Observational Report

# Short-Term Therapeutic Efficacy of the Isobar TTL Dynamic Internal Fixation System for the Treatment of Lumbar Degenerative Disc Diseases

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**Background:** At present, posterior interbody fusion surgery with pedicle internal fixation is the gold standard for the treatment of lumbar degenerative disc diseases. However, an increasing number of studies have shown that because fused lumbar vertebrae lose their physiological activity, the compensatory range of motion (ROM) of the adjacent levels increases. To address this issue, dynamic internal fixation systems have been developed.

**Objective:** Our goal was to investigate the short-term therapeutic efficacy of the Isobar TTL dynamic internal fixation system for the treatment of lumbar degenerative disc diseases and its effect on the ROM of the surgical segments.

**Study Design:** Retrospective Evaluation.

**Setting:** Tertiary hospital setting in China.

**Methods:** Twenty-four lumbar degenerative disc disease patients who underwent posterior lumbar decompression and single-segment Isobar TTL dynamic internal fixation at our hospital between January 2013 and July 2014 were retrospectively analyzed.

The preoperative and one month, 3 month, and 12 month postoperative visual analog scale (VAS) pain scores, Japanese Orthopedic Association (JOA) scores, and Oswestry Disability Index (ODI) scores were observed and recorded to assess the clinical therapeutic effect; the lumbar ROM was measured preoperatively and at the last follow-up to evaluate the preservation of functional movement in the dynamically stabilized segment.

**Results:** All patients underwent the operation successfully without complications during hospitalization and were followed for 12 to 27 months, with an average of 18 months. The patients' preoperative and one month, 3 month, and 12 month postoperative VAS scores were 6.42 ± 0.72, 1.71 ± 0.86, 1.38 ± 0.65, and 1.37 ± 0.58, respectively, and their JOA scores were 9.54 ± 1.89, 21.21 ± 1.98, 22.50 ± 1.47, and 23.46 ± 1.32, respectively. The preoperative ODI score was 42.04 ± 2.63; the one month, 3 month, and 12 month postoperative ODI scores were 22.79 ± 1.61, 18.63 ± 1.61, and 15.08 ± 1.21, respectively. These results suggest that the VAS score at each postoperative time point was significantly lower than the preoperative score and that function was significantly improved postoperatively compared with preoperative function; all of the differences had statistical significance ($P < 0.05$). The patients' preoperative lumbar ROM and the ROM at 12 months post operation were 3.46 ± 1.02 and 2.25 ± 0.79, respectively; the difference was not statistically significant ($P = 0.11$).

**Limitations:** The follow-up time is not long enough.

**Conclusions:** The treatment of lumbar degenerative disc diseases with the Isobar TTL dynamic internal fixation system can effectively relieve pain, improve quality of life, and preserve the lumbar ROM of the stabilized segment with a satisfactory clinical therapeutic effect.

**Key words:** Lumbar degenerative disc diseases, dynamic internal fixation system, Isobar TTL, range of motion

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Lumbar degenerative disc disease is a common disease that causes pain in the lower back and legs. Lumbar degeneration can cause lumbar disc herniation, lumbar spinal stenosis, and lumbar instability, which in turn can compress nerve roots and cause pain in the waist and legs, numbness in the lower limbs, and changes in muscle strength. In severe cases, patients can experience bowel and bladder dysfunction, which seriously affects quality of life. Reports have shown that up to 84% of people have some degree of lower back pain (1). Among all lower back pain patients, most of their symptoms are caused by lumbar degeneration. At present, the treatment of lower back and leg pain caused by lumbar degeneration mainly includes bed rest, back muscle exercises, and other conservative treatments as well as surgical treatment. Posterior interbody fusion surgery with pedicle internal fixation is the gold standard for the treatment of lumbar degenerative disc diseases, and it offers a significantly better clinical therapeutic effect than conservative treatment does. However, an increasing number of studies have shown that because fused lumbar vertebrae lose their physiological activity, the compensatory range of motion (ROM) of the adjacent levels increases; this greatly increases the probability that these levels will degenerate, resulting in a recurrence of the clinical symptoms and the need for another surgery. Nakashima et al (2) conducted a 10 year follow-up of 101 lumbar degenerative disc disease patients who had undergone lumbar fusion surgery and found that 9.9% of the patients required a second operation and that 80% of these second operations occurred 5 years after the first surgery. In addition, although it has been reported that the fusion rate could be as high as 95%, the clinical satisfaction rate for fusion surgery is much lower than the fusion rate (3). To address this issue, dynamic internal fixation systems, including Coflex, X-STOP, and Dynesys, have been developed. There are many reports on these 3 dynamic internal fixation systems, all of which show some clinical effect (4-6). Our research group has used posterior lumbar decompression accompanied by Isobar TTL dynamic internal fixation to treat lumbar degenerative disc diseases. This procedure relieves the radicular pain caused by nerve compression while preserving the lumbar ROM of the surgical segments, thus achieving a satisfactory clinical therapeutic effect. The results are reported below.

