# Informed Consent Form for Scientific Research

**Study Title**: Standardization of Puncture Path for Percutaneous Vertebroplasty Based on the Pedicle Nine-Grid Zoning Method

**Principal Investigator**: Fei Qi

**VersionNumber**:V1.3

VersionDate:January19,2026

**Sponsor**: Beijing Friendship Hospital, Capital Medical University

Dear Participant:

You are invited to participate in this clinical study concerning the standardized puncture path of percutaneous vertebroplasty (PVP) based on the pedicle nine-grid zoning method. Please read this informed consent form carefully and make a voluntary decision on study participation. You may consult your research physician or research staff to explain any unclear contents of this document. You are encouraged to fully discuss your participation intention with your family members and friends before making a decision. If you are currently enrolled in any other clinical study, please inform your research physician immediately. The detailed study background, objectives, procedures and other key information are stated as follows.

## 1. Study Background

Transpedicular percutaneous vertebroplasty (PVP) is the primary surgical treatment for osteoporotic vertebral compression fractures (OVCF). The traditional ideal bony puncture point for lumbar PVP is defined as the "10 o’clock (left pedicle) and 2 o’clock (right pedicle)" position on the pedicle projection. Conventional puncture procedures highly rely on individual surgeon experience and repeated C-arm fluoroscopy, resulting in a long surgical learning curve. Based on abundant preliminary studies, our research team confirmed that the single traditional ideal puncture point can be expanded to multiple ideal bony puncture surfaces. Accordingly, we proposed the innovative "nine-grid zoning method" to standardize the ideal bony puncture surface of lumbar pedicles.

This study consists of three parts: retrospective imaging analysis, model verification using the German PHACON surgical navigation training system, and a prospective randomized controlled clinical trial. It aims to evaluate the safety and efficacy of the nine-grid zoning method in lumbar transpedicular PVP. This study is expected to establish a novel, safe and standardized transpedicular puncture approach for PVP, reduce unnecessary intraoperative fluoroscopy times and operative time caused by

repeated puncture adjustment in conventional surgery, and ultimately improve surgical efficiency and clinical outcomes.

# 2. Study Objectives

To further validate the safety and efficacy of unilateral transpedicular PVP assisted by the pedicle nine-grid zoning method via a prospective randomized controlled clinical trial.

# 3. Study Procedures

## 3.1 Study Sample Size

Approximately 68 participants will be enrolled in this study conducted at Beijing Friendship Hospital, Capital Medical University.

## 3.2 Eligibility Criteria

**Inclusion Criteria**: 1. Confirmed diagnosis of single-segment acute lumbar osteoporotic vertebral compression fracture (L1-L5) with typical MRI manifestations (low signal on T1-weighted imaging, high signal on T2-weighted and STIR sequences); 2. First-time PVP surgery; 3. Complete preoperative imaging data including X-ray, CT, and MRI/bone scan.

**Exclusion Criteria**: 1. Patients with old OVCF, congenital pedicle malformation or pedicle lesions; 2. Patients with bone tumors or other systemic bone metabolic diseases; 3. Patients with incomplete or ruptured posterior wall of fractured vertebral body on CT; 4. Patients who refuse to sign informed consent.

## 3.3 Surgical Procedures

**Control Group (Traditional Puncture PVP)**: 1. Routine skin disinfection, surgical draping and local anesthesia; 2. Identify the puncture site under C-arm fluoroscopy according to the traditional "10 o’clock/2 o’clock" pedicle projection standard; 3. Perform longitudinal incision and initial puncture, and adjust the needle position under anteroposterior fluoroscopy; 4. Fix the puncture needle on the articular process cortical bone, confirm needle position and depth under lateral fluoroscopy, and advance the needle to break through the posterior vertebral edge under fluoroscopic guidance; 5. Verify the needle is within the medial margin of the pedicle projection on anteroposterior view; 6. Further advance the needle to the anterior 1/3 of the vertebral body (lateral view) and the vertebral midline (anteroposterior view); 7. Complete bone cement mixing, injection and incision suture to finish the operation.

**Experimental Group (Nine-Grid Zoning Method Assisted PVP)**: 1. Routine skin disinfection, surgical draping and local anesthesia; 2. Determine the optimal puncture site based on the pedicle nine-grid zoning method under C-arm fluoroscopy; 3. All subsequent surgical procedures are identical to the control group.

## 3.4 Data Collection and Follow-Up

We will collect participants' demographic information, laboratory test results, medical history, intraoperative surgical data, imaging data, and preoperative and postoperative clinical scale scores. All participants will receive a 1-year standardized postoperative follow-up. Free X-ray and CT re-examinations will be provided during follow-up to verify the accuracy of evaluation indicators, together with professional health education and clinical guidance. All collected data will be statistically analyzed for research conclusions.

