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

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I. Background

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.

II. Objectives

1. Primary Objective

To compare the Oswestry Disability Index (ODI) at 24 months post-surgery between full-endoscopic decompression and Endo-LIF in middle-aged and older adult patients with LSS, testing the non-inferiority of full-endoscopic decompression in terms of functional improvement.

2. Secondary Objectives

2.1 To compare the performance of full-endoscopic decompression and Endo-LIF regarding Oswestry Disability Index (ODI) at 24 months post-surgery in middle-aged and older adult patients with LSS, testing the non-inferiority of full-endoscopic decompression in functional improvement.
Assessment measures include: ODI, Zurich Claudication Questionnaire (ZCQ), Numeric Rating Scales (NRS), and EuroQol 5-Dimension Questionnaire (EQ-5D-5L). Additionally, the Minimal Clinically Important Difference (MCID) achievement rates between the two groups at various time points will be analyzed and compared (ODI, $\geqslant$12-13 points / $\geqslant$30%).

2.2 To compare perioperative parameters and early safety between the two surgical techniques.
Minimally invasive related parameters include: operation time, radiation dose (DAP), hidden blood loss, time to first ambulation, length of hospital stay. Safety outcomes are

the incidence of complications within 30 days and 90 days post-surgery.

2.3 To compare the long-term risk of reoperation between the two surgical techniques (using survival analysis).
This analysis will clearly distinguish between same-level revision and adjacent segment reoperation. Furthermore, composite endpoints for treatment failure, including reoperation and severe complications, will be compared.

2.4 In the subgroup of patients undergoing fusion surgery, to evaluate the radiological fusion rate at 12 months post-surgery, and further analyze the association between fusion status and long-term functional outcomes and reoperation risk.

2.5 To test whether patients' baseline instability status (defined by pre-specified radiographic criteria) influences the ultimate efficacy of the different surgical approaches, aiming to identify patient subgroups that might benefit most from a specific procedure (effect modification analysis).

2.6 To explore key prognostic factors influencing the efficacy of both surgical techniques.

III. Study Design

A prospective, multicenter, randomized, parallel-group, open-label, outcome-assessor-blinded, non-inferiority clinical trial.

IV. Study Population

1. Inclusion Criteria

1.1 Age 50-75 years, male or female.
1.2 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).
1.3 Pathology involves only a single level (L2-S1).
1.4 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.
1.5 (Clinical equipoise) After evaluation by at least two senior spine surgeons, both agree that the patient's condition meets the surgical indications for both full-endoscopic decompression and endoscopic lumbar interbody fusion.
1.6 Patient fully understands the randomized nature of this study (including random

assignment, relinquishing choice by both physician and patient) and voluntarily signs the Informed Consent Form.

2. Exclusion Criteria

2.1 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°).
2.2 Definite decompression-alone indications: Stenosis caused solely by soft disc herniation, without accompanying bony central canal or lateral recess stenosis.
2.3 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).
2.4 Severe spinal structural abnormalities: Presence of severe spinal deformity (e.g., degenerative scoliosis with Cobb angle > 20°).
2.5 Prior relevant surgical history: History of previous lumbar surgery at the same or adjacent level.
2.6 Systemic diseases precluding tolerance of surgery: Presence of severe dysfunction of vital organs such as heart, lung, liver, kidneys, or ASA grade > III, deemed unable to tolerate anesthesia or surgery upon evaluation.
2.7 Comorbidities that may confound outcome assessment: Presence of other conditions that could cause lower limb claudication or dysfunction, such as severe hip or knee osteoarthritis (including history of total hip or knee arthroplasty), peripheral vascular claudication, polyneuropathy, etc. Presence of other neurological or muscular system diseases that seriously affect efficacy evaluation (e.g., Parkinson's disease, amyotrophic lateral sclerosis).
2.8 Participation in other studies: Currently participating in other clinical trials that may affect the outcomes of this study.

