ORIGINAL RESEARCH

To study the pain relief, visual analogue scale (VAS) and oswestry disability index (ODI) in patients operated for moderate lumbar instability with interspinous distraction and stabilization

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ABSTRACT

Aim: The aim of the present study was to assess the pain relief, Visual Analogue Scale (VAS), and Oswestry disability index (ODI) in patients operated for moderate lumbar instability with interspinous distraction and stabilization.**Methods:** This was a hospital based prospective study. The Institutional Ethical Committee approved it. The study population consisted of 50 indoor patients with a history of low back pain with or without pain radiating down to lower limbs and operated with Synthes 'In-Space' interspinous distraction and stabilization and who also met the inclusion and exclusion criteria.**Results:** 60% were male. Most of patients i.e. 23(46%). were from age group 41 to 60 years. Instability with prolapsed intervertebral disc (PIVD) i.e.20 (40%) was more common than only instability or instability with lumbar canal stenosis. Majority of surgical procedures done was IDSS (26 i.e.52%) alone followed by IDSS with discectomy. In most cases the implant was placed at L-L5 level (i.e. 70%). 12 mm (i.e. 37.04%) sized implant was mostly used in the patients.**Conclusion:** We have found it to stabilize the spine in moderate instability. IDSS for lateral recess stenosis was performed with micro techniques using micro lumbar approach and is also minimally invasive. The post-operative morbidity is the least and quick mobilization within hours of the surgery and quick discharge from the hospital gives added confidence to the patient. Using the In-space interspinous distraction and stabilization alone or in combination with fixation and fusion methods in the treatment of moderate lumbar instability and lumbar degenerative disease is a simple, safe and effective treatment, with a good curative effect observed in the initial follow up. The results were statistically significant at 6 months.

Key words: Visual Analogue Scale (VAS), Oswestry disability index (ODI), lumbar instability with interspinous distraction, stabilization

INTRODUCTION

In 1954 Verbiest[1] was the first to explain the pathology of spinal stenosis. He declared that lumbar spinal stenosis refers to a pathological condition resulting in the narrowing of the spinal canal and compression of the neurological structures. Lumbar spinal stenosis is therefore a clinical condition and not a radiological finding or diagnosis. The most common cause of lumbar spinal stenosis is degenerative disc disease; therefore, especially elderly people in increasing numbers require spinal decompression surgery[2].Further reasons for lumbar spinal stenosis can be disc herniation[3,4], hypertrophy of the ligamentumflavum, spondylolisthesis, disc bulge, degenerative facet joint arthritis and thickened laminae[3,5,6].

The compression of the neurological structures leads to a reduction in walking distance, weakness, numbness and tingling. The symptoms increase in lumbar extension and are relieved in lumbar flexion[7].On the other hand degenerative spondylolisthesis, described by Newman[8] in 1955,

causes segmental instability with sagittal and axial malalignment, which induces local back pain. The primary levels of lumbar instabilityaffected are L4-5, followed by L3-4, L5-S1, L2-3 and L1-2[1, 9, 10].With the population continuously aging, the incidence of surgical decompression will rise. When conservative physical therapy fails, decompression of the spinal canal is recommended to improve walking distance and relieve pain.

The 'In-Space' interspinous distractor has been made and designed to reduce painful segmental motion particularly in extension while allowing unconstrained movement in flexion, axial rotation and lateral bending of the treated as well as untreated level. Although the effectiveness and indications of dynamic stabilization have yet to be further studied, the concepts and methods behind dynamic stabilization have already been accepted by the majority of doctors. Dynamic stabilization has shown good primary clinical outcomes and increased clinical applications in artificial intervertebral discs, elastic pedicle system and interspinous process fixation system. Further clinical and basic investigations are currently being processed[11-13].

The aim of the present study was to assess the pain relief, Visual Analogue Scale (VAS), and Oswestry disability index (ODI) in patients operated for moderate lumbar instability with interspinous distraction and stabilization.