## Methods

### General Information

Twenty-four lumbar degenerative disc disease patients who underwent posterior lumbar decompression and Isobar TTL dynamic internal fixation surgery at our hospital between January 2013 and July 2014 were included in the study. There were 13 men and 9 women aged 25 – 76 years old, with an average age of 47 years. Of these patients, 16 had lumbar disc herniation, 5 had lumbar spinal stenosis, and 3 had lumbar spondylolisthesis. The patient inclusion criteria were as follows:

1) Clinical manifestations consisting mainly of lower back and leg pain on one side, with or without intermittent claudication.
2) L4/5 or L5/S1 disc herniation or significant prolapse (accounting for more than half of the spinal canal) confirmed with magnetic resonance imaging (MRI), nerve root compression, and reduction of the intervertebral space.
3) Lumbar degenerative spondylolisthesis ≤ II°.
4) Ineffective symptom relief after half a year of regular conservative treatment.
5) Good general condition, with no contraindications for internal fixation implants. Patient exclusion criteria: prior lumbar surgery, trauma history, lumbar deformity and infection, multi-segment lumbar disc herniation, and osteoporosis.

### Operation Procedures

All of the patients assumed a prone position. After successful general anesthesia and endotracheal intubation, the surgical segments were localized using a C-arm imaging machine, and routine disinfection and draping was performed. The intervertebral space of the surgical vertebra was used as the center, and a midline incision was made from one vertebra above to one vertebra below the surgical vertebra. The skin, subcutaneous tissue, and deep fascia were sequentially cut. A periosteal raspatory was used to strip the erector spinae on both sides of the spinous processes. Dry gauze was used to stop the bleeding, and the upper and lower facet joints of the surgical segment were exposed. The surrounding soft tissues and ligaments were removed. After the "U-shaped" vertebra and small joints were located, a hand drill was used to sequentially drill holes and make openings, and pedicle-positioning pins were inserted into the pedicles of the vertebrae above and below the surgical segment. After C-arm imaging confirmed that the pins were positioned well, pedicle screws were

inserted. A laminectomy rongeur was moved up and down along the vertebral space of the surgical segment to remove the lamina and the ligamenta flava. The posterior nerve was sufficiently decompressed, and a periosteal elevator was used to lift the dura and the compressed nerve root from the interior of the vertebra. A cotton pad was applied for protection, and a sharp scalpel was used to cut the annulus fibrosis. A nucleus pulposus clamp was used to remove the protruding nucleus pulposus and residual disc tissues, and an appropriate elastic connection rod was left in place. The nut of the screw was tightened after pressing, and the tail cap was cut. C-arm imaging was used to confirm the satisfactory position of the pedicle screws. After rinsing, complete hemostasis was ensured, and a suction drainage tube was kept in place. After the gauze pieces and instruments were counted, the incision was sutured layer by layer.

## Therapeutic Effectiveness Assessment

Visual analog scale (VAS) pain scores, Japanese Orthopedic Association (JOA) scores, and Oswestry Disability Index (ODI) scores were used to evaluate the clinical therapeutic effect at one and 3 months postoperatively and at the last follow-up. The VAS was used to assess the degree of pain on a scale of 0 to 10 on which 0 represented no pain and 10 represented the most severe pain. The patients chose the number on this scale that represented the degree of pain they were experiencing. The ODI questionnaire examined the pain intensity the patients experienced in 10 different aspects of life: daily self-care, bearing weight, walking, sitting, standing, sleep, sex life, social life, and travel. Each question was answered on a scale of 0 to 5 points on which 0 represented no dysfunction and 5 represented pronounced dysfunction. The JOA lumbar score mainly assessed subjective symptoms, clinical symptoms, limitations of daily activities, and bladder function. The highest possible score was 29, with lower scores indicating more significant dysfunction.

