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ORIGINAL ARTICLE

Sacropelvic fixation in adult spinal deformity (ASD); a very high rate of mechanical failure

Umit Ozgur Guler · Engin Cetin · Onur Yaman · Ferran Pellise · Alba Villa Casademut · Montse Domingo Sabat · Ahmet Alanay · Francesco Sanchez Perez Grueso · Emre Acaroglu · European Spine Study Group

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Abstract
Background Sacropelvic fixation (SPF) is an integral part of ASD surgery. Literature suggests that combination of S1 and iliac screws may be associated with lowest rate of complications.
Aim To analyze the rate and potential factors of mechanical failure associated with SPF in adult spinal deformity surgery.
Materials and methods Of 504 patients enrolled in a prospective multicentric database, 239 were treated conservatively and 265 were treated surgically. Forty-five of those who had sacroiliac fixations and with >6 months (or to failure) f/up constitute the population. Type of iliac fixation was S2 alar/iliac (S2AI) screws in 20 (44.4 %) and iliac screws with lateral connectors (IwL) in 25 (55.6 %). Diagnoses were degenerative in 20, failed back in 11 and other in 14. Average instrumentation length was 11.6 ± 4.0 levels. Cases with failure were compared to those without using Fisher's Exact and Mann–Whitney *U* tests.
Results A total of 16 implant related complications were identified (35.6 %). Failures were identified on an average of 224.1 days (8–709) following index surgery. Failure rate of S2AI screws was 35 vs. 12 % for IwL screws ($p > 0.05$). All broken screws were associated with S2AI technique with polyaxial screws. Comparison of failed cases to others revealed that failed cases had inadequate restoration of Lumbar Lordosis but this was not statistically insignificant. Only age was a significantly different, patient with failure being older.
Discussion Pelvic fixation is still associated with a very high rate of mechanical failure. Major risk factors appear to be age and type of fixation. Although could not be shown to be statistically significant, failure to restore the optimal sagittal balance may be a contributing factor as well. So in conclusion, in cases with suboptimal sagittal plane correction, S2AI with polyaxial screws seem to have higher risk of short-term acute failure compared to IwL.

Keywords Adult spinal deformity · Surgery · Sacropelvic fixation · HRQOL · Radiology

Introduction

Aging of population and an increasing demand to remain independent without significant disability in older ages resulted in an increased number of surgeries performed for adult spinal deformity in the recent decades. Obtaining a balanced spine and a solid fusion mass with improvement of function and pain are the main purposes of this type of surgery. Due to the advanced techniques in sacropelvic fixation, lumbosacral junction can now be fixed more rigidly but this zone is still challenging for surgeons. Poor bony quality of sacrum, complex anatomy and substantial shear forces at the lumbosacral junction may be listed as the main reasons for that challenge.

U. O. Guler · E. Cetin · O. Yaman · E. Acaroglu (✉)
Ankara Spine Center, Iran Caddesi 45/2 Kavaklidere, Ankara 06800, Turkey
e-mail: acaroglue@gmail.com

F. Pellise · A. V. Casademut · M. D. Sabat
Hospital Universitari Vall d'Hebron, Barcelona, Spain

A. Alanay
Acidadem Maslak Hospital, Istanbul, Turkey

F. S. P. Grueso
Hospital Universitari La Paz, Madrid, Spain

Kim and coworkers have reported a pseudoarthrosis rate of 24 % at L5–S1 junction in adult scoliosis surgery [1]. To overcome the complications associated with fusions ending at S1, sacropelvic fixation (SPF) has been introduced as a safer alternative [2, 3]. Currently, available SPF fixation alternatives include but are not limited to bicortical/tricortical S1 pedicle screws, additional pelvic/sacral fixation with iliac screws or S2 alar iliac (S2AI) screws, multiple screw/rod constructs and anterior interbody supports.

Multiple studies have shown that S1 pedicle screws, when used alone in long constructs, are prone to pullout failure or breakage (44 %) and allow for motion increasing the rates of pseudoarthrosis (33 %) especially at the L5–S1 level [3, 4].