MATERIALS AND METHODS

This was a hospital based prospective study. The Institutional Ethical Committee approved it. The study population consisted of 50 indoor patients with a history of low back pain with or without pain radiating down to lower limbs and operated with Synthes 'In-Space' interspinous distraction and stabilization and who also met the inclusion and exclusion criteria. Detailed history of patients with low back pain and low back pain with radiation to lower limb(s) taken using Oswestry Disability Index (ODI) and Visual Analogue Scale (VAS). The study was carried out in Lilavati Hospital and Research Centre, Mumbai. During our study we were able to collect 50 cases and study was done using statistical analysis.

INCLUSION CRITERIA

1. **AGE GROUP:**18 years and above.
2. Degenerative spondylolisthesis up to Grade I with hyperlordotic curve identified on digital dynamic X-ray, MRI of lumbosacral spine.
3. Degenerative Disc Disease with retrolisthesis with disc prolapse at single or more levels on MRI of lumbosacral spine.
4. Interspinous pain arising from Baastrup syndrome (Kissing Spine).

EXCLUSION CRITERIA

1. **AGE GROUP:**<18years of age (Paediatric patients).
2. >grade I spondylolisthesis on digital dynamic X-ray, MRI of lumbosacral spine.
3. Severe osteoporosis.
4. Fractures.
5. Scoliotic deformity at that level.
6. Infection.
7. Morbid obesity.
8. Previous surgery.
9. Post trauma patients.

IMAGING EVALUATION

Pre-operative X-rays of lumbar spine in antero-posterior view and lateral in flexion and extension positions were taken. MRI of the lumbar spine was also done pre-operatively.

SURGICAL TECHNIQUE

The procedure is done under general anesthesia. (It can be done under local anesthesia as well, in cases where internal decompression is not mandatory).

PATIENT POSITIONING

A radiolucent table is used. The patient is placed in prone position over the bolsters and the table may be flexed slightly to decrease the lordosis of the spine.

PROCEDURE

Under fluoroscopic guidance, the level is identified and entry point is marked approximately 9 cm away from midline on either side. A small incision (1 cm) is made at entry point and guide wire mounted in its handle is then inserted under fluoroscopy to lie between the two spinous processes. Over the extended guide wire multiple distraction sleeves are passed while holding the guide wire still in place. The distraction sleeves are available in sizes ranging from 8-16 mm. sequentially; increasing sleeves are inserted till sufficient distraction is achieved suggested by parallel vertebral end plates. An excessive distraction should be avoided as it leads to loss of physiological lordosis.

Through a small incision about 9 cm away from the midline the guide wire is inserted percutaneously into the interspinous space. The position of guide wire is checked with C-arm. The direction is slightly oblique in keeping the shape of the spinous process. Set of dilators starting with 8 mm and increasing in width by 2 mm are serially inserted until it snugly fits the spinous processes. Once the desired distraction is achieved, the corresponding implant insertion sleeve is inserted over the last dilator. The maximum insertion depth is verified on fluoroscopy where the makings on the inserter sleeve are equidistant on the either side of the spinous processes. The implant size corresponding to the diameter of implant insertion sleeve is selected and attached to the implant holder. The implant is then inserted into the insertion sleeve

and a screw driver is attached to it. The screw driver is turned clockwise to deploy the wings of the implant under fluoroscopic imaging. A green coloured ring appears on the screw driver shaft once wings are completely deployed. The implant holder is then disconnected from the implant and removed. The inserter sleeve is then pulled out slowly. The stability of In-Space depended on the integrity of certain elements including the supraspinal ligament, vertebral plate, spinous process and zygapophyseal joints. Therefore, considering majority of the patients had prolapsed disc or lateral recess stenosis, discectomy or spinal expansion was undertaken using inter decompression of spinal stenosis (IDSS). The surgical site is then infiltrated with 0.25% or 0.5% Bupivicaine and the wound is closed meticulously in layers.