By measuring the patients' lumbar ROM preoperatively and postoperatively at one month, 3 months, and the last follow-up visit, we evaluated the lumbar ROM and surgical segment preservation resulting from the Isobar TTL internal fixation. The following method was used to measure lumbar ROM (Fig. 1): straight lines

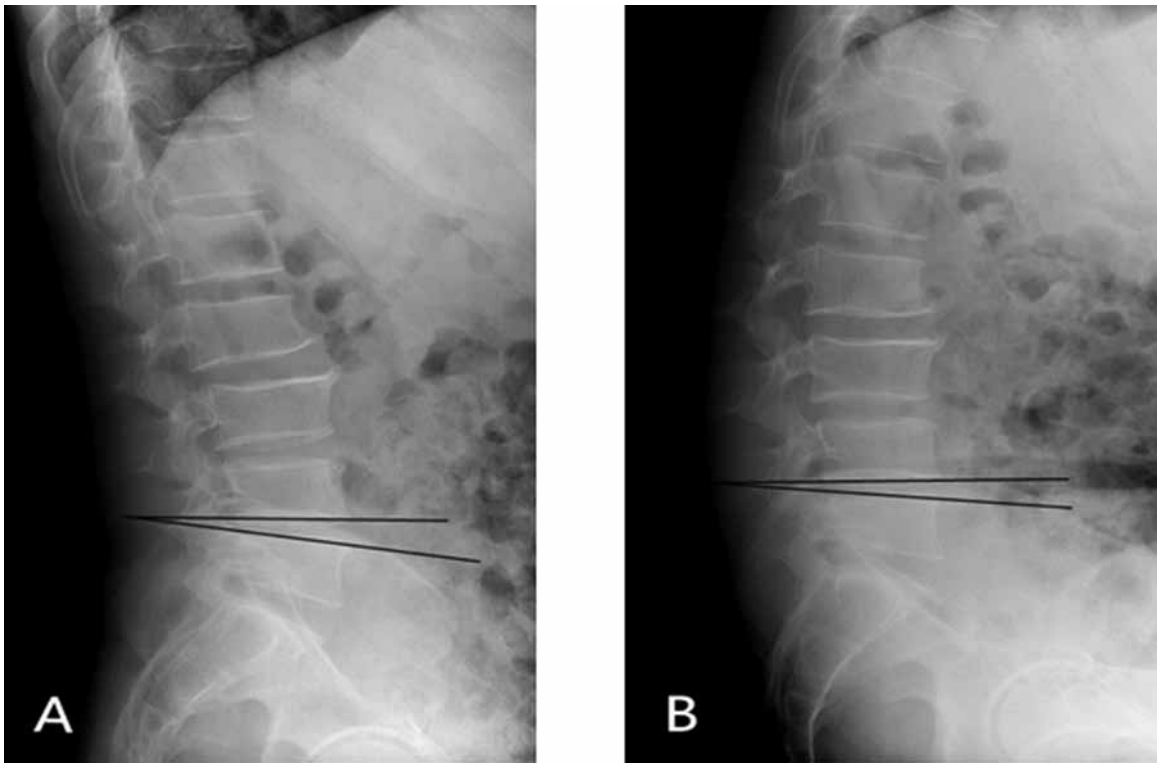


Fig. 1. *Lumbar range of motion measurement. A: extension angle* α*, B: flexion angle* β.

Table 1. *Comparison of the preoperative, one month and 3 month postoperative, and last follow-up VAS, JOA, and ODI scores ( $\bar{x} \pm s$) of 34 lumbar degenerative disc disease patients.*

| Score | Preoperative | One month postoperative | 3 months postoperative | 12 months postoperative |
|---|---|---|---|---|
| VAS | 6.42 ± 0.72 | 1.71 ± 0.86[a] | 1.38 ± 0.65a | 1.37 ± 0.58[b] |
| JOA | 9.54 ± 1.89 | 21.21 ± 1.98[a] | 22.50 ± 1.47a | 23.46 ± 1.32[b] |
| ODI | 42.04 ± 2.63 | 22.79 ± 1.61[a] | 18.63 ± 1.61a | 15.08 ± 1.21[a] |

