

ISSN 1220-8841 (Print)
ISSN 2344-4959 (Online)

ROMANIAN
NEUROSURGERY

Vol. XXXVIII | No. 2

June 2024

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DOI: 10.33962/roneuro-2024-027



Outcomes of dynamic lumbar fixation in young patients with minimal lumbar instability

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ABSTRACT

Background data: Lumbar instability is considered an essential aetiology of low back pain (LBP) which is always accompanied by considerable disability. The term 'instability' remains poorly defined. But it is most broadly explained by any change of the normal mechanism of spinal motion which leads to pain and/or neurological impairment. It was reported that, 'Segmental instability can be defined as a pathological reaction to the applied loads, characterized by motion in motion segments more than normal constraints. The dynamic system can stabilize an unstable segment adequately but permits more mobility in the fixed levels than the conventional fixation systems.

Study design: prospective, consecutive study

Patients and methods: This study was conducted in Mansoura University hospitals over one year (starting from September 2019 till August 2020) Twenty patients who presented with back pain fulfilled our criteria and were included in this study and underwent surgery for lumbar fixation using a hybrid performance system with dynamic coupler. The history of all patients was taken and they were subjected to clinical examination and preoperative full radiological examination. Visual Analogue Scale (VAS) was used to evaluate POP. Regular follow-up visits were arranged for our cases 6 weeks, three months and 6 months postoperative.

Results: This study included 20 patients (7 males and 13 females). The ages of the studied patients ranged from 20 to 33 years. 9 patients presented with L4- 5 affection, 8 patients with L3- 4 affection and three patients with L2-3 affection. The mean basal VAS score was 5.45 (range=4-6) while the mean six months VAS score was 0.40 (range=0-1) with a statistically significant difference from the basal VAS score ($p < 0.001$). Also, the results show that post-operative QoL scale scores was significantly higher ($p < 0.001$) compared with pre-operative QoL scale scores (Physical function (54.30 vs. 67.10), limitations due to physical health (55.55 vs. 67.90)).

Conclusion: The current study suggested that Dynamic lumbar fixation provides favourable and stable clinical mid-term results in patients suffering from a degenerative lumbar spinal disease (DLSD) and can be a considerable alternative to fusion surgery in these patients.

Keywords

pedicle screw-rod-based hybrid stabilization, interspinous device-based hybrid stabilization, dynesys stabilization, rod contour, visual analogue score



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ISSN online 2344-4959
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First published
June 2024 by
London Academic Publishing
www.lapub.co.uk

INTRODUCTION

The spinal column, spinal muscles, and brain control unit comprise the three subsystems that make up the spine's stabilizing system. Numerous biomechanical investigations of the spinal column have shed light on the various spinal column components' functions in promoting spinal stability.[1]

Clinical instability is an essential etiology of LBP. As we all know there are many controversies about its exact definition, it is most broadly accepted that any change of the normal pattern of spinal motion leads to pain and/or neurological deficits. It is very important to identify the difference between clinical and mechanical instability. The former defines inability of the spine to withstand spinal loads, whereas the latter involves the clinical consequences of neurologic deficit and/or pain.[1] The lumbar spine checklist uses a lot of elements, as biomechanical forces, neurological insult and anticipated stresses on the spine. A point value system could be utilized to detect clinical stability or instability. The spine is deemed clinically unstable if the total of the points is five or higher.[2]

The Notion of Micro instability: The first phase of the degenerative cascade, described as the phase of unstable dysfunction, involves several pathologic changes affecting the constitutive elements of the motor spinal unit. Spondylarthrosis will inevitably result from those changes over time. These changes are explained by a dynamic stress over of the articular surfaces in the motor spinal unit, which includes the articular processes (which are responsible for the movement) and the intervertebral disc (which are responsible for the characteristics of load and torsion resistance). The alterations are generated by an anomalous hyper movement, an overstress of an articulation that isn't able to bear the applied load. In the phase of unstable dysfunction there are ongoing anatomopathological changes in lack of vertebral slippage.[3]

Adjacent segment disease is a broad term as it can explain most of abnormal changes that happen in the nearest motion segment to a spinal fusion. The most common finding is degenerated disc but also listhesis, instability, facet joints hypertrophy, disc herniation, and canal stenosis were frequently reported. Less commonly reported changes included scoliosis and vertebral compression fractures.[4]