*All investigators at participating sites will record screening results in the 'Screening Log' within the file and specify the reason for exclusion. *

V. Randomization, Allocation Concealment, and Blinding

1. Randomization and Allocation Concealment

Supported by the Clinical Medical Center Randomization System (Notification 2025-09-22) --- Using double-stratified randomization by center and presence/absence of Grade I spondylolisthesis.

1.1 Method: Centralized, web-based randomization system (e.g., REDCap).

1.2 Stratification: Using block randomization (Block Size = 4, 6), stratified double by ① Study Center and ② Baseline presence/absence of Grade I spondylolisthesis.
1.3 Procedure: After the surgeon confirms "clinical equipoise" in the CRF, they log into the system, enter stratification information, and the system provides the randomization result (Decompression Group vs. Fusion Group) in real-time. This process ensures allocation concealment.

2. Blinding

2.1 Patients and Surgeons: Blinding cannot be achieved (surgical techniques are fundamentally different, making it impossible to blind the performers and recipients).
2.2 Outcome Assessors: Must be *single-blinded*. CRCs or research nurses responsible for all post-operative follow-up (phone or clinic) and collecting PROMs must strictly avoid accessing the patient's surgical records or imaging and must not inquire about surgical details.
2.3 Data Analysts: Blinding can be achieved (the two groups can be named "Group A" and "Group B" during the analysis phase, with unblinding only after the primary analysis is completed).

(Add a question in the follow-up module of the CRF specifically for the assessor: "At the end of this follow-up visit, did you guess or become aware of the patient's surgical group assignment? [☐ No / ☐ Yes, I guessed Decompression / ☐ Yes, I guessed Fusion / ☐ Yes, I was informed]". This data must be presented in the final report.)

VI. Interventions (Study Groups)

1. Eligible patients will be randomly assigned 1:1 to one of the following two groups: Group A (Decompression Group), Group B (Fusion Group).

2. Surgical Criteria
2.1 Decompression Group: Standard full-endoscopic decompression (with a choice of interlaminar or transforaminal approach); performed solely for the purpose of thorough neural decompression, with no implantation of any internal fixation or fusion devices.
2.2 Fusion Group: Standard Endo-LIF; while completing decompression, an interbody fusion cage (Cage) and a percutaneous pedicle screw system must be implanted to achieve segmental fusion. Cage material (e.g., PEEK, Titanium) and bone graft type (e.g., autograft, allograft) are chosen by the surgeon according to clinical routine but must be detailed in the CRF.

3. Standardization of Interventions

3.1 Postoperative Management (Key Confounder): Patients in both groups must strictly

adhere to the same standardized postoperative rehabilitation SOP. All patients will wear a lumbar brace for 12 weeks and will be guided to ambulate for the first time at 24 hours post-surgery. A standardized postoperative rehabilitation SOP must be pre-defined, and strict adherence must be ensured for both groups.
3.2 Surgeon Qualification Criteria: Surgeon experience is collected in the variable table, but the protocol must clearly define the minimum qualification criteria for participating surgeons (e.g., must have independently completed >40 cases of Endo-LIF and >40 cases of full-endoscopic decompression) to ensure all surgeries are performed after passing the learning curve.

VII. Study Variables and Data Collection

1. Primary Outcome Measure
Change from Baseline in Oswestry Disability Index (ODI) at 24 Months Post-surgery.

Definition:
ODI is the gold standard questionnaire for assessing low back pain and its impact on activities of daily living, with a total score ranging from 0-100, where higher scores indicate greater disability.

Time Frame: Baseline, 24 months post-surgery.

2. Secondary Outcome Measures

Longitudinal Trends in Patient-Reported Outcome Measures (PROMs):
Including ODI score, Zurich Claudication Questionnaire (ZCQ, covering symptom severity, physical function, and satisfaction domains), Numeric Rating Scales for back and leg pain (NRS, 0-10), EuroQol 5-Dimension Questionnaire (EQ-5D-5L).