Note: Compared with preoperation, a$P < 0.05$; compared with 3 months post operation, b$P > 0.05$

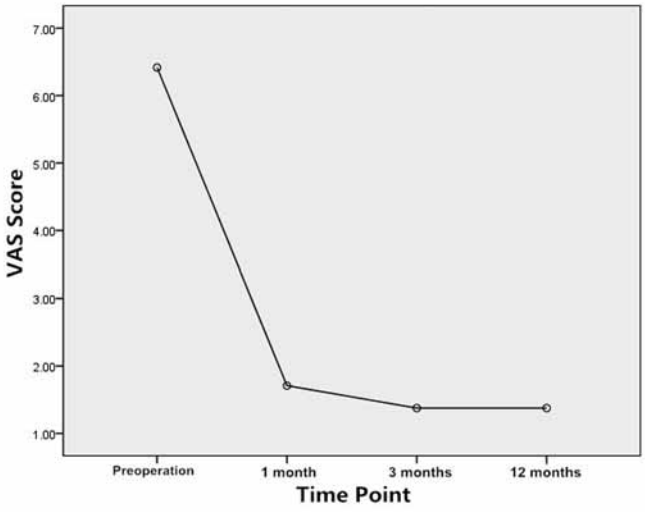


Fig. 2. *Patients' preoperative, one month and 3 months postoperatively, and last follow-up VAS scores (mean).*

were drawn at the upper and lower edges of the dynamically stabilized vertebral segment in the lumbar flexion-extension position before and after the operation. The angle measured at the hyperextension position was extension angle $\alpha$; similarly, the angle measured at the hyperflexion position was flexion angle $\beta$. When the angle was toward the front, it was denoted as "+"; when it was toward the back, it was denoted as "-."The difference between the extension angle and the flexion angle was the lumbar ROM, i.e., ROM = $\alpha - \beta$.

### Data Analysis

SPSS 17.0 statistical analysis software was used to analyze the data. The measurement data are reported as the mean ± standard deviation (± s). The preoperative and one month, 3 month, and 12 month postoperative VAS scores, ODI values, and JOA scores were analyzed using the variance of repeatedly measured data. The preoperative and 12 month postoperative ROM values were analyzed with the independent samples t test; $P < 0.05$ represented statistical significance.

## Results

As described in Table 1, the patients' VAS scores were 6.42 ± 0.72 preoperatively, 1.71 ± 0.86 at one month, 1.38 ± 0.65 at 3 months, and 1.37 ± 0.58 at the last follow-up visit. The difference between the patients' preoperative VAS scores and the VAS score at each follow-up visit had statistical significance ($P < 0.05$), but the difference in the VAS scores for each postoperative follow-up visit was not significant ($P > 0.05$); see Fig. 2.

The patients' postoperative JOA score at each follow-up point increased significantly compared with the preoperative score, and the difference had statistical significance ($P = 0.000$); see Fig. 3.

The results showed that Isobar TTL dynamic internal fixation could significantly improve the patients' functional status one month after surgery. With increased stabilization time, the ODI gradually decreased. All of the differences had statistical significance ($P < 0.05$); see Fig. 4.

The patients' change in postoperative lumbar function was small. The preoperative lumbar ROM of the surgical segment was 3.46 ± 1.02, while the ROM at the last follow-up was 2.25 ± 0.79; the difference did not have statistical significance ($P > 0.05$). All of the patients were followed up and checked with x-ray imaging, which indicated that the internal fixation system was intact without broken screws (for a typical case see Fig. 5).

## Discussion

Lumbar degenerative disc diseases refer to lumbar diseases with the primary manifestation of lower back and leg pain, which is caused by the interaction of the degenerated lumbar intervertebral disc, bone, facet joints, ligaments, and soft tissue. Lumbar degenerative disc

diseases encompass the most common spinal diseases, including lumbar disc herniation, lumbar spinal stenosis, lumbar instability, and degenerative spondylolisthesis. For most lumbar degenerative disc disease patients, conservative treatment can effectively relieve the symptoms. At present, posterior decompression combined with pedicle internal fixation of the interbody fusion is the major surgical treatment method. With the improvement of pedicle screw technology and fusion, the clinical satisfaction rate for this operation has gradually increased. However, an increasing number of studies have shown that the fusion of the spinal segments can increase the stress on adjacent unfused segments, thereby causing adjacent-level degeneration (2,7,8). Meanwhile, relevant biomechanical studies have confirmed that after lumbar fusion, the intervertebral discs and facet joints of adjacent levels experience supraphysiological stress (9). Current spine surgery studies have focused on the use of dynamic internal fixation, which is characterized by spine non-fusion technology, to relieve clinical symptoms while restoring and maintaining the postoperative stability of the surgical segment and mitigating or reducing the degeneration of adjacent levels.