Recently, non-fusion stabilization of the lumbar spine has become more popular. These non-fusion systems intend to keep or restore the intersegmental motions to magnitudes of the intact spine and showed no harmful consequences on the adjacent segments.[5]

The dynamic system can stabilize the unstable segment adequately but permits more motion in the segment than the conventional systems. The neighboring segment doesn't appear to be affected by the stiffness of the fixed segment under the loading situations. [6] Biomechanical changes could impact the nearby disc affection. In vitro experimental researches have shown that increased motion in the disc nearby to a vertebral fusion.[7] Moreover, recent literature have documented that dynamic stabilization can offer better surgical option rather than conventional fusion for managing lumbar degenerative diseases.[8] By prevention of additional progression of instability, dynamic stabilization might also avoid the use of a bone graft and its complications (such as wound problems, neurovascular injury, infections, pelvic fracture)[5]

In this study "pedicle screw-based dynamic systems" was used. They consist of titanium alloy pedicle screws and connecting rods that fit between the pedicle screw heads. The rod in the rigid fusion system is rigid, whereas it is movable in the dynamic system. This is the only distinction between the two systems. Thus, in theory, motion in the treated spinal segment can be preserved by the pedicle screw-based dynamic system.[8]

The study was done to evaluate the outcomes of dynamic spine fixation regarding the severity of postoperative pain measured by numerical analogue score (NAS), adjacent segment disease, range of motion (ROM) and quality of life.

PATIENTS AND METHODS

This prospective, randomized, double-blinded, comparative study was conducted at Mansoura university hospitals over one year (starting from September 2019 till August 2020) after approval of ethical committee and getting informed verbal and written consent from all patients. The study included Twenty patients their age ranged from 20 to 35 years. Their Inclusion criteria was Lumbar micro- instability (the concept of micro instability, intended as biomechanical dysfunction of the motor spinal unit, responsible for clinical presentation but not

demonstrated by dynamic X-Rays), grade 1 and angular spondylolisthesis, Intact motor power and the Main complaint of the them was low back pain. While the Exclusion criteria was younger than 18 years and older than 35 years, patient with more than grade 2 spondylolisthesis, presence of Neurological deficit and if the patient had Previous spine surgery.

Preoperative evaluation was done by History taking from every included case. Assessment of Vital signs, Neurological examination, Investigations as Dynamic X-ray of Lumbosacral spine & MRI of affected segment all were done to the all patients.

Evaluated parameters was done by assessing presurgical and postsurgical pain using Visual analogue score (VAS) score after asking the patient to rate his own pain according to 0 – 10 pain score severity (VAS score) where zero represents no pain while 10 represent worst pain imaginable (Zero = No pain, one = Minimal pain, two = Mild pain, three = Uncomfortable, four = Moderate, five = Distracting, six = Distressing, seven = Unmanageable, eight = Intense, nine = Sever & ten = Unable to move). Pre- and post-operative NSAIDS and needed Hospital stay were also checked in this study.



Figure 1. Pre-operative Dynamic Xray LSS (flexion and extension) showing L5-S1 spondylolisthesis.

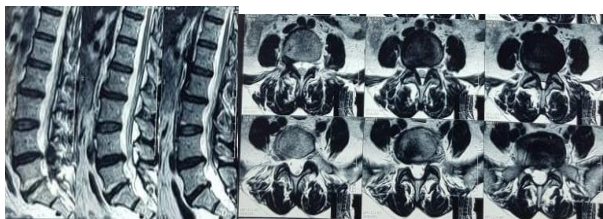


Figure 2. Pre-operative MRI lumbosacral spine showing instability L5 over S1 with modic changes and L4-5 disc prolapse.

SURGICAL TECHNIQUE

Midline spinal Approach was used. Then the Pedicle was Prepared, the pedicles are exposed then the trocar was used to open the cortical bone and form an initial entry into the pedicle. The pedicle entry point was marked under X-ray. The length and diameter of the Screw was chosen by the depth marks of the awl which commences at 30mm with five mm increments. Screw were placed after usage of K-wires that was placed within the cannulated pedicle, then the pedicle was prepared with a tap prior to screw placement. Determining Rod Contour and Coupler Fit was done through putting the coupler template on the template rod then the template rod was bent as important to accomplish an adequate alignment to the screw heads and to use it for the contouring of the rod. The Rod Length was determined by calculating the following, required rod length = Measured total length minus coupler length (35 mm) and the total rod length has to show overhang of five mm on each side. The screws were Inserted and Tightened by applying the persuader onto the screw head and compress the handle to reduce the rod into place.

