Clinical effect analysis and radiographic outcomes of Isobar TTL system for two-segmental lumbar degenerative disease: a retrospective study

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Research article

Keywords: Isobar TTL, Dynamic stabilization system, Two-segment, Lumbar degenerative disease, Selective fusion

Posted Date: September 10th, 2019

DOI: https://doi.org/10.21203/rs.2.14254/v1

Version of Record: A version of this preprint was published on January 17th, 2020. See the published version at https://doi.org/10.1186/s12893-020-0680-8.

Abstract

Background: Non-fusion fixation is an effective way to treat lumbar degeneration. The present study evaluated the clinical effect analysis and radiographic outcomes of Isobar TTL system for two-segmental lumbar degenerative disease. Method: Forty-one patients with two-segmental lumbar degenerative disease who underwent surgical treatment by Isobar TTL dynamic stabilization system (n=20) and rigid system (n=21) from January 2013 to June 2017. The mean follow-up period was 23.6 (range 15–37) months. Clinical outcomes were evaluated by oswestry dysfunction index (ODI), visual analogue score (VAS) and modified Macnab. Radiographic evaluations included the height of intervertebral space and range of motion (ROM) of the operative segments and proximal adjacent segment. The intervertebral disc signal change was classified by the modified Pfirrmann grade and University of California at Los Angeles (UCLA) system. Results: The clinical outcomes including the ODI and VAS were significantly improved in two groups after operation, but the difference between two groups was not significant. In addition, the clinical efficacy of modified Macnab in two groups was similar too. Radiologic outcomes include height of intervertebral space, lumbar mobility and intervertebral disc signal. The height of intervertebral space of upper adjacent segments of L2/3 in the rigid group were significantly lower than those in the Isobar TTL group at the last follow-up. Furthermore, the number of fixed segment ROM of L3/4 in Isobar TTL group was significantly lower than pre-operation, suggesting that fixed segment ROMs in Isobar TTL group were limited. And, the ROM of upper adjacent segments of L2/3 in the last follow-up of rigid group increased significantly, while the ROM of L2/3 in Isobar TTL group haven't changed after operation. At last, the incidence of adjacent segment degeneration was significantly greater in the rigid group than the Isobar TTL group according to modified Pfirrmann grading system and the UCLA system.
Conclusion: Isobar TTL system could get a good clinical effect for treatment of two-segmental lumbar degenerative disease. Compared with rigid fixation, Isobar TTL system can get better radiographic outcomes and maintain the mobility of the stabilized segments with less influence on the proximal adjacent segment.

Background

Low back pain (LBP) affects approximately 60–85% of adults during some point in their lives [1]. Lumbar disc herniation is one of the most common spinal degenerative disorders which may lead to LBP and radicular leg pain [2]. Furthermore, the degeneration of the intervertebral disc in the elderly is often multisegmental and sometimes it needs surgical treatment [3]. Interbody fusion is considered the "gold standard" in the treatment of lumbar degenerative diseases, but spinal fusion surgery often brings many complications to patients, including donor place ailment, the morbidity of the surgery, and adjacent segment disease [4]. Accelerated degeneration of discs adjacent to fused spinal levels has been observed in numerous case-series studies [5-7]. The available data document this phenomenon and provide information on its time to occurrence but show huge variations in incidence rates (5% to 70%) [8].

Clinical experience shows that the limitation, not the abolition of the spinal activity, can relieve the symptoms of the lumbocrural pain, and it is possible to treat the lumbar disease by changing the stresstransfer mode from the point of view of the biomechanics [9, 10]. With the development of new spinal surgery concepts, non-fusion internal fixation systems have been proposed [11]. Based on the above-mentioned theory, the research and development and clinical application of the Isobar TTL non-fusion internal fixation system [12]. 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 two dynamic rods. The dynamic rod is the key component and it is a unique shock-absorption joint composed of internally superimposed titanium rings. The elastic range of motion (ROM) of the shock-absorption element is similar to the physiological motion of the spine [13]. The system is a semi-strong internal fixation device based on a pedicle screw, which can bear the load of different directions and plane of motion of the fixed section, and retain a certain range of motion. The application of the set of internal fixation system in the degenerative diseases of the lumbar vertebra can theoretically preserve the activity of the lumbar vertebra and reduce the occurrence of the adjacent segment degeneration (ASD). Even more, Isobar TTL dynamic stabilization fixation system could perform selective fusion of spinal segments, which means it can fix both the fusion segment and the non-fusion segment of the spine.