The Isobar TTL system is a semi-rigid pedicle-screw stabilization system that was first reported by Perrin in 1993. This system consists of a universal pedicle screw and 2 dynamic rods. The dynamic rod is the key component; it is a unique shock-absorption joint composed of internally superimposed titanium rings. The elastic ROM of the shock-absorption element is similar to the physiological motion of the spine; it acts as a shock absorber with a ± 2 mm longitudinal displacement and a ± 2°, three-dimensional ROM. In a biomechanical study, Chuang et al (10) confirmed that the Isobar TTL internal fixation system could share 43% of the pressure of the dynamically stabilized segment, thereby slowing the degeneration of intervertebral discs effectively.

Because semi-rigid pedicle-screw stabilization systems are a relatively new technology, the surgical indications for the Isobar TTL are still unclear; Benezech and Mituleseu (11) suggested that the following spinal diseases could be considered indications for using the Isobar TTL: discogenic instability; grade I or grade II degenerative lumbar spondylolisthesis; Iatrogenic instability (decompression laminectomy or unilateral facet joint resection); and dislocation, spinal stenosis, kyphosis, spinal tumor, and failed spinal fusion (pseudoarthrosis formation) after a spinal fracture (in such cases, spinal fusion surgery is used as an auxiliary application to prevent adjacent

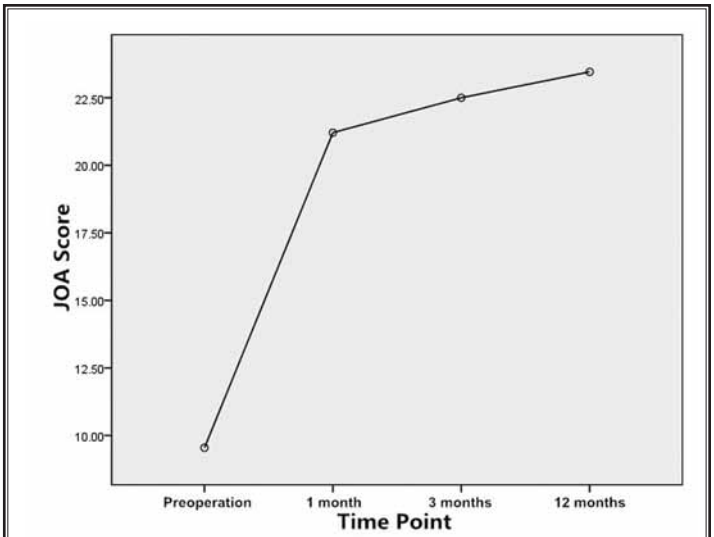


Fig. 3. *The patients' JOA scores preoperatively, one and 3 months postoperatively, and at the last follow-up (mean).*

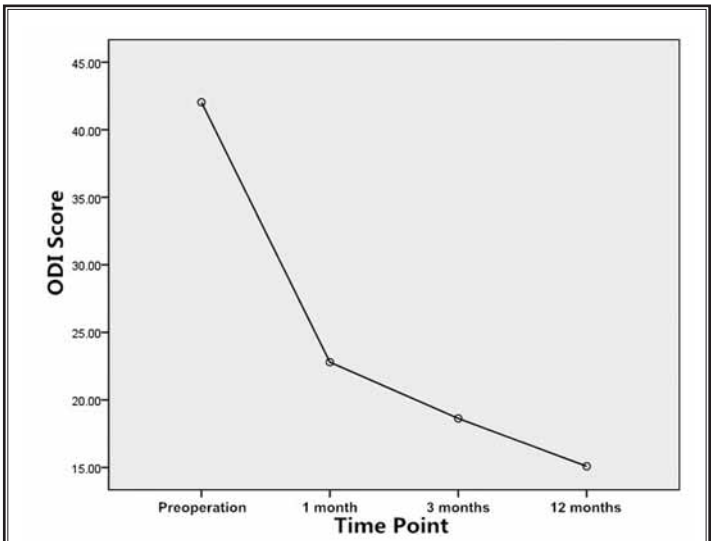


Fig. 4. *The patients' ODI values preoperatively, one and 3 months postoperatively, and at the last follow-up (mean).*

