Comparison between posterolateral fusion using flexible rods and posterolateral fusion using rigid rods in patients with degenerative lumbar disc diseases

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ABSTRACT

Background: Degenerative lumbar disc conditions are the main cause to nerve roots compression. Lumbar spine decompression and fusion have been considered the gold standard operation in managing lumbar degenerative disc disease after failure of conservative measures. **Purpose:** To compare bone fusion rate using flexible and rigid rods with posterolateral fusion in patients with degenerative lumbar disc diseases. **Patient sample:** Prospective study of 50 patients with degenerative lumbar disc disease. Twenty-five patients were treated by lumbar posterolateral fusion using flexible rods (group 1) while the other twenty-five patients were treated by rigid rods (group 2). **Outcome measures:** functional evaluation by fusion rate was detected in the first group fused with flexible rods, compared to the second group fused with rigid rods. **Methods:** This study was conducted in the spine unit at Cairo university hospital, Shark El-Madinah Hospital, Alexandria, Egypt on 50 patients with degenerative lumbar disc disease. Twenty-five patients were treated by lumbar posterolateral fusion using flexible rods (group 1) while the other twenty-five patients were treated by rigid rods (group 2). **Results:** Fusion rate was faster in the first group fused with flexible rods, compared to the second group fused with rigid rods. **Conclusion:** When performing posterolateral fusion with flexible titanium rods in the treatment of degenerative lumbar diseases, the fusion rate was quicker than rigid rods. However, there was no clinical or radiological difference between the two fusion methods.

Keywords: Lumbar degeneration, Lumbar fusion, Flexible rods, Rigid rods.

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INTRODUCTION

Most lumbar disc degenerations are asymptomatic and do not need evaluation in the absence of pain or limitations. Subsequent backpain and neural compression symptoms can negatively affect normal daily activity[1, 2]. Fortunately, most patients show a significant improvement with conservative measures [3-8]. However, patients who rapidly deteriorates of who don't show improvement with conservative measures are candidate for surgical intervention.

Lumbar spine discectomy and fusion have been considered the gold standard operation in managing lumbar degenerative disc disease [9]. Instrumented pedicle screws and rods provides immediate and appropriate fusion and stabilization [10–12]. It was reported in literature, that the overall satisfactory outcomes of fusion surgery are 68% [13].

We aim in this study to compare the fusion rate, safety, and efficacy following lumbar posterolateral fusion using flexible and rigid rods.

PATIENTS AND METHODS

This study included 50 patients with degenerative lumbar disc diseases. Ty-five patients were treated by lumbar posterolateral fusion using flexible rods (group 1) while the other twenty-five patients were treated by rigid rods (group 2).

Inclusion criteria: We included all patients with degenerative lumbar disease at any level with any degree of neurological affection after the failure of conservative treatment for 3 months.

Exclusion criteria: Patients who were suffering from discitis.

Medically unfit patients: Interbody fusion, patients who had an allergy to metal and patients refusing surgery or follow-up.

Preoperative assessment: The demographic data of all participants were obtained. A detailed history was taken from all patients. Clinical examination both general and back examination were done including inspection for any deformities, palpation for local tenderness on the lumbar spine, iliosacral joints, or paravertebral muscles. A meticulous full neurological examination for all patients was carried out including proper sensory and motor assessment. Besides, the assessment of gait and the neurological special tests such as straight leg raising test, cross straight leg raising test, bragard's test, and examination of the hip joints.

Pre-operatively every patient was subjected to radiographs: anteroposterior, lateral, obliques, and dynamic views. MRI was performed to determine the level of neural compression and to get an idea about the condition of the discs and the degree of facet osteoarthritis and foraminal morphology.

All patients were followed up clinically using the visual analogue pain scale (VAS), and Oswestry disability index (ODI) (Oswestry Low Back Pain Disability Questionnaire). We used the Arabic version Tunisian part of ODI in the form of underlined Arabic questionnaire [14-16].

Operative procedure

All patients were thoroughly informed about the procedure, its benefits and risks, approximate recovery time postoperatively, and possible complications. Informed consent was taken from every patient. Half of the patients in the study were subjected to decompression and posterior lumbar fusion using rigid rods and the other half using flexible rods. The procedure was performed under general anesthesia and the patients were in the prone position on a special frame. This frame supported the chest and pelvis leaving the abdomen free. Soft pads under the knees and ankles were put to avoid pressuring the skin covering these areas. The arms were supported with abducted shoulders 90 degrees and flexed elbows 90 degrees with padding beneath the elbows. The head was placed in the neutral midline position and supported by special head support. The low back hair was shaved and the area was disinfected using betadine, including the iliac crests bilaterally.