Iliac screws have comparatively easier insertion technique compared to more demanding Galveston technique. Modern segmental instrumentation allows for the insertion of screws in the ilium independent of the proximal construct and connection to longitudinal rods by offset connectors [5]. They have three times higher pullout strength than that of the Galveston rods. It has also been shown that additional iliac screws may be effective in protecting the S1 screws and enhancing fusion rates at the lumbosacral junction [6–8]. High fusion rates were reported with this technique [9, 10]. Combined bilateral iliac screws and bilateral S1 screws demonstrated fusion rates up to 95.1 % in long segment fusions extending to the sacrum [8, 9]. One major drawback of iliac screws has been reported to be pain and prominent screw head that especially in small and thin patients, necessitating implant removal in up to 22 % of patients [11]. Likewise, Tsuchiya et al. reported seven cases of iliac screw breakages and 23 cases necessitating removal due to prominence in 5 years follow-up study of 67 ASD patients with SPF [8].

S2AI method popularized by Kebaish and coworkers seems to provide a solution for the problem of prominence as the screw head is concealed underneath the PSIS, as well as allowing for the placement of longer and large diameter screws through the S2 alar iliac [7]. In addition, as S2AI screws would be inline with S1 screws, the need to use offset connectors is eliminated. Original authors report a fusion rate of 92 %, and an overall complication rate of 40.4 % (34.6 % major) at 2 years follow-up. Complications related to S2AI screws were three screw breakages in two patients (had not required revision) and one screw misplacement.

This study is based on our observation of a very high rate of mechanical failures associated especially with a particular type of sacropelvic fixation in ASD. The aims of this study were (a) to analyze the early mechanical failure rate and potential factors (type of fixation, diagnosis, residual sagittal plane imbalance) related to failure in ASD patients instrumented with two different SPF techniques; and (b) to analyze the effect of SPF failure on patient outcomes.

Materials and methods

Study population consists of patients enrolled into a European multicentric adult spinal deformity (ASD) database, ASD defined as age >18 years; coronal deformity >20°; sagittal vertical axis (SVA) > 5 cm; pelvic tilt (PT) > 25°; thoracic kyphosis >60°. IRB approvals from all participating centers as well as informed consents from all enrolled patients were obtained. Based on the clinical observation of fairly frequent early failures, a minimum of 6 months of clinical and radiographic follow-up (or to failure) was adopted.

Radiographic parameters assessed preoperatively and postoperatively were spinal vertical axis (SVA), T1 sagittal tilt, global tilt (the angle between the line drawn from the center of C7 to center of the sacral endplate and the line drawn from the center of the sacral endplate to the center of femoral heads; is equal to the arithmetic sum of pelvic tilt and T1 sagittal tilt) and Lordosis gap (L-Gap) (defined as the posterior angle between the line connecting the centroid of T1 to the center of the upper end plate of sacrum and the line connecting the center of the femoral heads to the center of the upper endplate of sacrum, hence, the arithmetic sum of T1 sagittal tilt and pelvic tilt) [12]. The health related quality of life (HRQoL) parameters included Oswestry disability index (ODI), 36-item short form health survey physical component and mental component (SF-36; PCS and MCS) and Scoliosis research society 22-item patient questionnaire (SRS-22). HRQoL measurements were done preoperatively and also 1 and 2 years after the index surgery. Information on gender, age, diagnosis, the length of instrumentation and types of pelvic fixation were also recorded.

Statistical analysis was performed using SPSS statistical software (SPSS Inc, Chicago, Ilinois, USA). Cases with failure were compared to those without using Fisher's Exact and Mann–Whitney *U* tests. Alpha error margin for significance was accepted at $p < 0.05$.

Results

Of 504 patients with adult spinal deformity enrolled in the multicentric prospective international database, 239 patients were treated conservatively and 265 with surgery. Of these 265 who underwent surgery, a total of 45 (17.0 %) patients were identified as having had SPF and had been followed for more than 6 months (or to failure) constitute the study population. The follow-up periods were

24 months for 25 patients, 12 months in 12 patients, and 6 months in eight patients as the data is entered into the database in those timelines (average follow-up 17.6 months, median 24 months). Indications for SPF varied with the surgeons and centers and included degenerative problems located at the lumbosacral junction, longer posterior instrumentations that had to be extended to sacrum and the perceived need to have a powerful pelvic foundation to achieve better sagittal plane pelvic/sacrum rotation. Forty (88 %) of the 45 patients were women and the average age of the study group was 63 ± 14 years. Diagnoses were degenerative in 20, failed back in 11 and other in 14. Type of sacropelvic fixation was S2 alar/iliac (S2AI) screws in 20 (44.4 %) and iliac screws with lateral connectors (IwL) in 25 (55.6 %) in addition to uni/bilateral S1 pedicle screws. Average instrumentation length was 11.6 ± 4.0 levels. None of these patients had additional anterior fusions at the lumbosacral junction (ALIF, TLIF or PLIF). All patients had posterior and/or posterolateral fusions using auto (local and iliac crest) grafts supplemented with freeze dried allografts in some. RhBMP2 was not used in any of the cases.

