ORIGINAL RESEARCH

# Comparative Analysis of Therapeutic Outcomes and Prognoses Among Osteoporosis Patients with Varied Bone Mineral Density T-Values Following Percutaneous Kyphoplasty

Yongxia Li, BD; Qinglin Jing, BD; Feng Chen, MD; Yong Xu, MD

## ABSTRACT

**Objective** • This study aims to evaluate and compare the therapeutic outcomes and prognoses of osteoporotic fracture (OSF) patients undergoing percutaneous kyphoplasty (PKP), emphasizing the role of bone mineral density T-values (BMD-T) as a guiding factor in the surgical intervention for OSF.

**Methods** • An observational cohort study was conducted, and 162 OSF patients admitted to our hospital from March 2021 to December 2021 were selected. Patients were categorized based on BMD-T into mild ($-2.5 \leq$ BMD-T $\leq -4$, n=40), moderate ($-4 <$ BMD-T $\leq -5$, n = 78), and severe groups (BMD-T $< -5$, n = 44). All patients underwent PKP treatment, and vertebral body (VB) lavage fluid was analyzed for calcium (Ca), magnesium (Mg), and zinc (Zn) levels. X-ray assessments were performed before and after surgery to examine changes in wedge and kyphosis angles and VB height. Additionally, the Oswestry Disability Index (ODI), Visual Analogue Scale (VAS), and Barthel Index (BI) scores were recorded.

**Results** • The mild group exhibited the highest Ca, Mg, and Zn contents in VB lavage fluid, while the severe group had the lowest ($P < .05$). A positive correlation was observed between patients' Ca, Mg, and Zn levels and BMD-T ($P < .05$). The severe group, characterized by lower BMD-T, required a higher amount of bone cement injection, resulting in more significant differences in wedge angle, kyphosis angle, and VB height before and after surgery ($P < .05$). Moreover, the severe group demonstrated a higher incidence of postoperative adverse reactions ($P < .05$). Age, bone cement leakage, BMD-T, Ca, Mg, and Zn were identified as independent factors influencing post-PKP re-fracture in OSF patients ($P < .05$).

**Conclusion** • In PKP for OSF, lower BMD-T correlates with improved correction but is also associated with a higher likelihood of cement leakage. (*Altern Ther Health Med.* [E-pub ahead of print.])

**Yongxia Li, BD;** Department of Surgical Anesthesia, Qinghai University Affiliated Hospital, Xi Ning, Qinghai, China. **Qinglin Jing, BD; Feng Chen, MD; Yong Xu, MD;** Department of Spinal Surgery, Qinghai University Affiliated Hospital, Xi Ning, Qinghai, China.

*Corresponding author: Yong Xu, MD*
*E-mail: xuyongxuyong1985@163.com*

## INTRODUCTION

Osteoporosis is an age-related disease with a prevalence of approximately 30-40% in individuals over 60 and poses a particular risk to females.[1] As our global population continues to age, the incidence of osteoporosis is on the rise, with a projected 300 million sufferers by 2030.[1] Osteoporosis is emerging as a significant global health concern, with a notable predilection for females and an increasing incidence among individuals aged over 60. Amidst the growing challenges posed by an aging population, it becomes important to understand the increased risk of osteoporotic fractures (OSF) attributed to bone brittleness in the aging population.[2]

Statistics indicate that OSF occurs in approximately 30-50% of osteoporosis patients.[3] At present, commonly employed clinical procedures for managing OSF encompass percutaneous vertebroplasty (PVP), kyphoplasty, and percutaneous kyphoplasty (PKP), evolving from the earlier technique of percutaneous vertebroplasty.[4] Assessing the degree of fracture injury in patients before and after surgery is a crucial aspect of these clinical interventions.[5]

Thoracolumbar injury severity score (TLICS) serves as a conventional tool for assessing fractures, but its applicability diminishes in OSF patients. OSF, characterized by low-energy injuries and distinct fracture morphology compared to traditional traumatic fractures, poses a challenge for the utility of TLICS in this context.[6] Therefore, there is an urgent need to identify a more suitable clinical method to evaluate the severity of OSF.

The primary cause of OSF lies in the diminished bone strength resulting from osteoporosis, determined by both bone mass and bone quality. The bone mineral density T-value (BMD-T) serves as a crucial index for quantifying bone mass, contributing to approximately 70% of bone strength.[7] While BMD-T proves effective in detecting the onset of osteoporosis, its guidance value for predicting OSF is limited.[8]

With the recent advancements in science and technology, the methods and tools for assessing BMD-T have significantly progressed, substantially minimizing the potential human errors observed in the past.[9] In recent studies, BMD-T has consistently emerged as a confirmed risk factor for fractures.[10] This observation implies its potential for significant advancements in the evaluation of modern OSF. However, the existing research on its guiding role in surgical treatment remains relatively scarce.