STATISTICAL ANALYSIS

After data collection, data entry was done in Excel. Data analysis is done with the help of SPSS Software version 15 and Sigmaplot Version 11. Quantitative data is presented with the help of Mean, standard deviation, Median and IQR, pre and post-operative comparison among study group is done with the help of Friedman RM Analysis as per results of normality test, multiple pairwise comparison among group is done with Tukey test.Qualitative data is presented with the help of Frequency and Percentage table, association among study group is assessed with the help of Chi-Square test.P value less than 0.05 is taken as significant level". Normality test (SaphiroWhilks) failed thus Friedman Repeated Measures Analysis of Variance on Ranks test was applied for analysis of Oswestry Disability Index and Visual Analogue Scale at different time intervals.

RESULTS

Table 1: Baseline characteristics

Sex	Frequency	Percent
Male	30	60.00%
Female	20	40.00%
Age		
Upto 40 Yrs.	14	28.00%
41 to 60 Yrs.	23	46.00%
61 to 80 Yrs.	1	2.00%
Above 60 Yrs.	12	24.00%
Diagnosis		
Instability* only	15	30.00%
Instability* with Lumbar Canal Stenosis	15	30.00%
Instability* with PIVD	20	40.00%
Surgical Procedure		
IDSS	26	52.00%
IDSS with Discectomy	23	46.00%
HYBRID*	1	2.00%

60% were male. Most of patients i.e. 23(46%). were from age group 41 to 60 years. Instability with prolapsed intervertebral disc (PIVD) i.e.20 (40%) was more common than only instability or instability with lumbar canal stenosis. Majority of surgical procedures done was IDSS (26 i.e.52%) alone followed by IDSS with discectomy.

Table 2: Distribution of study group as per level and as per size of implant inserted

Level	No. of Cases Operated	Percent
L1-L2	0	0.00%
L2-L3	3	6.00%
L3-L4	5	10.00%
L4-L5	35	70.00%
L5-S1	6	12.00%
HYBRID*	1	2.00%
Total	50	100.00%
Size	No. of ‘In-Space’ Used	
8 MM	2	3.70%
10MM	9	16.67%
12 MM	20	37.04%
14 MM	17	31.48%
16 MM	6	11.11%
Total	54*	100.00%

In most cases the implant was placed at L-L5 level (i.e. 70%). 12 mm (i.e. 37.04%) sized implant was mostly used in the patients.

Table 3: Comparison among study group for ODI Score

ODI Score	N	Mean	Std. Dev	Median	IQR	Friedman RM Analysis		Minimum	Maximum
ODI Pre OP. (%)	50	44.93	7.73	44.00	13.11	Chi-Square	P Value	31.11	62.22
ODI Post 10 Days	50	33.37	6.32	32.00	7.64	133.82	<0.001	22.22	57.77
ODI Post 3 MTHS	48	18.68	4.72	18.00	4.34	Difference is significant		11.11	35.55
ODI PO 6 MTHS	46	10.58	3.95	8.88	5.33			4.00	26.00