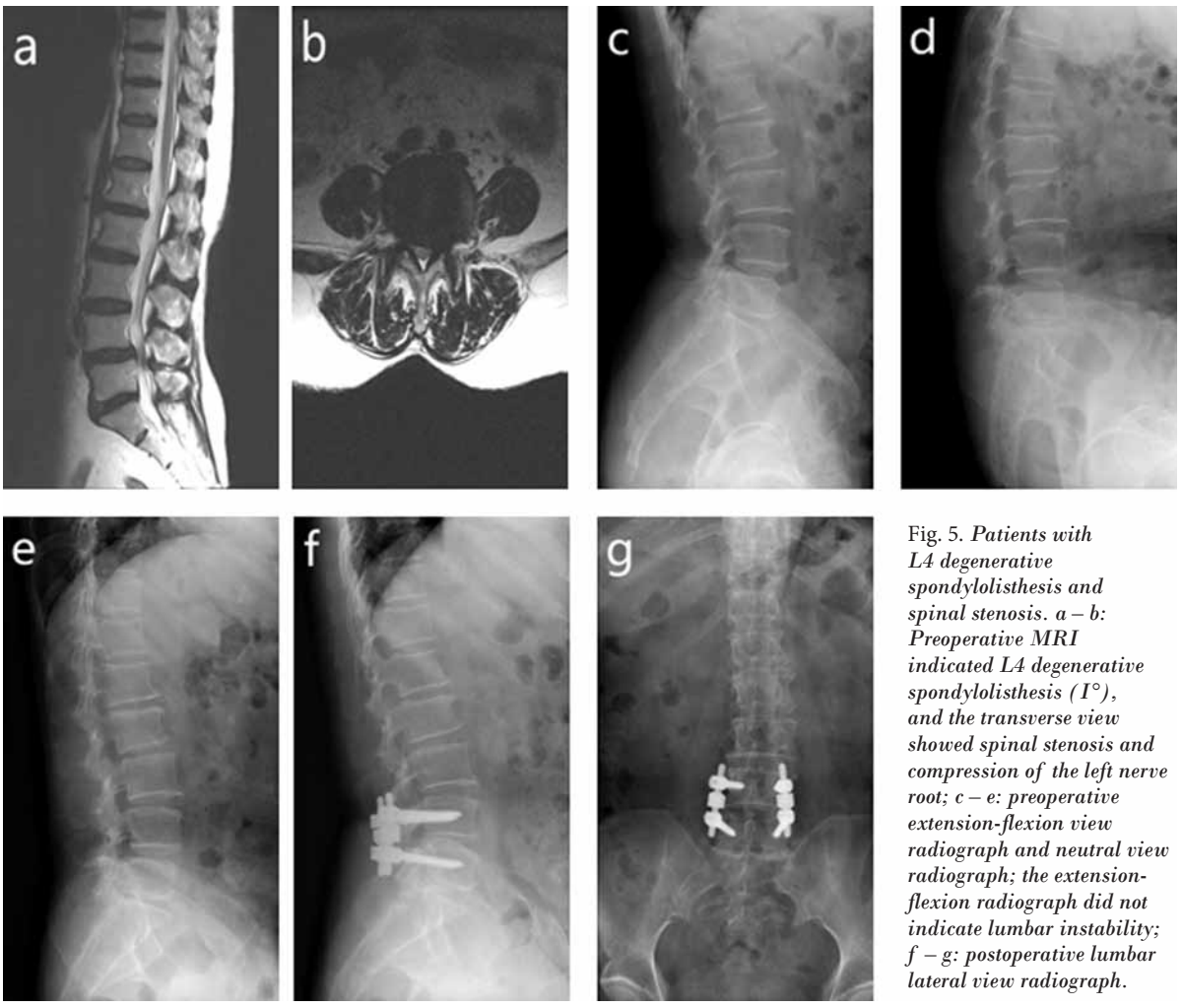


Fig. 5. *Patients with L4 degenerative spondylolisthesis and spinal stenosis. a – b: Preoperative MRI indicated L4 degenerative spondylolisthesis (I°), and the transverse view showed spinal stenosis and compression of the left nerve root; c – e: preoperative extension-flexion view radiograph and neutral view radiograph; the extension-flexion radiograph did not indicate lumbar instability; f – g: postoperative lumbar lateral view radiograph.*