Considering the rising prevalence of OSF, this study seeks to compare the therapeutic outcomes and prognoses among OSF patients with varying BMD-T following PKP. The objective is to validate the guiding significance of BMD-T in the prospective surgical management of OSF, thereby offering a dependable reference for the clinical diagnosis and treatment of individuals facing this condition.

## DATA AND METHODS

### Study Design

The research employed an observational cohort design, and a total of 162 cases of OSF treated between March 2021 and December 2021 were carefully selected as research participants. These cases were categorized into three groups based on their BMD-T: mild (-2.5 ≤ BMD-T ≤ -4, n = 40), moderate (-4 < BMD-T ≤ -5, n=78), and severe (BMD-T < -5, n = 44). This study adhered strictly to the principles of the Declaration of Helsinki, and all research participants provided signed informed consent. Ethical approval for this study was obtained from the Ethics Committee of Qinghai University Affiliated Hospital (P-SL-202192).

### Criteria for Patient Enrollment

Patients were enrolled based on specific criteria aligned with the clinical manifestations of osteoporosis. Confirmation of osteoporosis relied on a bone densitometer (dual-energy X-ray bone densitometer, Discovery A, HOLOGIC, USA), ensuring a BMD-T of ≤ -2.5.[11] Inclusion criteria included: (1) the presence of vertebral fractures confirmed by imaging examinations; (2) alignment with indications for PKP performed in our hospital; (3) a fracture duration of ≥ 1 week; (4) age exceeding 60 years: (5) complete medical records; and (6) a clear and independent state of consciousness enabling active participation in this study.

Exclusion criteria involved: (1) patients with mental disorders; (2) cognitive dysfunction; (3) organic diseases; (4) abnormal coagulation function; (5) autoimmune diseases; and (6) severe liver and kidney dysfunction. These strict criteria aimed to ensure a homogeneous and well-defined study population.

### Bone Mineral Density (BMD) Examination

Prior to the examination, patients were required to remove all metal articles. For hip scanning, patients assumed a supine position with the detected thigh slightly abducted and rotated by 15-25° while their feet were secured with a fixing band. The laser marking line was positioned at the midpoint of the femur, initiating the scan 3-5cm below the pubic symphysis. The scan covered the femoral neck, intertrochanteric area, Ward's area, and the total hip.

The femoral neck was kept parallel to the scanning table, preventing a reduction in the scanning area due to femoral neck shortening to maintain accuracy. Lumbar spine scans were conducted with hips and knees flexed, resting on support to straighten the spine on the platform, thereby avoiding errors induced by lumbar lordosis. The scanning range included the 1st, 2nd, 3rd, and 4th lumbar vertebrae, with lumbar segments exhibiting apparent abnormalities excluded from the scanning site. BMD-T was calculated as the ratio of the bone mineral content to the area of the measured site.

$$BMD\text{–}T = \text{Bone Mineral Content/ Area of the Measured Site}$$

### PKP Therapy Procedure

All PKP procedures were conducted by a consistent surgical team within our hospital, ensuring uniformity and expertise in the process.

**Anesthesia and Patient Positioning.** Routine local anesthesia was administered, and patients were placed in a prone position to facilitate the procedure.

**Needle Insertion and Puncture Process.** During the operation, a needle with a puncture guide was inserted using a unilateral pedicle approach, guided by a C-arm X-ray machine. Precision was maintained until the needle tip reached the anterior 2/3 of the vertebral body (VB), ensuring that both the lateral and frontal needle tips reached the vertebral fissure.

**Bone Cement Injection.** After the inner core was removed, the prepared bone cement was loaded into the injection syringe. Utilizing high-viscosity bone cement, injection into the vertebral fissure was carefully performed under the guidance of C-arm fluoroscopy. Monitoring the real-time distribution of bone cement in the affected vertebra, injection ceased upon detection of cement extravasation or reaching the posterior wall of the vertebra.

**Device Removal.** Subsequently, the needle syringe was slowly extracted, and the inner core was reinserted. The puncture device was then carefully withdrawn through multiple rotations before the bone cement solidified. This standardized PKP protocol was consistently followed to ensure procedural precision and patient safety.

### Analysis of Calcium (Ca), Magnesium (Mg), and Zinc (Zn) in Local Lavage Fluid

During the PKP puncture procedure, the fractured VB underwent lavage with 5 mL of normal saline through the lateral channel. Subsequently, 5 mL of lavage fluid was carefully collected for the biochemical analysis of calcium (Ca), magnesium (Mg), and zinc (Zn) levels. This analysis was carried out using the Myers BS-600M Automatic Biochemistry Analyzer from the USA, ensuring precise and efficient measurement of the specified elements in the VB lavage fluid.

**Evaluation of Vertebral Body (VB) Improvement**

To assess the improvement in the VB, anteroposterior and lateral lumbar X-rays were taken using Siemens LUMINOS Lotus Max multifunctional X-ray diagnostic equipment from Germany. These radiographic images were centered on the injured vertebra and captured both before and 48 hours after surgery.

