A Multicenter Randomized Controlled Clinical Study on the Application of a Novel Expandable OLIF Cage with Posterior Bone Grafting

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This project aims to systematically evaluate the safety, efficacy, and clinical value of the novel expandable OLIF cage through a prospective, multicenter, randomized controlled trial, providing scientific evidence for the advancement of spinal surgical techniques. Specific components include:

1. Study Population:

Inclusion criteria: (1) Age between 40 and 80 years; (2) Diagnosed with lumbar disc degeneration, lumbar spinal stenosis (Grade A–C), degenerative spondylolisthesis (Grade I–II), or isthmic spondylolysis with or without spondylolisthesis (Grade I–II); (3) Single-level lumbar disease located at L2/3, L3/4, or L4/5; (4) Completed all necessary assessments and scheduled for OLIF surgery under general anesthesia; (5) Willing and able to comply with the study protocol; (6) Provided written informed consent prior to registration and fully understands their right to withdraw at any time without penalty.

Exclusion criteria: (1) Bony central canal or lateral recess stenosis, or non-contained disc herniation requiring direct decompression; (2) Previous lumbar posterior or retroperitoneal surgery, or abnormal iliac vascular sheath-psoas interval; (3) Severe spinal deformity or osteoporosis (T-score < -3.0); (4) Severe cardiac dysfunction (LVEF < 30% or NYHA Class IV), severe hepatic dysfunction (Child-Pugh Class C), severe renal dysfunction (on dialysis), or ASA Class IV or above; (5) Recurrent severe infections or other serious comorbidities; (6) Conditions requiring simultaneous surgeries; (7) Participation in other clinical trials; (8) Inability to comply with follow-up requirements.

2. Surgical Protocol and Procedure Standardization:

The novel expandable OLIF cage with posterior bone grafting will be used. Intraoperatively, height expansion technology will restore intervertebral height and lumbar lordosis, while posterior grafting promotes interbody fusion. All procedures will follow standard surgical protocols and be performed by trained spine surgeons to ensure consistency.

3. Evaluation Indicators:

Perioperative data will be recorded, including operative time, intraoperative blood loss, time to ambulation, length of hospital stay, and complications. Clinical outcomes will be assessed using the Visual Analogue Scale (VAS) and Oswestry Disability Index (ODI). Imaging assessments will include intervertebral height, coronal and sagittal Cobb angles, and evaluation of interbody fusion.

4. Data Collection and Analysis:

An electronic medical record system and follow-up platform will be used to establish a multi-dimensional data collection framework:

- **Preoperative baseline data:** Demographics (age, sex, BMI), disease duration, comorbidities, radiological parameters (intervertebral height, lumbar curvature);
- **Intraoperative data:** Operative time, blood loss, graft volume, number of fluoroscopy exposures, neuro-monitoring data;
- **Postoperative follow-up data:**
    - **Imaging (Immediate/6M/12M):** Bridwell grading for fusion, intervertebral height restoration rate, cage subsidence;
    - **Clinical (Pre/3M/6M/12M):** VAS (back/leg), ODI, SF-36 quality of life scale;
    - **Complications:** Categorized records of neurological injury, adjacent segment degeneration, instrumentation-related complications;
    - **Dynamic monitoring:** Scheduled follow-up at 1, 3, 6, and 12 months with electronic follow-up records.

Efforts will be made to ensure data integrity and accuracy. Statistical analysis will compare clinical parameters across groups to evaluate the superiority of the novel cage.

5. Sample Size Calculation:

The baseline incidence of cage subsidence after OLIF surgery is approximately 30%. The expected reduction to 15% with the novel expandable OLIF cage was used in the calculation. With a two-sided alpha of 0.05 and power of 90%, the total sample size is estimated to be approximately 340 participants. There will be 7 centers, each expected to enroll 45–50 patients.

6. Randomization Method:

Eligible participants will be randomized using PASS 11.0 software. Once written informed consent is obtained and baseline assessments are completed, eligible patients will be randomized in sequence according to the pre-generated randomization list.