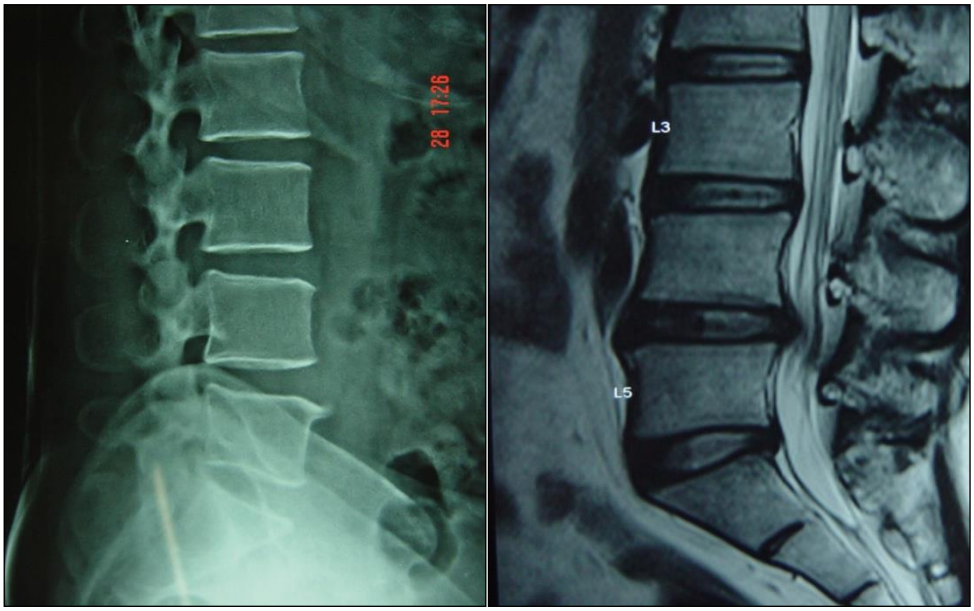
There was statistically significant difference in ODI post operatively at 10 days, 3 months and 6 months (P < 0.001) as compared to before the operation. All Pair wise Multiple Comparison Procedures (Tukey Test) showed statistically significant difference (p<0.05) in ODI pre-operative versus post-operative at 10 days, 3 months and 6 months. Also statistical significant difference (p<0.05) 10 days post operatively versus 3 and 6 months. And statistical significant difference (p<0.05) 3 months postoperatively versus 6 months post operatively. The mean ODI for the study group pre operatively was 44.93% ± 7.73 and post operatively at 10 days, 3 months and 6 months were 33.37% ± 6.32, 18.68% ± 4.72 and 10.58 % ± 3.95 respectively. The ODI decreased by 34.35 percentage points, an improvement by 77.44% at 6 months as compared to pre operatively.

Table 4: Comparison among study group for VAS score

VAS Score	N	Mean	Std. Dev.	Median	IQR	Friedman RM Analysis		Minimum	Maximum
VAS Pre Op	50	4.86	1.12	5.00	1.13	Chi-Square	P Value	2.00	7.00
VAS Post Op 10 Days	50	5.87	1.31	6.20	2.45	121.02	<0.001	3.00	8.30
VAS Post Op 3 MTHS	48	2.87	0.92	3.00	1.10	Difference is significant		1.50	6.00
VAS Post Op 6 MTHS	46	1.22	0.78	1.00	0.40			0.30	5.10

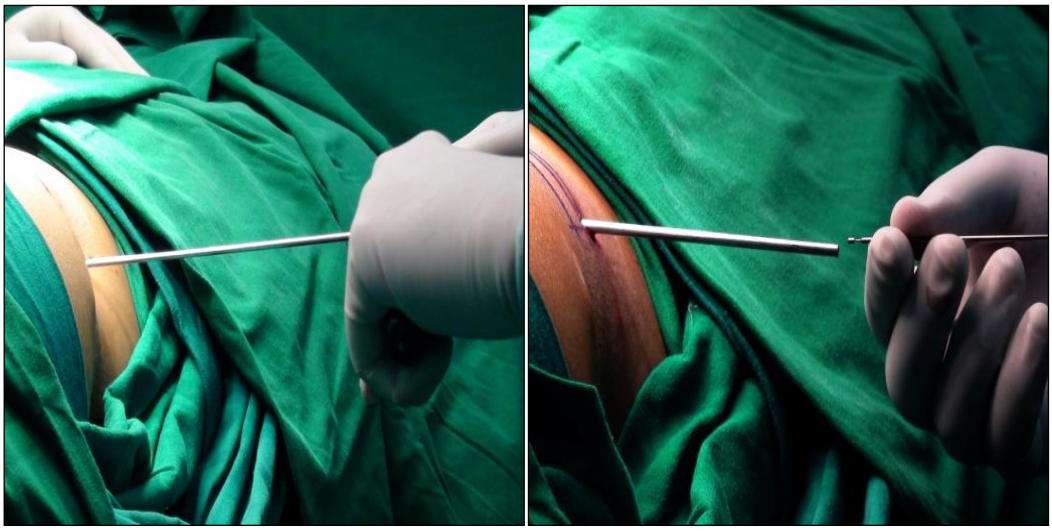
There was statistically significant difference in VAS score post operatively at 3 months and 6 months (p<0.05) as compared to before the operation. However, VAS score at 10 days as compared to pre operatively was not statistically significant. But VAS score was statistically significant at 10 days versus 3 and 6 months (p<0.05) respectively. The mean VAS score was 4.86 ± 1.12 points before the surgery and 5.86 ± 1.31, 2.86 ± 0.92 and 1.22 ± 0.78 at the 10 days, 3 months and 6 months respectively. The VAS score decreased by 3.64 points, an improvement by 74.89% at 6 months compared to pre operatively.