Time Frame: Baseline, 1 month, 3 months, 6 months, 12 months, 24 months post-surgery.

MCID Achievement Rate:
Proportion of subjects achieving the Minimal Clinically Important Difference in ODI improvement (improvement $\geqslant$12 points or improvement rate $\geqslant$30%) at 24 months post-surgery.

Perioperative Parameters:

Operation Time: Time from skin incision to skin closure (minutes).

Intraoperative Blood Loss and Hidden Blood Loss:

Record intraoperative suction volume and gauze weights; calculate hidden blood loss using the Gross equation or Nadler equation combined with pre- and postoperative hematocrit (Hct).

Tissue Trauma Markers:
Serum creatine kinase (CK) and C-reactive protein (CRP) concentrations preoperatively and on postoperative days 1 and 3.

Intraoperative Radiation Exposure: Record fluoroscopy times and Dose Area Product (DAP).

Recovery Parameters: Time to first ambulation (hours), total length of hospital stay (days).

Radiographic Outcomes (Fusion Group Only):

Fusion Rate:
CT scan at 12 and 24 months post-surgery to assess interbody fusion according to Bridwell grading criteria.

Cage Subsidence: Measurement of changes in disc height.

3. Safety Outcomes

Adverse Events (AE): Record all adverse medical events occurring during the perioperative period and follow-up.

Complications:
Focus on recording dural tears, nerve root injury, incision infection, deep vein thrombosis, implant-related complications, etc. Severity grading according to the Clavien-Dindo classification system.

Reoperation Rate:
Record the rate of reoperations at the same or adjacent level within 24 months post-surgery due to any cause (e.g., recurrence, instability, adjacent segment degeneration).

VIII. Statistical Analysis Plan (SAP)

All statistical analyses for this study will follow a pre-specified SAP, which will be finalized and locked before the enrollment of the first patient. The primary non-inferiority test uses a one-sided $\alpha = 0.025$ (presented as comparing the upper limit of the two-sided 95% CI with $\Delta = 8$); all other superiority tests use a two-sided $\alpha = 0.05$.

(I) Non-inferiority Hypothesis and Margin (Δ)

1. Study Hypothesis: The core hypothesis of this study is that, for middle-aged and older adult LSS patients without definite instability, "full-endoscopic decompression" (Decompression Group) is non-inferior to "Endo-LIF" (Fusion Group) regarding the 2-year functional outcome (ODI).

2. Non-inferiority Margin (Δ)

2.1 Definition: Δ is the pre-specified, clinically acceptable maximum difference by which the efficacy of the "Decompression Group" could be inferior to the "Fusion Group".

2.2 Margin Setting: Based on the MCID for ODI (10-12 points) from previous literature (e.g., Ghogawala et al., Försth et al.) and referencing the rationale from Austevoll et al. (i.e., decompression may accept some loss of efficacy due to advantages in safety and cost), the non-inferiority margin (Δ) for this study is set at 8 points for the ODI score difference.

3. Statistical Hypothesis: (Let μ_{Decomp} and μ_{Fusion} represent the mean change in ODI score at 2 years for the two groups)

3.1 Null Hypothesis (H₀): Decompression is non-inferior to fusion. (H₀: μ _{Decomp} - μ _{Fusion} ≥ Δ) (Note: ODI is a negative directional measure; improvement yields negative values. Therefore, we compare whether the difference is inferior to the margin. For ease of understanding, we define "treatment difference" = μ_{Decomp ODI} - μ_{Fusion ODI}, higher ODI is worse.)

3.2 Alternative Hypothesis (H₁): Decompression is non-inferior to fusion. (H₁: μ_{Decomp} - μ_{Fusion} < Δ)

4. Conclusion Determination

Primary Conclusion: If the upper limit of the 95% Confidence Interval (CI) for the "treatment difference" is less than the pre-specified non-inferiority margin (Δ = 8 points), we will reject H₀ and declare "non-inferiority".

