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Clinical and radiological mid- to long-term investigation of anterior lumbar stand-alone fusion: Incidence of reoperation and adjacent segment degeneration

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ABSTRACT

Introduction: Anterior stand-alone fusion (ASAF) devices have been developed in an attempt to reduce adjacent segment degenerative changes observed with posterior instrumented fusion techniques.
Research question: The purpose of this study was to assess mid- to long-term clinical and radiological results following ASAF at the lumbosacral junction with special emphasis on the assessment of adjacent level pathologies.
Materials & Methods: Clinical outcome scores and radiological data were acquired within an ongoing single-center prospective cohort study. Progression of adjacent level degeneration was evaluated based on MRI scans according to the Pfirrmann and Weishaupt classification system by two independent radiologists.
Results: The results from 37 patients (FU $\geq$ 5 years) demonstrated high satisfaction rates and significant improvements in VAS and ODI scores. N = 8 patients (21.6%) had to undergo subsequent surgery at the cranially adjacent level. The incidence of adjacent level disc degeneration and adjacent facet joint degeneration was 24.3% and 35.1%, respectively. More pronounced degenerative changes of the adjacent level discs ($p = 0.005$) and facet joints ($p = 0.042$) prior to surgery and a lower segmental lordosis reconstruction at the lumbosacral junction ($p = 0.0084$) were identified as potential risk factors for the development of subsequent adjacent level pathologies.
Discussion & Conclusion: The study revealed satisfactory clinical results at a mid-to long-term FU of $\geq$5 years. The incidence of adjacent level degeneration was higher than initially expected. Patients with preexisting radiographic signs of degenerative adjacent level changes have a higher risk for subsequent deterioration necessitating reoperation at the adjacent segment at later stages. Furthermore, adequate intraoperative segmental lordosis reconstruction at the index segment is paramount as the present data reveal this to be a key protective factor for adjacent segment preservation.

1. Introduction

Posterior instrumentation with or without additional interbody fusion is the most commonly performed surgical intervention to date for the treatment of intractable low back pain (LBP) resulting from degenerative pathologies at the lumbosacral segment which has been unresponsive to an intensive conservative treatment program (Fritzell et al., 2001; Carreon et al., 2008). Despite overall satisfactory results, posterior fusion techniques are associated with a considerable number of major drawbacks such as mediocre clinical results, adjacent level

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degenerative changes, and high cumulative re-operation rates (Lee et al., 2009; Wang and Ding, 2020; Kong et al., 2010; Martin et al., 2007).

These degenerative changes are likely related to biomechanical changes and increased loads which occur at junctional levels adjacent to the fused segment (Akamaru et al., 2003). Preexisting degeneration, a more sagittal orientation of facet joints as well as an abnormal sagittal alignment have been identified as additional potential risk factors (Lee et al., 2009; Hikata et al., 2014; Jiang and Li, 2019). Furthermore, adjacent segment pedicle screw facet joint violations and/or damage to the paraspinal structures as well as iatrogenic lack of lordosis have been held responsible for poor clinical outcome and progressive adjacent level degenerative changes following posterior instrumentation (Amato et al., 2010; Fan et al., 2010).

Adjacent level degeneration (ALD), as a radiographic entity, may become symptomatic and is then referred to as adjacent segment disease which may occur at a reported incidence between 5.2 and 18.5% (Park et al., 2004). Adjacent segment disease is associated with pain and dysfunction and frequently necessitates revision surgery, leading to substantial costs for the health care system, additional risk of subsequent surgical interventions as well as an inferior overall clinical outcome (Lee et al., 2009; Park et al., 2004; Christensen et al., 1998; Lee, 1988).

For anterior stand-alone fusion (ASAF), anterior cage-screw constructs have been developed in an attempt to reduce these above-mentioned negative side effects of posterior instrumented fusion techniques (Cain et al., 2005). Improved reconstruction of segmental and global lumbar lordosis, avoidance of cranial facet joint violation, and posterior collateral muscle damage may contribute to reducing that rate of ALD (Siepe et al., 2015; Strube et al., 2012). Whether ASAF may, however, live up to its expectation and reduce the rate of reoperations in comparison to posterior fusion techniques remains to be a matter of debate.

The goal of this present investigation was therefore to prospectively establish the rate of ALD and reoperation rates following ASAF using an anterior cage-screw construct at a minimum 5-year FU and to determine risk factors that may predispose the development of ALD at later stages.

2. Materials and methods

2.1. Patient selection/inclusion-exclusion criteria

All patients included in this study are part of an ongoing prospective cohort study with the Synfix-LR device (DePuy Synthes, West Chester, PA, USA). The minimum follow-up (FU) for inclusion in this study was 60 months.