A midline longitudinal posterior incision of the skin over the lower lumbar and upper sacral area was done. The subcutaneous tissues were dissected, with complete hemostasis before deeper dissection. Self-retaining retractors were then placed. The cautery dissection was then started till the supraspinous ligament and the spinous processes. The paraspinal muscles were stripped subperiostially on one side from caudal to cranial and from dorsal to volar along the affected side of the spinous processes till the exposure of the transverse processes and lateral gutter Supplementary Figure 1. Care was taken to avoid damage to facet joint capsules of segments that would not be fused. The insertion of the pedicular screws was made by the free hand technique at the site of the intersection of a horizontal[17-18] line bisecting the transverse process and a vertical line just medial to the lateral aspect of the superior facet. The awl was used to puncture the cortex, then the pedicle finder was used to track through the medulla of the pedicle, and then a sensor was used to be sure that the track was surrounded by bone and that there was no breach in the pedicle cortex that may compromise insertion of the screw or injure the nerve root. This would lead to the insertion of the screw inside the medulla of the pedicle. The screws used were 6.5 mm screws of 35-50 mm length according to the levels of fusion all rods were from egy fix company and half of them were flexible titanium rods (G2) and the other half were (G5) titanium rigid rods,we used the same manufacture company in all cases in both groups. The position of the screws was checked by the C-arm Supplementary Figure (2). A Chiari retractor was then used to open the space between the two vertebrae or between the screws for adequate exposure followed by removal of the ligamentum flavum to expose the dura. Medial facetectomy, partial laminectomy, foraminotomy, and discectomy at the targeted level were done from one side that coincides with the patient complaint. Care was taken to ensure complete nerve root decompression above and below the disc figure. After contouring the rod in lordosis, it was placed in position on the screws and the screw knots were tightened. The final construct was checked by C-arm and graft was impacted between the transverse process as poster lateral fusion will occur. Finally, Irrigation with saline, paravertebral muscles debridement, and gel foam was used to cover the dura, the suction drain was inserted and the wound was closed in layers. Sterile dressing was then applied.

Post-operative care and Follow up protocol: A complete neurological examination was done to all patients following recovery from anesthesia. Analgesics were given for the first week post-operatively. The suction drain was removed within 48 hours post-operatively. If there were no complications, the patients were taken out of bed the day following surgery and allowed comfortable mobilization two-three days post-operatively. The patients were then discharged provided that there were no neurological or wound complications. Instructions of wound care and mobilization with lumbar support were given to the patients and the stitches were removed two-three weeks post-operatively, in the out-patient clinic. Patients were assessed clinically and radiologically immediately post-operatively, 3 months, 6 months, and 12 months All patients underwent postoperative assessment using Oswestry disability index (ODI) and visual analogue score (VAS) for back and leg pain[14-16].

Radiological assessment: Postoperative radiographs was performed to document the position of the construct as well as multislice C.T if there is any doubt about the screw position. Radiographs will be repeated every 3 months. CT scans of the fused segment were taken postoperatively at 12 months. Reconstructions were made in both the coronal and the sagittal planes. A classification to optimally determine the presence of bridging trabecular bone between the fused levels. The status of the fusion was quantified using the 'bridging trabecular bone scale' (BTB) scale[19]: Visual rating from CT-reformatted images using a percentage based on the total length of the vertebra interface superiorly and inferiorly. The rating was determined by combining both the superior and inferior edges of the vertebra interface to yield an overall percentage of bridging bone [20].

THE STATISTICAL ANALYSIS:

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Qualitative data were described using numbers and percentages. The Kolmogorov-Smirnov test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation, median, and interquartile range (IQR). The significance of the obtained results was judged at the 5% level.

RESULTS

This prospective study includes 50 patients with degenerative lumbar disc diseases who underwent instrumented posterolateral fusion. 25 of them were operated using rigid rods and the other 25 patients were operated using flexible rods. The mean age of participants in group (1) was 42±8.52 (range: 32-65) years, while the mean age of patients in group (2) was 47.68±10.47 (range: 28-65) years. We included 26 male patients (52%) and 24 female patients (48%). Supplementary Table 1 shows the demographic data of the patients from both groups.

Regarding the comorbidities among the included participants, there were four diabetic patients, three hypertensive patients, and one patient with bronchial asthma in group (1). While the group (2) included two diabetic patients, one hypertensive patient, and two rheumatoid patients as shown in Supplementary Table 2.