**Parameters for VB Geometry and Kyphosis Evaluation.** The geometry of the VB was represented by the wedge angle of the compressed VB, calculated as the angle between the connecting line of the upper and lower endplates of the injured vertebra. The degree of kyphosis was assessed using the three-segment kyphosis angle, considering both the upper and lower vertebrae adjacent to the injured vertebra. This angle is measured as the angle between the connecting line of the superior and inferior endplates of the injured VB.

**Recording VB Height.** The VB height, recorded at the most severely collapsed part of the fractured VB, was a crucial parameter for evaluating structural improvements post-surgery.

**Analysis of Bone Cement Leakage.** Bone cement leakage, defined as the diffusion of bone cement beyond the upper and lower endplates and the anterior and posterior borders of the VB, was carefully examined to monitor and assess the integrity of the surgical site.

**Scoring Assessment**

A comprehensive scoring survey was conducted both before and 48 hours after surgery.

**Oswestry Disability Index (ODI).** The ODI comprises 10 questions,[12] each scored from 0 to 5, with a total score of 50. Questions encompass various aspects, including pain intensity, daily life, sleeping, and sex life. The total score is directly proportional to the level of dysfunction, providing insights into the impact of surgery on different facets of the patient's life.

**Visual Analogue Scale (VAS).** For the VAS assessment, patients were instructed to indicate a number between 0 and 10,[13] reflecting their most intense pain sensation within 24 hours. The scale provides a direct representation of pain intensity, with higher scores indicating more severe pain experiences. This evaluation offers valuable insights into the effectiveness of surgical intervention in managing pain.

**Barthel Index (BI).** The BI, consisting of 10 questions related to activities such as feeding, dressing, and bladder and bowel functions, provides a total score of 100.[14] Higher scores correlate with enhanced daily living abilities, offering a quantitative measure of the patient's functional independence.

**Follow-Up Survey.** All patients underwent a complete follow-up for a duration of 6 months, with regular reviews conducted monthly. The cut-off event for analysis was a patient's re-fracture. The prognostic re-fracture rate was calculated using the formula:

Re-fracture Rate = (Total Number of Patients Number of Patients with Re-fracture During Follow-Up) × 100%

This approach ensured ongoing monitoring of patient outcomes and facilitated the assessment of the re-fracture risk over the specified follow-up period.

**Outcome Indicators**

A comprehensive set of indicators was used to ensure a thorough evaluation of both primary and secondary outcomes, contributing to a nuanced understanding of the intervention's effectiveness and its impact on patient outcomes.

**Patients' Clinical Baseline Data.** A thorough examination of patients' baseline health information was conducted before and after intervention.

**Electrolyte Ca, Mg, and Zn Levels and Their Correlation with BMD-T.** Analysis of electrolyte levels (Calcium, Magnesium, Zinc) and their correlation with BMD-T was conducted.

**Operation-Related Indexes.** An in-depth investigation into operation-specific metrics, including operation time, intraoperative bleeding, and bone cement injection volume, was also conducted.

**Improvement of VB.** Assessment of changes and differences in the wedge angle, kyphosis angle, and VB height before and after surgery were performed, providing insights into the procedural impact on vertebral geometry.

**Secondary Indicators.** Secondary indicators included: (1) Clinical Scores: Evaluation of clinical scores, including the DOI, VAS, and BI to evaluate postoperative functional outcomes; (2) Adverse Reactions: Compilation and analysis of adverse reactions, such as infection, fever, spinal cord injury, and bone cement leakage, during the postoperative to discharge period (incidence = number of cases of adverse reactions/total number of people × 100%); (3) Prognosis (Re-fracture Rate): Assessment of the re-fracture rate as a key prognostic indicator; (4) Related Factors: Exploration of factors contributing to the occurrence of re-fracture, providing valuable insights into potential risk factors.

**Statistical Analysis**

The data were subjected to statistical analysis using SPSS 16.0, with statistical significance denoted by $P < .05$. Categorical data, including patients' gender, family medical history, and other countable variables, were recorded as percentages (%), and between-group comparisons were conducted using the chi-square test ($\chi^2$). Measurement data, such as Calcium levels and bone cement injection volume, were recorded as mean and standard deviation ($\bar{x} \pm s$), and

