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Research Paper

The Effect of Rod Bending on Long-term Lumbar Sagittal Parameters in Spondylolisthesis Patients Treated With Short Segment Posterior Fusion: A Randomized Clinical Trial

Peyman Gholipour[1], Arad Iranmehr[2], Seyed Taher Mousavi[1], Mohamad Namvar[2], Reza Bahrami Ilkhchi[1], Mohammad Reza Fattahi[3], Mohammad Kazem Sarpolaki[2*]

1. Department of Neurosurgery, Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran
2. Neurological Surgery Department, Imam Khomeini Hospital Complex (IKHC), Tehran University of Medical Sciences, Tehran, Iran
3. Faculty of Medicine, Tehran University of Medical Sciences, Tehran, Iran

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ABSTRACT

Background and Aim: Although rod bending is a universal method for maintaining lumbar lordosis (LL), its long-term efficacy in short-segment posterior fusion is still a challenge. This study aimed at evaluating the long-term effect of rod bending in patients with grade one L4/L5 spondylolisthesis with a short segment fusion.

Methods and Materials/Patients: A double-blind prospective randomized clinical trial was conducted from 2016 to 2018 and patients who met the inclusion criteria were enrolled in the study. The participants were randomized into two treatment arms: open posterior fusion with rod bending and without rod bending. The baseline data, including leg and back pain scores, were evaluated before surgery. Lumbar, focal, and segmental lordosis were measured before surgery. After surgery and a one-year follow-up, pain scores and lordosis measurements were re-evaluated and compared between and within groups.

Results: A total of 60 patients were analyzed. Leg and back pain scores improved significantly after the follow-up in both groups (P<0.0001). However, there was no significant difference between the two groups before and after the surgery. LL did not change in either group after surgery. Focal and segmental lordosis significantly increased in both groups but showed no difference between the groups at either time. Complications were not significantly different in either group.

Conclusion: In this study, no significant difference concerning the radiological and pain outcomes was observed in either group; therefore, rod bending to reach the desired LL may be an unnecessary spend of time.

*** Corresponding Author:**
Mohammad Kazem Sarpolaki, MD.
Address: *Neurological Surgery Department, Imam Khomeini Hospital Complex (IKHC), Tehran University of Medical Sciences, Tehran, Iran*
Tel: *+98 (912) 8215563*
E-mail: *Kazmo885@gmail.com*

Highlights

• Rod bending is a common method for maintaining lumbar lordosis but its effectiveness in short-segment posterior fusion in the long period is controversial.

• This double-blind randomized clinical trial evaluated the long-term effect of rod bending in patients with grade one L4/L5 spondylolisthesis with a short segment fusion.

• Focal and segmental lordosis significantly increased in both groups.

• Complications were not significantly different in the groups.

• Rod bending to reach a desired lumbar lordosis may be a waste of time.

Plain Language Summary

Although rod bending is a universal method for maintaining lumbar lordosis (LL), its long-term efficacy in short-segment posterior fusion is open to question. This research examined the long-term impact of rod bending in patients with grade one L4/L5 spondylolisthesis with a short-segment fusion. In this double-blind randomized clinical trial which was performed from 2016 to 2018, eligible patients entered the study. The participants were randomized into two treatment arms: open posterior fusion with rod bending and without rod bending. Lumbar, focal, and segmental lordosis were assessed before surgery. After surgery and a one-year follow-up, pain scores and lordosis measurements were re-evaluated and compared between and within groups (n=60). Leg and back pain scores improved significantly after the follow-up in both groups (P<0.0001). No significant difference was observed between the two groups before and after the operation. LL increased in both groups but no difference was reported between the groups at either time. Meanwhile, complications were not significantly different in patients. In this study, no significant difference concerning the radiological and pain outcomes was observed between the groups. Thus, using rod bending to achieve favorable LL may be time-consuming.