Due to the multicentric nature of the database, three different instrumentation systems had been used in this series of patients (Blackstone SFS, Orthofix Spine, Lewisville, TX; Expedium Posterior instrumentation system, Depuy Spine, Raynham, MA; and Legacy posterior instrumentation system, Medtronic, Memphis, TN). All systems were Ti alloys and all screws used were polyaxial screws with the exception of monoaxial S2AI screws used with connectors in four cases (Legacy PIS, Medtronic, Memphis, TN). All screws were used as preassembled at factory, none of the polyaxial screws were clip-ons. All rods were 5.5 mm Ti alloy rods, CoCr rods or (so called) four rod technique had not been used in any of the cases during their primary surgeries.

Of the 45 patients, a total of 16 implant-related complications were identified (35.6 %), seven had to be revised. Ten were disengagements of SPF (screw head/shaft disengagement, set screw dislodgement, rod/lateral connector separation) (22.2 %), four were rod breakages, and two were screw loosenings. Failures were identified on an average of 224.1 days (8–709 days) following surgery; all SPF disengagements were identified within the first year. The follow-up lengths for this group were 24 months in 12, 12 months in two and less than 6 months in two (average 19.88 months, median 24 months). Average follow-up lengths of these failed cases were not statistically different compared to those cases without failure (19.88 vs. 16.14; $p = 0.90$). For the failed cases, failure rate of S2AI screws compared to IwL screws was 35 vs. 12 % ($p = 0.07$) (Table 1). Of note, all screws with head/shaft disengagement (three cases) and four out of five cases with

Table 1 Distribution of SPF failures by fixation type *S2AI* S2 alar screws, *IwL* iliac screws with lateral connectors ($p = 0.07$)

N (%)/type of fixation	S2AI	IwL	Total
Failed	7 (35)	3 (12)	10
Not failed	13 (65)	22 (88)	35
Total	20 (100)	25 (100)	45

set screw dislodgements were associated with S2AI technique with polyaxial screws and the same implant brand (Blackstone SFS, Orthofix Spine, Lewisville, TX) (p value for failure by brand >0.05) (Fig. 1). None of the monoaxial S2AI screws were associated with any failure. IwL type of fixations however, was more prone to fail through the rod/lateral connector separations (Fig. 2). Analysis based on diagnosis stratified as degenerative or others revealed that degenerative patients were more likely to have failure but this tendency did not reach to statistical significance ($p = 0.07$) (Table 2). Of note, age was identified as a factor in failure (independent of diagnosis) as the average age of patients with failures was significantly higher than those without (70 ± 11 vs. 61 ± 14; $p = 0.05$).

Analysis of sagittal balance parameters in the entire population revealed modest rates of correction for all parameters (Table 3) ($p > 0.05$ for all). Comparison between failed cases and others for sagittal plane alignment however, revealed that failed cases had higher SVA and L Gap values, although not statistically significant ($p > 0.05$) (Table 4).

Finally, looking at the HRQL parameters, it was seen that for all 45 patients with SPF, there was a modest improvement in ODI at 6 months as well as the latest follow-up (12.4 ± 8.4 months), whereas all other parameters (SRS22, SF36 PCS, SF36 MCS) were essentially unchanged ($p > 0.05$ for all) (Table 5). When compared to each other the non-failed patients at latest follow-up, it was seen that the failed cases had relatively worse outcomes in ODI and SF36 MCS ($p = 0.18$ for both, not significant) but not for SF36 PCS and SRS22 (Table 6).