(II) Analysis Populations

To ensure transparency and robustness of the analysis, the following three analysis populations will be defined:

1. Intention-to-Treat (ITT) Population

1.1 Definition: Includes all randomized patients.

1.2 Analysis Attribution: Strictly follows the "intention-to-treat" principle. All patients will be analyzed according to the group they were originally randomly assigned to (Full-endoscopic Decompression vs. Endo-LIF), regardless of whether they

subsequently received the assigned treatment, experienced intraoperative conversion (protocol deviation), or were lost to follow-up.

1.3 Purpose: Primary analysis population for all efficacy-related endpoints (including primary and secondary endpoints) in this study.

2. Per-Protocol (PP) Population

2.1 Definition: A subset of the ITT population, including only patients who strictly adhered to the study protocol. Exclusions include: not receiving the assigned surgery, experiencing major intraoperative protocol deviations (e.g., "intraoperative conversion"), incomplete primary endpoint (24 months ± 2 months) follow-up, or other major protocol violations (e.g., incorrect inclusion/exclusion criteria).

2.2 Purpose: Key validation population for non-inferiority trials. The non-inferiority conclusion of this study must hold true in both the ITT and PP populations.

3. Safety Population

3.1 Definition: Includes all randomized patients who actually received at least one of the study surgeries.

3.2 Analysis Attribution: Analyzed according to the surgical technique the patient actually received (As-Treated).

3.3 Purpose: Used for analyzing all perioperative parameters and safety events (harms).

4. Robustness Requirement for Non-inferiority Conclusion

Following the CONSORT extension for non-inferiority trials and precedent from Austevoll et al., the "non-inferiority" conclusion of this study will be considered robust only if it holds true in the analyses of both the ITT and PP populations.

(III) Statistical Methods

1. Description of Baseline Data

1.1 Continuous variables will be described using means ± standard deviations (or medians [IQR]), categorical variables using frequencies (%).

1.2 According to CONSORT guidelines, no significance testing will be performed on baseline data (i.e., no P-values will be reported).

2. Primary Outcome Analysis - Mean Change in ODI Score from Baseline to 2 Years Post-surgery

2.1 Core Analytical Tool: Mixed-Effects Model for Repeated Measures (MMRM) .

2.1.1 Rationale: The primary question of this analysis is to compare the treatment difference between the two groups at the specific time point of "2 years post-surgery". To obtain the most reliable and robust estimate at the "2-year time point", the MMRM model will utilize all longitudinal data (i.e., baseline, 3 months, 6 months, 1 year, 2 years).

2.1.2 Advantages: This method leverages information from all patients (including

those lost to follow-up), handles missing data scientifically under the "Missing At Random" assumption, thereby maximizing statistical power and minimizing bias.

2.2 Model Construction: The model will include ODI score as the dependent variable; fixed effects will include treatment group (Decompression vs. Fusion), time point (categorical variable), "treatment group × time" interaction term, baseline ODI score (as covariate), presence/absence of Grade I spondylolisthesis (as stratification covariate), and center (if the number of centers is large and enrollment uneven, treat as random effect).

2.2.1 Covariance Structure and Convergence Strategy: The model will initially use an unstructured (UN) covariance matrix to model the correlations between repeated measures. If the model fails to converge, the following pre-specified hierarchy of covariance structures will be attempted sequentially until convergence is achieved:

Heterogeneous Toeplitz (TOEPH) → Heterogeneous Autoregressive (ARH(1)) → Heterogeneous Compound Symmetry (CSH) → Compound Symmetry (CS). The model with the smallest Akaike Information Criterion (AIC) among the converged models will be selected for the final report.

2.3 Result Determination:

2.3.1 Extract the Least-Squares Mean Difference in ODI scores between the two groups at the 2-year post-surgery time point from the MMRM model, along with its two-sided 95% Confidence Interval (CI) and P-value.

