

The Quest of Sagittal Balance Parameters and Clinical Outcome after Short Segment Spinal Fusion

Rami Alqroom

Neurosurgery department, KHMC- Royal Medical Services, Amman, Jordan

Corresponding author: Alqroom Rami, MD.FACS. Neurosurgery department, KHMC. Royal Medical Services, Amman, Jordan. ORCID ID: <http://www.orcid.org/0000-0001-7338-8243>. Tel.: 00962797017870. E-mail: dr.alqroomrami@gmail.com

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ABSTRACT

Introduction: Sagittal imbalance leads to muscular distress and results in low back pain. **Objectives:** This study scrutinize the segmental impact of short spinal fusion on spinopelvic parameters and the global patient's clinical outcome. **Materials and Methods:** A retrospective analysis evaluated 56-patients who underwent lumbar fusion surgery at Klinikum Dortmund, from July 2013 to February 2014. The population was allocated into two groups: (1-level group), (2-levels group). EOS imaging applied for radiological evaluation and measurements of the following spinopelvic parameters: pelvic incidence (PI), sacral slope (SS), pelvic tilt (SS), lumbar lordosis (LL), and sagittal vertical axis (SVA). The radiological measurements were implemented during the preoperative, postoperative, 3 months and 1 year follow-up visits. All patients completed clinical questionnaires. **Results:** Statistically, the Pearson correlation coefficient revealed in the 1-level group that the clinical parameters correlated with the PT ($R=0.40$), SSA ($R=-0.38$) and SVA ($R=-0.41$) ($p<0.05$). While clinically, the mean preoperative VAS and mean ODI improved significantly in both groups. There was also a high correspondence between LL and SS ($R=0.90$); this relationship persisted at the same level even after a year. For the 2-level group, the only parameter that was interrelated with clinical parameters was the SVA ($R=0.49$) ($p<0.05$). There was also a high correlation between LL and SS ($R=0.88$). **Conclusion:** Scrutiny conducted showed: Patient with one level would improve clinically in terms of pain and radiculopathy, with only small alterations in spino-pelvic parameters. Meanwhile, two-level fusions have a statistically substantial clinical improvement interrelated to re-establishment of lumbar lordosis and sagittal vertical axis.

Keywords: Sagittal balance; Segmental imbalance; spinopelvic parameters.

1. INTRODUCTION

Degenerative lumbar disease nowadays is a common condition which causes anatomical and morphological changes leading to a combination of low back pain, leg pain and spinal imbalance clinical syndromes (1). Sagittal imbalance leads to muscular distress and results in low back pain. Low back pain is a multifactorial process caused by facet joint arthrosis, disc degeneration, and the loss of lumbar lordosis (2). In cases in which conservative therapies fail, surgery is the proper treatment to relieve low back pain; it is then recommended to restore sagittal imbalance. Operative treatment for lumbar back pain has long been a topic of debate. Several surgical options have been performed for patients with degenerative lumbar disease. Decompression surgery is essential for the symptoms of neurogenic claudication. Most surgeons rec-

ommend fusion and instrumentation at the time of decompression (3). Spinal fusion technique has become one of the most common options for the management of spine degenerative disease nowadays and is consequently a challenging area for investigation and study (4). However, spinal fusion is not completely without consequence; it alters the normal biomechanics of the spine and eliminates mobility (4, 5). To our knowledge, there is a lack of studies evaluating the results of surgical procedures and the actual changes of sagittal alignment after lumbar lordosis reconstruction in patients with degenerative lumbar disease. Furthermore, in the literature the significance and the role of sagittal balance following spinal fusion are unknown (6-9). Some other studies have attempted to correlate spinopelvic parameters with health-related quality of life (HRQoL) and pain scores in

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order to provide some understanding during surgical management (10, 11). These studies identified that pelvic tilt (PT) is the key radiographic parameter that is correlated with patient pain and disability, and found it is correlated with health-related quality of life (HRQoL) (12). The purpose of this current study was: to investigate the correlation and the impact of short spinal segment fusion on segmental sagittal balance and the overall patient's mid-term clinical follow-up outcome.