Discussion

This study aimed to report the rate of early failure (within the first year following surgery; ten disengagements and one screw prominence, 24.4 %) and to analyze the relation between the type of fixation and the restoration of spinopelvic balance as a potential cause in ASD patients. Our results reveal a very high (37.7 %) rate of mechanical failure in early/mid-term (within the 2 years following surgery) follow-up. This rate was not significantly affected by the residual spinal imbalance although a trend of lesser

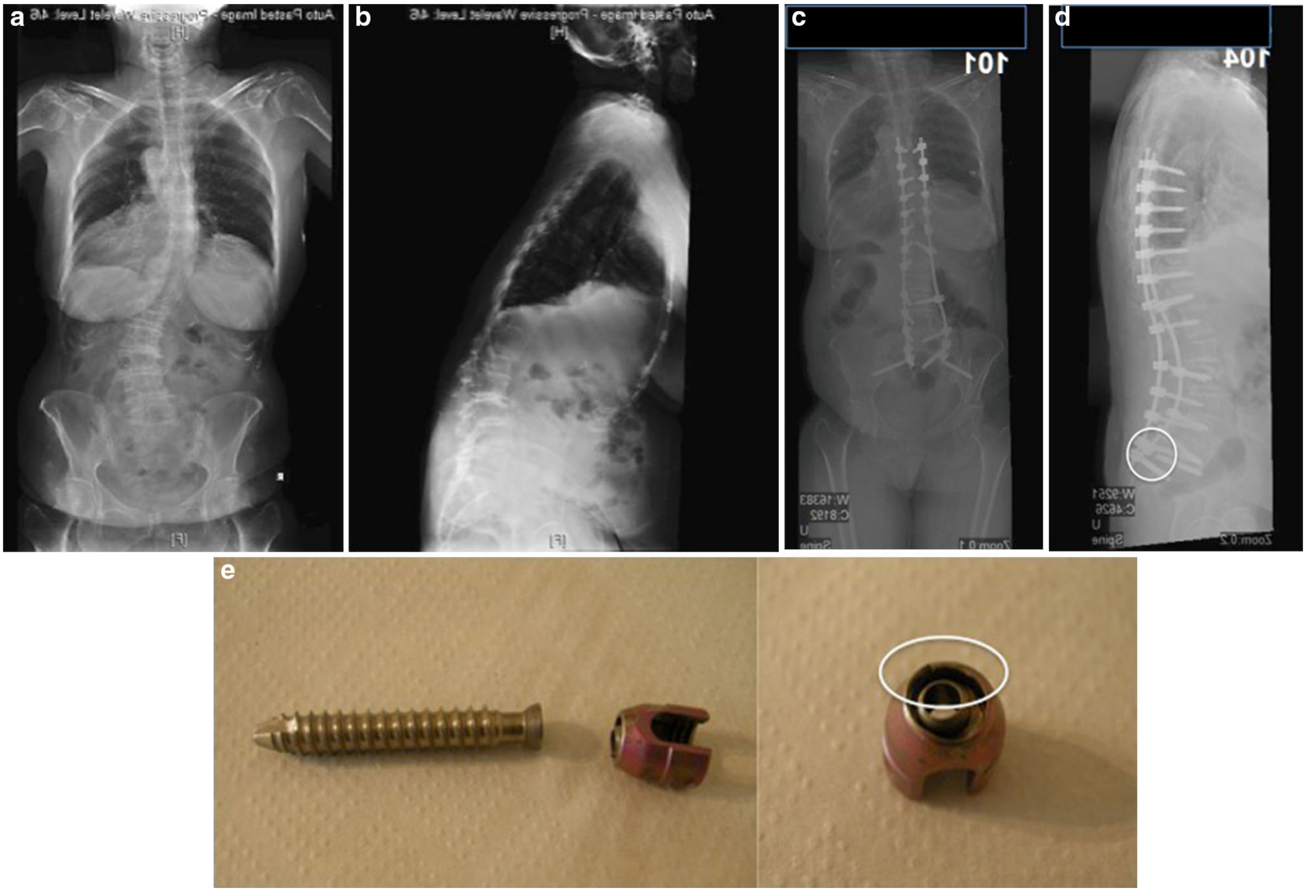

Fig. 1 **a** and **b** AP and lateral X-rays of an 80-year-old woman with significant back pain and forward listing. **c** and **d** AP and lateral X-rays of the same patient taken 8 days after surgery. The disintegrated screw head/shaft is highlighted in the *white circles*. The exact time of this failure could not be identified, as the patient did not have any immediate post-op X-rays. A decision of not to perform revision had to be revised at the 6th month follow-up because of continuous pain at that location. **e** Picture of the removed screw shaft and head and the detail of screw head. Note the deformation of the screw head located at the opening for the screw shaft, highlighted in the *white circle*

balance restoration in failed cases could be identified. A similar trend was also identified in having more failures with a distinct type of SPF (S2AI). Of note, our study also demonstrated that these failures might affect the patient outcomes negatively.