However, at present, the clinical research of Isobar TTL dynamic stabilization system in the treatment of two-segmental lumbar degenerative disease is still scarce. Therefore, the purpose of this retrospective study is to analyze the clinical effects and radiographic results of Isobar TTL dynamic stabilization system in the treatment of two-segmental lumbar degenerative disease.

Methods

General data

From January 2013 to June 2017, 41 patients with two-segmental lumbar degenerative disease (L3/4 and L4/5) were selected according to inclusion and exclusion criteria in the First Affiliated Hospital of Jinan University. Among them, 20 cases (12 males and 8 females) were included in the Isobar TTL dynamic stabilization system fixation group and 21 cases (10 males and 11 females) were included in the rigid internal fixation system fixation group. All patients were followed up for at least 15 months and underwent X-ray and magnetic resonance imaging (MRI) examinations (Table 1).

Inclusion, exclusion and fusion criteria

Inclusive criteria: (a) Spinal surgery patients in the First Affiliated Hospital of Jinan University from January 2013 to June 2017; (b) Diagnosis for two consecutive segmental lumbar degenerative disease (L3/4 and L4/5), conservative treatment for more than 3 months was ineffective; (c) Good compliance, informed consent to the surgical program, actively cooperate with the treatment of clinical researchers; (d) The patients were followed up for more than 15 months. Exclusive criteria: (a) Severe scoliosis, sagittal or coronal imbalance; (b) Poor physical condition, unable to tolerate surgery or complicated with surgical contraindications; (c) Incomplete medical records or imaging data. Fusion criteria: (a) Severe disc degeneration; (b) Intervertebral instability; (c) Significant lumbar degenerative scoliosis, kyphosis or spondylolisthesis; (d) Bilateral facetectomy >1/3-1/2, excision more than 50% of the pars interarticularis, bilateral discectomy in addition to partial facetectomy.

Operative methods and postoperative management

All operations were performed by the same surgical team. The patients were placed in the prone position, and used for posterior lumbar spine surgery. Through a midline incision and after subperiosteal dissection of the erector spine muscles, the affected segment and entrance points for the pedicle screws were exposed. Radiographic guidance with a C-arm X-ray machine was used to ensure that the pedicle screws were safely inserted. The scope of the decompression of the spinal canal were performed depending on each patient’s condition. The nucleus pulposus was carefully removed, nerve root was completely released, and an interbody fusion cage filled with bone was inserted. The selection of fusion segments is based on the degree of disc degeneration and the severity of their disease in Isobar TTL group, but all surgical segments were fused in rigid group. In the rigid group, rigid titanium rods were placed at the end of the nail, but in the Isobar TTL group L3/4 was selected for non-fusion.

After the operation, the patients were given broad-spectrum antibiotics 1 to 3 days, and the drainage tube was removed when the drainage volume was less than 50 mL in 24 hours. After discharging from hospital, patients were ordered to have regular reexamination, wear waist circumference protection for 3 months, and not to do excessive weight-bearing activities in six months.

Clinical and radiological evaluation

Evaluations were performed preoperatively and at the final follow-up. The scores of VAS and ODI were used to evaluate the patients' low back pain and their quality of life. The clinical efficacy of the two groups was evaluated by Greenough judge standard clinical curative effect.

Radiological measurements were performed as follows: (a) Fusion rate was established according to the judgment standard of bone fusion segment by Suk[14]; (b) Segmental ROM was calculated as the angle between the inferior surface of the upper vertebrae and the superior surface of the lower vertebrae on the lateral standing lumbar flexion-extension X-ray; (c) the ventral intervertebral space height; (d) All patients underwent lumbar MRI both at the final follow-up to evaluate changes in the height of the adjacent degenerative intervertebral discs (L2/3) and signals of the intervertebral discs. Disc degeneration was graded on T2-weighted sagittal and axial MRI according to the modified method described by Pfirrmann; (e) University of California at Los Angeles Grading Scale (UCLA) system: The degree of intervertebral space degeneration was evaluated by X-ray. Radiographs were evaluated three times independently by two experienced spine surgeons in this study.