Our hypotheses were:

- Interbody fusion of one and two levels would affect the spinopelvic parameters.
- Improvement of health related quality of life (HRQoL) would be significant in these two groups.
- Which spino-pelvic parameters affect the clinical outcome.

2. MATERIALS AND METHODS

Patient characteristics

This retrospective study evaluated 56 patients (24 males, 32 females) who underwent lumbar fusion surgery from July 2013 to February 2014 for the treatment of degenerative spine conditions of the lumbar spine at the Department Of Spinal Surgery, Klinikum Dortmund, Germany. (Table 1) The population was allocated into two groups: single level instrumentation (1-level group) and 2 instrumented levels (2-level group). All patients were operated on by (ALQ, FJ). Patients were selected for this study by applying the following criteria: a) One or two levels spine disease; b) Treatment by posterior inter-body fusion; c) Patients having radiological pre and follow up EOS® measurements; and d) A minimum clinical and radiologic follow up of 12 months. The following exclusion criteria were applied: a) Inadequate documentation of follow up; b) Inadequate documentation of EOS® follow up measurement according to scheme; and c) The presence of severe systemic disease.

Clinical and radiological evaluation

Following the acquisition of the EOS images, personalized 3D bone demonstration of the patient in a weight-bearing position (spine and lower limb) were created and clinical parameters automatically calculated. The result is a customized report of each patient for spinopelvic parameter measurements including: pelvic incidence (PI), sacral slope (SS), Pelvic tilt (PT), lumbar lordosis (LL), and sagittal vertical axis (SVA). The radiological measurements were performed during the preoperative, postoperative, 3 months and 1 year follow-up visits (Figure 1). All patients completed the clinical

Parameter	patients number
GENDER	
Male	24
Female	32
AGE	
<60	17
60<	39
INSTRUMENTED LEVEL	
1 level	34
2 levels	22

Table 1. Demographic details of all patients

Parameter	Number
1-Instrumented Level	
L3/L4	4
L4/L5	18
L5/S1	12
2-Instrumented Levels	
L3-L5	10
L4-S1	12

Table 2. Demographic details of patients and levels instrumented

Groups	PI		PT		SS	
	Pre-op	Last follow-up	Pre-op	Last follow-up	Pre-op	Last follow-up
1-level group	54.8°	55.1°	18.1°	16.2°	37.3°	38.9°
2-level group	55.5°	55.6°	21.8°	17.5°	33.6°	37.3°

Table 3: Comparison of pelvic parameters between the two groups

questionnaires [Oswestry disability index (ODI), Visual analogue scale (VAS)] at same time table (Figure 2).

The follow-up rate was for one year. The average age was 66.7 years (range, 27–89 years). We allocated and investigated two groups: the first group included 34 patients with one level lumbar fusion (Table 1). The second group included 22 patients with two level lumbar fusion. The first group included 34 patients with single level fusion, of which 4 were at L3-4, 18 were at L4-L5 and 12 at L5/S1. There were 22 patients in the second group with two levels fusion: 12 patients had L4- S1 and 10 L3- L5 (Table 2).

Statistical analysis

In order to compare clinical and radiological outcomes for the periods; pre-operative, post-operative, 3 months and 1 year we conducted unpaired sample t-test (Excel 2010) for 3 scenarios: pre- operative vs post- operative, pre-operative vs 3months follow-up, pre-operative vs 1 year follow-up. This was done individually for the 1-level group and the 2-level group. Further statistical analysis was conducted to investigate the correlations between the spino-pelvic parameters and the clinical outcome using xlstat (version 7.5.20) for the Mann-Whitney U-test and Pearson correlation matrix. The unpaired Student's t-test was used to compare between the two groups. Correlation studies were performed using Pearson's coefficients to investigate relations between all radiologic parameters and VAS and ODI improvements.