In our study, 17 patients (68.00%) were diagnosed as having Degenerated Disc (DD), 8 patients (32%) with lumbar canal stenosis in group (1). Moreover, 17 patients (68.00%) were diagnosed as having Degenerated Disc (DD) and 8 patients (32%) with lumbar canal stenosis in group (2).

Distribution of operated levels

One patient (4%) was operated on L3/4 level in both groups, eleven (44%) patients were operated on L4/5 level in both groups, which is the most common level, and seven patients (28%) were operated on L5/S1 level in group (1), while 4 patients were operated at the same level in group (2), one patient (4%) were operated on L3/4, L4/5 levels in group(2) only and 3 patients (12%) were operated on L4/5, L5/S1 levels in group (2) only, one patient(4%) was operated at level L2-3 at group(1). One patient was operated at level L2-S1 in group (1) only, one patient was operated at L3-S1 in group (1) while 3 patients were operated at the same levels in group (2).

Data about the operation time, blood loss, the need for blood transfusion, and the duration of hospital stay were assessed as follows: The operation time ranged from 85-150 min. the operations that exceeded 120 min were double-level operations in both groups. The operative time was nearly the same with a mean of 110.3 ± 28.19 minutes in both groups. The range of blood loss was between 350 – 150000 cc with an average of 680. ±289 SD cc in both groups. P-value was statistically insignificant in comparison between both groups regarding intraoperative data as shown in Supplementary ***Table 1.***

Table (1): Distribution of the studied group regarding demographic data

	Frequency	
	No.	**%**
Age		
Group (1)		
Min. - Max.	32 – 65	
Mean ± S.D.	42.84± 40	
Median	8.52	
Group(2)		
Min. - Max.	28 – 65	
Mean ± S.D.	47.68 ± 10.47	
Median	49	
Sex		
Group (1)		
Male	13	52%
Female	12	48%
Group(2)		
Male	13	
Female	12	
Sciatica		
Group (1)	6	35%
Left	10	58%
Right	1	5.9%
Bilateral		
Group (2)		
Left	4	26.7%
Right	9	60%
Bilateral	2	13.3%
Occupation		
Group (1)		
Manual worker	9	36%
Office worker	5	20%
House wife	10	40%
Retired	1	1%
Group (2)		
Manual worker	10	40%
Office worker	1	4%
House wife	13	52%
Retired	4	4%

Postoperative clinical outcome: All 50 patients in both groups were evaluated postoperatively at 1, 3, 6, and 12 months. The clinical outcome was measured by ODI categorizing the patients into four categories: Minimal, Moderate, Severe disability, or Crippled. Back pain and Leg pain VAS immediately postoperative and at 1, 3, 6, and 12 months.

Back pain VAS score (comparison between the preoperative and postoperative scores in each group): Mean Back pain VAS decreased significantly from 5.68±0.63 preoperatively to 2.96±0.61 at 1 month, 2.28 ±0.84 at 3 months, 1.767 ± 0.935 at 6 months, and 1.44 ±0.51 at 12 months. P-value showed a statistically significant decrease in VAS score in the postoperative assessment when compared with the preoperative VAS score in group (1). Regarding group (2) the mean back pain VAS decreased significantly from 5.64±0.49 SD preoperatively to 3.12±0.53 SD at 1 month, 2.36 ±0.76 SD at 3 months, 1.92 ± 0.64 SD at 6 months, and1.48 ±0.51 SD at 12 months.

Back pain VAS score (comparison between both groups): We found no statistically significant difference between both groups regarding postoperative VAS score of back pain.

Leg pain VAS score (comparison between the preoperative and postoperative scores in each group): The mean leg pain VAS score decreased significantly from 6.64±1.29 preoperatively to 2.96±0.61 at 1 month, 2.68 ±0.69 at 3 months, 1.92± 0.57 at 6 months, and 1.28 ±0.61 at 12 months in group (1). Concerning group (2) the average leg pain VAS score reduced significantly from 6.52 ±1.19 preoperatively to 2.92±0.76 at 1 month, 2.52 ±0.65 at 3 months, 2.24± 0.60 at 6 months, and 1.28± 0.61 at 12 months.

Leg pain VAS score (comparison between both groups): We found no significant difference between post-operative leg pain VAS scores as shown in Supplementary.