Statistical assessment

The clinical data and imaging measurements of 41 patients were analyzed by SPSS19.0 software. Measurement data are presented as mean ± standard deviation (SD). Enumeration data were evaluated with the chi square test and categorical data were compared by the Wilcoxon signed rank test. And *P*-value of < 0.05 was considered statistically significant.

Results

Patient baseline characteristics

All patients were followed up for 15~37 months, of which Isobar TTL group had an average of 22.00 months and rigid group had 25.18 months. Operation time of patients in Isobar TTL group ranged from 125 to 199 minutes, and the average time were 163.64 minutes. In addition, rigid group operation time were 145~222 minutes, and the average time were185.67 minutes. Intraoperative blood loss of Isobar TTL group was 245 ml and blood loss in rigid group was from 300 to 1300 ml. In a word, there was no significant difference between the two groups in age, bleeding volume during operation, follow-up time, total hospitalization time and operation time (Table 1).

Clinical efficacy

Isobar TTL group of patients on admission ODI was 81.84±6.63 at pre-operation, at the time of the last follow-up it was 30.15±4.38. Compared with pre-operation, it improved significantly. Grading rigid group patients on admission ODI was 82.21±5.86 at preoperation and it was 28.06±5.39 at the last follow-up. Compared with pre-operation, it improved 65.87%. Isobar TTL group on VAS was 6.82±1.77 points at pre-operation, but at the time of the last follow-up it was 2.75±0.86 points. Rigid group on VAS was 6.70±1.51 points preoperatively, but at the time of the last follow-up it was 2.58 ±0.86 points. The scores of ODI and VAS at post-operation were not significantly different between Isobar TTL group and rigid group. But the *P* value of ODI and VAS in Isobar TTL group was less than 0.05 at before and after operation. However, there was no significant difference in the improvement rates of ODI and VAS between the two groups (Table 2).

Greenough judge standard clinical curative effect, postoperative dynamic group at the time of the last follow-up, excellent good rate was 85.0%, but excellent good rate in the rigid group was 71.4%. However, there was no significant difference between Isobar TTL group and rigid group ($P > 0.05$) (Table 3).

Radiologic outcomes of fusion rate

At the last follow-up, there were 20 fusion segments in the Isobar TTL group, 19 segments were judged as strong fusion, and 1 segment was judged as possible fusion, with a fusion rate of 95.00%. There were 42 fusion segments in rigid fixation group, 40 segments were judged as strong fusion, and 2 segments was judged as possible fusion. The fusion rate was 97.30%. There was no significant difference in fusion rate between the two groups ($P > 0.05$).

Radiologic outcomes of lumbar mobility and height of intervertebral space

The preoperative and postoperative height of intervertebral space in the Isobar TTL and rigid groups are shown in Figure 1. The pre-operative height of intervertebral space of L2/3 and L3/4 between the two groups was similar ($P > 0.05$). And, the surgery intervertebral space height of L3/4 in rigid group at the last follow-up was better than these in Isobar TTL group, which means intervertebral fusion cage is helpful to the recovery of intervertebral height. However, the height of intervertebral space of upper adjacent segments of L2/3 in the rigid group were lower than those in the Isobar TTL group at the last follow-up ($P < 0.05$), indicating that Isobar TTL could slow down the degeneration of adjacent segments to a certain extent (Fig. 1b).

The preoperative and postoperative radiologic parameters including total lumbar mobility, L2/3 and L3/4 ROM in two groups are shown in Figure 1. The total lumbar ROM of the two groups at the last follow-up was significantly lower than pre-operation ($P < 0.05$). There was no statistical difference in the total lumbar ROM between the two groups at last follow-up ($P > 0.05$) (Fig. 1c).

At the last follow-up, the number of fixed segment ROMs of L3/4 in Isobar TTL group was significantly lower than pre-operation ($P < 0.05$), suggesting that fixed segment ROMs in Isobar TTL group were limited, but it still retains some of the spinal motion. Nevertheless, the fixed segment ROMs of L3/4 in rigid group is immobile because of fusion in L3/4 (Fig. 1d).

The ROM of upper adjacent segments of L2/3 in the last follow-up of rigid group increased significantly ($P < 0.05$), while the ROM of L2/3 in Isobar TTL group haven't changed between pre-operation and the last follow-up. In addition, the ROM of upper adjacent segments in the rigid group increased significantly compared with these in the Isobar TTL group at the last follow-up ($P < 0.05$). It indicated that the Isobar TTL group was better than the rigid group to retain a certain range of motion of the lumbar spine.