1. Introduction

Degenerative spondylolisthesis (DS) or previously known as pseudo-spondylolisthesis was first described by Junghanns in the 1930s. Ever since it has been a source of various studies worldwide. While studies are showing the benefits of surgical intervention over non-surgical treatments, controversies remain when it comes to the optimal surgical approach [1-3]. Despite different surgical approaches suggested in the literature, the posterior fusion technique using pedicular screws is one of the main surgical approaches to treat DS patients with good clinical outcomes [4]. On the other hand, there have been many studies in the last two decades concerning the importance of global and regional sagittal alignment, especially lumbar lordosis (LL) [5]. These spinal parameters play an important role in both the patient's quality of life and post-operative complications. Therefore, surgical approaches to treat DS should maintain the physiological LL and other parameters in addition to constructing a firm fusion. Bending a rod is one of the techniques to create and maintain LL, especially in multi-level constructs. Rod bending is an operator-dependent procedure that consumes time and alters the biomechanical parameters of the rod [6] intraoperative rod contouring is required to realign the spine. A French bender is the most common contouring tool used. There are several reports on the mechanical properties of various rods with manufactured straight rod; however, few reports describe the changes in a rod's mechanical properties after rod contouring. The authors investigated the influences of rod contouring on rod strength and stiffness. A 3-point bending test was conducted. Each 18-cm rod was loaded at a rate of 10 mm/min with a load applicator. Three different rod diameters (5.5, 6.0, and 6.35 mm. Meanwhile, studies are showing the mismatch between rod bending and the actual post-operative LL [7]. To our knowledge, no randomized clinical trial (RCT) has explored the effects of rod bending in a single-level fusion construct; therefore,

this study sought this effect on low-grade DS patients radiographically considering the patient's quality of life.

2. Methods and Materials/Patients

This prospective randomized clinical trial was performed at Imam Reza Hospital in Tabriz, Iran from 2016 to 2018 (Clinical Trial Registration Code: IRCT20120527009878N9). Patients with low-grade DS who met our inclusion and exclusion criteria, and gave written informed consent were enrolled in this clinical trial and grouped randomly in two treatment arms: posterior pedicular fusion with rod bending and without rod bending. The Iranian Registry of Clinical Trials approved this study before any patient enrollment. The inclusion criteria were having DS grade I in L4/L5 level (based on the Meyerding classification) [8] and providing an informed consent form to participate in the study. The exclusion criteria included the following items: having more than one level of listhesis; spondylolisthesis types other than the degenerative, including isthmic, traumatic, dysplastic, iatrogenic, or pathologic; any previous lumbar spine surgery; any signs of infection or malignancy pre-or intra-operatively; any mental status preventing consent or reliable examination; any degenerative lumbar pathologies other than the spondylolisthesis in another level which required surgical intervention (e.g. an extruding disc, canal stenosis, foraminal stenosis, etc.); any lower limb neurological deficits before surgery; and not returning for the one-year follow-up.

Study design

The diagnosis was confirmed by dynamic upright x-rays. All patients underwent computed tomography (CT) scan and magnetic resonance imaging (MRI) before the surgery to rule out any other pathologies and help the surgical planning. For each individual, leg and back pain was evaluated by the visual analog scale (VAS) and the participants' demographic data were collected as well. LL (defined as the Cobb angle between the upper endplate of L1 and the upper endplate of S1), focal lordosis (FL) (defined as the angle between the lower endplate of L4 and the upper endplate of L5), and segmental lordosis (SL) (defined as the upper endplate of L4 and lower endplate of L5) was measured for each patient.

Surgical intervention

All patients were randomly divided into two treatment arms and were taken to the operating room. A midline incision was performed and subperiosteal dissection was done while pedicular screws were inserted in L5 and L4 pedicles. Next, laminectomy and foraminotomy were preceded until decompression was achieved. Based on the treatment arm, the rods were either bent or fixed without bending. Dorsolateral fusion was achieved by the auto and allograft bone. Both groups received pre- and post-operative care based on our institutional protocol.

Outcome measures

All patients were asked to return after one year. Back and leg VAS scores were measured and a follow-up upright lumbar radiography was obtained. LL, FL, and SL were measured as the radiological outcomes in this study. Any surgical or medical complications (including wound complications, pre-operative death, deep vein thrombosis/pulmonary embolism, failed back surgery syndrome, adjacent segment disease, screw pullout, etc.) were also included in the data analysis as the secondary outcomes.

