The Study of INTRA Spine Non Fusion Technique in the Treatment of Lumbar Degenerative Disease

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Study Design

Inclusion and Exclusion Criteria

Inclusion Criteria: Patients exhibiting clinical manifestations, physical examination findings, and imaging data consistent with a diagnosis of degenerative lumbar spinal disease. All patients underwent rigorous and standardized conservative treatment for a minimum of three months preoperatively, with no significant improvement in symptoms. Preoperative imaging studies indicated the presence of protrusion in a single segment or protrusion resulting in segmental stenosis. All patients required surgical intervention for degenerative disease affecting the L4-5 segments.

Exclusion Criteria: Presence of lumbar instability or grade II or higher spondylolisthesis. Diagnosis of severe osteoporosis, tuberculosis, or tumors. Systemic diseases, such as cardiac, hepatic, or renal conditions, that could adversely affect surgical treatment or medication administration. Patients with psychiatric disorders, poor compliance, or those unable to cooperate with follow-up assessments were excluded from the study.

General demographic characteristics, clinical scores, and imaging data were collected for all enrolled patients both preoperatively and one year postoperatively.

Clinical Data

The patients were categorized into two groups based on the surgical approach: the observation group, which received surgery utilizing the Intra-Spine dynamic stabilization system, and the control group, which underwent spinal fusion surgery. All patients had no prior history of lumbar spine surgery, and this study represented their first surgical intervention.

Before the operation, all patients underwent anteroposterior and lateral X-rays of the lumbar spine, as well as dynamic X-rays in flexion and extension positions, along with lumbar spine CT and MRI scans. Postoperatively, follow-up evaluations included anteroposterior X-rays of the lumbar spine and CT scans at six months and one year after the operation. If conditions permitted, some patients also underwent MRI scans for further evaluation. Data were collected preoperatively, seven days postoperatively, and at six-month intervals up to one year postoperatively.

Clinical Evaluation Method

The clinical outcomes and patient improvement were assessed using the Japanese Orthopaedic Association (JOA) score, the Visual Analogue Scale (VAS), and the Oswestry Disability Index (ODI).

Radiographic Evaluation Method

Radiographic evaluations were conducted through measurements obtained from lateral X-rays of the lumbar spine,

including neutral, over-extension, and over-flexion positions. We assessed the surgical gap and Cobb angle for both the operated segment and adjacent segments to determine the range of motion (ROM). Posterior disc height (PDH) was defined as the vertical distance between the lower edge of the upper vertebral body and the upper edge of the lower vertebral body, measured in the lateral X-ray at the neutral position. Similarly, foraminal height (FH) was defined as the vertical distance between the lower margin of the upper vertebral pedicle notch and the upper margin of the lower vertebral pedicle notch in the lateral X-ray of the upper vertebral body.

Statistical Analysis

All data are presented as mean ± standard deviation (SD). Statistical analyses were conducted using a one-way analysis of variance (ANOVA) to assess differences between baseline measurements within the treatment groups. All statistical analyses were performed utilizing SPSS software (version 26.0), and differences were considered statistically significant at a p-value of less than 0.05.