Radiologic outcomes of degeneration in adjacent segments

According to the modified Pfirrmann grading system of adjacent segment and dynamic fixed segment disc to evaluate the degree of degeneration. The incidence of degeneration of adjacent segments was 10.00% in Isobar TTL group, and 14.3% in rigid group. The incidence of adjacent segment degeneration of Isobar TTL group was significantly slow than the rigid group ($P < 0.05$) (Table 5).

According to the UCLA system, the incidence of adjacent segment degeneration was 5.0% in the Isobar TTL group and 19.0% in the rigid group. The incidence of adjacent segment degeneration of Isobar TTL group was significantly slow than the rigid group ($P < 0.05$) (Table 6).

Discussion

The Isobar TTL dynamic stabilization system is used to preserve the normal function of the fixed segments and maintain spinal stability, thus avoiding ASD. After traditional rigid fusion, the transmission mode of spinal mechanics was changed, the stress of adjacent segments was increased, and ASD was easy to occur. Isobar TTL dynamic stabilization system has many advantages in the treatment of two-segment lumbar degenerative diseases: the semi-rigid internal fixation device of pedicle screw can reduce the pressure of intervertebral joint, protect the interbody joint of non-fusion segment [15], bear the load of different directions and motion planes of fixed segment, disperse the axial load and flexion and extension shear force of intervertebral disc, stabilize the lumbar vertebrae and retain a certain degree of lumbar motion at the same time. To disperse the stress of adjacent segments and reduce or delay the degeneration of adjacent segments [16]. Therefore, the, Isobar TTL dynamic stabilization system is particularly suitable for the treatment of two-segment lumbar degenerative diseases, in the relatively mild symptoms of segmental motion fixation, rather than all rigid fusion[17]. Therefore, the occurrence of ASD can be avoided or delayed. Theoretically, Isobar TTL dynamic stabilization system has more advantages than rigid system.

Isobar TTL dynamic stabilization system and rigid system for the treatment of two-segmental lumbar degenerative disease both got a good clinical effect. In this study, the clinical outcomes including the VAS score and ODI were significantly improved in both groups at post-operative and the final follow-up, but the difference between the Isobar TTL group and rigid group was not significant. In addition, in the evaluation of clinical efficacy of Greenough, the excellent and good rate of Isobar TTL was 85.0%, and rigid group was 71.4%, but the difference was not statistically significant ($P > 0.05$). Therefore, compared to rigid group, Isobar TTL group got similar the outcome to the traditional internal fixation system. It suggested that Isobar TTL dynamic stabilization has a definite therapeutic effect in treating multilevel lumbar degenerative disease.

Additionally, Isobar TTL dynamic stabilization system partially preserves the motion of the operated segment based on stabilization of the lumbar vertebrae. And it also preserves ROM of the lumbar spine. Some studies have reported that the intervertebral space can be restored a little early after operation, but the intervertebral space will gradually decrease after long-term follow-up [18, 19]. The possible reason is that the intervertebral space will be properly elevated during lumbar surgery. In this study, the height of intervertebral space in Isobar TTL group was slightly higher than pre-operation, which provided the possibility of maintaining a better and stable level of intervertebral space after internal fixation. However, with the occurrence of intervertebral space degeneration, the height of intervertebral space gradually lost. In addition, the height of intervertebral space of upper adjacent segment in rigid group decreased more rapidly than that in Isobar TTL group, indicating that the Isobar TTL dynamic stabilization system could slow down the degeneration of adjacent segments.