Randomization, blinding, and analysis

The statistical significance was chosen at $P<0.05$ and the power was set to 80% ($\alpha=0.05$ and $\beta=0.2$). Using previous studies and the effect size of 0.4, the sample size was estimated at 52, and for the sake of simplicity, we chose at least 60 samples (30 samples in each treatment arm). Using the R software, we used a blocked randomization technique (for equal treatment arm sizes) along with a double-blinding strategy. Only the surgical staff and the surgeon were aware of the randomization and the researcher and the patients were blind about the details.

The paired t-tests were used to compare outcomes in each group and the student t-test was employed to compare the outcomes between the treatment arms. All analysis was done using the SPSS software, version 16.

3. Results

Baseline data

Overall, 82 patients were initially included but 65 patients participated in the study (1 patient did not give consent for entering the randomized controlled trial, 13 patients were excluded because of the non-degenerative nature of their spondylolisthesis, and 4 patients had multi-level pathologies). Subsequently, 5 patients (3 in the rod bending group and 3 in the without rod bend-

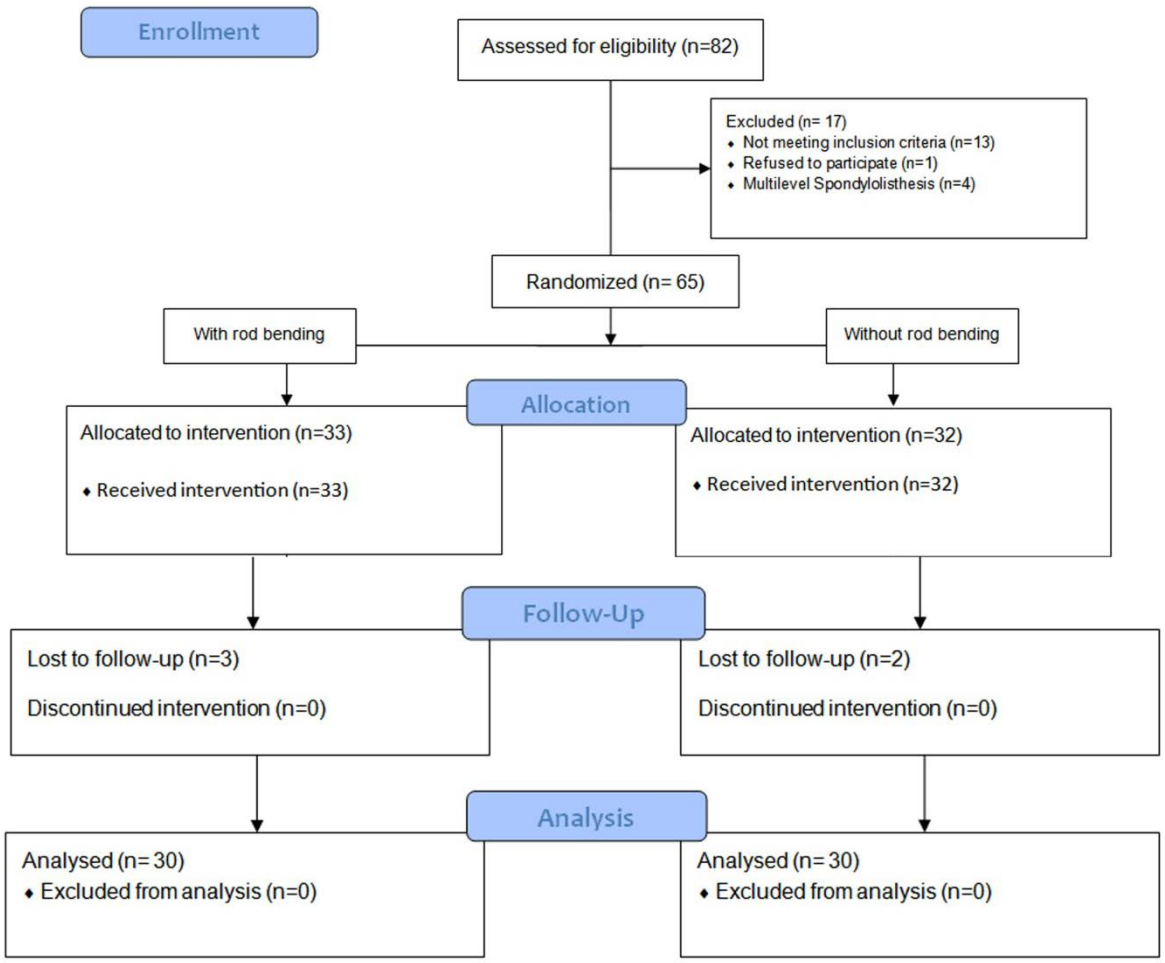

Figure 1. Flow diagram of the data collection

ing group) did not complete their follow-ups and were excluded from the analysis which led to the final 60 patients (Figure 1).

The Mean±SD age of the patients was 57.55±7.02 (40-70). The treatment arm with and without rod bending had a mean age of 57.37±6.09 and 57.73±8.08 years, respectively but their difference was insignificant (P=0.84). A total of 42 patients were female and 18 were male while the sexual distribution between the two groups was not statistically significant (P=0.57). Another important demographic indicator was the body mass index (BMI). The total mean BMI was calculated at 31.57±6.51. After grouping the patients, their BMI was not statistically different (P=0.22) (Table 1).