Follow up was done by Evaluating the clinical outcome at the time of hospital discharge, 3, 6, 12 weeks then 6 months post procedure and MRI of the spine was done immediate post procedure and 6 months after treatment.

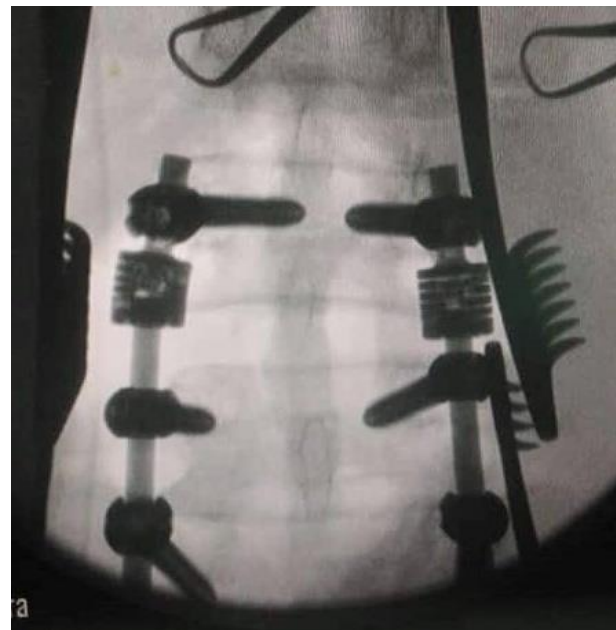


Figure 3. Intraoperative picture using C arm AP view showing fixation by 6screws and 2 rods with couplers.

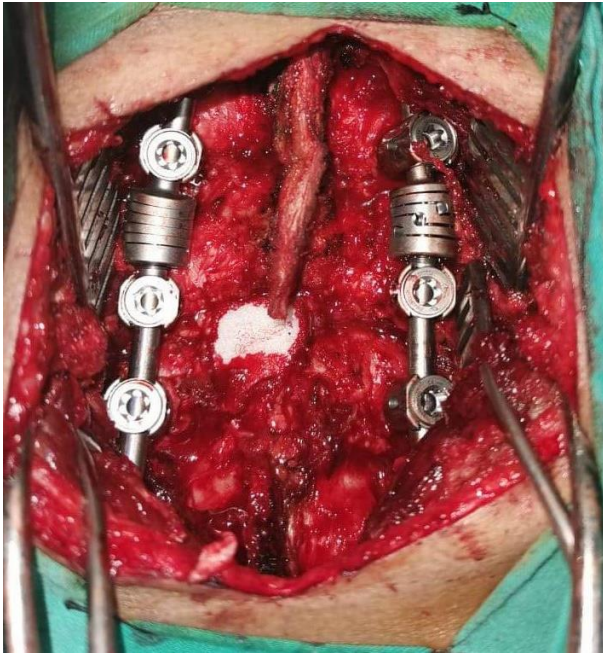


Figure 4. Intraoperative picture showing skin incision with L4-5 decompression with dynamic fixation.



Figure 5. Postoperative MRI LSS sagittal cuts 6 months postoperative, No detected adjacent segment disease.

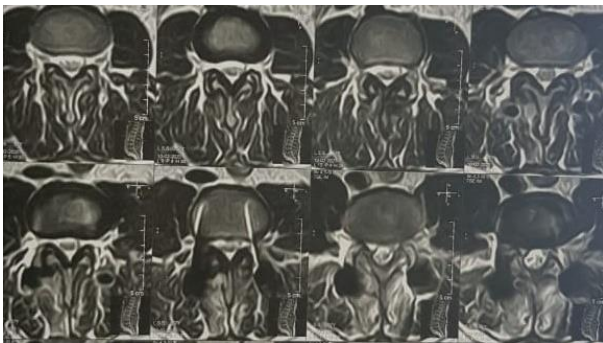


Figure 6. Postoperative MRI LSS axial cuts 6 months postoperative, No detected adjacent segment disease.