When comparing simple lumbar discectomy and lumbar interbody fusion, Isobar TTL dynamic stabilization system can restore the lumbar disc height of the operative segment and maintain the structure of the lumbar spine. Furthermore, it can preserve the ROM of the operative segment, reduce the stress load on the adjacent segment, and compensation of motion range [20, 21]. Many studies have also supported the idea that dynamic stabilization system can delay the occurrence of adjacent-level degeneration [22-24]. In patients with two level lumbar degenerative disease, the influence of Dynesys stabilization on the development of ASD is a current area of clinical research [20]. In this study, lumbar total ROM of Isobar TTL group at the last follow-up was significantly higher than the rigid group, indicating that Isobar TTL can retain a certain degree of lumbar total ROM. For adjacent segment ROMs, the upper adjacent segment ROM in the Isobar TTL group changed less than those in the rigid group. It can be seen that Isobar TTL dynamic stabilization system can little effect the relative activity of adjacent segments. Postoperative fixation segmental mobility of Isobar TTL group was significantly lower than that pre-operation, but part of the activity was retained. It can be seen that Isobar TTL system has a stable effect on the surgical segment of lumbar vertebrae, but it is different from the lack of intervertebral motion of rigid fusion segment.

The idea of Isobar TTL dynamic stabilization system is to preserve the dynamic changes of the surgical segment, reduce the pressure on the intervertebral joint and reduce its compensatory activity, and dynamic stabilization may indirectly reduce the adjacent segment degeneration[25]. One hand, the improved Pfirrmann classification system was adopted in this study, and 2 segments (10%) in the adjacent segment of the Isobar TTL group had degeneration, and 3 segments of the rigid fixation group had degeneration (23.8%). On the other hand, the incidence of adjacent segment degeneration was evaluated by UCLA system. It was found that one segment in Isobar TTL group (5%) and four segments in rigid group had degeneration (19%). In the evaluation of the two evaluation systems, the degeneration of adjacent segments in rigid group was more obvious than that in Isobar TTL group, which indicated that Isobar TTL dynamic system might slow down the degeneration of adjacent segments to a certain extent, and also accord with the design concept of Isobar TTL dynamic stability system [26].

In general, for degenerative spinal disease, it is necessary to maintain the stability of spine after operation, and also to solve the further degeneration of the lumbar vertebra, retain the normal range of motion of the treated segment, minimize the complications caused by internal fixation in the middle and long term [27, 28]. The use of Isobar TTL posterior internal fixation system in the treatment of two-segmental lumbar degenerative disease provides a new way of thinking for the clinical preservation of spinal joint motility. This retrospective study suggests that the Isobar TTL is no worse than that of the traditional method, especially in the preservation of motion degree of spinal motor joint. And, further randomized, controlled, prospective, multicenter clinical studies are needed to provide more scientific basis and evidence for the indication and therapeutic effect of the system in the treatment of lumbar degenerative diseases.

Conclusions

Compared with rigid system for the treatment of two-segmental lumbar degenerative disease, Isobar TTL dynamic stabilization system can obtain good treatment effect， get better radiographic outcomes and maintain the mobility of the stabilized segments with less influence on the proximal adjacent segment by preserving the segmental motion and intervertebral height, and maintaining lumbar lordosis, so it may reduce the degeneration of adjacent segments.

Abbreviations

ODI: oswestry dysfunction index; VAS: visual analogue score; ROM: range of motion; UCLA: University of California at Los Angeles; MRI: magnetic resonance imaging; LBP: low back pain; ASD: adjacent segment degeneration

Declarations

Acknowledgements

None

Authors' contributions

HL and GZ contributed to the conception and design of the study; HY, YY, SL contributed to the acquisition of data; JL and GZ performed the experiments; ZJ and HL contributed to the analysis of data; ZJ wrote the manuscript; All authors reviewed and approved the final version of the manuscript.

Funding

This work was supported by Contract grant sponsor: National Natural Science Foundation of China (81771331), Natural Science Foundation of Guangdong Province of China (2017A030313595), Science and Technology Program of Guangzhou (201707010370) and supported by The Fundamental Research Funds for the Central Universities (No. 21618304 and 21617498).

Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

This retrospective study was approved by the Institutional Ethics Committee of the First Affiliated Hospital of Jinan University. Informed consent was waivered due to the retrospective and non-interventional nature of this analysis.

Consent for publication

Written informed consents for publication were obtained from all participants.

Competing interests

The authors declare that they have no competing interests.

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Tables

Table 1 General data of two groups

General data	Isobar TTL(N=20)	Rigid (N=21)	*P*
Age(years)	64±7.78	61±6.50	0.338
Sex			
Female	12(60%)	10(47.62%)	0.427
Male	8(40%)	11(52.38%)	
Follow-up (months)	22.00±7.01	25.18±4.75	0.227
Operation Time (mins)	163.64±42.42	185.67±27.80	0.138
Intraoperative blood loss (mL)	245.45±145.70	445.00±305.00	0.067
Hospital stay (days)	20±4.22	18.6±1.92	0.187

Note：Data are presented as mean ± standard deviation. *P* values are based on the t test; *P* >0.05 compared with Isobar TTL and Rigid.