The indication for ASAF was intractable and clearly predominant low back pain resulting from single-level degenerative disc disease (DDD) at the lumbosacral junction (referred to as the level L5/S1). Surgery was indicated when extensive conservative therapy, conducted over a minimum period of 6-months, did not achieve any adequate pain relief. For cases where there was any doubt, for instance preoperative radiologically detectable degenerative changes at the adjacent level, fluoroscopically guided spinal infiltrations were used to establish the clinical relevance of the varying degenerative changes and thus confirm the level L5/S1 to be the clearly predominant source of pain.

Spondylolysis and/or any kind of translational instabilities such as spondylolisthesis at the index segment were considered a contraindication against ASAF in accordance with the manufacturer's marketing approval guidelines.

Women older than 45 and men older than 55 years of age routinely underwent dual radiograph absorptiometry (DXA) for bone density measurements. In accordance with the WHO definition of osteoporosis, a T-score below −2.5 was considered a contraindication against ASAF.

Preoperative diagnosis was made based on standardized standing lumbar X-rays taken in AP and lateral view, functional flexion/extension for detection of potential instabilities, as well as pre-operative MRI images of the lumbar spine.

Patients with a history of previous or additional instrumentation beyond the index level procedure were excluded from participation in this study.

Patients that were not able to undergo an MRI examination (i.e. due to pacemaker) were likewise excluded from participation in this study.

2.2. Study population

From 2005 to 2015, n = 46 patients met the above-mentioned inclusion criteria. N = 2 patients were lost to FU, and n = 4 patients were not able to undergo MRI-examination at final FU. They were investigated for clinical results but could not be integrated in the study cohort. For n = 3 patients, no digital documentation of the preoperative MRI could be retrieved due to technical difficulties and had to be excluded for final evaluation. Thus, n = 37 patients were available for final analysis with complete clinical and radiological data, resembling an overall FU-rate of 80.4% (n = 37/46).

The mean follow-up was 71.7 months. The average age was 48.3 years (range 18.7–73.9 years) with an almost equal gender distribution between male and female patients (n = 18 male; n = 19 female patients, respectively). N = 16 patients (n = 16/37; 43.2%) were smokers and n = 21 patients (n = 21/37, 56.7%) were non-smokers. The average BMI was 26.2 (range 19–34).

Indications for ASAF at the lumbosacral segment were degenerative pathologies and included 20 patients with DDD with (n = 12/37; 32.4%) or without accompanying MODIC changes (n = 8/37; 21.7%). In n = 10 patients, DDD occurred following a previous discectomy at the index segment (n = 10/37; 27.0%). 5 patients presented with DDD and an additional foraminal stenosis (n = 5/37; 13.6%). N = 1 patient presented with DDD and an additional recurrent disc herniation (n = 1/37, 2.7%).

2.3. Surgical procedure

Access to the lumbosacral junction was achieved via a mini-open laparotomy using a retroperitoneal approach (Kim et al., 2020; Mayer and Wiechert, 2002). The surgical procedure has previously been described in detail (Siepe et al., 2015). Following a complete anterior discectomy and meticulous endplate preparation, the Synfix-LR device (DePuy Synthes, West Chester, PA, USA) was inserted into the intervertebral space. The Synfix-LR device is a PEEK spacer attached to an anterior titanium locking plate. It is available in various heights (12–19 mm), surface geometries (26 × 32mm, 30 × 38mm), and lordosis angles (8°,12°). Implant geometries were chosen with the largest available footprint, implant height, and lordosis angle in order to achieve adequate segmental lordosis reconstruction and primary press-fit stability.

In order to induce a solid bony intervertebral osteointegration, rhBMP-2 (recombinant human bone morphogenic protein; InductOs 12 mg, Medtronic, Heerlen, Netherlands) was used as a bone graft substitute in the majority of cases (n = 25/37, 67.6%). Cancellous bone graft, which was harvested via a small, minimally invasive incision from the anterior iliac crest (n = 10/37, 27.0%) or ChronOS Granules (DePuy Synthes, West Chester, PA, USA) (n = 2/37, 5.5%) were used alternatively.

The choice of bone graft substitute as outlined above was subject to change during the course of this ongoing clinical trial as it was largely influenced by the availability, reimbursement, and access to varying graft materials at the time of surgery. The bone graft substitute was placed inside the cage. Remaining substitute was packed around the cage as well in order to promote solid bony consolidation of the disc space.

2.4. Study documentation/patient-reported outcome parameters

All patient data, clinical and radiological examinations were documented within the framework of an ongoing prospective clinical trial. Data acquisition was performed prior to the surgical intervention at baseline at baseline and regularly thereafter for up to 80 months. FU examinations were performed by medical staff members of the clinic's

spine unit who were not involved in the process of pre- or postoperative decision-making.