Table 1. Demographic characteristics of the studied patients

All patients (n= 20)		Mean & SD	Median	Range	IQR
Age (year)		26.50 ± 4.249	27.50	20, 33	22.25, 29.00
Gender	Male	35.0% (7)			
	Female	65.0% (13)			

Table 2. Affected level and Spondylolisthesis grade of the studied patients

		All patients (n= 20)
Affected level	L2- 3	15.0% (3)
	L3- 4	40.0% (8)
	L4- 5	45.0% (9)

Table 3. Total post-operative hospital stays in the current study:

All patients (n= 20)	Mean & SD	Median	Range	IQR
Hospital stays (days)	3.10 ± 1.683	3.00	1, 5	1.25, 5.00

RESULTS

Ours study comprised 20 patients (7 males and 13 females). The age of the studied patients ranged from 20 to 33 years. The mean age was 26.50 years (table 1). According to level affection, L2- 3 affection was the least commonly reported where it was revealed in 3 patients (15%), L3- 4 affection was revealed in 8 patients (40%) while the majority of patients (9 patients) presented with L4- 5 affection (table 2). The post-operative hospital stay ranged from 1 day to 5 days. The mean post-operative hospital stay was 3.10 days (table 3).

The mean basal VAS score was 5.45 (range=4-6). The mean one-day VAS score was 5.80 (range=4-7) with a statistically significant difference from the basal VAS score (p=0.005). The mean three weeks VAS score was 2.80 (range=1-4) with a statistically significant difference from the basal VAS score (p < 0.001). The mean six weeks VAS score was 2.30 (range=4-7) with a statistically significant difference from the basal VAS score (p < 0.001). The mean three months VAS score was 1.15 (range=0-3) with a statistically significant difference from the basal VAS score (p < 0.001). The mean six months VAS score was 0.40 (range=0-1) with a statistically significant

difference from the basal VAS score ($p < 0.001$) (table 4).

The mean basal daily ketolac consumption was 34.50 (range=20-50). The mean six weeks post-operative daily ketolac consumption was 14.50 (range=10-20) with a statistically significant difference from the basal ketolac consumption ($p < 0.001$). The mean three months post-operative daily ketolac consumption was 9.00 (range=0-30) with a statistically significant difference from the basal ketolac consumption ($p < 0.001$). The mean six months post-operative daily ketolac consumption was 4.00 (range=0-10) (IQR: 0.00, 10.00) with a statistically significant difference from the basal ketolac consumption ($p < 0.001$) (table 5).

The final results shows that post-operative quality of life scale scores was significantly higher ($p < 0.001$) compared with pre-operative quality of life scale scores (Physical function (54.30 vs. 67.10), limitations due to physical health (55.55 vs. 67.90), Bodily pain (61.25 vs. 75.65), Social function (55.90 vs. 68.15), limitations due to emotional health (50.90 vs. 62.30), General health (59.65 vs. 73.45), Vitality (54.95 vs. 67.20) and Mental health (58.95 vs. 72.20)) (Table 6).

DISCUSSION

Lumbar instability has been considered as an essential cause of LBP and could be accompanied by considerable disability. The word 'instability' remains poorly defined. But it is most broadly believed that the loss of a normal pattern of spinal motion causes pain and/or neurological impairment. Many authors assumed that, 'Segmental instability is considered to be an abnormal reaction to applied loads, featured by motion in motion segments beyond accepted constraints.[9]

Dynamic stabilization showed an essential role in the management of the degenerative lumbar spine disease (DLSD). Although fusion of one or two motion levels will not cause a big difference in the overall motion range of the lumbar spine, but keeping flexibility of a motion segment could prevent neighboring segment pathology and might allow disc replacement, even when facet joints excision is needed. When a promising environment is kept in the motion segment by preventing overstresses on the disc and providing an acceptable range of motion, the disc can be capable of repairing itself. Although dynamic stabilization can play a role in treating these patients, any new stabilization system

should be cautiously approached. Any fusion system only has to work as a temporary stabilization till fusion occurs; in contrast, a dynamic stabilization system should offer stability throughout its life.[10].

Thus, we aimed to evaluate the outcomes of dynamic spine fixation regarding the severity of postoperative pain measured by numerical analogue score (NAS), adjacent segment disease, ROM and QoL. This prospective, randomized, double-blinded, comparative study was conducted at Mansoura university hospitals over one year (starting from September 2019 till September 2020) after approval of ethical committee using Dynamic transpedicular lumbar fixation.

Dynamic stabilization is based on the notion that pain might be relieved and neighboring segment degeneration could be avoided by controlling abnormal motions and increasing physiologic load transmission. It is unlikely that the injured disc will repair itself once normal motion and load transmission are completed, unless the degeneration is evidently very severe [10]. As regards, demographic characteristics, the mean age of the studied cases was 26.50 ± 4.249 and the majority of which were female (65%). The current study revealed that, post-operative hospital stay ranged from 1 day to 5 days. The mean post-operative hospital stay was 3.10 days while the median post-operative hospital stays 3.00 days.