Table 2 Scores of ODI and VAS

Index	Isobar TTL (N=20)		Rigid (N=21)	
	ODI	VAS	ODI	VAS
Pre-operation	81.84±6.63	6.82±1.77	82.21±5.86	6.70±1.51
Post-operation	30.15±4.38	2.75±0.86	28.06±5.39	2.58±0.86
P	0.000	0.000	0.000	0.000
P'		ODI (0.182)		VAS (0.530)

Note：Data are presented as mean± standard deviation. *P* values are based on the aired t test, *P* means Post-operative compared with preoperative, *P* < 0.05; *P'* means Isobar TTL group compare with rigid group, *P* >0.05. *P* <0.05 mean statistical significant differences.

Table 3 Clinical assessment of Greenough clinical effect judgment.

Group	N	Excellent	Good	Fair	Poor	Excellent Good rate	*P*
Isobar TTL	20	4	13	3	0	85.00%	1
Rigid	21	2	13	5	1	71.40%	

Note：*P* values are based on the chi-square test, $P<0.05$ means statistically significant differences.

Table 4 The fusion rate of two groups

Grading	Isobar TTL (N=20)	Rigid (N=42)	*P*
Fusion	19	40	
Possible fusion	1	2	
Non-fusion	0	0	
Fusion rate (%)	95.00%	95.20%	1.000

Note：*P* values are based on the chi-square test, $P < 0.05$ means statistically significant differences.

Table 5 The modified Prirrmann grade rate of proximal adjacent in two groups

Segment	Isobar TTL (N=20)	Rigid(N=21)
L2/3	2（10.0%）	3（14.3%）
L3/4	1（5.0%）	0（0.0%）

Note：*P* values are based on the chi-square test, $P < 0.05$ means statistically significant differences.

Table 6 The UCLA system evaluation of intervetebral space (n=41).

Segment	Isobar TTL (N=20)	Rigid (N=21)
L2/3	1（5.0%）	4（19.0%）
L3/4	1（5.0%）	0（0.0%）

Note：*P* values are based on the chi-square test, $P < 0.05$ mean statistical significant differences.