PHOTOGRAPH-1



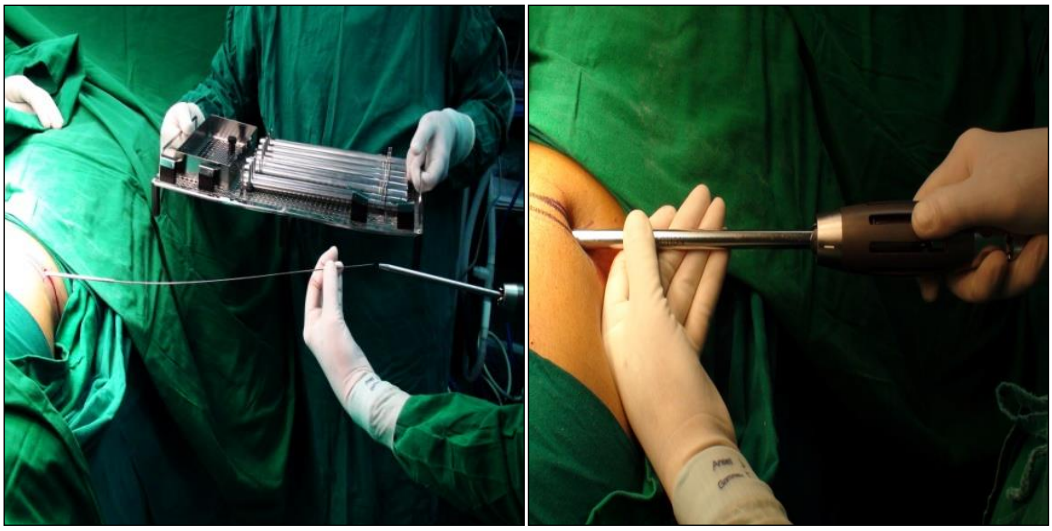
Pre-operative X-ray showing lateral recess stenosis

Pre-operative MRI showinglateral recess stenosis

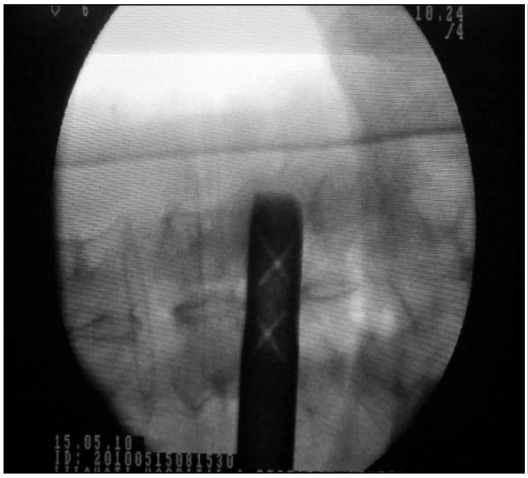


Insertion of the guide wire through a small incision

PHOTOGRAPH-2



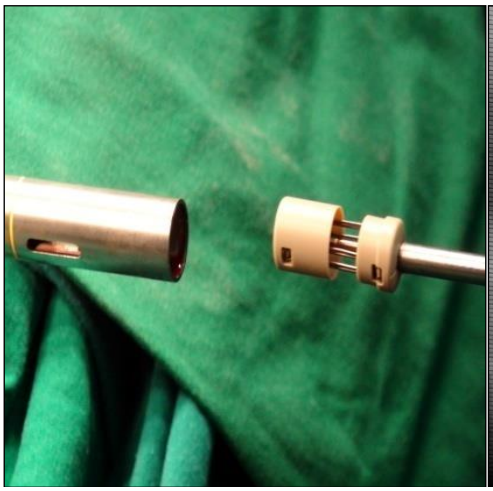
Insertion of dilators in serially increasing diameter