**Table 1.** Comparison of Clinical Baseline Data

| Variables | Mild Group (n = 40) | Moderate Group (n = 78) | Severe Group (n = 44) | t/$\chi^2$ value | *P* value |
|---|---|---|---|---|---|
| Age | 66.14±6.66 | 65.88±6.02 | 66.13±7.06 | 0.031 | .969 |
| BMD-T | -3.40±0.36 | -4.56±0.28[a] | -5.63±0.30[a,b] | 553.700 | <.001 |
| Gender | | | | 0.095 | .953 |
| Male/Female | 14 (35.00)/26 (65.00) | 26 (33.33)/52 (66.67) | 14 (31.82)/30 (68.18) | | |
| Smoking | | | | 0.603 | .740 |
| Yes/No | 22 (55.00)/18 (45.00) | 39 (50.00)/39 (50.00) | 25 (56.82)/19 (43.18) | | |
| Drinking | | | | 0.582 | .748 |
| Yes/No | 16 (40.00)/24 (60.00) | 30 (38.46)/48 (61.54) | 20 (45.45)/24 (54.55) | | |
| Hypertension | | | | 0.312 | .856 |
| Yes/No | 26 (65.00)/14 (38.46) | 48 (61.54)/30 (38.46) | 26 (59.09)/18 (40.91) | | |
| Diabetes | | | | 0.148 | .929 |
| Yes/No | 22 (55.00)/18 (45.00) | 45 (57.69)/33 (42.31) | 26 (59.09)/18 (40.91) | | |
| History of Previous Fractures | | | | 0.519 | .772 |
| Yes/No | 5 (12.50)/35 (87.50) | 12 (15.38)/66 (84.62) | 8 (18.18)/36 (81.82) | | |
| Surgical Segment | | | | 2.330 | .675 |
| $T_{12}/L_1/L_2$ | 10 (25.00)/20 (50.00)/10 (25.00) | 22 (28.21)/42 (53.85)/14 (17.95) | 10 (22.73)/21 (47.73)/13 (29.55) | | |

[a]*P* < .05 compared with the Mild group
[b]*P* < 0.05 compared with the Moderate group

Note: The chi-square test ($\chi^2$) was used for categorical variables, and the ANOVA was used for continuous variables. T1:Thoracic 1; L1: Lumbar 1; L2: Lumbar 2.

**Figure 1.** Comparison of Electrolyte Levels. (a) Comparison of Ca levels among three groups. (b) Comparison of Mg levels among three groups. (c) Comparison of Zn levels among three groups. (d) Correlation analysis between Ca level and BMD-T. (e) Correlation analysis between Mg level and BMD-T. (f) Correlation analysis between Zn level and BMD-t. *indicates statistical significance with *P* < .05.

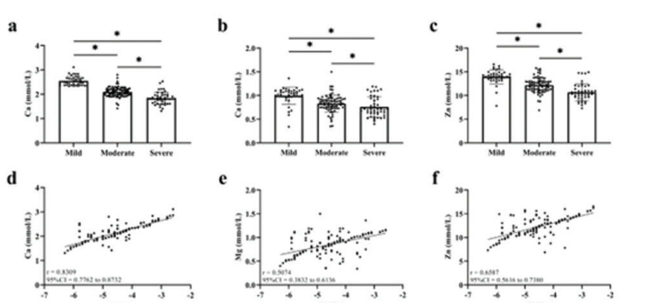
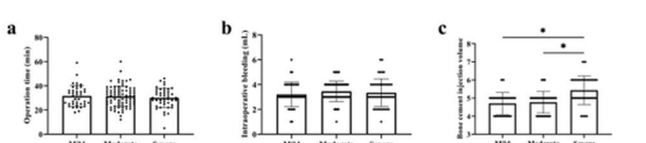



**Figure 2.** Comparison of Surgical Indexes. (a) Comparison of operation time among three groups. (b) Comparison of intraoperative bleeding among three groups. (c) Comparison of bone cement injection volume among three groups. *indicates statistical significance with *P* < .05.




comparisons among groups were performed using analysis of variance (ANOVA) with the LSD post-hoc test. Correlation analyses were executed using Pearson correlation coefficients to explore relationships between variables. Additionally, related influencing factors were identified through logistic multiple regression analysis.

## RESULTS

### Comparison of Clinical Baseline Data

We conducted an initial comparison of clinical baseline data among the three patient groups to establish the credibility of the experimental results. No significant differences were observed in age, sex composition, smoking, and drinking patterns among the three groups (*P* > .05, Table 1), validating the clinical comparability of the groups. This result ensures that any observed variations in outcomes can be confidently attributed to the experimental interventions rather than pre-existing demographic differences.

### Comparison of Electrolyte Levels

In the analysis of electrolyte levels, the mild group exhibited the highest concentrations of Ca, Mg, and Zn in VB lavage fluid among the three groups. Conversely, the severe group displayed the lowest concentrations, with statistically significant differences noted among the groups (*P* < .05), refer to Figure 1a-1c. Pearson correlation coefficient analysis showed a positive association between the levels of Ca, Mg, and Zn and BMD-T) (*P* < .05), refer to Figure 1d-1f). This result implies that as BMD-T decreases, there is a corresponding reduction in the levels of Ca, Mg, and Zn.