Comparison between the two studied groups according to ODI: The mean ODI decreased significantly from 56.16 ±8.56 preoperatively to 26.44 ±4.95 at 6 months and 20.16 ±3.72 at 12 months in group (1). The mean ODI reduced significantly from 59.52 ±6.37 preoperatively to 27.32 ±4.26 at 6 months, and 21.08 ±3.37 at 12 months in group (2). We found no significant difference between the postoperative ODI in comparison between the two groups. We also found no significant difference between gender distribution or the presence of comorbidities and post-operative ODI in both groups Supplementary

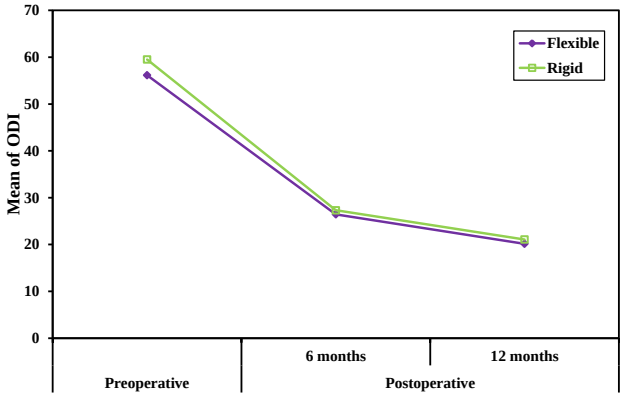

Figure 1: supplementary

Bridging trabecular bone (BTB) scale: The mean BTB scale in the first 3 months was 1.76 ±0.93, 2.12 ±1.01 within 6 months, and 2.96 ±1.37 by the end of 12 months in group (1). The mean BTB scale in the first 3 months was 1.28 ±0.84, 2.04 ±1.17, within 6 months, and 2.88 ±1.67 by the end of 12 months scale in group (2) Supplementary Table 2.

Table (2)

	Flexible (n = 25)	**Rigid (n = 25)**	**U**	**P**
Postoperative 3 months				
Min. – Max.	0.0 –3.0	0.0 –3.0		
Mean ± SD.	1.76 ±0.93	1.28 ±0.84	219.5	0.055
Median (IQR)	2.0 (1.0 –2.0)	1.0 (1.0 –2.0)		
6 months				
Min. – Max.	0.0 –4.0	0.0 –4.0		
Mean ± SD.	2.12 ±1.01	2.04 ±1.17	312.0	0.992
Median (IQR)	2.0 (2.0 –3.0)	2.0 (2.0 –3.0)		
12 months				
Min. – Max.	0.0 –5.0	0.0 –5.0		
Mean ± SD.	2.96 ±1.37	2.88 ±1.67	303.50	0.856
Median (IQR)	3.0 (3.0 –4.0)	3.0 (2.0 –4.0)		

The rate of fusion: Fifteen patients (60%) were fused in the first six months while 22 patients were fused by the end of the year (88%) in group (1). Eight patients (32%) were fused in the first six months while 20 (80%) patients were fused by the end of the year in group (2). In this study, the rate of fusion is faster in group (1) than in group (2) with a significant p-value.

The Union: Three patients (12%) were not united in group (1), while 5 patients (20%) were not united in group (2). We found no significant relationship between the type of rod and nonunion

Complications: Four patients (66.7%) were infected and treated conservatively with repeated dressings and antibiotics 2 patients (33.3) had Dural tear and were treated conservatively in group (1). Two patients (33.7%) were infected and treated with dressings and antibiotics and one patient (16.3%) had a Dural tear in group, one patient had a mechanical failure in the form of knot failure. We

found non-significant relationship between the rate of complications.

DISCUSSION

In our trial, we found that the VAS score of back pain improved from 5.68±0.63 preoperatively to 2.28±0.61 at three months postoperative in the first group, while in the second group the VAS score for back pain improved from 5.64 ± 0.49 preoperatively to 2.36±0.76. After 12 months of follow-up, the VAS score for back pain was 1.44±0.51 in the first group and 1.48±0.51 in the second group. In terms of the VAS score for leg pain, the score improved from 6.64±1.29 preoperatively to 1.92±0.57 SD postoperatively at 6 months in the first group and improved from 6.52±1.19 preoperatively to 2.24±0.60 postoperatively. Besides, there was no significant difference between both groups regarding ODI. As regards the fusion rates, 15 of 25 cases (60%) reported successful fusion at 6 months in group one while only 11 cases (56%) fused in the first 6 months in group two. In terms of complications, four cases reported wound infection and two patients had an intra-operative dural tear in the first group. While the rigid fixation group, only two patients reported wound infection, and one patient had a mechanical failure.