Clinical outcome was documented by standardized outcome measures such as the Oswestry Disability Index (ODI) or Visual Analogue Scale scores (VAS) (Fairbank et al., 1980). In addition, a 3-scale-grading system was used to assess the patient's subjective outcome evaluation ('highly satisfied', 'satisfied' or 'not satisfied'). Clinical data acquisition was performed by members of the clinic's spine unit including medical staff, research assistants, and research nurses.

Data on complications and reoperations were reported by the surgeons as part of the spine unit's internal quality assessment. The peri- and post-operative course of all surgeries was furthermore controlled independently by members of the spine unit who followed the surgeries and the surgical protocols and who searched the procedures for any kind of critical adverse event that had occurred in the subsequent course. All complications and reoperations were documented accordingly.

2.5. MRI-investigation

All patients included in this study underwent MRI-diagnostics at baseline as part of their preoperative assessment. A follow-up MRI was performed with a minimum of ≥5 years following the surgical intervention.

The assessment of potential degenerative changes at the adjacent segments at baseline was done for the purpose of the study alone.

To ascertain the full range of adjacent segment degeneration, cases where fusion operations at the adjacent segment were necessitated prior to the minimum 5year FU (n = 3) were included likewise.

Degenerative changes of the discs at the index- as well as at adjacent segment levels were classified according to Pfirrmann et al. on a 5-scale grading system (Pfirrmann et al., 2001).

In addition, the degree of facet joint degeneration was obtained both at the index- as well as at adjacent segment levels on pre- and post-operative MRI images using the Weishaupt classification system (Weishaupt et al., 1999).

Both classification systems have been widely used and high inter- and intra-observer reliability have been reported previously (Urrutia et al., 2016).

All pre- and postoperative MRI images were evaluated by 2 independent and highly specialized skeletal radiologists with expertise in the assessment of spinal pathologies. Both radiologists were blinded to the patient's outcome as well as clinical decision making.

Adjacent level degeneration (ALD) either of the adjacent disc or the adjacent facet joint was defined as a progression of degenerative changes ≥1° from preoperative to 5years postoperative according to the Pfirrmann or Weishaupt classification system. This had to be confirmed by both radiologists independently.

2.6. X-Ray analysis

X- Ray images were obtained at baseline and regularly thereafter for up to 80 months after surgery. Standard Cobb measurements were used to determine global lumbar lordosis (superior endplate L1 – superior endplate S1) as well as the segmental lordosis of the index segment L5/S1 (superior endplate L5 – superior endplate S1) and the cranially adjacent segment L4/5 (superior endplate L4 – inferior endplate L5) at each time point (Harrison et al., 2001).

2.7. Statistical analysis

Data consistency was checked, and data were screened for outliers and normality by using quantile plots. Crosstabulation tables with Fisher's Exact test, Linear-by-linear association, or Pearson's test were used to analyze crosstabulations. Independent and dependent Student and bootstrap t-tests were used to compare means and Pearson's correlation coefficients were computed and tested. Whisker plots with means and 95% confidence intervals were used to illustrate results. All reported tests were two-sided, and p-values < 0.05 were considered as statistically significant.

All statistical analyses in this report were performed by use of STATISTICA 13 (Hill, T. & Lewicki, P. Statistics: Methods and Applications. StatSoft, Tulsa, OK) (Hill and Lewicki, 2007).

3. Results

3.1. Clinical outcome analysis

Data obtained from VAS and ODI scores revealed a statistically significant and maintained improvement in comparison to baseline levels ($p < 0.05$; Fig. 1).

At the final FU investigation, n = 24 patients (64.9%) reported a "highly satisfactory outcome", n = 10 patients were "satisfied" (27.0%), whilst n = 3 (8.1%) reported an unsatisfactory outcome of their surgery. When asked if they would, retrospectively, be willing to undergo surgery again, n = 28 patients (75.5%) responded with "yes", n = 3 patients (8.1%) answered "no", whilst n = 6 (16.2%) were "unsure".

3.2. Incidence of adjacent segment surgery

A total of 10 subsequent operations at the cranially adjacent segment were performed in 8 patients at some stage during the postoperative course following ASAF.

A microsurgical decompression and/or discectomy was required due to clinically symptomatic compression syndromes at the adjacent level resulting from either lumbar disc herniation or adjacent level spinal stenosis in n = 6 cases, of which 3 surgeries were performed in the same patient. In n = 2 patients, a posterior instrumented fusion of the adjacent segment and in n = 2 patients posterior instrumented fusion with additional decompression of the adjacent segment was performed due to clinically symptomatic adjacent level disease.