### Comparison of Surgical Indexes

The mild, moderate, and severe groups demonstrated no significant differences in operation time and intraoperative bleeding (*P* > .05); refer to Figures 2a and 2b. Regarding the volume of bone cement injected, the mild, moderate, and severe groups recorded volumes of (4.70 ± 0.61) mL, (4.77 ± 0.60) mL, and (5.43 ± 0.79) mL, respectively. No significant differences were observed between the mild and moderate groups or between the moderate and severe groups (*P* > .05). However, there was a notable difference in the amount of bone cement injected between the mild and severe groups, with the mild group showing a lower volume (*P* < .05), refer to Figure 2c.

### Comparison of Vertebral Body (VB) Improvement

Preoperatively, the three groups exhibited no statistically significant differences in wedge angle, kyphosis angle, and VB height (*P* > .05). Postoperatively, the mild and moderate groups demonstrated similarity in all three parameters (*P* > .05). However, in the severe group, the VB height was higher compared to the mild and moderate groups, while the wedge angle and kyphosis angle were  (*P* < .05), Figure 3a-3c. Furthermore, intra-group comparisons before and after treatment highlighted greater differences in wedge angle, kyphosis angle, and VB height in the severe group compared to the other two groups (*P* < .05), refer to Figure 3d-3f.

### Comparison of Clinical Scores

There were no notable differences in preoperative VAS, ODI, and BI scores among the three groups (*P* > .05). After surgery, a significant reduction in VAS and ODI scores, combined with a marked increase in BI scores, was observed

**Figure 3.** Comparison of VB Improvement. (a) Comparison of wedge angles before and after surgery among three groups of patients. (b) Comparison of kyphosis angles among three groups before and after surgery. (c) Comparison of vertebral body height among three groups before and after surgery. * means $P < .05$ compared with Mild group, # means $P < .05$ compared with Moderate group. (d) Comparison of the difference in wedge angle before and after operation. (e) Comparison of the difference in kyphosis angle before and after operation. (f) Comparison of the difference in vertebral body height before and after operation. *$P < .05$.

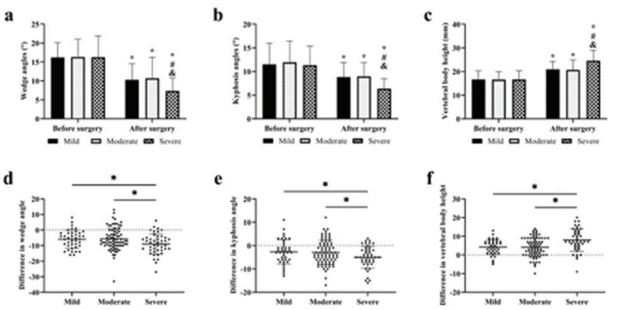
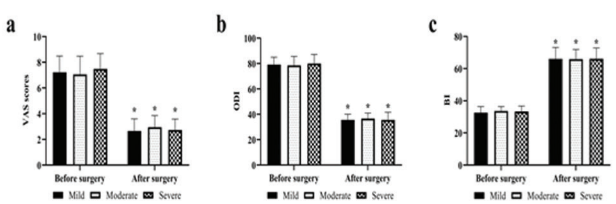



**Figure 4.** Comparison of Clinical Scores (a) Comparison of VAS scores before and after surgery among three groups of patients. (b) Comparison of ODI among three groups before and after surgery. (c) Comparison of BI among three groups before and after surgery. * means $P < .05$ compared with Mild group, # means $P < .05$ compared with Moderate group.




in all groups ($P < .05$), refer to Figure 4a-4c. These findings indicate a substantial alleviation of postoperative pain and a notable improvement in the mobility of patients across all three groups.

### Comparison of Adverse Reactions

Postoperatively, there were no instances of pulmonary embolism, spinal cord injury, or infection in any of the three groups. The incidence of adverse reactions in the mild group was 7.50%, which did not significantly differ from that in the moderate group (10.26%, $P > .05$). However, the severe group exhibited a higher incidence of adverse reactions at 25.00%, with three patients experiencing bone cement leakage. This incidence was significantly elevated compared to the other two groups ($P < .05$, Table 2). These findings highlight the differential occurrence of adverse reactions, emphasizing the increased risk associated with severity, particularly in the context of bone cement leakage in the severe group.

**Table 2.** Comparison of Adverse Reactions

| Groups | Dizziness And Headache | Bloating And Diarrhea | Nausea And Vomiting | Bone Cement Leakage | Incidence of Adverse Reactions (%) |
|---|---|---|---|---|---|
| Mild Group (n = 40) | 1 (2.50) | 1 (2.50) | 1 (2.50) | 0 (0.0) | 7.50% |
| Moderate Group (n = 78) | 4 (5.13) | 1 (1.28) | 3 (3.85) | 0 (0.0) | 10.26% |
| Severe group (n = 44) | 3 (6.82) | 3 (6.82) | 2 (4.55) | 3 (6.82) | 25.00%[a,b] |
| $\chi^2$ value | | | | | 6.884 |
| *P* value | | | | | .032 |

[a]$P < .05$ compared with the Mild group
[b]$P < .05$ compared with the Moderate group

**Table 3.** Comparison of Prognostic Re-Fracture Rate Among Three Groups

| Groups | Re-Fractures | No Fractures |
|---|---|---|
| Mild Group (n = 40) | 1 (2.50) | 39 (97.50) |
| Moderate Group (n = 77) | 4 (5.19) | 73 (94.81) |
| Severe group (n = 41) | 16 (39.02) | 25 (60.98) |
| $\chi^2$ value | 31.980 | |
| *P* value | <.001 | |

Note: Numbers in parentheses represent percentages.