The VAS scores were measured for leg and back pain in both groups. The mean VAS score for leg pain in the rod bending group and without rod bending group was 7.27±1.7 and 7.7±1.66, respectively. Comparingly, the means showed no significant difference (P=0.32). Also, the mean VAS score for back pain in the rod bending group and without rod bending group was 7.47±1.63 and 7.6±1.6, respectively. The means showed no significant difference (P=0.75).

Three parameters (LL, FL, and SL) were utilized for the baseline radiographic assessment. The mean LL before the surgery was 35.77±12.41 for the rod-bending and 37.67±12.66 for the non-rod-bending group. the analysis indicated no statistical difference between them (P=0.56). Similarly, the mean FL before the surgery was 3.13±4.26 for the rod-bending group and 1.47±2.6 for the non-rod-bending group and their statistical difference was not significant (P=0.07). Finally, the mean SL before the surgery was 11.83±6.07 and 11.77±6.16 for the rod-bending and the non-rod-bending group, respectively. Further analysis demonstrated no significant difference between SL before the surgery between the two groups (P=0.16).

Table 1. Between-group analysis before surgery (n=30)

Variables	Mean±SD		Mean Difference	P
	With Rod Bending	Without Rod Bending		
Age (y)	57.37±6.01	57.73±8.01	-0.36	0.84
Gender (%)	66.7	73.3	-6.6%	0.58
BMI	30.53±6.63	32.60±6.32	-2.07	0.22
LL	35.77±12.41	37.67±12.66	0.1	0.56
FL	3.13±4.26	1.47±2.6	1.6	0.07
SL	11.83±6.07	11.77±6.16	0.77	0.16
Leg pain VAS	7.27±1.7	7.7±1.66	-0.5	0.32
Back pain VAS	7.47±1.63	7.60±1.6	-0.13	0.75

Abbreviations: LL: lumbar lordosis; FL:/ Focal lordosis; SL: Segmental lordosis; VAS: Visual analog scale.

Study outcomes

Surgical complications

Overall, 7 surgical complications occurred in each group. Mortality and neurological deficits were not seen in either group. A total of 7 dural tears were seen and all of them were treated based on a single institutional protocol and none of them developed any further complications (e.g. meningitis). Both groups had one case of deep vein thrombosis/pulmonary embolism which was treated with intravenous heparin and did not cause any significant disability or further complications. Meanwhile, no significant differences were observed in the statistical analysis between the complications (Table 2).

Pain scores

Before and after surgery, leg and back pain was measured using the VAS score, each within and between the groups.