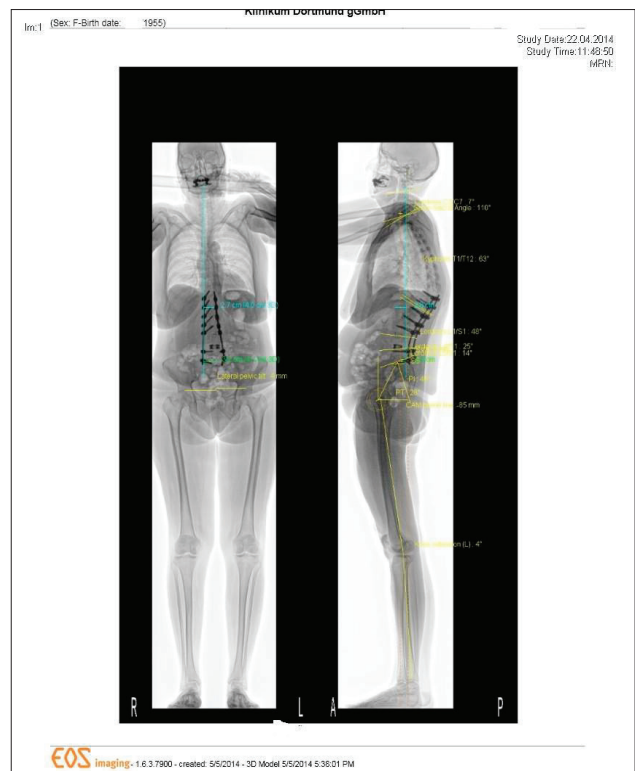


Figure 1. Different spinopelvic parameters demonstrated on antero-posterior and Lateral full body views

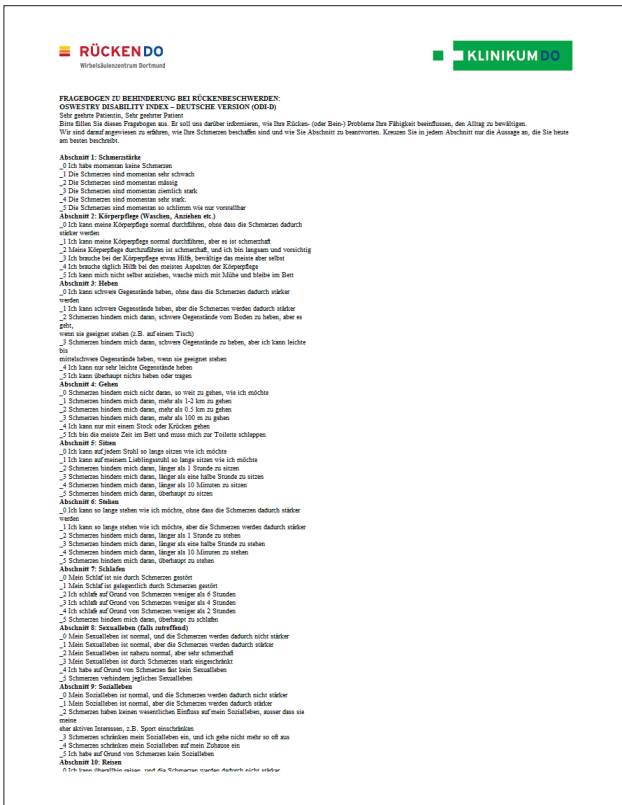


Figure 2: The Oswestry Disability Index (ODI) questionnaire (German version).

The Minimal Clinically Important Difference (MCID) was calculated with respect to deltas between pre-op and an interval post-op so we calculated three MCID: Delta Post-Pre, Delta 3M-Pre, Delta 1yr-Pre. We have used a distribution based approach and the MCID is calculated as 0.5* standard deviation of the deltas, with 0.5 meaning that we have the hypothesis that the effect of the treatment will be ‘moderate’, (we can use 0.2 for slight improvement or 0.8 for high improvement). We calculated the MCID in correlation to the number of positive or negative deltas for VAS and ODI for 1-2 levels fusion. For VAS the MCID difference was (1.1), for ODI the MCID difference was (5.5). These values were used as the thresholds to define clinical improvement.