Thus, the overall reoperation rate encountered in this study was n = 8/37 patients (21.6%).

The need for subsequent surgery at the adjacent segment had a significantly negative impact on the patient's overall satisfaction ($p = 0.038$) with only 3 patients reporting their outcome as 'highly satisfied' (n = 3/8, 38%) in comparison to 21 'highly satisfied' patients in the cohort without later surgery (n = 21/29, 72%)

Likewise, patients with subsequent adjacent level surgeries demonstrated a significantly lower reduction of VAS- (-0.73 ± 2.71 vs. -4.18 ± 3.21, $p = 0.011$; Fig. 2A) and ODI-scores ($-2\% \pm 17\%$ vs. $-19 \pm 15\%$, $p = 0.01$; Fig. 2B).

3.3. MRI assessment

In accordance with the inclusion criteria of this study, pre- and postoperative MRI-images were available in all patients (n = 37). Preoperatively, all discs of the index segment L5/S1 demonstrated severe degenerative changes (n = 37; ≥4° Pfirrmann classification). Facet joint degeneration of grade 1 or 2 were identified preoperatively in 32 or 35 cases at L5/S1. These degenerative changes of the index segment facet joints did not reveal any further deterioration at the 5-year FU except for one single case.

The overall incidence of adjacent level disc degeneration after ≥5 years FU, which was defined as a deterioration of the adjacent level disc L4/5 by ≥ 1° according to the Pfirrmann classification score, was 24.3% (n = 9/37). Interestingly, gender was identified as the only factor associated with the development of adjacent level disc degeneration, with a significantly higher prevalence for women with 42% (n = 8/19) vs 6% in men (n = 1/18), respectively ($p = 0.019$). Thus, the relative risk for the occurrence of adjacent level disc degeneration between genders was 7.6 ($p = 0.02$; 95% CI: 1.3–203).

The occurrence of these radiological adjacent level degenerative

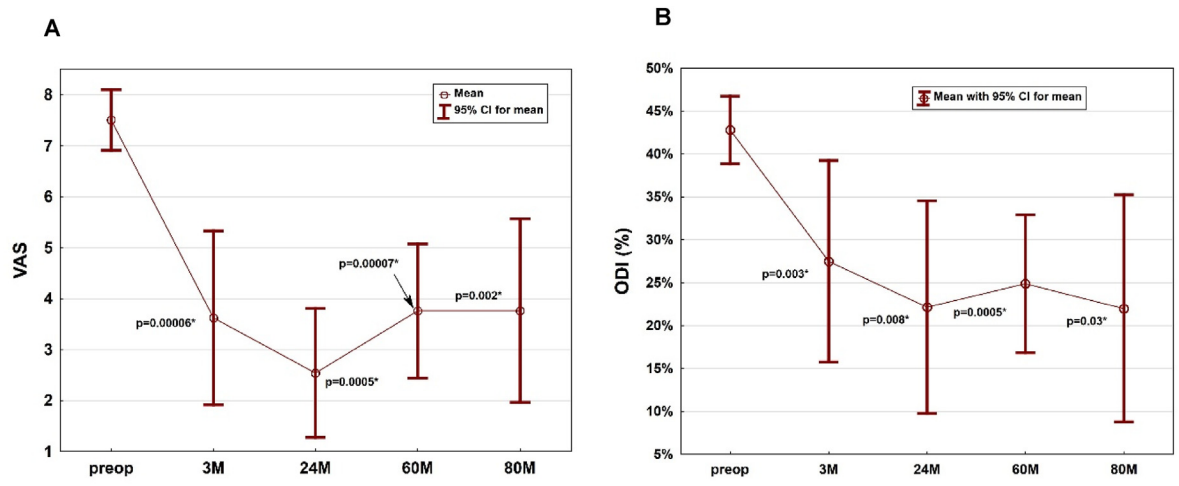

Fig. 1. Delineation of mean pre-and postoperative VAS (Fig. 1A) and ODI-scores (Fig. 1B) as calculated over the entire study cohort.