Figures

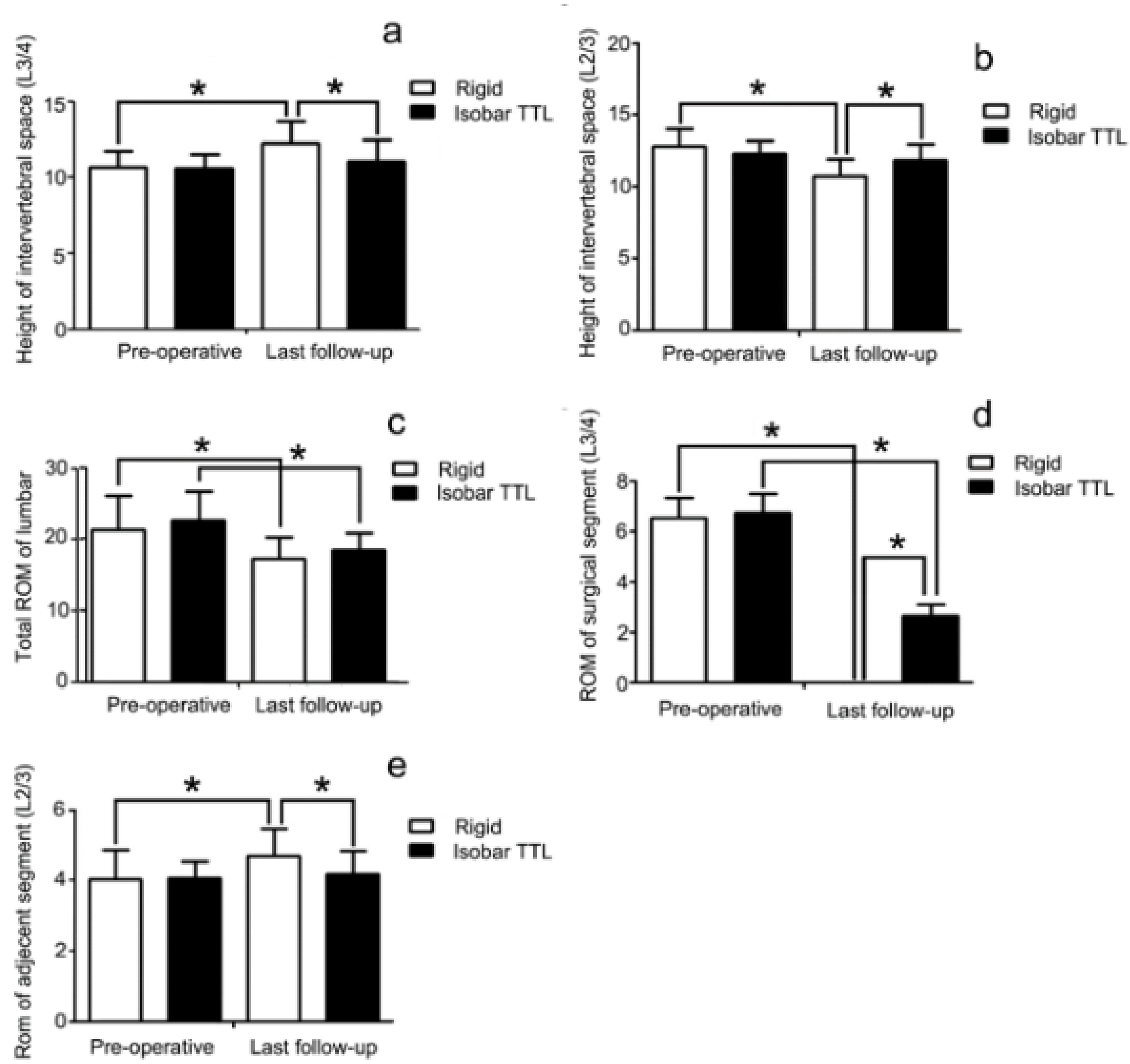

Figure 1

Comparison of the effects of Isobar TTL dynamic stabilization system and rigid system on lumbar mobility and height of intervertebral space. (a) The intervertebral space height of L3/4 of in surgery segment in Isobar TTL and rigid groups at pre-operative and last follow up; (b) The intervertebral space height of L2/3 of in upper adjacent segment in Isobar TTL and rigid groups at pre-operative and last follow up; (c) ROMs of non-fusion fixed segment in pre-operative and last follow up; (d) The ROM of surgery segment of L3/4 at pre-operative and last follow-up in the two groups; (e) The ROM of upper adjacent segment by L2/3 at pre-operative and last follow-up in the two groups; * means $P < 0.05$.