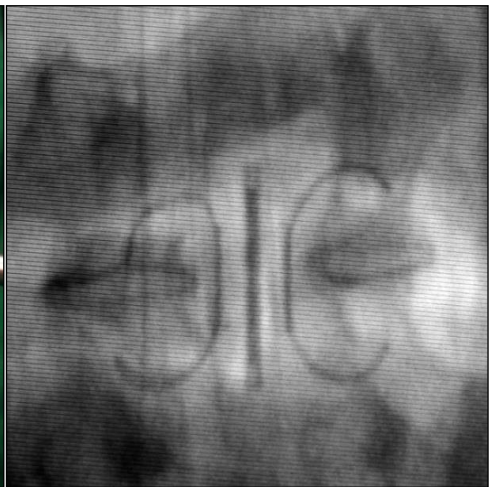
The sheath in position under fluoroscopic guidance with markers on either side

In-Space implant readied for insertion of spinous processes.

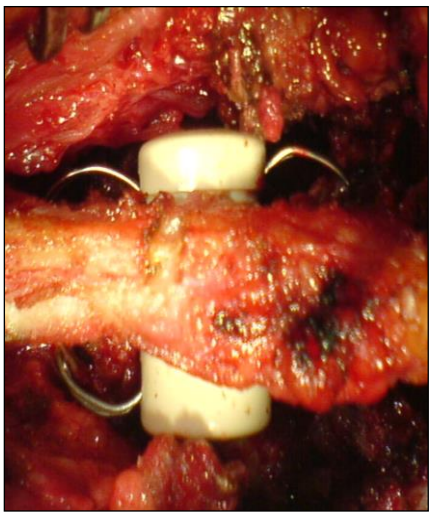
PHOTOGRAPH-3



In-Space mounted on carrier to be guided through insertion sheath

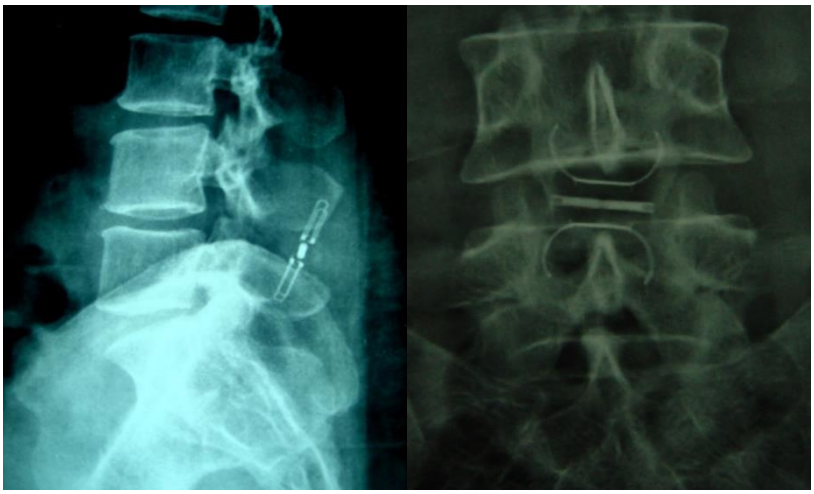


Fluoroscopic image showing In-Space in position holding upper and lowerspinous processes



Operative exposure of the implant showing it in position

PHOTOGRAPH-4



Postoperative lateral and antero-posterior radiographic views showing In-Space interspinous spacer inposition.