**Table 4.** Univariate Analysis of Prognostic Factors for Re-Fracture

| Variables | No Fractures (n=137) | Re-Fractures (n=21) | t/$\chi^2$ value | *P* value |
|---|---|---|---|---|
| Age | 65.76±5.65 | 72.24±5.62 | 4.897 | <.001 |
| BMD-T | -4.41±0.80 | -5.39±0.75 | 5.268 | <.001 |
| Gender | | | 0.338 | .561 |
| Male/Female | 48 (35.09)/89 (64.96) | 6 (28.57)/15 (71.43) | | |
| Smoking | | | 0.000 | .988 |
| Yes/No | 72 (52.55)/65 (47.45) | 11 (52.38)/10 (47.62) | | |
| Drinking | | | 0.058 | .809 |
| Yes/No | 56 (40.88)/81 (59.12) | 8 (38.10)/13 (61.90) | | |
| Hypertension | | | 0.909 | .340 |
| Yes/No | 83 (60.58)/54 (39.42) | 15 (71.43)/6 (28.57) | | |
| Diabetes | | | 0.002 | .964 |
| Yes/No | 79 (57.66)/58 (42.34) | 12 (57.14)/9 (42.86) | | |
| History of Previous Fractures | | | 0.280 | .597 |
| Yes/No | 20 (14.60)/117 (85.40) | 4 (19.05)/17 (80.95) | | |
| Surgical Segment | | | 5.166 | .076 |
| $T_{12}/L_1/L_2$ | 34 (24.82)/72 (52.55)/ 31 (22.63) | 6 (28.57)/6 (28.57)/ 9 (42.86) | | |
| Ca (mmol/L) | 2.18±0.33 | 1.91±0.33 | 3.491 | <.001 |
| Mg (mmol/L) | 0.87±0.20 | 0.74±0.22 | 2.737 | .007 |
| Zn (mmol/L) | 12.41±1.92 | 11.01±2.10 | 3.073 | .003 |
| Operation time (min) | 31.20±8.26 | 30.67±10.18 | 0.265 | .791 |
| Intraoperative bleeding (mL) | 3.34±0.92 | 3.52±1.17 | 0.804 | .423 |
| Bone cement injection volume (mL) | 4.79±0.64 | 5.76±0.70 | 6.388 | <.001 |
| Wedge angles (°) | 9.82±4.67 | 10.33±4.60 | 0.467 | .641 |
| Kyphosis angles (°) | 8.07±2.84 | 9.43±3.68 | 1.960 | .052 |
| VB Height (mm) | 21.85±4.54 | 21.43±3.40 | 0.406 | .685 |
| VAS Scores | 2.80±0.90 | 2.90±0.89 | 0.475 | .636 |
| ODI | 36.02±4.86 | 35.95±4.92 | 0.061 | .951 |
| BI | 66.09±6.33 | 65.57±7.23 | 0.344 | .731 |
| Bone Cement Leakage | | | 13.560 | <.001 |
| Yes/No | 1 (0.73)/136 (99.27) | 3 (14.29)/18 (85.71) | | |

Note: Values are presented as mean± SD or [n (%)]. BMD-T, bone mineral density T-score; Ca, calcium; Mg, magnesium; Zn, zinc; VAS, Visual Analogue Scale; ODI, Oswestry Disability Index; BI, Barthel Index.

**Table 5.** Multivariate Analysis of Prognostic Factors for Re-Fracture

| Variables | β | SE | Wald $\chi^2$ | OR | 95%CI | *P* value |
|---|---|---|---|---|---|---|
| Age | 0.842 | 0.216 | 15.042 | 2.264 | 1.621-3.442 | <.001 |
| BMD-T | 1.161 | 0.264 | 20.661 | 0.784 | 0.413-1.364 | <.001 |
| Ca | 1.264 | 0.618 | 14.264 | 0.486 | 0.018-0.973 | <.001 |
| Mg | -1.436 | 0.346 | 20.960 | 0.816 | 0.264-1.762 | <.001 |
| Zn | 0.694 | 0.592 | 11.627 | 0.692 | 0.126-0.943 | <.001 |
| Bone Cement Injection Volume | 1.184 | 0.264 | 20.642 | 3.241 | 1.942-5.642 | <.001 |
| Bone Cement Leakage | 1.064 | 0.184 | 33.164 | 2.864 | 2.004-4.162 | <.001 |

Note: β, regression coefficient; SE, standard error; OR, odds ratio; 95%CI, 95% confidence interval.