2.3.2 If the upper limit of this 95% CI < 8 (our Δ margin), non-inferiority is declared.

2.3.3 This analysis will be performed in the ITT and PP populations separately.

3. Secondary Outcome Analyses

3.1 Longitudinal PROMs (ZCQ, NRS-Back/Leg, EQ-5D-5L): Analyzed using the same MMRM model as the primary endpoint, and their non-inferiority will be assessed (using their respective pre-specified Δ margins).

3.2 MCID Achievement Rate (categorical variable): The proportion of patients achieving ODI MCID in both groups will be analyzed using a Generalized Linear Mixed Model (GLIMM) , and the Risk Difference with its 95% CI will be calculated and compared to the non-inferiority margin of -15 percentage points used by Austevoll et al.

3.3 Secondary endpoint analyses are exploratory, no multiplicity correction will be applied, and P-values for secondary endpoints are for reference only.

4. Perioperative and Safety Analyses - Safety Population

4.1 Analysis Objective: The objective here shifts to "superiority" – testing whether the "Decompression Group" is superior to the "Fusion Group" regarding safety/minimally invasive parameters.

4.2 Perioperative Parameters (continuous variables): Such as operation time, radiation dose (DAP), hidden blood loss, time to first ambulation, length of hospital stay, will be compared using Student's t-test or Mann-Whitney U test.

4.3 Safety Events (categorical variables): Such as complications (30/90 days),

cage subsidence, will be compared using Chi-square test or Fisher's exact test to calculate Relative Risk (RR) and 95% CI.

4.4 Reoperation Rate (time-to-event variable): Kaplan-Meier survival curves ("reoperation-free survival") will be plotted and compared using the Log-rank test. A Cox proportional hazards model will be used to calculate the adjusted Hazard Ratio (HR).

(IV) Handling of Missing Data

1. Primary Analysis Strategy: We have chosen MMRM as the primary model for the primary endpoint and longitudinal PROMs analysis. Under the "Missing At Random (MAR)" assumption, this model handles missing data in longitudinal datasets (e.g., a patient misses a follow-up visit) scientifically and effectively, without requiring data imputation.
2. Sensitivity Analysis Strategy: To verify the robustness of the non-inferiority conclusion, we will use Multiple Imputation (MI) (e.g., imputing 5-10 datasets using MCMC methods) to impute missing PROMs data and repeat the primary endpoint analysis on the imputed complete datasets (ITT and PP) (see 2.1d).

IX. Sample Size Estimation

1. Non-inferiority Trial

1.1 Objective: To demonstrate that the efficacy of the "Decompression Group" is not unacceptably worse than that of the "Fusion Group".

1.2 Calculation Logic: What sample size do we need to have 80% power to rule out a clinically unacceptable "maximum loss of efficacy"?

1.3 Key Parameters (New): We must introduce a parameter not present in superiority trials – the "Non-inferiority Margin (Δ)".

2. Sample Size Calculation (Based on Non-inferiority Design)

2.1 Sample size formula for non-inferiority trials, based on the following new parameters:

2.1.1 Non-inferiority Margin (Δ): 8 points (our pre-specified acceptable maximum loss of efficacy)

2.1.2 Standard Deviation of outcome (σ): 16 points (based on NEJM)

2.1.3 Statistical Power (1-β): 80% (0.80)

2.1.4 Significance Level (α): 0.025 (one-sided) (Non-inferiority tests typically use a one-sided α, which corresponds to the two-sided 95% CI we will ultimately examine)

2.1.5 Allocation Ratio: 1:1

2.2 Determine Z-values: Z_α (corresponding to α = 0.025, one-sided): 1.96, Z_β (corresponding to Power = 0.80): 0.842

2.3 Calculate required sample size per group (n) (excluding loss to follow-up):

$$n(\text{per group}) = \frac{2 \times {(Z_{\alpha} + Z_{\beta})}^{2} \times \sigma^{2}}{\Delta^{2}}$$

Parameter Substitution: n $\approx$ 62.8

Conclusion: To achieve 80% power, at least 63 patients per group completing 2-year follow-up are needed.