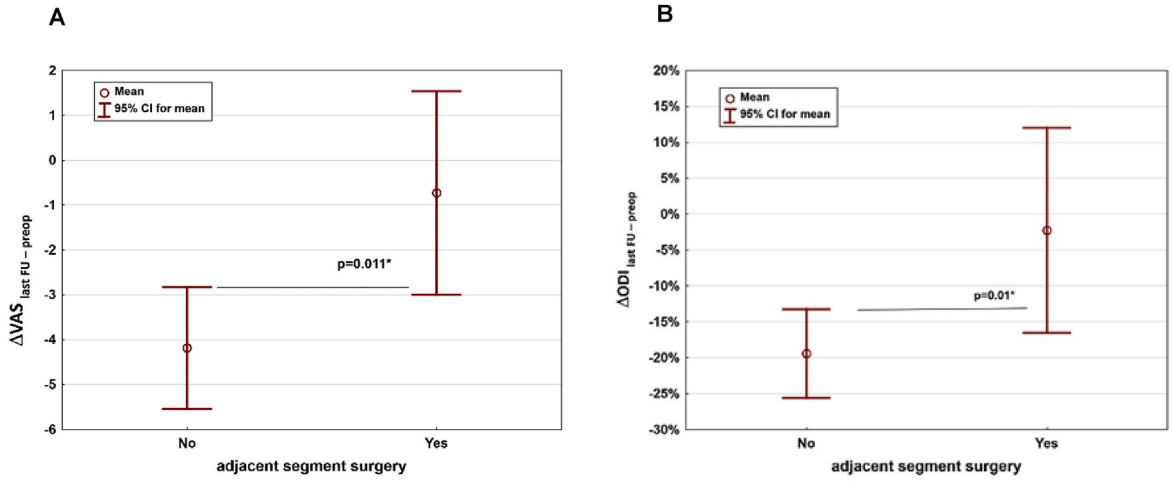

Fig. 2. Comparison of improvement of (A) VAS and (B) ODI for patients with subsequent adjacent level surgeries at the adjacent level L4/5 (Yes), compared to those without any adjacent level surgeries (No).

changes did not negatively impact the clinical outcome in terms of inferior VAS or ODI scores ($p < 0.05$).

A significant deterioration of the cranially adjacent facet joints, which was defined as an increase by $\geq 1^{\circ}$ at L4/5 according to the Weishaupt classification system, was noted in 35.1% (n = 13/37) of all cases. Comparing the group of patients with adjacent facet joint degeneration to the group without, no significant difference in clinical outcome scores could be detected.

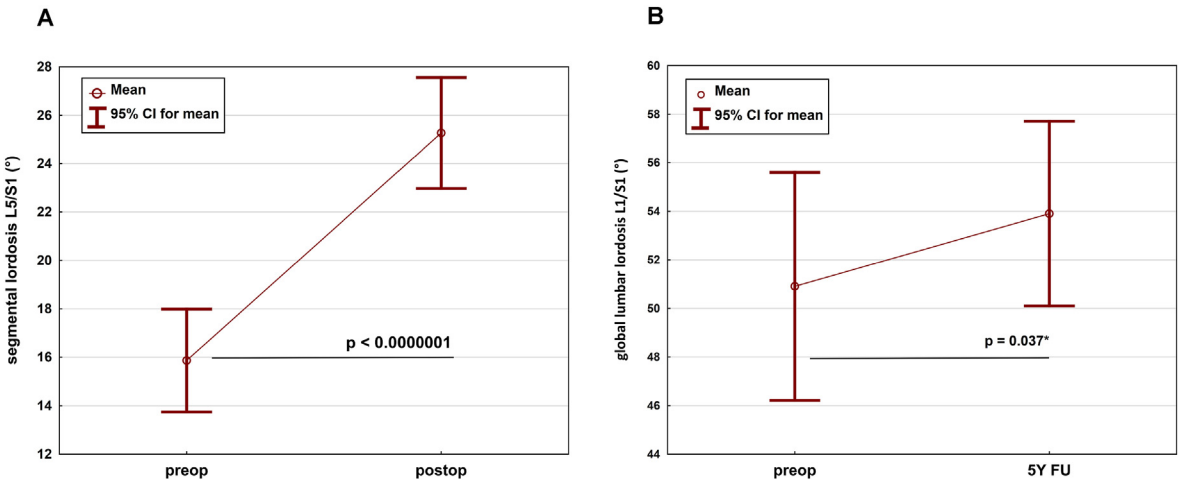

Fig. 3. Change in segmental lumbar lordosis at the lumbosacral junction (Fig. 3A) as well as in global lumbar lordosis (Fig. 3B).

3.4. X-Ray analysis

ASAF performed via an anterior approach yielded a highly significant reconstruction of segmental lordosis at the lumbosacral junction with an increase from 15.9° to 25.3°, respectively ($p < 0.0001$, Fig. 3A).

Global lumbar lordosis values showed a small, yet statistically significant increase at ≥5 years FU in comparison to preoperative values (48.8° ± 8.9°–52.1° ± 11.1°, $p = 0.037$; Fig. 3B).

3.5. Risk factors for adjacent segment surgery

Patient-related factors such as BMI, age, gender, nicotine, or previous operations at the index segment were not associated with an increased risk for subsequent operation at the adjacent segment ($p > 0,05$).

