Informed Consent Form

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Dear Sir/Madam:

We invite you to participate in the research study titled "Full-Endoscopic Decompression (FED) versus Endoscopic Lumbar Interbody Fusion (Endo-LIF) in Middle-Aged and Older Adults with Lumbar Spinal Stenosis: A Prospective Randomized Controlled Trial." This study is led by [Principal Investigator's Name] and will be conducted at The First Affiliated Hospital of Nanjing Medical University (Jiangsu Provincial People's Hospital). It is estimated that 180 volunteers will participate nationwide, with our center planning to enroll 150 participants. This study has been reviewed and approved by the Ethics Committee of The First Affiliated Hospital of Nanjing Medical University (Jiangsu Provincial People's Hospital), with the ethical review number: .

Why is this study being conducted?

Lumbar Spinal Stenosis (LSS) is a syndrome characterized by anatomical narrowing of the central canal, lateral recess, or intervertebral foramen of the lumbar spine, leading to compression of nerve roots, the cauda equina, and their associated blood supply. Its clinical manifestations primarily include neurogenic intermittent claudication and/or radiating pain and numbness in the lower extremities. LSS is a common cause of disabling low back and leg pain and neurogenic intermittent claudication in middle-aged and older adults. Epidemiological studies confirm that its prevalence increases significantly with age, affecting approximately 11% of the general population and rising to 19.4% among individuals over 60 years old. Against the backdrop of accelerating population aging in China, LSS not only severely threatens the quality of life and physical and mental health of middle-aged and older adults but also imposes a substantial economic burden on society.

For patients who do not respond to systematic conservative treatment, surgery can provide rapid relief from low back and leg pain. In recent years, high-quality evidence from randomized controlled trials (RCTs) has shown that in specific LSS subgroups with Grade I lumbar spondylolisthesis, the two-year clinical outcomes of decompression alone are non-inferior to those of decompression with instrumented fusion. This finding suggests that fusion is not an absolute indication for such patients and challenges the potential trend of overuse of fusion in clinical practice, prompting surgeons to more carefully evaluate the risk-benefit ratio of fusion surgery. However, it is important to note that this evidence primarily originates from traditional open surgical approaches and highly selected study populations. Therefore, whether these conclusions can be directly extrapolated to full-endoscopic techniques and their applicability in complex middle-aged and older patient populations with multiple

comorbidities remain unclear and warrant further investigation.

Against this backdrop, minimally invasive spine surgery technology, guided by the core principle of "achieving maximum efficacy with minimal trauma," has developed rapidly. Over the past decade, full-endoscopic spine techniques, representing the concept of "ultra-minimally invasive" surgery, have made significant progress. This technology, relying on high-definition endoscopic systems, enables precise decompression of neural structures under a magnified and clear surgical field through tiny skin incisions less than 1 cm in diameter and sequentially dilated working channels. Its clinical advantages in reducing perioperative pain and accelerating postoperative recovery have been widely confirmed. Innovations in full-endoscopic techniques have allowed the classic clinical debate of "decompression alone versus decompression with fusion" to be re-examined within a new technological platform. However, high-quality prospective studies directly comparing full-endoscopic decompression alone with Endoscopic Lumbar Interbody Fusion (Endo-LIF) remain scarce, especially evidence specific to the unique patient population of middle-aged and older adults. Consequently, in current real-world clinical practice, a surgeon's choice between these two endoscopic procedures often relies more on personal clinical experience than on support from high-level evidence-based medicine.

Based on the aforementioned background, this study aims to conduct a prospective randomized controlled trial comparing the efficacy and safety of full-endoscopic decompression versus endoscopic fusion in middle-aged and older adult patients with LSS, thereby providing a scientific basis for individualized and precise surgical decision-making for this patient population.

The primary objective of this study is to compare the clinical efficacy and safety of full-endoscopic decompression versus endoscopic lumbar interbody fusion in middle-aged and older adult patients with lumbar spinal stenosis, providing evidence-based support for the selection of minimally invasive surgical techniques for patients.

Who is suitable (or not suitable) to participate in the study?

Inclusion Criteria: Age 50-75 years, male or female. Definite diagnosis of lumbar spinal stenosis syndrome, with typical clinical symptoms (e.g., radiating leg pain, neurogenic claudication) and signs, confirmed by imaging (MRI or CT). Pathology involves only a single level (L2-S1). Failure of at least 3 months of systematic conservative treatment, significantly impacting quality of life, and the patient has a clear willingness to undergo surgery.