Back pain VAS score

On the follow-up, the total mean VAS score for the back pain was measured at 2.43±1.52. The VAS score for back pain was measured at 2.67±1.67 and 2.2±1.35 for the rod-bending and non-rod-bending groups, respectively.

A paired sample t-test was conducted to compare the back pain VAS score for the rod bending group before the surgery and after one year of follow-up. There was a significant difference before (Mean±SD 7.47±1.63) and after the surgery in follow-up (Mean±SD 2.67±1.67; t [29]=14.86; P<0.0001).

Similarly, a paired sample t-test was conducted to compare the back pain VAS score for the group without rod bending before the surgery and after a one-year follow-up. There was a significant difference before the surgery Mean±SD 7.6±1.59) and after the surgery (Mean±SD 2.2±1.35; t [29]=14.59, P<0.0001).

The pairwise analysis to compare the VAS score between the two groups before the surgery showed no significant difference (P=0.75) between the back pain VAS scores (-0.96–0.7 for 95% CL). Similarly, the pairwise analysis to compare the VAS score between the two groups after one year of surgery showed no significant difference (P=0.24) between the back pain VAS scores (-0.32–0.12 for 95% CL).

Leg pain VAS score

After the one-year follow-up, the total mean VAS score for leg pain was measured at 2.98±1.85. For the rod bending group and the group without rod bending the VAS score for back pain was measured at 3.17±1.72 and 2.8±1.99, respectively.

A paired sample t-test was conducted to compare the leg pain VAS score for the rod bending group before and after the one-year follow-up. There was a significant difference before the surgery (Mean±SD 7.27±1.7) and after the follow-up (Mean±SD 3.17±1.72; t [29]=9.6, P<0.0001).

Table 2. Surgical complication analysis

Complication	Rod Bending	Non-Rod Bending	Mean Difference	P
Wound infection	3	2	0.04(-0.1027±0.1827)	0.58
Dural tears	3	4	-0.03(-0.1985±0.1385)	0.72
DVT/PTE	1	1	0	-
Proximal junctional kyphosis	0	0	-	-
Death	0	0	-	-

DVT/PTE: Deep vein thrombosis/pulmonary embolism

Similarly, a paired sample t-test was conducted to compare the leg pain VAS score for the group without rod bending before and after the one-year follow-up. There was a significant difference before the surgery (Mean±SD 7.7±1.66) and after the follow-up (Mean±SD 2.8±1.99; t [29]=10.93, P<0.0001).

The pairwise analysis to compare the VAS score for the leg pain between the two groups before the surgery showed no significant difference (P=0.32) between the leg pain VAS scores (-1.30–0.44 for 95% CL). Similarly, the pairwise analysis to compare the VAS score between the two groups after one year of surgery showed no significant difference (P=0.45) between the back pain VAS scores (-0.59–1.32 for 95% CL).

Radiological outcomes

Three parameters were used to assess the radiological outcomes: LL, FL, and SL.

Lumbar Lordosis: After the one-year follow-up, the mean LL was 38.58±12.8. The group with rod bending and without rod bending had a mean LL of 37.23±13.74 and 39.93±11.87, respectively.

A paired sample t-test was conducted to compare LL for the rod bending group before and after the one-year follow-up. There was no significant difference before the surgery (Mean±SD 35.77±SD=12.41) and after the follow-up (Mean±SD 37.23±13.74; t [29]=-0.96, P=0.34).

Similarly, a paired sample t-test was conducted to compare LL for the group without rod bending before and after the one-year follow-up. There was no significant difference before the surgery (Mean±SD 37.67±12.66) and after the follow-up (Mean±SD 39.93±11.87; t [29]=-1.48, P=0.15).

Based on the pairwise analysis, comparing LL between the two groups before the surgery showed no significant difference (P=0.56) between LL (-8.38–4.58 for 95% CL). Similarly, no significant difference (P=0.42) between LL (-9.34–3.94 for 95% CL) was found in the pairwise analysis of LL after one year of the surgery.

Segmental lordosis

After one year of follow-up, the mean SL was 12.82±6.33. The group with rod bending and without rod bending had a mean SL of 13.87±6.43 and 11.77±6.16, respectively.