Nevertheless, a number of radiological factors were identified to be associated with a higher risk for adjacent segment surgery. As such, MRI-assessment of the adjacent segments revealed more pronounced degenerative discs and facet joints prior to the index surgery at baseline in cases where an adjacent level surgery was mandated at some stage during the postoperative course ($p = 0.017$, $p = 0.042$, Table 1).

The occurrence of radiological signs of ALD however did not have a significant negative impact on the patient's clinical symptomatology ($p > 0.05$).

Data from the X-Ray analysis revealed that a sufficient lordosis reconstruction of the lumbosacral segment seemed to have a protective effect on adjacent level reoperation rates. Patients with adjacent level revision surgeries demonstrated a significantly lower segmental lordosis reconstruction at the index segment (mean increase of +2.2° ± 4.21°, n = 5) when compared to the group of patients that did not require an additional surgery (mean increase of +10.44 ± 6.17°, n = 25, $p = 0.0084$; Fig. 4, Table 1).

Changes in global lumbar lordosis angles showed a decrease in the adjacent segment surgery-group (−2.75° ± 11.5°, n = 4) in contrast to the non-surgery-group (+2.13° ± 8.44°, n = 16). However, no significant difference between means of Δ global lumbar lordosis and segmental lordosis L5/S1 postop were found between both adjacency surgery groups (±) (Table 1). However, the corresponding power at the observed difference in these samples is quite small with 10% and 15%, respectively, indicating that future studies investigating these parameters should use increased sample sizes to achieve higher power and determine if means are in fact different.

4. Discussion

For patients suffering from intractable low back pain resulting from lumbar DDD, fusion of lumbar motion segments is currently the mainstay of surgical treatment for patients in whom an intensive conservative treatment program conducted over a minimum of 6 months has not achieved adequate pain relief. In the majority of cases, fusion of lumbar motion segments is achieved via posterior approaches, with or without instrumentation or additional interbody fusion (DiPaola and Molinari, 2008; Resnick et al., 2005). Posterior lumbar instrumentation and fusion, however, is associated with a variety of negative side-effects such as access related collateral muscle damage, sagittal imbalance, residual or increased kyphosis, graft site morbidity, implant loosening, pseudarthrosis as well as considerable complication and reoperation rates and mediocre clinical results as a wide variety of studies have demonstrated (Kong et al., 2010; Martin et al., 2007; Akamaru et al., 2003; Lee, 1988; Cardoso et al., 2008; Fan et al., 2012; Gillet, 2003; Goulet et al., 1997; Ha et al., 2008; Howe et al., 2011; Katz et al., 2003; Kumar et al., 2001; Lazennec et al., 2000; Maigne and Planchon, 2005; Moshirfar et al., 2006; Park et al., 2011; Shah et al., 2003; Umehara et al., 2000). Adjacent level facet joint violations have similarly been described which, in terms of an iatrogenic weakening of the adjacent segment, may similarly be held responsible for advanced and accelerated degenerative changes at the cranially adjacent segment (Anandjiwala et al., 2011; Levin et al., 2018).

In an attempt to avoid or reduce the incidence of these above-mentioned negative side effects, anterior stand-alone fusion techniques (ASAF) have been introduced. By achieving intervertebral fusion via the anterior approach alone posterior access-related collateral muscle damage as well as pedicle screw-related cranial facet joint violations can be avoided. Several studies have reported satisfactory clinical results, high fusion rates, adequate segmental and global sagittal balance reconstruction as well as a substantial restoration of disc space height and hence opening of the neuroforamen (Siepe et al., 2015; Strube et al., 2012; Hoff et al., 2010; Lammli et al., 2014; Manzur et al., 2019). A number of additional studies confirmed the safety and efficacy of ASAF procedures at short- to mid-term FU (Hoff et al., 2010; Lammli et al., 2014; Behrbalk et al., 2013; Li et al., 2010; Norotte and Barrios, 2018). Giang et al. in a systematic literature review analysed the results from 17 studies that investigated the outcome of ASAF procedures and confirmed the efficacy and safety of this procedure (Giang et al., 2017).

Therefore, the goal of this present study was to investigate the clinical and radiological results of ASAF after a longer FU period of ≥5 years. Special emphasis was placed on the assessment of the adjacent levels and whether ASAF may, in fact, serve to reduce the incidence of adjacent level degenerative changes and reoperation rates in comparison to posterior pedicle screw-based techniques.