### Comparison of Prognosis

Throughout the 1-year prognostic follow-up, successful tracking was achieved for all patients in the mild and severe groups and 158 patients in the moderate group, generating an overall success rate of 97.53%. The comparison of the 1-year re-fracture rate indicated that the severe group had a higher rate than both the mild and moderate groups ($P > .05$); see Table 3.

### Univariate Analysis of Prognostic Factors for Re-fracture

In this univariate analysis, patients experiencing prognostic re-fractures comprised the research group, while those without re-fractures constituted the control group. The two groups did not exhibit statistical differences in terms of gender composition, the number of fractured vertebrae, and fracture site ($P > .05$). However, the research group demonstrated an older age, a higher incidence of bone cement leakage, and lower levels of BMD-T, Ca, Mg, and Zn compared to the control group ($P < .05$), Table 4. This analysis highlights age, bone cement leakage, BMD-T, Ca, Mg, and Zn as individual factors significantly influencing the occurrence of re-fractures.

### Multivariate Analysis of Prognostic Factors for Re-fracture

The significantly different individual factors were assigned values for the Logistic multiple regression analysis. The occurrence of bone cement leakage was assigned a value of 1, while the absence of such occurrence was assigned a value of 0. All other indicators were measured and analyzed using raw data. These variables were then subjected to multivariate analysis. The dependent variable was whether the patient experienced a re-fracture, with other factors serving as covariates. Through this analysis, age and bone cement leakage emerged as independent risk factors for re-fracture in patients with OSF. Conversely, BMD-T bone cement injection volume, Ca, Mg, and Zn were identified as independent protective factors ($P < .05$), see Table 5.

## DISCUSSION

In this study, we observed that OSF patients with lower BMD-T exhibited a more substantial correction of vertebral height and convex deformity following PKP treatment. However, it was noted that the risk of postoperative adverse events was increased in this group. These findings offer valuable insights and guidance for future clinical considerations during PKP surgery, thereby enhancing the reliability of prognoses for OSF patients.

PKP stands as the preferred and optimal approach for treating OSF at present. This procedure distinguishes itself by streamlining the operation, eliminating the necessity for intraoperative balloon expansion. Utilizing a hydraulic high-pressure perfusion apparatus, high-viscosity bone cement can be injected into the affected vertebra, facilitating the restoration of its height after precise needle placement.[15] This innovative method, as opposed to traditional PVP, not only reduces operation time and alleviates pain but also fortifies the vertebral structure. However, it is crucial to acknowledge that despite these advantages, there remains a possibility of postoperative re-fracture, as indicated by current studies.[16,17]

In clinical practice, the general view is that variations in BMD constitute a critical factor influencing the outcomes of surgical interventions. It is postulated that distinctions in BMD may contribute to variations in postoperative symptom relief and VB height recovery among OSF patients. However, it is noteworthy that current research predominantly utilizes BMD for diagnosing and assessing the occurrence of osteoporosis without a comprehensive understanding of its relationship with the efficacy of PKP in treating OSF. Therefore, our study holds substantial reference significance for guiding early treatment and evaluating OSF patients in the future.

Fractures resulting from osteoporosis have been associated with physical impacts and diminished Ca absorption in the blood.[19] Supporting this perspective, subsequent research in follow-up studies has revealed that supplementing electrolytes, such as Ca and Vitamin D3, can effectively mitigate the occurrence of femoral and non-spinal fractures.[20] At the same time, within the pathological progression of osteoporosis, a group of hormones and cytokines can directly influence electrolyte absorption, thereby regulating the delicate equilibrium between bone remodeling and absorption. This complex relation activates the formation of new bone, highlighting the dynamic processes during osteoporosis pathogenesis.[21] The findings suggest that the measurement of Ca levels may serve as an indicator of the severity of OSF, offering valuable guidance for clinical intervention and the assessment of patient prognosis.

The close association of Ca, Mg, and Zn with osteoporosis and OSF has been established in existing research, which predominantly focuses on blood sample analysis. Limited knowledge exists regarding their levels in fractured VB lavage fluid and their correlation with BMD-T. Thus, our study is the first to analyze the correlation of Ca, Mg, and Zn in VB lavage fluid obtained during local puncture with BMD-T.