A paired sample t-test was conducted to compare SL for the rod bending group before and after the one-year follow-up. There was a significant difference before the surgery (Mean±SD 11.83±6.07) and after the follow-up (Mean±SD 13.8±6.43; t [29]=-2.56, P=0.02).

Similarly, a paired sample t-test was conducted to compare SL for the group without rod bending before and after one year of follow-up. There was a significant difference before the surgery (Mean±SD 9.83±4.7) and after the follow-up (Mean±SD 11.77±6.16; t [29]=-2.35, P=0.03).

The pairwise analysis to compare SL between the two groups before the surgery suggested no significant difference (P=0.16) between SL (-0.80–4.80 for 95% CL). Similarly, no significant difference was present in the pairwise analysis and comparisons of SL after one year of surgery (P=0.20) between SL (-11.52–53.52 for 95% CL).

Focal lordosis

After one year of follow-up, the mean FL was 3.67±4.56. The group with rod bending and without rod bending had a mean FL of 4.6±4.87 and 2.73±4.09, respectively.

A paired sample t-test was conducted to compare FL for the rod bending group before and after one year of follow-up. There was a significant difference before the surgery (Mean±SD 3.13±4.26) and after the follow up (Mean±SD 4.6±4.87; t [29]=-2.17, P=0.04).

Similarly, a paired sample t-test was conducted to compare FL for the group without rod bending before and after one year of follow-up. There was a significant difference before the surgery (Mean±SD 1.47±2.6) and after the follow-up (Mean±SD 2.73±4.09; t [29]=-2.26, P=0.03)

The pairwise analysis to compare FL between the two groups before the surgery showed no significant difference (P=0.07) between FL (-0.16 30.49 for 95% CL). Similarly, the pairwise analysis to compare FL after one year of surgery showed no significant difference (P=0.11) between FL (-0.46–4.19 for 95% CL).

A summary of the between-group and within-group analysis is provided in Table 3 and Table 4.

4. Discussion

Rod bending in spine surgery has caused some problems and is not without difficulty. It is time-consuming and even the best spine surgery teams spend time contouring the rod properly to gain the desired lumbar lordosis. Previous studies have shown that the surgery length is related to surgical complications and decreasing the surgery time reduces the complications [9]. On the other hand, technical issues should be kept in mind. To develop the perfect curve of the rod, sometimes the contouring process is repeated several times and studies have shown that it alters the biomechanical parameters of the rod [6] intraoperative rod contouring is required to realign the spine. A French bender is the most common contouring tool used. There are several reports on the mechanical properties of various rods with manufactured straight rod; however, few reports describe the changes in a rod's mechanical properties after rod contouring. The authors investigated the influences of rod contouring on rod strength and stiffness. A 3-point bending test was conducted. Each 18-cm rod was loaded at a rate of 10 mm/min with a load applicator. Three different rod diameters (5.5, 6.0, and 6.35 mm [10] titanium-aluminum-vanadium alloy (SDI™. The ultimate purpose of rod contouring is to reach the desired sagittal alignment; therefore, our hypothesis was to evaluate the differences between LL in bent and unbent constructs.

Comparing the two treatment arms before the surgery showed that the groups had no difference in the sagittal alignment and pain scores. The baseline difference could influence the interpretation of the results after the surgery.

After the surgery, in a one-year follow-up evaluation, it was shown that the pain scores of both legs and back had improved significantly. This is consistent with various other studies which showed that posterior pedicular fusion can reduce the patient's pain (although we are aware that our study does not show fusion superiority against non-operative strategies, previous studies do so).

The between-group analysis for the pain scores showed no difference between the two treatment arms which may show that pain scores, no matter how the rod is employed, did reduce because of the fusion effects of the surgery and time.