Similarly, Baliga *et al.*, 2015 [11] demonstrated that, the average hospital stay of 2 to 4 days in terms of non-fusion lumbar stabilization with mean post-operative hospital stay of 3 days. As regards, VAS score, there were significant differences between basal and post-operative follow-up till 6 months ($P < 0.001$). In the same line, Schnake *et al.*, 2006 [5] demonstrated that, clinical data of their cases improved significantly. Pain on VAS ($P \leq 0.001$) and the use of pain killers ($P = 0.013$) may be diminished and walking distance ($P \leq 0.001$) and neurological manifestations ($P \leq 0.001$) improved. About 87.5% of the studied cases were active at their preceding level without restriction, while only 12.5% of them didn't reach the pre-morbid level. In general, the majority of the studied cases were satisfied.

The same line, Greiner-Perth *et al.*, 2016 [12] conducted a prospective study on dynamic posterior stabilization for DLSD and demonstrated that, the NRS back and leg pain improved markedly from that reported preoperatively 6.2 and 7.1 (SD 2.4 range 0–

10) points to postsurgical mean 3.5 and 3.5 points, correspondingly (each $p=0.0001$).

As regards, daily ketolac consumption there was significant difference between basal and postsurgical follow-up till 6 months ($P<0.001$). This came in accordance with several researches who demonstrated significant reduction in pain following operation with a subsequent reduction in the analgesic requirements. [12]

As regards comparison of presurgical and postsurgical QoL scale scores in the studied patients, there were significant differences between means of presurgical and postsurgical QoL scale scores as regards Physical function (54.30 vs. 67.10), limitations due to physical health (55.55 vs. 67.90), Bodily pain (61.25 vs. 75.65), Social function (55.90 vs. 68.15), limitations due to emotional health (50.90 vs. 62.30), General health (59.65 vs. 73.45), Vitality

Table 4. Basal and post-operative follow-up of VAS score in the studied patients

All patients (n= 20)	Mean & SD	Median	Range	IQR	p
Basal	5.45 ± 0.605	5.50	4, 6	5.00, 6.00	-
One day	5.80 ± 0.834	6.00	4, 7	5.00, 6.00	0.005
Three weeks	2.80 ± 1.005	3.00	1, 4	2.00, 4.00	< 0.001
Six weeks	2.30 ± 0.865	2.00	1, 4	2.00, 3.00	< 0.001
Three months	1.15 ± 0.875	1.00	0, 3	0.25, 2.00	< 0.001
Six months	0.40 ± 0.503	0.00	0, 1	0.00, 1.00	< 0.001

P is significant when < 0.05.

Table 5. Basal and post-operative daily ketolac consumption (mg) in the studied patients

All patients (n= 20)	Mean & SD	Median	Range	IQR	p
Basal	34.50 ± 10.501	30.00	20, 50	30.00, 40.00	-
Six weeks	14.50 ± 5.104	10.00	10, 20	10.00, 20.00	< 0.001
Three months	9.00 ± 8.522	10.00	0, 30	0.00, 10.00	< 0.001
Six months	4.00 ± 5.026	0.00	0, 10	0.00, 10.00	< 0.001

P is significant when < 0.05.

Table 6. Basal and post-operative daily ketolac consumption (mg) in the studied patients

All patients (n= 20)	Pre-operative	Post-operative	95% CI	p
Physical function	54.30 ± 16.086	67.10 ± 20.442	- 15.04, - 10.46	< 0.001
limitations due to physical health	55.55 ± 19.508	67.90 ± 24.666	-12.83, -9.07	< 0.001
Bodily pain	61.25 ± 19.298	75.65 ± 24.564	-14.73, -10.57	< 0.001
Social function	55.90 ± 21.957	68.15 ± 26.019	-12.87, -9.53	< 0.001
limitations due to emotional health	50.90 ± 20.576	62.30 ± 24.942	-13.34, -8.86	< 0.001
General health	59.65 ± 18.204	73.45 ± 22.814	-15.43, -10.87	< 0.001
Vitality	54.95 ± 18.597	67.20 ± 22.659	-13.08, -9.82	< 0.001
Mental health	58.95 ± 15.436	72.20 ± 18.831	-14.67, -11.03	< 0.001

P is significant when < 0.05.

