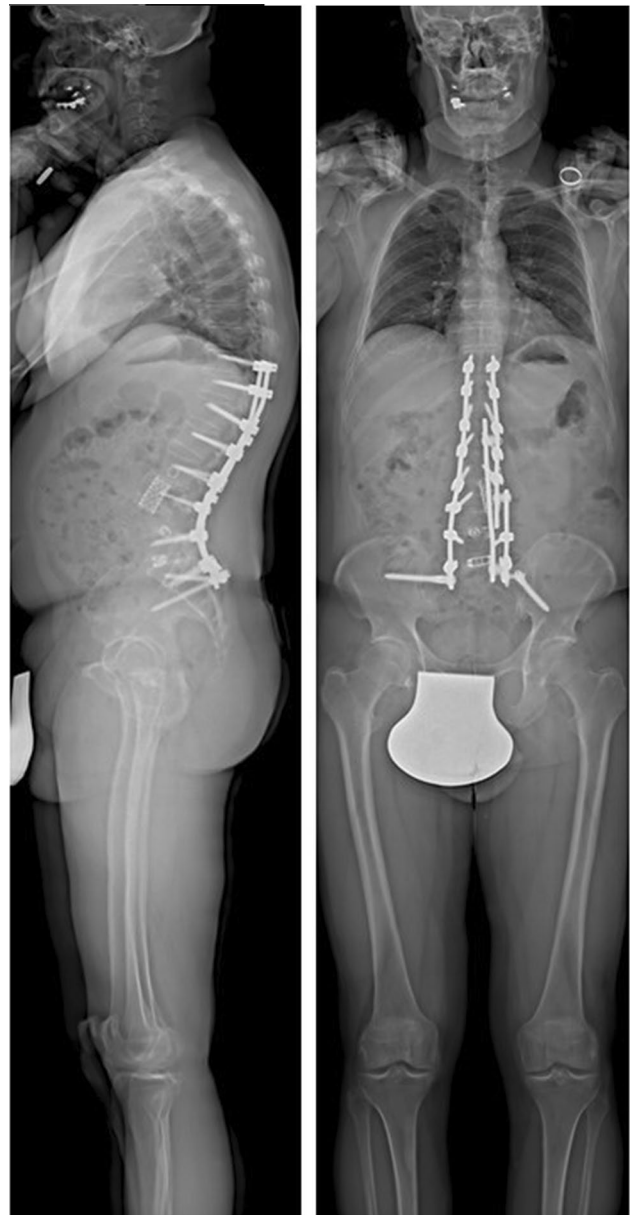


Fig. 2 Multiple rod construct and anterior support lower the risk of occurrence of pseudarthrosis when high risk procedures are needed to correct sagittal balance

[16, 20–22]. Despite this, it is interesting to note the low usage of multi-rod constructs in our series, perhaps showing a trend not yet identified.

Some of the factors related to the presence of pseudarthrosis in our series are also crucial to treat the deformity. These treatment techniques are indispensable for the achievement of satisfactory postoperative alignment and the desired construct stability. It is also logical that the most challenging cases that need extreme corrective measures have a higher incidence of complications, in particular pseudarthrosis. However, several ways to lower the incidence of pseudarthrosis in the presence of an osteotomy may be proposed. Barrey and colleagues emphasized the importance of closure of the osteotomy with bone-to-bone contact posteriorly and fusion of the adjacent levels [23]. Another possible solution is to do a bone-disc-bone osteotomy also known as Schwab type 4 osteotomy, whereby all the disc material is removed and this permits a better bony contact [24].

Our data also highlight the importance of anterior stability, which is consistent with the literature [25, 26]. However, it remains unclear if spinal surgeons should systematically perform interbody procedures, because the evidence in the literature is lacking. In the face of our data, we are persuaded to consider mandatory anterior fusion for patients undergoing Schwab type 3 or 4 osteotomies in the presence of long constructs and pelvic fixations. Especially in Schwab type 3 osteotomies, where the absence of the lamina at the disc level confers an even higher risk of pseudarthrosis and the wide laminectomy required for PSO's makes posterior grafting more challenging. Surgical strategies could then be second stage surgery for anterior support or when performing Schwab type 3 and 4 osteotomies, although it can be a disputable approach with a non-negligible economic impact that needs to be considered.

The approaches used for the treatment of symptomatic pseudarthrosis are very similar to the ones suggested in the primary prevention of this complications. Interbody fusion, either by an anterior or posterior approach, rod substitution and/or multi-rod constructs, biological adjuncts (BMP and iliac bone graft) and further osteotomies to improve the correction achieved with the primary procedure are some of the viable options [15, 26–28].

Despite being a review of a multicenter prospective database and having a large sample size, this study has several limitations, including its retrospective design and lack of long-term FU (medium FU 2.9 years). The systematic use of CT-scan and the assessment of fusion status with cross-sectional imaging in different centers and surgeons was not standardized. Rod fracture was the main criteria that we used for the diagnosis of pseudarthrosis and the use of rod fracture as a definition of pseudarthrosis has obvious limitations. Notably, the lack of rod fracture does not necessarily mean that the spine has fused, but rather adequate stability

achieved in some cases. Rod fracture in the presence of solid radiographic fusion is also reported in the literature and could be a consequence of mechanical failure and not only pseudarthrosis [13]. Overall we believe the definition of pseudarthrosis in this study underestimates the true incidence. In a study by Bourghli and colleagues performed with the objective of finding clinical or radiological factors that could predict revision surgery in the second postoperative year for ASDS, it was observed that HRQLS scores continue to improve even after the 1-year follow-up period [29]. No improvement or worsening HRQOL scores after 6 months of follow-up was highly correlated with the occurrence of a complication after the 1 year period, even though no radiographic alteration was yet present. Because of this, we believe that the incidence of pseudarthrosis could be under reported in our study. In addition, the surgical technique employed in the 6 institutions was not standardized. The fact that pseudarthrosis and non-pseudarthrosis cohorts are very different at baseline with the pseudarthrosis cohort containing more revision surgeries, more osteotomies, more average number of levels fused, and longer surgeries is also a limitation of our study, making inferences regarding the impact of any one factor on the rate of pseudarthrosis difficult.

Despite these limitations, our data suggest that malalignment is not an independent risk factor for pseudarthrosis in multilevel lumbar fusion in ASDS. Long fusions, osteotomies, and pelvic fixation all increase the rate of pseudarthrosis, while the additional anterior approaches and anterior support can decrease its rate by 30%. The final outcome is not compromised by the development of pseudarthrosis as patients revised do as well as those that never required a reoperation.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

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