The authors' primary working hypothesis prior to the study was that ASAF would serve to reduce the incidence of ALD, predominantly by avoidance of the above-mentioned and posterior pedicle screw-related

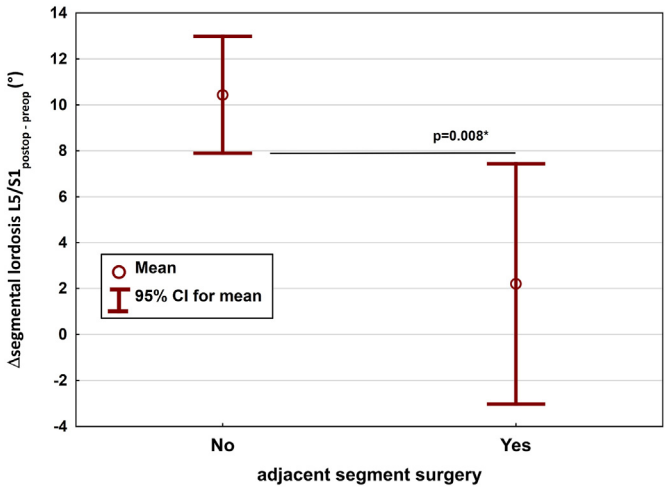

Fig. 4. Comparison of improvement of the monosegmental lordosis reconstruction at the index segment for patients with subsequent adjacent level surgery at L4/5 (Yes) in comparison to those without (No).

Table 1
Comparison of radiological parameters between patients with (+) or without (−) subsequent adjacent level surgery at the level L4/5. SD = Standard Deviation; n = number of patients.

	+ Adjacent Surgery			- Adjacent Surgery			p
	mean	SD	n	mean	SD	n	
Δ segmental lordosis L5/S1	2.20°	4.21°	5	10.44°	6.17	25	**p = 0.0084**
segmental lordosis L5/S1 postop	23.9°	4.14	7	25.6°	6.58	29	p = 0.39
Δ global lumbar lordosis	−2.75°	11.5	4	2.13°	8.44	16	p = 0.3471
Pfirrmann L4/5 preop (grade)	3.5	0.53	8	2.7	0.83	29	**p = 0.017**
Weishaupt L4/5 re preop (grade)	1.4	0.35	8	1.0	0.62	27	**p = 0.042**

negative side effects.

To the author's knowledge, the presented study entails the longest FU published for ASAF thus far.

Overall, the data from this present investigation reveal that ASAF with the Synfix-LR device achieved adequate satisfactory clinical results after a mean FU of ≥5 years with 64.9% (n = 24/37) of all patients reporting a highly satisfactory and 27% (n = 19/37) of all patients reporting a satisfactory n = 10/37) outcome as well as a statistically significant improvement in VAS and ODI scores.

However, these satisfactory clinical results were accompanied by a higher-than-expected rate of radiological degenerative changes at the adjacent segment for both discs and facet joints (adjacent level disc degeneration = 24.3% (n = 9/37); adjacent facet joint degeneration = 35.1% (n = 15/37)) as well as a considerable rate of consecutive adjacent level surgeries in 21.6% of all cases (n = 8/37).

The rate of ALD as well as the rate for operation at the adjacent segment following ASAF from this present investigation is higher than initially expected and seems to be comparable to those that have previously been published following posterior instrumented fusion procedures (Park et al., 2004; Gillet, 2003; Horsting et al., 2012; Okuda et al., 2018; Sears et al., 2011). However, the comparison to previously published data investigating ALD after posterior instrumented fusion is hampered by the lack of one uniformly accepted definition for this entity.

A literature review by Park et al. including 22 studies that investigated adjacent level changes after lumbar and lumbosacral fusion revealed an incidence of 5.2–100% of radiological signs of adjacent segment degeneration and an incidence of symptomatic adjacent segment disease ranging from 5.2 to 18.5% over a 45–164 months observation period (Park et al., 2004). In a study by Sears et al., a 5- and 10-year prevalence of 9% and 16% were detected with respect to subsequent surgeries for ALD after posterior single-level lumbar fusion (Sears et al., 2011). Gillet et al. (Gillet, 2003) reported an incidence of ALD in 37% of their patients following fusion for lumbar degenerative disc disease, 50% of which required secondary surgery. Lee et al. investigated 1069 patients who underwent lumbar fusions, 28 of which (2.62%) necessitated secondary operations resulting from ALD (Lee et al., 2009).

The deterioration of the adjacent segment is multifactorial, and a multitude of possible risk factors and explanations for the development of ALD after lumbar fusion have been highlighted in the literature. Patient-related factors such as age, gender, BMI, nicotine abuse, and/or previous operations at the index segment have been reported, frequently with contradictory results (Park et al., 2004; Chen et al., 2011; Ghasemi, 2016; Lawrence et al., 2012; Soh et al., 2013; Tsuji et al., 2016). We investigated all these above-mentioned criteria and were able to identify gender as a significant risk factor, with female patients being more prone to developing ALD after ASAF (OD = 7.6).