LL before and after the surgery was evaluated between and within groups and neither of them showed any significant difference. This could mean that regardless of rod bending, after one year of follow-up, LL will not change in single-level fusion patients. This is consistent with several studies. Han et al. showed that LL, after

Table 3. Between-group analysis after the one-year follow-up

Variables	With Rod Bending	Without Rod Bending	P
Leg pain VAS score	3.17±1.72	2.8±1.99	0.45
Back pain VAS score	2.67±1.67	2.2±1.35	0.24
LL	37.23±13.74	39.93±11.87	0.42
SL	13.87±6.43	11.77±6.16	0.20
FL	4.6±4.87	2.73±4.09	0.11

Abbreviations: LL: Lumbar lordosis; FL: Focal lordosis; SL: Segmental lordosis; VAS: Visual analog scale.

Table 4. Summary of within-group analysis

Variables	Treatment Group	Mean±SD		P
		Before Surgery	One-Year Follow-Up	
Leg pain VAS score	With bending	7.27±1.7	3.17±1.72	<0.0001*
	Without bending	7.7±1.66	2.8±1.99	<0.0001*
Back pain VAS score	With bending	7.47±0.63	2.67±1.67	<0.0001*
	Without bending	7.6±1.59	2.2±1.35	<0.0001*
LL	With bending	35.77±12.41	37.23±13.74	0.34
	Without bending	37.67±12.66	39.93±11.87	0.15
SL	With bending	11.83±6.07	13.87±6.43	0.02*
	Without bending	9.83±4.7	11.77±6.16	0.03*
FL	With bending	3.13±4.26	4.6±4.87	0.04*
	Without bending	1.47±2.6	2.73±4.09	0.03*

* Significant.

Abbreviations: LL: Lumbar lordosis; FL: Focal lordosis; SL: Segmental lordosis; VAS: Visual analog scale.

one level of fixation, did not change significantly after one year. In a similar article from Lee et al., pedicular screws and the posterior lumbar interbody fusion technique were utilized and the long-term follow-up (one year) showed no difference in the LL [11]. These results seem to confirm the results of Liu et al. who mentioned the relationship between the construct length and the changes in sagittal parameters [12] the shorter the construct, the least observed effects on LL.

Although this study has shown the increment of SL and FL, previous studies demonstrate different results. In a study by Han et al., SL angles increased immediately after the surgery but comparing the SL angles after 6 months and after one year to pre-operative SL, angles did not have significant differences. Of note, this study measured SL differently, using the angle between the upper endplate of the upper vertebral body and the lower endplate of the lower vertebral body. Additionally, the gap between SL angles in flexion and extension imaging at L4/L5 level decreased. Similarly, Lee et al. showed that SL (which was measured in the present study) did not change even after one year of follow-up. We can conclude that the increase in SL angles in our study may be because of the measurement errors before the surgery. Patients with DS prefer not to extend their lumbar spine; therefore, producing a wrong measurement of both SL and FL angles before the surgery, which this error is not seen in a long-term follow-up, produces a significant difference in the analysis. Further studies are required for a better understanding of these relationships.

There are some limitations to our study. 1st, considering the low sample size and the data sampling from only one center, the generalizability of this study could be under question. Secondly, only patients with single-level L4/L5 DS who were fixed by posterior pedicular screws were included in our study which again could cause a problem in making a general conclusion for all single-level fusions (e.g. patients fused with interbody techniques). Thirdly, only one year of follow-up of our patients could be insufficient to evaluate the long-term effects of surgery on sagittal parameters and complications. Adjacent segment disease and other pathologies would mostly be seen in a longer follow-up interval. Fourthly, we did not measure the dynamic imaging parameters and global sagittal measurements due to the lack of resources. Utilizing these parameters could help us understand the effects of single-level fusion better.

5. Conclusion

Considering multiple difficulties for bending and contouring rods in spine surgery, the present study suggested that bending the rod would not present any ad-

ditional advantages. LL, SL, and FL do not change based on the rod shape in a single-level posterior fusion.

Ethical Considerations

Compliance with ethical guidelines

This article was extracted from a thesis (number: 61744). Written consent letter was obtained from all the patients/participants in this study (Iranian registry of clinical trials Code: IRCT20120527009878N9).

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Authors' contributions

All authors contributed equally in all stages of this study.

Conflict of interest

The authors declare that they have no conflicts of interest.

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