level degeneration). Recently, postoperative adjacent segmental degeneration develops more frequently in patients who had advanced disc degeneration preoperatively. Therefore, we consider early disc degeneration preoperatively might be specific indication for the ISOBAR TTL system.

When the Isobar TTL dynamic internal fixation system is used to treat lumbar degenerative disc diseases, it provides necessary stability while preserving partial motion of the surgical segment, and most patients report a satisfactory clinical therapeutic effect. However, in terms of preventing adjacent level degeneration, there is considerable controversy, which may be related to the numerous factors that affect degeneration (12,13).

Li et al (14) retrospectively analyzed 37 clinical patients and found that the patients' 3-month postoperative VAS scores and ODI values decreased significantly compared with their preoperative values, and the differences were statistically significant. In the long term, the pain was relieved gradually, and the functional status was consistent with the results at 3 months after surgery. In terms of adjacent level degeneration, MRI indicated that 14 (39%) of the patients who received follow-up care had adjacent level degeneration. Consequently, the authors suggested that although the Isobar TTL could effectively relieve lower back and leg pain with a high degree of patient satisfaction, it could not prevent adjacent level degeneration.

Gao et al (15) suggested that Isobar TTL dynamic internal fixation could prevent or delay the occurrence of adjacent level degeneration. After comparing an Isobar TTL group with a Posterior Lumbar Interbody

Fusion (PLIF) group, the authors found that the differences between the postoperative and the preoperative JOA scores and ODI scores of the patients in both groups had statistical significance, but there was no significant difference between the groups ($P > 0.05$). When the Pfirrmann system was used to assess intervertebral disc degeneration, the authors found that the grades of the dynamic group gradually decreased with increased follow-up duration and that at the 2 year follow-up, there was a significant difference compared with the preoperative values. The PLIF group showed opposite results, with a trend toward a gradual increase in grading.

Fu et al (16) performed Isobar TTL dynamic internal fixation surgery on 36 degenerative lumbar discopathy and instability patients with mild adjacent level degeneration, and the clinical therapeutic effect at the 2 year follow-up was similar to other reported findings. However, the authors found that the Pfirrmann score of the stabilized level changed from 2.86 preoperatively to 2.92 postoperatively, while the Pfirrmann score of the adjacent levels changed from 1.92 to 1.96. Therefore, these authors suggested that semi-rigid internal fixation could not effectively prevent adjacent level degeneration, in contrast to the findings of Gao et al (15).

Korovessis et al (17) compared and analyzed the clinical data of 80 cases, including 25 cases of semi-rigid internal fixation and 55 cases of rigid internal fixation, with an average follow-up duration of 39.8 months. The follow-up results showed that there was no significant difference between the 2 groups for the remission rate of lower back and leg pain, imaging examinations of vertebral instability, and pseudoarthrosis formation. Most of the patients were satisfied with the clinical therapeutic effect of the Isobar TTL.

Zhang et al (18) performed a similar comparative study of the treatment of lumbar degenerative disc diseases with dynamic internal fixation and rigid internal fixation. A total of 100 patients were divided into a dynamic internal fixation group (50 cases) and a rigid internal fixation group (50 cases). Among the stabilized vertebrae in the rigid internal fixation group (2.6 ± 0.5), 6 cases showed adjacent level degeneration, and 2 cases had broken screws. Among the stabilized vertebrae in the dynamic group (2.5 ± 0.6), only one case had adjacent level degeneration, and there were no broken screws. The authors found that both internal fixation methods could reduce the pain to no pain or mild pain at 2 years after surgery. However, with increased stabilization time, the lower back pain symptoms of the rigid stabilization group gradually worsened, and at 3 years after surgery, the pain became significantly worse than that of the dynamic group. The authors suggested that Isobar TTL dynamic internal fixation could effectively prevent adjacent level degeneration and screw breakage.

