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

Participant Name：

Contact Number：

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Dear Patient: You are invited to participate in a multicenter randomized controlled clinical trial on the application of a novel expandable OLIF (Oblique Lateral Interbody Fusion) cage with posterior bone grafting. This document will help you understand the purpose, procedures, potential benefits, risks, and discomforts associated with this study. The research physician will explain the study to you and provide this written informed consent form. You are encouraged to read it carefully, discuss it with your family or friends, and ask the study doctor for clarification before making a decision.
If you voluntarily decide to participate, you will be asked to sign this consent form. You will receive a signed copy, and the original will be kept at the study center.

Why are you being invited to participate? (Study Background) Minimally invasive spine surgery is a rapidly evolving field and an inevitable trend in surgical development. OLIF, a novel minimally invasive technique, has shown significant advantages in treating degenerative lumbar diseases. It provides effective indirect decompression and a high fusion rate while minimizing disruption to the spinal canal, posterior muscles, and ligaments. However, conventional fixed-height cages may not match the patient's anatomical intervertebral space, leading to subsidence (up to 30%), endplate collapse, and inadequate decompression. In patients with osteoporosis or endplate damage, traditional cages may lack sufficient stability, often requiring additional fixation such as pedicle screws, which increases surgical complexity and complication risk.

This study aims to address the limitations of traditional OLIF cages in grafting, expansion, and postoperative stability using a novel expandable cage with posterior bone grafting.

What is the purpose of this study? This study aims to:

1. Explore the indications and clinical application range of the novel expandable OLIF cage;
2. Establish technical standards and expert consensus based on study outcomes;
3. Promote and apply this promising innovation by evaluating its efficacy and safety in treating degenerative lumbar diseases through a multicenter, large-sample, randomized controlled trial.

What type of study is this? This is a prospective, multicenter, randomized controlled clinical trial.

What does participation involve? The study will start in June 2025 and enroll approximately 260 patients with a follow-up period of 12 months.

Inclusion criteria:

- Lumbar disc degeneration, lumbar spinal stenosis (Grade A-C), degenerative spondylolisthesis (Grade I-II), or isthmic spondylolisthesis (Grade I-II);
- Single-level lesion;
- Lesion located at L3/4 or L4/5.

Exclusion criteria:

- Bony central or lateral recess stenosis, or non-contained disc herniation requiring direct decompression;
- Bone mineral density T-score < -3.0;
- Lumbar facet joint fusion at the surgical segment;
- Prior lumbar posterior or retroperitoneal surgery, or obliteration of the iliac vascular sheath-psoas interval;
- Severe comorbidities making surgery intolerable.

Clinical data including surgical time, blood loss, ambulation time, hospital stay, and complications will be collected. Clinical outcomes will be evaluated using the Visual Analogue Scale (VAS) and Oswestry Disability Index (ODI). Radiological assessments will include intervertebral height,

lumbar Cobb angles (coronal and sagittal), and fusion status.

How can you participate? You may participate if you meet the inclusion criteria and none of the exclusion criteria apply. Participation is entirely voluntary.

What will happen if you participate? Participants will be randomly assigned (1:1) to either the experimental or control group:

- Experimental group: surgery using the novel expandable OLIF cage with posterior bone grafting.
- Control group: surgery using the conventional OLIF cage.

Follow-up will be conducted in accordance with the study protocol to monitor outcomes.

What are the possible benefits? You may experience improvement in your condition, faster recovery, shorter hospital stay, and better quality of life. Participation also includes close medical monitoring and guidance. However, there is no guarantee of direct benefit.

You will be responsible for treatment and examination costs incurred during participation. Even if you do not receive direct personal benefit, your contribution will support future treatment improvements.

What are the risks? There is no evidence that the novel cage poses a higher risk than conventional cages.

What happens in case of injury? If you follow the protocol and experience study-related adverse events, the physician will provide medical care and follow-up, and the sponsor will provide compensation in accordance with legal requirements.

How will your information be protected? All study data will be managed by the study physician using a secure electronic data system. Authorized personnel (e.g., ethics committees, regulators) may access your records to verify data accuracy, but your identity will remain confidential. Your data will be de-identified using codes known only to your physician.

No personally identifying information will be published or disclosed without your permission unless required by law. Any publications will not include personal identifiers.

Who to contact for more information: For questions about this study or your rights as a participant, contact:

Study Physician Name:

Contact Number:

Ethics Committee Contact:

Contact Number:

Voluntary Participation Statement Your participation is entirely voluntary. You may withdraw at any time without affecting your routine medical care. You are encouraged to fully understand this study and discuss it before making a decision.

Informed Consent Signature Page

By signing this form, I confirm that I understand the purpose of the study, that my questions have been satisfactorily answered, and that I agree to allow my data to be collected and used for this research. I will receive a copy of this signed consent form.

Participant Name (Printed):

Participant Signature:

Date:

Legal Representative (if applicable):

Signature of Legal Representative:
Date:
Investigator Name (Printed):
Investigator Signature:
Date:

Investigator Declaration

Compliance with Laws and Ethics: The Investigator will adhere to all relevant national and international regulations, ethical principles, and guidelines governing human subject research, ensuring the study is conducted with scientific and ethical integrity.

1. **Protection of Participant Rights:** The Investigator will ensure all participants (or legal representatives) provide voluntary informed consent with full understanding of the study purpose, risks, benefits, and privacy protections. Participants will be treated fairly, and their rights fully respected.
2. **Confidentiality and Data Security:** The Investigator will implement all necessary measures to protect the confidentiality, integrity, and security of participant data in compliance with legal and institutional policies.
3. **Transparency and Integrity:** The Investigator will ensure the accuracy and reliability of study results, free from bias or conflict of interest. Results will be reported truthfully and in a timely manner to regulatory authorities and the scientific community.
4. **Emergency Preparedness:** The Investigator will establish emergency response plans for adverse events and ensure appropriate medical care and support during and after the study.
5. **Ongoing Monitoring and Improvement:** The Investigator will regularly monitor study conduct and take corrective actions when necessary, reporting all issues to the ethics committee.
6. **Respect for Withdrawal:** The Investigator respect every participant's right to withdraw without penalty and will provide follow-up care or referrals as needed.