(54.95 vs. 67.20) and Mental health (58.95 vs. 72.20). The results shows that post-operative QoL scale scores was significantly higher ($p<0.001$) compared with pre-operative QoL scale scores. In the same line, Greiner-Perth et al., 2016² [12] conducted a prospective study on 436 cases treated with DSS. In addition, 387 patients (189 male, 198 females; mean age 67.3 years) with DLSD such as degenerative spondylolisthesis (6.1%) may be assessed. The type

of degeneration was primarily spinal stenosis (89.9%). Following a mean follow-up of 1.94 years, the COMI score and NRS back and leg pain improved significantly. The postsurgical trend analysis couldn't detect a relevant deterioration of such outcomes until four years postoperative. Ten cases were revised (2.6%) and the implant was excised; in the majority of cases, a fusion was conducted. Another five cases (1.3%) had an extension of the dynamic

stabilization system to the adjacent level. In addition, 84.2% of cases rated that the surgery had helped a lot or had helped. [5,12,13]

Similarly, Schnake *et al.*, 2006 [5] conducted a study on prospectively assessed 25 cases with lumbar spinal stenosis and degenerative spondylolisthesis demonstrated that, the mean leg pain diminished significantly ($P \leq 0.01$), and mean walking distance improved significantly to more than 1000m ($P \leq 0.01$) following induction of dynamic stabilization with the Dynesys system. Therefore, they demonstrated that, no significant progression of spondylolisthesis was determined; asymptomatic implant failure was noted in 17% of cases due to screw loosening. Signs of adjacent segment degeneration were demonstrated in seven cases following 24 months.

Furthermore, Delamarter *et al.*, 2006 [14] presented results of a major study conducted on a total of 84 cases managed with Dynesys or instrumented fusion for degenerative lumbar spondylolisthesis and/or stenosis at one or two contiguous levels at 24-month follow-up, ODI scores improved from 56.4 to 31.2, VAS leg pain improved from 82 to 15, and VAS back pain reduced from 52 to 21. Re-operation rate was 4%. Remarkably, the investigators recorded no examples of device failure, though 5% had asymptomatic radiolucency. While, Lee *et al.*, 2017 [15] assumed that, in comparison with normal case, fusion on L4–5 induces 18.8%, 9.3%, 11.7%, and 13.7% increments during motion at L3–4 under flexion, extension, lateral bending, and axial rotation, respectively. Additional stabilization at L3–4 in hybrid models decreased motion range which can occur at that segment. The IH model revealed 8.4%, -33.9%, 6.9%, and 2.0% change in motion at the segment, while the PH model revealed -30.4%, -26.7%, -23.0%, and 12.9%. At L2–3, the PH model revealed 14.3%, 3.4%, 15.0%, and 0.8% of motion increment in comparison to the motion in the IH model. These two hybrid systems expressed low intradiscal pressure at the transition segment compared with that in the conventional system, but the loads at L2–3 (adjacent segment) increased in all loading positions except during extension. Thus, they concluded that, lumbar hybrid stabilization using both Pedicle screw-rod-based hybrid stabilization (PH) and interspinous device-based hybrid stabilization (IH) decreased the fusion-induced excessive motion at the transition segment.

At the level next to the transition level, the PH model created more stress than the IH model under the hybrid loading condition. Such a difference could ultimately interfere with the possibility of ASD.

Although this study showed encouraging results and statistically significant percent of improvement, we are still in need for long-term follow up of cases at least 2 years with follow up VAS score and MRI lumbosacral spine to detect adjacent segment disease.

CONCLUSION

The current study suggested that Dynamic lumbar fixation provides a favorable and stable clinical mid-term results in patients suffering from degenerative lumbar spinal disease (DLSD) and can be a considerable alternative to fusion surgery in these patients.

List of abbreviations:

- (ASD): Adjacent segment disease
- (COMI): Core outcome measure index
- (DLSD): Degenerative lumbar spinal disease
- (DSS): Dynamic stabilization system
- (IH): Inter-spinous device-based hybrid stabilization
- (NAS): Numerical analogue score,
- (NRS): Numeric rating scale
- (ODI): Oswestny disability index
- (PH): Pedicle screw-rod-based hybrid stabilization
- (POP): Postoperative pain
- (ROM): Range of motion
- (QoL): Quality of life
- (VAS): Visual Analogue Scale

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