Benezech et al.[21] performed a retrospective analysis to demonstrate the effect of treatment with Initial VEOS PEEK-Optima in a cohort of 21 patients with a minimum of 2.5-year follow-up. They found that PEEK-OPTIMA spinal rods were a very effective and well-tolerated alternative to rigid fixation. They were associated with a low incidence of complications and reoperation, a high degree of patient quality of life, and satisfaction, and a high degree of disc preservation. Besides, may be regarded as a promising material for rods to stabilize a degenerative lumbar column without introducing further danger to the patients, especially if utilized as a way of stabilization without arthrodesis. The mechanical properties of PEEK-OPTIMA, particularly its limited rigidity and high fatigue resistance, provide the appropriate load sharing on the lumbar column to create more favorable conditions for the adjacent discs and reduce the likelihood of secondary deterioration and thus a subsequent operation.

The main symptoms of progressive lumbar degeneration are pain and walking difficulties due to compression of the nerves and their blood supply [22,23]. This represents particular conditions such as spinal canal constriction, herniated disc, degenerative disc disease, and any degenerative deterioration of the posterior arch [10]. In most cases, operative management is the treatment of choice to correct this pathology [24]. One of the most common methods of correction is the pedicle screw instrumentation to ensure immediate stabilization and the rate of fusion. However, this technique of treatment was associated with the persistence of symptoms in about 40% of cases and progressive degeneration which in turn would lead to a second operation [11, 25]. This generated pathology is known as "adjacent segment disease" (ASD), with a varied prevalence that can range from 30% to 100% within a year, with a rate of 35% to 45 percent being the most commonly observed [26]. Dynamic systems (nonfusion) have been developed to decrease the chances of problems associated with arthrodesis.

Nonetheless, no statistically significant difference in the risk of problems and surgical revisions has been observed between dynamic stabilization and fusion [27].

Fu et al.[28] studied the effect of radiographic K-Rod dynamic stabilization compared with the rigid fixation in the management of multisegmental degenerative lumbar spinal stenosis. They found that in comparison to the rigid approach for treating multisegmental degenerative lumbar spinal stenosis, dynamic K-Rod stabilization improves radiography results and increases the mobility of the stabilized segments while limiting the impact on the proximal adjacent segment.

Galbusera et al. [29] performed a biomechanical comparison between the rigid and the flexible spine fixation. They found that the effect of all rigid (stainless steel, titanium) and semirigid (PEEK, ostaPek) rods on the range of motion (ROM) reduction was discovered to be significant (from 72 percent for PEEK rods to 83 percent for stainless steel rods in flexion). This finding was consistent with **Rohlmann et al.**[30] and **Schmidt et al.**[31]. The study concluded that the ROM and shared the load in the spine segments were very sensitive to the device's design and materials used for stabilization. We propose distinguishing between "flexible" devices, which can maintain only a minimal percentage (e.g., at most 50%) of physiological ROM, and "dynamic" devices, which produce a lesser ROM restriction.

Poster lateral fusion (PLF) has long been considered the “gold standard” for surgical treatment of lumbar spondylosis. Superior results have subsequently been reported with interbody fusion with cages and posterior instrumentation.

Lamartina et al. [32] reported that the use of hybrid system in the form of thicker rods (6 mm vs. 5.55 mm) was associated with better correction.

However, this study did not focus exclusively on pe dicle screw designs and was not accompanied by pr oper statistical analysis.

Qi et al. [33] compared the PEEK rods with the ally rods in posterolateral fusion as methods of treatment of degenerative lumbar diseases. They reported that there was a significant improvement in the VAS score for back and leg pain and JOA

scores at 3 months, 6 months, and 1 year postoperatively as compared with preoperative scores in both groups (p0.05).

LIMITATION

The first limitation was that both types of rods were made of titanium but the rigid was stiffer as regards it contains some steel percentage. Secondly, there was still concern regarding the heterogeneity between patients with lumbar disc prolapse and lumbar canal stenosis. Although these two disease groups have different pathogenesis, it is believed that treatment principles are the same. Thus, it was thought it was reasonable to put them together in this study. The third limitation was the follow-up period of 12 months which might be insufficient for assessment of possible adjacent segment disease seen with longer follow-up periods.

CONCLUSION

When performing posterolateral fusion with flexible titanium rods in the treatment of degenerative lumbar diseases, there is no clinical or radiological difference from the rigid titanium rods except that the fusion rate is quicker with the flexible rods.

Abbreviations

Adjacent segment disease (ASD), range of motion (ROM), bridging trabecular bone (BTB), (VAS) visual analogue scale, Oswestry disability index (ODI

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