2.4 Adjust for Loss to Follow-up

2.4.1 Assumed Loss to Follow-up Rate: 20%

2.4.2 Final Calculation (N):

$$N(\text{needed to recruit per group}) = \frac{n}{1 - \text{loss to follow-up rate}}$$

N = 78.75

2.5 Adjust for Protocol Deviation Rate

2.5.1 Assumed Protocol Deviation Rate: 10%

2.5.2 Final Calculation (N):

$$N(\text{needed to recruit per group}) = \frac{n}{(1 - \text{loss to follow-up rate}) \times (1 - \text{deviation rate})}$$

N $\approx$ 87.5

3. Final Sample Size Conclusion: To achieve 80% statistical power (Power) and a one-sided significance level (α) of 2.5% for this non-inferiority RCT, aiming to exclude (i.e., demonstrate non-inferiority for) an ODI score difference of 8 points (Δ margin), assuming a standard deviation of 16 points, and accounting for a potential 20% loss to follow-up rate and 10% protocol deviation rate: A total of 176 patients need to be recruited for this study (i.e., 88 patients in the "Full-endoscopic Decompression Group" and 88 patients in the "Endo-LIF Group").

X. Data Management

1. Data Collection: An electronic Case Report Form (eCRF) system (e.g., REDCap) will be used for data collection in this study.
2. Data Entry and Verification: Data entry will be performed by trained Clinical Research Coordinators (CRCs). The system will have built-in logic checks for

automatic flagging of unusual values. Data managers will periodically perform data cleaning and manual verification, issuing queries to the study sites, which investigators must address promptly.
3. Database Lock: After all subjects have completed follow-up, all data queries have been resolved, and the database has been cleaned, the database will be locked. The locked data will be exported and handed over to the statistician for analysis.

XI. Ethical Considerations

1. Ethical Approval: This study protocol, informed consent form, and recruitment materials will be submitted to the Institutional Review Board / Ethics Committee (IRB/EC) of the leading center for approval before the study initiation and obtain written approval. Each participating center must obtain approval or filing from their local ethics committee.
2. Informed Consent: The investigator must thoroughly explain the purpose, procedures, potential risks (including the specific nature of the non-inferiority design), and benefits of the study to each subject. Subjects have the right to withdraw from the study at any time without discrimination. All subjects must sign a written informed consent form before enrollment.
3. Declaration of Helsinki: This study will be strictly conducted in accordance with the Declaration of Helsinki and the Chinese Good Clinical Practice (GCP) for Drugs/Medical Devices.
4. Clinical Trial Registration: This study will be registered in a public clinical trial registry (e.g., ClinicalTrials.gov or ChiCTR) before the enrollment of the first subject.

XII. Study Organization and Personnel

1. Principal Investigator (PI): Responsible for the overall design of the study, quality control implementation, and final report writing.
2. Steering Committee (SC): Composed of the Principal Investigator and PIs from each participating center, responsible for major academic decisions.
3. Data Safety Monitoring Board (DSMB): Composed of independent clinical experts and statisticians, responsible for periodic review of safety data, ensuring subject safety, and authorized to recommend early termination of the trial.
4. Statistical Analyst: Responsible for sample size calculation, development of the Statistical Analysis Plan, and final data analysis.

XIII. Study Schedule

1. Preparation Phase (Months 1-3): Finalize protocol, obtain ethical approval, complete clinical trial registration, set up database, and conduct initiation meeting/training.
2. Enrollment Phase (Months 4-18): Complete screening, enrollment, and surgery for all subjects.
3. Follow-up Phase (Months 19-42): Complete postoperative follow-up for all subjects (until the last subject reaches 24 months post-surgery).
4. Close-out Phase (Months 43-48): Complete data cleaning, database lock, statistical analysis, and writing of the study report/manuscript.