3. RESULTS

In terms of clinical improvement related to radiculopathy in both groups, most of the patients showed significant improvement of symptoms at postoperative evaluation. The mean pre-operative VAS improved significantly in both groups (Figure 3). The mean ODI was 44.5% and 58.2 % at the beginning and improved to 29.2 % and 36.0 % in the 1-level group and the 2-level group respectively (Figure 4). The Pearson correlation coefficient revealed that in the 1-level group the clinical parameters (ODI) correlated with the PT (R=0.40), SSA (R=-0.38) and SVA (R=-0.41) (p<0.05). There is also a high correlation between LL and SS (R=0.90); this relationship persisted at the same level even after a one-year follow-up. For the 2-level group, the parameter that correlated with clinical parameters (ODI and VAS) was the SVA (R=0.49) (p<0.05). There is also a high correlation between LL and SS (R=0.88). (Figure 5).

In summary for the minimal clinically important differ-



Figure 3: Visual Analogue Scale- Clinical Improvement

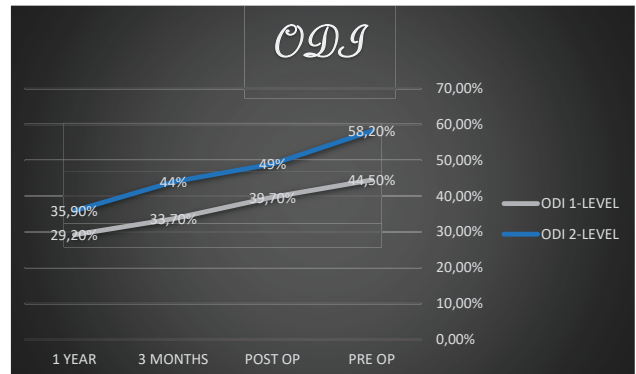


Figure 4: Oswestry Disability index- Clinical Improvement

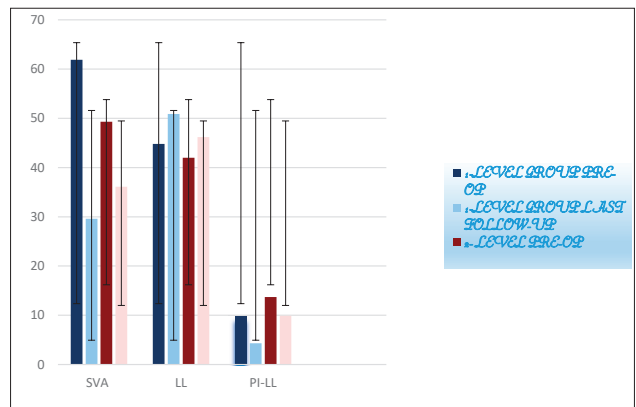


Figure 5: Comparison of spinopelvic parameters between the two groups

ences (MCID), for the 1-level group, 88% of patients were improved after a year based on VAS and 73% based on ODI. For the 2-level group, 91% of the patients were improved after a year based on VAS and 86% based on ODI.

4. DISCUSSION

The purpose of this study is to address the clinical outcome in patients, who underwent instrumented spinal procedures in correlation with parameters of global sagittal alignment and simultaneously the spino-pelvic parameters restoration.

Patient’s symptoms and clinical examination are the determinant basis for the surgical management decisions as well as the clinical outcomes and/or the prevention of further decompensation. All these aspects are critical for the patients in terms of health-related quality of life. One of the utmost factors, based on recent outcomes-related research, which has been emphasized through previous studies might be the restoration of normal sagittal alignment to improve

the over-all outcome. (13-16). In recent years, there has been an increasing emphasis on the importance and role of the sagittal spino-pelvic alignment and balance in relation to the functioning of the spine, and in the pathogenesis of different spinal pathologies as compensatory mechanisms or as failure of the addressed therapy, also in terms of quality of life (17-19).

Adult spinal deformity (ASD) is a major and disabling condition, which has multiple causes such as the degenerative process of aging, iatrogenic postoperative flat back syndrome, posttraumatic kyphosis, etc. (20-24). Management of patients remains one of the most challenging issues in the field of spinal surgery due to the complexity and the varieties of pathologies and clinical presentations. Efforts have been made to identify the ideal postoperative sagittal profile for degenerative spinal diseases. Accurate analysis of the morphology of the spine in the sagittal plane is essential to adequately treat its pathology. Some authors have proposed formulas to achieve a satisfactory postoperative alignment related to outcomes and statistical models (25-28). Schwab et al. proposed some figures for optimal correction, with SVA less than 50 mm, PT less than 25°, and PI-LL less than 10°.(29). However, little has been published about the actual changes of sagittal alignment after lumbar lordosis reconstruction. Several studies introduced parameters, which have been described to measure spinal deformity and global spinal malalignment and to correlates with disability by validated health measures (30-34).