The rate of mechanical failure reported in this series is much higher than the previous reports in the literature [1–4, 7]. This is unique for this type of fixation as SPF had been the proposed solution for a fairly high rate of failure with the use of only S1 screws at the lower end of long fusion constructs in adults. There may be several explanations for this significantly higher rate of mechanical failure in our series. One factor may be the inability in correction of sagittal balance (inadequate restoration of LL). This factor was tested in our study and although it did not reach the level of statistical significance, a tendency for the failed patients having lesser correction in SVA and lesser restoration of LL could be identified. This factor has been stressed in several other papers previously. Pateder et al. emphasized that ASD patients with greater sagittal plane imbalance had a higher risk of pseudoarthrosis [13]. Emami and coworkers also proposed an ideal post-operative sagittal balance as one of the major factors for a stable lumbosacral fusion [11]. Therefore, failure to restore the ideal sagittal alignment might have been a major reason for the high rate of mechanical failure.

Another factor may be the lack of anterior column support at the lumbosacral junction (in association with less than ideal bone quality due to higher age). A study by Emami et al. indicated that in long segment instrumentation extending to the sacrum, the rate of pseudoarthrosis development was 14 % when iliac and sacral screw combination compared to 8.5 % when only sacral screws were used. They have identified good bone quality, the use of bicortical or tricortical sacral screws, the use of anterior interbody fusion and a good sagittal balance as factors

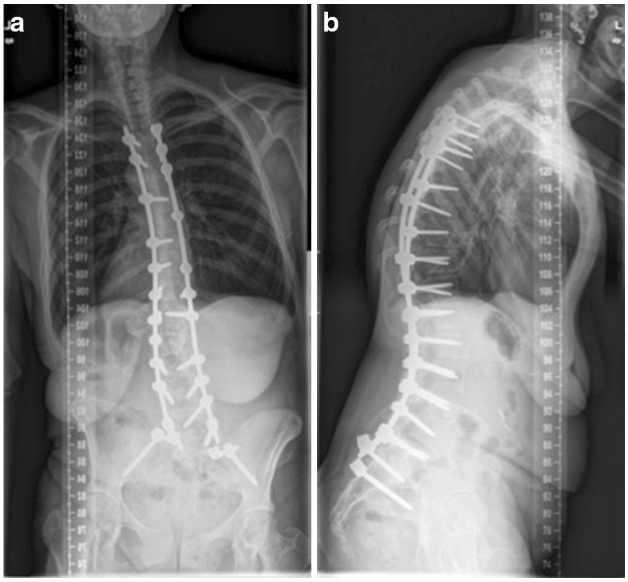

Fig. 2 **a** and **b** AP and lateral X-rays of a 64-year-old woman who had undergone surgery for ASD 1-year ago. The patient describes newly developed low back pain as well as listing forward and to the right side starting from the 6th month; separation of the lateral connector/rod connection was noted at this time (on routine 1-year follow-up control). A revision was performed

Table 2 Distribution of SPF failures by diagnosis ($p = 0.07$)

N (%)/diagnosis	Degenerative	Other	Total
Failed	7 (35)	3 (12)	10
Not failed	13 (65)	22 (88)	35
Total	20 (100)	25 (100)	45

Table 3 Sagittal balance parameters of the entire group of patients with SPF ($p > 0.05$ for all parameters on comparison of pre vs. post-op values)

	Pre-op	Post-op
SVA (mm)	66 ± 68	44 ± 53
T1 sagittal tilt (°)	1 ± 8	−2 ± 5
Global tilt (°)	32 ± 17	26 ± 14
L-Gap (°)	25 ± 19	15 ± 15

Table 4 Comparison of failed and not-failed patients for age and post-operative sagittal parameters

SPF failure	Age	SVA post op	T1 sagit. tilt post op	Global tilt post op	L-Gap post op
Present	70 ± 11	67 ± 56	0 ± 6	31 ± 11	19 ± 16
Absent	61 ± 14	37 ± 51	−2 ± 5	23 ± 14	14 ± 15
P value	0.05	0.16	0.38	0.12	0.46

Only average patient age is significantly different between groups

Table 5 HRQoL parameters for the entire SPF population at pre-operative, 6 months and latest follow-up points

	Pre-op	6 months	Follow-up
ODI	57 ± 22	43 ± 22	45 ± 22
SF36 v2 MCS	40 ± 12	41 ± 12	41 ± 13
SF36 v2 PCS	30 ± 8	35 ± 9	38 ± 9
SRS 22 subtotal	3 ± 1	3 ± 1	3 ± 1