Hrabálek et al (19) reported that 65 degenerative spinal stenosis patients achieved satisfactory mid-term therapeutic effects after Isobar TTL treatment, and no symptomatic restenosis and disc herniation occurred in the stabilized segment.

Most existing studies used an integrated method of fusion combined with Isobar TTL dynamic stabilization. In contrast, in our studies, all patients underwent single-level dynamic internal fixation, which achieved a similar good clinical therapeutic effect, and the follow-up one year after the operation found significant relief of lower back and leg pain symptoms. It is noteworthy that most of the included patients had considerable lumbar disc herniation. For symptoms caused by this type of intervertebral disc damage, simple nucleus pulposus removal has been reported to cause postoperative lumbar instability. Therefore, we combined nucleus pulposus removal with the Isobar TTL dynamic stabilization operation method, which not only eliminated the nerve compression but provided some stability while avoiding the loss of ROM caused by fusion surgery. Our method had a satisfactory short-term clinical therapeutic effect.

The Isobar TTL dynamic internal fixation system is a semi-rigid internal fixation system based on pedicle screws. With the improvements in pedicle technologies, no intraoperative complications have been reported. All of the reported complications have been postoperative; they include screw breakage and loosening. There are several existing reports of the abovementioned complications; compared with the currently most frequently used system, the Dynesis dynamic internal fixation system, the complication rate is significantly decreased (20-22). We suggest that compared with other operation methods for treating lumbar degenerative disc diseases, especially for younger patients with disc herniation, the Isobar TTL offers significant advantages: 1) For the treatment of disc herniation, we often use simple intervertebral disc nucleus pulposus removal or decompression fusion operations; however, clinical follow-up studies have found that after simple intervertebral disc nucleus pulposus removal, the height of the intervertebral space is often reduced (23), thereby causing relevant segment instability, recurring nerve compression, and nerve radicular symptoms. At

the same time, the literature has reported that the incidence of reherniation is 5% to 11% after intervertebral disc nucleus pulposus removal surgery; this is the major reason for the failure of such surgery (24). As a semi-rigid internal fixation method, the Isobar TTL can provide necessary stability and effectively maintain the intervertebral space height, thereby preventing the secondary degenerative diseases caused by the narrowing of the intervertebral space after the intervertebral disc nucleus pulposus removal operation. In addition, when the Isobar TTL is used to treat intervertebral reherniation, only the replacement of the connecting rod and interbody fusion is needed; the pedicle screws can continue to be used, and the adjustment is relatively simple. Compared with fusion surgery, the Isobar TTL offers the advantage of preserving some degree of lumbar ROM, as previously discussed. 2) For patients with the degeneration of multiple lumbar segments, rigid stabilization is performed at the segment(s) with more severe symptoms and obvious instability, and semi-rigid Isobar TTL internal fixation is used at the segment(s) with less severe symptoms to reduce the number of fused segments and to maintain greater lumbar ROM. Meanwhile, because this dynamic internal fixation system can limit the abnormal activity at the dynamically stabilized segments and can reduce the stress borne by the intervertebral space and facet joints in all directions, it can facilitate the recovery of the degenerated intervertebral disc. 3) With the widespread use of pedicle screws, pedicle-screw technology has continuously improved. The Isobar TTL dynamic internal fixation system still uses the traditional screw-rod system, and the only difference is in the connecting rod; therefore, we believe that this operation method is simple and avoids the need for special equipment and techniques, and the surgeon only needs to master the pedicle screw technique to successfully perform the operation.

The major problem with the Isobar TTL dynamic internal fixation system is its service life. Because the screws and the rods used for the dynamic stabilization bear long-lasting stress, there is a risk of internal fixation breakage over time. Meanwhile, the system's reliability for maintaining spinal height, the bone resorption around the screw, the failure of the amphiarthrodial joint, and the collision between screws, rods, and the facet joints are the hidden risks (25) that should be noted in future follow-up studies.

## Conclusions

In summary, the treatment of lumbar degenerative disc diseases with Isobar TTL dynamic internal fixation combined with posterior decompression can effectively relieve symptoms, reduce pain, and improve patient quality of life while maintaining some degree of lumbar ROM. This treatment technology has satisfactory clinical therapeutic efficacy and offers a new method for treating lumbar degenerative disc diseases. However, its long-term efficacy and complications need to be confirmed with additional clinical data.

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