The importance of positive sagittal alignment with increasing sagittal vertical axis (SVA), which correlated with pain and poor health-related quality of life scores was described by Glassman et al, and found that sagittal vertical axis was correlated with pain and a decrease in function as measured using ODI and SF-12 (8, 9, 28, 31). In our results, setting the threshold to the above mentioned value of SVA = 50 mm, we found a good clinical outcome in 90% of the patients when looking at the VAS and 85 % when looking at the ODI.

The pelvic tilt (PT) plays a master role as compensation in case of sagittal malalignment, and this should be considered during operative planning and management. (35) In the study done by Lazennec et al the correlation between PT and the increased residual pain in patients that underwent a lumbosacral fusion was investigated. They found that the larger the postoperative PT, the more likely the patients will experience residual pain (36). In our study we found no changes in the 1-level group, while in the 2-level group we found significant improvement regarding clinical outcome related to changes of PT (Table 3).

Pelvic incidence (PI) as the pelvic anatomical parameter and the determinant of the pelvic tilt and the sacral slope, also plays an important role in the lumbar lordosis degree. Pelvic incidence is considered to be invariable at the end of growth. PI represents the algebraic sum of the SS and the PT: $PI=SS+PT$.

PI is a strong determinant of the pelvic orientation in a standing position: as the PI increases, so does the SS, PT or both (17). Vaz et al. have demonstrated a correlation between PI and LL in normal subjects; a low PI is usually associated with a low lumbar lordosis, whereas a high PI is usually associated with a high lumbar lordosis. (37) Also, the correlation between LL and SS has been reported in normal populations;

LL increases linearly with SS (38). This is consistent with the correlation results between PI and LL of our cohort.

However, we found that one level operation could not affect any of the pelvic parameter (SS, PT). In the 2-level, PT and SS showed a significant improvement after 1 year, where the PT was more influenced than the SS. Regarding spinopelvic parameters both groups showed a significant change for LL, SVA at the 1-year time-point (Figure 5).

In terms of lumbar lordosis in correlation to pelvic incidence and regarding the amount of restoration: when SS angle is high, the values of lordosis increases, mainly on the distal segments L4-L5, L5-S1. Thus, it is mandatory to restore lordosis on this area, which is generally compromised by degenerative discopathies. Conversely, if SS is small, with less need of lordosis restoration.

Many studies reported previously that the sacral slope was relevant to the clinical outcome after one year, but we found that the sacral slope correlation was very weak in both of our groups (39-42).

5. CONCLUSION

This is one of the first studies to evaluate the impact of sagittal balance in patients with spine degenerative disease who underwent short segment spine fusion surgery. Thus, sagittal imbalance should be taken into consideration before initiation of any kind of treatment, as the initial spino-pelvic orientation will; interfere with the biomechanics of the spine; in addition, the spino-pelvic shape and some spinal curvatures and spino-pelvic situations are more frequently subject to specific degenerative evolution, analyses of spino-pelvic parameters, such as, pelvic tilt and lumbar lordosis, appear to be essential to the understanding of the impact of spinal deformity and the treatment choice in degenerative lumbar disease. According to our results, patients with spine degenerative disease after lumber fusion for one level will improve clinically in terms of pain and radiculopathy, with only small changes in spino-pelvic parameters. Meanwhile 2-level fusions have a statistically significant clinical improvement correlated to restoration of lumbar lordosis, sagittal vertical axis and pelvic tilt, also increased risk of developing symptomatic sagittal imbalance due to alteration of mobility and limited compensatory capacities of fixed mobile segments.

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- **Future works:** To assess the impact of the multiple levels instrumentation on the spinopelvic parameters.
- **Conflict of interest:** The author certify that he has no affiliation with or involvement in any organization or entity with any financial interest, or non-financial interest in the subject matter or materials discussed in this manuscript.

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