All $p > 0.05$ on comparisons between time points

Table 6 The effects of SPF failure on HRQoL parameters at 1-year follow-up

SPF failure at 1 year	ODI	SF36 v2 MCS	SF36 v2 PCS	SRS 22 subtotal
Present	52 ± 14	36 ± 7	38 ± 10	3 ± 1
Absent	42 ± 24	43 ± 15	39 ± 9	3 ± 1
P value	0.18	0.18	0.89	0.36

associated with success [11]. While most surgeons tend to think that iliac wing screws would provide adequate protection for S1 screws, biomechanical studies suggest that the system needs to be further protected by using anterior support to L4–5 and L5–S1 [14, 15]. Anterior lumbar interbody fusion allows for the placement of bone structures anterior to the pivot point as much as possible, fixation of the system at compression mode improves chances for fusion [16]. Based on these, in addition to the discussion above, lack of anterior column support (in all cases with failure) may be one of the major factors fin the high rate of mechanical failure reported in this series. Although the indications for the addition of anterior support at the lumbosacral (LS) junction in ASD surgery has not been precisely established and validated, it is a fairly common practice to feel the need and use anterior support in cases that the long deformity instrumentation (the definition of which being unclear) is being extended to the sacrum (alone) and not necessarily to pelvis. Our findings suggest that addition of anterior support at the lumbosacral junction may be indicated for any "long fusion" extending to pelvis in addition to sacrum. An additional advantage of anterior column support would apparently be the enhancement of the fusion rate at the LS junction, which by default, may also eliminate or at least decrease the chances of rod breakages.

On the other hand, in this series, the type of SPF emerges as one of the most important factors for failure. The failure rate of S2AI screws was 35 % compared to 12 % with iliac screws with lateral connectors. There were five cases instrumented with S2AI screws in which the screw head was totally disintegrated from the screw shaft, a mode of failure that had not been reported previously. There may be two reasons for this; one is the acute angle that develops between the screw head and shaft of the screw in this type of fixation. These screws are not biomechanically tested in these acute angles of fixation before marketing and may be more prone to failure in the extremes of head-shaft angulation [17]. The use of monoaxial screws may solve this problem. The second reason may be a flaw in the production of the specific brand of screws used in this series. This brand of screws may be specifically more prone failure when locked and stressed at the limits of polyaxial range of motion. Further biomechanical studies will be needed to develop a better understanding on these peculiar types of failure. Additional reasons may be the distribution of stresses into two connections with IwL type of instrumentation as opposed to a single one with S2AI screws and finally, our inability to identify potential screw/bone interface loosenings with IwL instrumentation as these may become evident in longer follow-up periods. A discussion on the mechanical failure of screws in spinal surgery need also to include the use of (or thereby lack of) cement augmentation so as to reinforce the screw-bone interface. As in vitro biomechanical studies suggest an advantage on the fixation strength, it may be assumed that the use of such might possibly have eliminated the two cases of iliac screw loosening [18, 19]. Another discussion pertaining to mechanics may be the potential detrimental effect of crossing the SI joints. It has to be acknowledged that this may be a factor in the relatively high incidence of mechanical failure in this series but does not explain the higher incidence compared to other series [7, 9, 10] nor that failure is more common with S2AI screws compared to the IwL screws.

The limitations of this study include the design of the database (a registry). As an inherent problem with registries, there is a chance that not all complications have been recorded. In addition, these surgical procedures were performed in five different hospital spine units, which may be associated with different surgical techniques. Another drawback is the relative shortness of follow-up. It needs to be recognized that the rate of complications including mechanical failures may grow to be even higher in longer follow-ups. Finally, due to the number of cases with failures, statistical analysis aimed to differentiate the potential causes of failure does not have adequate statistical power. On the other hand, the major objective of this study is to attract the attention of surgeons to an inherent problem associated with (a certain type of) SPF. Identifying the aim as such, the length of follow-up as well as the limited statistical power may as well not be considered as major shortcomings.

Conclusion

Surgeons engaged in complex surgery should be aware of the potential complications of SPF. It is still associated with a very high rate of mechanical failure. Major risk factors that were identified in this study were higher age, inadequate restoration of lordosis, and importantly, S2AI type of fixation with polyaxial screws. Lack of anterior column support might also have affected the rate of failure.

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Conflict of interest None.

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