DISCUSSION

Low back pain is by far the most common and distressing effect for the patients coming to us and effective pain relief is of paramount importance for any surgeon[14-17].The most widely used definition of moderate instability is: "A significant decrease in the capacity of the stabilizing system of the spine to maintain the inter vertebral neutral zones within the physiological limits so that there is no neurological dysfunction, no major deformity and no incapacitating pain" The task of identifying when instability exists in clinical situation is difficult and requires careful evaluation of all the available data. Instability of the lumbar spine is accepted by us as patho mechanical mechanism causing low back pain with or without sciatica. It is an important indication to stabilize the spine. Our patients come late and instability is associated with lateral recess stenosis and/or prolapsed lumbar inter vertebral disc. We look into this issue carefully and achieve microsurgical decompression by internal decompression of spinal stenosis (IDSS). Lumbar instability causing symptoms and necessitating surgical treatment to stabilize the spine was first thought by Dr. R.B. Cloward and introduced the concept to the world in 1943[18-20].

It was observed that maximum number of patients i.e. 23(46%) were between the age group of 41-60 years. The minimum age of patients was 21 years and maximum was 81 years with an average age of 49.68 years with a standard deviation of 14.61. It was close to a study done by Houdek*et al*.,[21] in which the average age of patients was 52.6 years. Similarly in a study done by Hrabalek*et al*.,[22], the average age of patients was 53.2 years. It was observed that maximum number of patients had instability with PIVD i.e. (20 %). This is similar to a study done by Houdek*et al*.,[21], patients were treated for degenerative disc disease. In a study at Nanjing Medical Centre, China all patients were having lumbar instability and were operated with In Space[23].

The mean ODI for the study group pre operatively was 44.93% ± 7.73 and post operatively at 10 days, 3 months and 6 months were 33.37% ± 6.32, 18.68% ± 4.72 and 10.58 %± 3.95 respectively. It was close to a study done by Houdek*et al*.,[22] with an average ODI of 47.2% pre operatively and 17.48% at 6 months post operatively while in our study the average ODI was 10. 58% at 6 months post operatively which suggests better improvement as compared to above mention study. In a study done by Zhou *et al*., the average ODI was 10.6±2.1 post operatively at 6 months[23].The mean VAS score was 4.86 ± 1.12 points before the surgery and 5.86 ± 1.31, 2.86 ± 0.92 and 1.22 ± 0.78 at the 10 days, 3 months and 6 months respectively. In a study done by Houdek*et al*.,[22] with an average VAS score of 6.62 pre operatively and 2.96 points at 6 months post operatively. In another study by Hrabalek*et al*.,[21] for juxtfacet cyst by same method, average VAS score was 6.7 points pre operatively and 3.5 points post operatively. In a study done by Zhou *et al*.,the average VAS score was 1.5± 0.7 post operatively at 6 months[23]. Compared with other spinous dynamic stabilizing devices, the simple In-Space system implantation used in our study took a short time and produced minimal intra operative bleeding. The mean surgical time for the implantation was 20 ± 5 minutes. The system had almost no learning curve period and with no special requirement for the surgical equipment. During the follow up, no implant shifting or loosening was observed. In our study, the segmental mobility following surgery was markedly less than prior to surgery. Therefore, patients with segmental instability should be provided with In-Space to prevent excessive sliding of the segments.

CONCLUSION

Percutaneous interspinous device is introduced percutaneously by minimally invasive technique and does not produce any morbidity. We have found it to stabilize the spine in moderate instability. IDSS for lateral recess stenosis was performed with micro techniques using micro lumbar approach and is also minimally invasive. The post-operative morbidity is the least and quick mobilization within hours of the surgery and quick discharge from the hospital gives added confidence to the patient. Using the In-space interspinous distraction and stabilization alone or in combination with fixation and fusion methods in the treatment of moderate lumbar instability and lumbar degenerative disease is a simple, safe and effective treatment, with a good curative effect observed in the initial follow up. The results were statistically significant at 6 months.

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