Preoperative disc and/or facet joint degeneration in the adjacent segment has similarly been identified as a risk factor for the development of ALD (Lee et al., 2009; Anandjiwala et al., 2011; Ghasemi, 2016; Heo et al., 2015; Li et al., 2015). Lee et al. in their study with 1069 patients demonstrated that preoperative facet joint degeneration in the adjacent segment was associated with a higher risk for adjacent segment problems following lumbar fusion procedures ($p < 0.01$) (Lee et al., 2009). The same observation was made by Anandjiwala et al. who, in a cohort of 68 patients, demonstrated a significant increase in the risk of ALD in the presence of preexisting degenerative changes ($p = 0.001$) (Anandjiwala et al., 2011). Li et al. reported that a higher prevalence of ALD was found in cranial discs with preexisting degeneration in comparison to those without ($p = 0.012$) and which also demonstrated superior clinical outcomes (Li et al., 2015).

Likewise, in this present study, the MRI-assessment of the adjacent segments revealed that more pronounced degenerative discs ($p = 0.005$) and/or facet joints ($p = 0.04$) at baseline were statistically significantly correlated with a higher rate of adjacent level revision surgeries over the subsequent postoperative course. Despite preoperative degenerative changes at the adjacent level, the pathology at the index segment was clearly the predominant source of pain. Only this segment was addressed surgically to avoid any extension of the fusion, which could increase the risk for additional perioperative complications as well as for reoperations (Martin et al., 2007; Park et al., 2004; Howe et al., 2011).

Restoration of disc space height, as well as segmental and global lordosis, are further essential key factors for a good clinical outcome and for the preservation of the adjacent segments (Akamaru et al., 2003; Park et al., 2004; Umehara et al., 2000; Kim et al., 2010; Nakashima et al., 2015). Umehara et al. measured the biomechanical effects of postoperative lumbar malalignment in 8 cadaveric specimens and found decreased lordosis in the instrumented (L4 –S1) segments indicating an increased loading of the posterior column in the segment above the instrumentation. He concluded that these biomechanical effects of postoperative sagittal malalignment on the loading of the adjacent segment may contribute to the degenerative changes at the junctional level reported as long-term consequences of lumbar fusion. (Umehara et al., 2000). In a systematic review, ALIF approaches were found to be superior to posterior PLIF/TLIF approach techniques with respect to segmental and global lumbar lordosis reconstruction ($p < 0.001$) (Ajiboye et al., 2018). Furthermore, previous studies have demonstrated a significant reconstruction of segmental and lumbar lordosis after ASAF with the Synfix-LR device (Siepe et al., 2015; Konig et al., 2013). The radiological evaluation from this present study confirmed this finding and demonstrated a highly significant reconstruction of segmental lordosis at the lumbosacral junction from 15.9° to 25.3°, respectively ($p < 0.0001$), and a small but statistically significant increase in global lumbar lordosis ($p = 0.037$). Patients in whom a consecutive surgery at the cranially adjacent level was mandated at some stage during the postoperative course demonstrated a significantly lower segmental lordosis reconstruction at the index segment in comparison to the group without (+2.2° vs. +10.44°, $p = 0.0084$).

However, a limitation of this study is the missing assessment of global spinal parameters, especially those of sagittal balance. These are of utmost importance with respect to adjacent level degeneration (Wang and Ding, 2020). The primary focus when this study was initiated was to perform an analysis of the safety and efficacy of this new fusion technique. Whilst the effect of a number of parameters could be assessed from the routinely performed postoperative X-Ray images in this present investigation, future studies should perform a more in-depth analysis of the effect of sagittal balance parameters.

In conclusion, ASAF serves as a safe and reliable procedure for patients suffering from intractable LBP from single-level DDD that are unresponsive to conservative therapy and suffer from inacceptable life circumstances and pain. ASAF results in an adequate number of satisfied patients even after mid- to long-term follow-up period of more than 60 months. Nevertheless data from this present investigation also reveal a higher-than-expected rate of ALD and adjacent level reoperation rates following ASAF procedures.

Signs of disc- and facet joint degeneration at the cranially adjacent level already at baseline should be seen as a potential risk factor for the progression of degenerative changes with an elevated risk of subsequent adjacent level revision surgeries in the due postoperative course.

Furthermore, the data from this study, although limited by the lack of sufficient spinopelvic parameters, provides additional insight into this new technology and highlights the importance of adequate segmental lordosis reconstruction at the index segment as a protective factor with respect to adjacent level preservation. It also aids spine surgeons to communicate realistic and honest expectations and risks to their patients, such as the possibility to develop adjacent level degeneration over time.

Ethics declarations

The authors have no competing or financial conflict of interest in relation to this work. No funding was received for conducting this study.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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