Exclusion Criteria: Definite fusion indications: Lumbar degenerative spondylolisthesis > Meyerding Grade I, presence of lumbar spondylolysis, definite lumbar instability confirmed on flexion-extension radiographs (e.g., segmental translation > 3mm or angular change > 10°). Definite decompression-alone indications: Stenosis caused

solely by soft disc herniation, without accompanying bony central canal or lateral recess stenosis. Spinal stenosis caused by non-degenerative conditions: Definite spinal stenosis caused by fracture, spinal tumor, active infection, or inflammatory disease (e.g., ankylosing spondylitis, rheumatoid arthritis). Severe spinal structural abnormalities: Presence of severe spinal deformity (e.g., degenerative scoliosis with Cobb angle > 20°).

What needs to be done if I participate in the study?

If you agree to participate in this study, you will be randomly assigned in a 1:1 ratio to receive either full-endoscopic decompression or endoscopic lumbar interbody fusion. Both surgical techniques are routine clinical treatments and are not considered investigational (experimental) treatments. We will conduct standardized assessments preoperatively (baseline) and at 1 week, 3 months, 6 months, and 12 months post-surgery. These assessments will include: Pain VAS score, ODI (Oswestry Disability Index), JOA score, EQ-5D quality of life questionnaire, and lumbar spine AP and lateral X-rays (flexion-extension views may be added if necessary) for radiological follow-up. Each follow-up visit is expected to take approximately half a day (including waiting time and examination time). Participating in this study does not involve any additional treatments beyond the randomly assigned surgical procedure. You may voluntarily withdraw at any time, and this will not affect your subsequent routine medical care.

What are the benefits of participating in the study?

By participating in this study, your condition may receive a more refined treatment plan. This study will also help deepen the medical community's understanding of the clinical efficacy and safety of comparing full-endoscopic decompression and endoscopic lumbar interbody fusion, contributing to the search for more effective treatments for lumbar spinal stenosis.

What are the risks of participating in the study?

The surgical treatments involved in the above protocols are all routine treatments within the current medical context. All treatment medications may have potential side effects. If you experience any discomfort or adverse reactions, please contact the study doctor promptly. Since the surgical methods used in this study protocol are routine clinical treatments for lumbar spinal stenosis, adverse reactions may occur even if you do not participate in this clinical study, as long as you receive this treatment method. Additionally, any treatment may be ineffective, or the condition may continue to progress due to treatment ineffectiveness or concurrent other diseases.

Are there any costs that need to be paid for participating in the study?

To compensate you for the inconvenience of participating in this study, the study will cover your registration fees for follow-up visits during your participation. Surgery costs,

routine preoperative and postoperative examinations, medication, and rehabilitation treatment costs are not covered. If you require treatment and examinations for other concurrent diseases, or if you switch to other treatments due to ineffectiveness, these costs will not be covered. If trial-related injury occurs, appropriate treatment and compensation will be provided in accordance with relevant national regulations.

Is my personal information kept confidential?

Your medical records will be kept at the hospital. Researchers, study sponsors, and the Ethics Committee will be permitted to access your medical records. Any public reports on the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical information within the limits permitted by law.

What other treatment options are available if I do not participate in this study?

If you do not participate in this study, or withdraw from it midway, it will not affect your choice of treatment options.

Do I have to participate in the study?

Participation in this study is entirely voluntary. You may refuse to participate or withdraw from the study at any time during the research process, and this will not affect the doctor's treatment for you. If you decide to withdraw from the study, please contact your doctor. You may be asked to undergo relevant examinations, which is beneficial for protecting your health.

If you have any questions related to your personal rights, you may contact our hospital's Ethics Committee at: 025-68306360.

Subject Statement:

I have read the above introduction to this study and fully understand the potential risks and benefits of participating. I voluntarily agree to participate in this study. I will receive a copy of this signed and dated informed consent form.

I ○ agree ○ disagree to other research use of my medical records and clinical specimens related to this study.

Subject Signature: _____ Date: _____

Subject's Contact Phone: _____ Mobile Phone: _____

(If applicable) Legal Guardian Signature: _____ Date: _____

Legal Guardian's Contact Phone: _____ Mobile Phone: _____

(If applicable) Impartial Witness Signature: _____ Date: _____

Impartial Witness's Contact Phone: _____ Mobile Phone: _____

Investigator Statement:

I confirm that I have explained the details of this study to the subject, especially the potential risks and benefits of participation, and have answered all of the subject's related questions. The subject is voluntarily agreeing to participate in this study. This informed consent form is made in duplicate, with the investigator and the subject each retaining one signed copy.

Study Physician Signature: _____ Date: _____

Study Physician's Work Phone: _____ Mobile Phone: _____