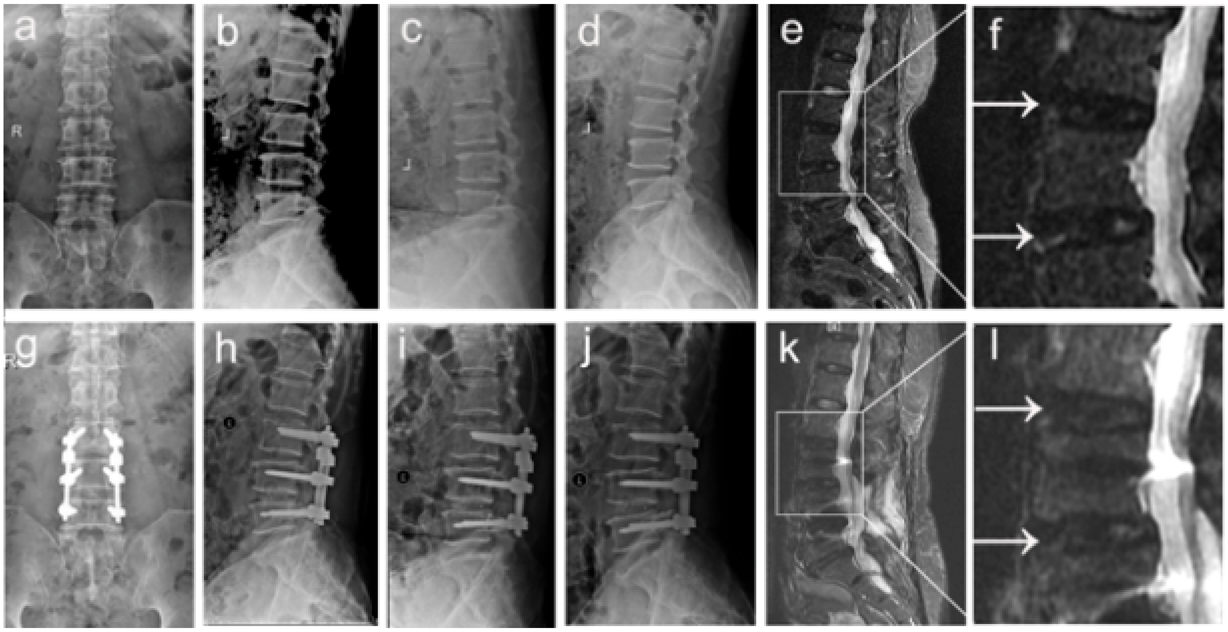

Figure 2

Typical case (Isobar TTL group): A 63-years-old male patient with two level degenerative lumbar disease (L3/4, L4/5). Figure a, b, c, d, e and f are the pictures of patient before operation (X-ray image include a, b, c and d; MRI image include e and f); Figure g, h, i, j, k and l are the pictures of patient at last follow up (X-ray image include g, h, i and j; MRI image include k and l.

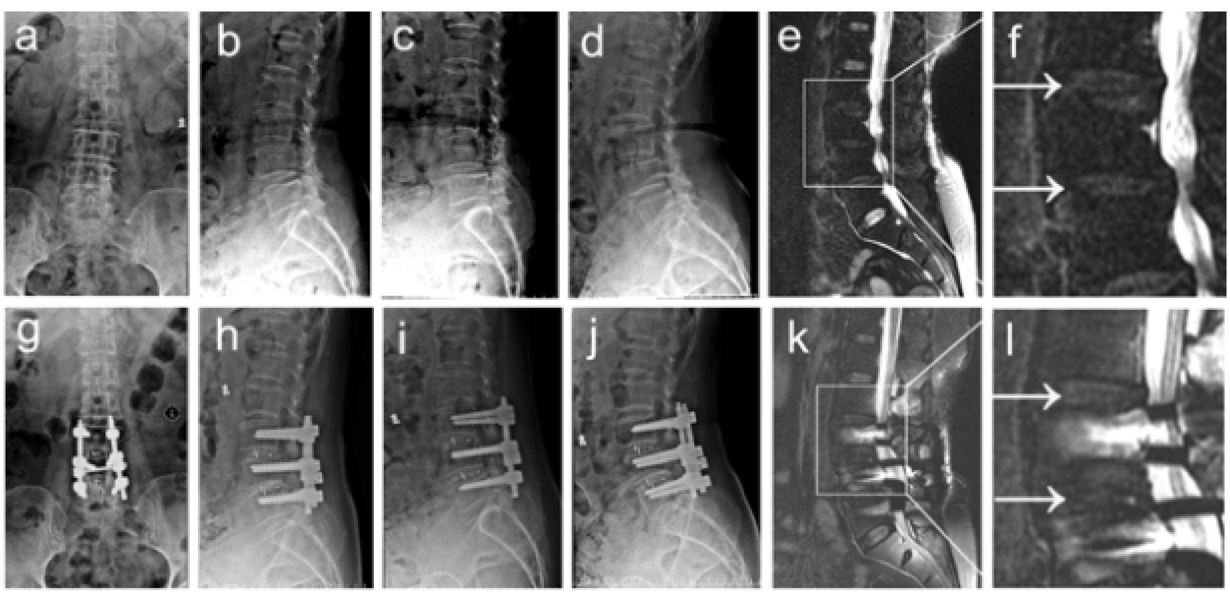

Figure 3

Typical case (Rigid group): A 61-year-old female patient with two level degenerative lumbar disease (L3/4, L4/5) underwent L3/4, L4/5 decompression and rigid fixation. Figure a, b, c, d, e and f are the pictures of patient before operation (X-ray image include a, b, c and d; MRI image include e and f); Figure g, h, i, j, k and l are the pictures of patient at last follow up (X-ray image include g, h, i and j; MRI image include k and l.