During hospitalization, preoperative and postoperative pain scores will be recorded. Outpatient follow-up will be conducted at 1 month, 3 months, 6 months and 1 year after discharge. Long-term anti-osteoporosis medication guidance will be provided without additional economic burden for participants. Telephone follow-up will be adopted for participants who cannot attend outpatient visits due to geographical or personal reasons.

## 3.5 Study Duration

The total study period is 3 years, with a postoperative follow-up duration of 1 year for each enrolled participant.

You have the right to withdraw from this study at any time without any penalty or loss of legitimate benefits. You are recommended to consult your research physician before withdrawal. For safety purposes, additional relevant examinations may be arranged after your withdrawal.

# 4. Risks and Benefits

## 4.1 Potential Risks and Adverse Reactions

The only difference between the experimental and control groups is the puncture positioning method. The surgical anatomical sites and overall operative risks are consistent with conventional PVP surgery. All operations are performed by experienced spine surgeons, with intraoperative tactile feedback combined with real-time C-arm fluoroscopy to minimize surgical risks. In cases of difficult puncture or puncture failure, the traditional puncture method will be adopted immediately with truthful record of all adverse conditions. No additional surgical risks are induced by this study.

Potential information confidentiality risks exist despite strict data protection measures. Absolute information security cannot be fully guaranteed. You may refuse to answer any sensitive questions during the study and take a rest at any time. Voluntary withdrawal from the study is permitted at any stage without restriction.

## 4.2 Study Benefits

You will not receive direct personal medical benefits from this study. However, the

research findings will provide clinical evidence for optimizing PVP puncture strategies, which may benefit patients with the same osteoporotic vertebral compression fractures in the future.

# 5. Confidentiality of Personal Information

The research results may be published in academic journals with the consent of all participants. All personal information of participants will be strictly confidential in accordance with relevant laws and regulations and will not be disclosed without legal requirements. Authorized personnel including government regulatory departments and hospital ethics committee members may access the research data for supervision and review purposes.

# 6. Study Costs and Compensation

## 6.1 Study-related Costs

All examination fees, surgical fees and consumable costs incurred in this study are consistent with conventional clinical treatment, with no additional charges for participants.

## 6.2 Participation Compensation

No direct financial compensation will be provided for study participation.

## 6.3 Compensation for Study-related Injuries

If any injury occurs due to study participation, you will receive free medical treatment from the Department of Orthopedics, Beijing Friendship Hospital. Corresponding compensation will be provided in accordance with relevant Chinese laws and regulations after official identification of study-related injuries.

# 7. Participant Rights

Your participation in this study is completely voluntary. Refusal to participate or voluntary withdrawal at any study stage will not affect your routine medical treatment and legitimate medical rights. You will sign this written informed consent form if you agree to participate.

Your research physician may terminate your participation if severe adverse reactions occur or continuous participation is not in your best interest. The sponsor or regulatory authorities may also terminate the study at any time due to participant loss to follow-up or failure to meet eligibility criteria, and you will be notified timely with alternative treatment options provided.

# 8. Participant Responsibilities

You shall truthfully report your medical history and current physical conditions, timely inform the research physician of any physical discomfort during the study period, avoid restricted drugs and foods specified by the researcher, and disclose any ongoing or recent participation in other clinical studies.

## 9. Contact Information

**For study-related questions**: Please contact Principal Investigator Fei Qi at 010-63138353 (available on working days, weekends and holidays).

**For rights and ethics-related questions**: Please contact the Ethics Committee of Beijing Friendship Hospital, Capital Medical University at 010-63139006 for complaints, consultations and suggestions.

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## Researcher Declaration

I have fully informed the participant of the study background, objectives, procedures, risks and benefits. I have reserved sufficient time for the participant to read this consent form, discuss with others and raise questions, and all questions have been fully answered. I have informed the participant of the contact information for study consultation and rights protection, and confirmed the accessibility of relevant contacts. I have clearly stated that the participant has the right to withdraw from the study at any time, and the participant will obtain a signed copy of this informed consent form.

**Researcher Signature**: _____; **Date**: _____

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## Participant Informed Consent Declaration

I have been fully informed of the study background, objectives, procedures, risks and benefits of this research. I have had sufficient time and opportunity to ask questions and obtain satisfactory answers. I have been clearly informed of the contact persons for study consultation and rights safeguarding. I have read and fully understood this informed consent form, and I voluntarily agree to participate in this study. I confirm that I have the right to withdraw from the study at any time without providing reasons or suffering unfair treatment. I will keep a signed copy of this consent form.

**Participant Signature**: _____; **Date**: _____

**Participant Phone Number**: _____

(For participants with insufficient capacity of informed consent)

**Guardian Signature**: _____ ; **Relationship with Participant**: _____

**Guardian Phone Number**: _____ ; **Date**: _____