The findings revealed the lowest levels in the mild group and the highest levels in the severe group. Furthermore, correlation analysis established a positive association between BMD-T and Ca, Mg, and Zn, indicating a preliminary connection between Ca, Mg, Zn, and BMD. Calcium is a vital mineral essential for bone growth and development, stored in bone tissue and integrated into the protein matrix. Adequate calcium intake contributes to the attainment of higher bone mass and a reduction in the rate of bone loss.[22]

Mg plays an important role in the synthesis of the organic bone matrix, exerting a significant influence on overall bone health.[23] Zn serves as a plentiful electrolyte in bone tissue and stands as an indispensable component in bone metabolism.[24] We postulated that the decline in Ca, Mg, and Zn levels surrounding the VB may influence bone mineralization and the formation of the bone matrix, potentially diminishing bone quality and elevating the risk of fractures. These findings suggest a close relationship between Ca, Mg, Zn, and BMD-T. We propose the potential utility of these elements as supplementary observational indices, guiding the surgical treatment of OSF. However, the absence of vertebral lavage fluid samples from post-surgical patients and individuals without surgical intervention for testing impedes the validation of this perspective. Additional evidence is required to substantiate this postulate.

Subsequently, we categorized patients based on their BMD-T and observed no disparity in operation time and intraoperative bleeding among the three groups. However, the severe group exhibited a higher volume of injected bone cement, along with more pronounced alterations in wedge angle, kyphosis angle, and VB height. Additionally, there were no discernible variations in postoperative VAS, ODI, and BI scores among the three groups. The differences in wedge angle, VB height, and kyphosis angle among them might be attributed to the lower BMD-T, reduced bone mineral salt content, increased osteoporosis, and diminished resistance to surgical distraction reduction in the severe group. Consequently, more noticeable corrections in VB height and wedge angle were achieved after surgery in the severe group.

There is also evidence suggesting that a sufficient injection of bone cement is closely linked to VB height and stiffness,[25] which may explain the slight elevation in VB height observed in the severe group. In other words, an increased amount of injected bone cement leads to a rise in VB height. However, there is no significant difference in postoperative pain relief and spinal function recovery among the three groups. This finding implies that PKP exhibits excellent therapeutic effects for OSF patients with varying BMD-T. These findings align with previous studies on the clinical efficacy of PKP, reaffirming its outstanding applicability.[26,27]

Combined with previous studies, we suggest that the outstanding efficacy of PKP is primarily due to the necrosis of peripheral sensory nerve endings induced by the transient high heat during the bone cement hardening process, effectively obstructing nociceptive conduction. Additionally, the cytotoxic effect of bone cement is identified as a contributing factor to the necrosis of nociceptive nerve terminals.[28]

The bone cement permeates into the crevices of fractures, securing microfractures upon solidification and thereby reinstating the stability of the VB and enhancing patient mobility.[29] Furthermore, the solidified bone cement exhibits notable hardness, reinforcing the fractured VB, restoring the stiffness of the injured vertebra, and enhancing the load-bearing capacity of the VB. Simultaneously, this process corrects and restores the physiological curvature of the spine, leading to pain relief.[30]

We observed a higher incidence of adverse reactions in the severe group, notably a bone cement leakage incidence of 6.82%. This finding could be attributed to the larger volume of injected bone cement in this group, or the fracture of the vertebral cortex caused by puncture or the fracture itself, leading to bone cement leakage through the bone fracture. Another potential factor is premature injection. These findings emphasize the importance of precise placement of the puncture needle during the PKP procedure. Specifically, the puncture needle should be positioned as close as possible to the upper part of the VB for ruptured inferior endplates and as far as possible for the ruptured posterior wall of the VB. It is advisable to conduct bone cement injection during the late stage of the "wire-drawing stage" to minimize the occurrence of bone cement leakage.

Moreover, the follow-up survey revealed no disparity in the prognostic re-fracture rate among the three groups, reaffirming the outstanding therapeutic efficacy of PKP for OSF. Ji et al.[31] have previously indicated that the one-year re-fracture rate for OSF patients following PKP falls within the range of 10-20%,[31] aligning closely with our study results.

During the analysis of factors associated with prognostic re-fracture, we identified age and bone cement leakage as independent risk factors, whereas BMD-T, Ca, Mg, and Zn emerged as independent protective factors. It emphasizes the significant correlation of BMD-T, Ca, Mg, and other indicators with OSF and highlights their evaluative importance in OSF. Notably, the impact of age, a key influencing factor in OS, OSF, and bone health,[32,33] is estimated in these findings.

The observed effects of BMD-T, Ca, Mg, and Zn may be intricately linked to our earlier inference. Bone cement leakage could contribute to suboptimal vertebral strength recovery, potentially leading to re-fracture. Intriguingly, the severe group exhibited lower BMD-T, Ca, Mg, and Zn levels along with a higher incidence of bone cement leakage, yet there was no significant disparity in the follow-up re-fracture outcomes compared to the other two groups. We speculate that this discrepancy may be attributed to a statistical anomaly arising from the relatively short follow-up period or the limited number of cases in the study. Therefore, an extension of the follow-up duration and an increase in the research sample size are warranted for further validation.

Additionally, a more detailed breakdown of the re-fracture sites among the patients is essential for validation of our findings that bone cement leakage may lead to unsatisfactory recovery of vertebral strength, resulting in re-fracture. Moreover, given the cohort nature of this study, potential information bias during data collection necessitates the initiation of a clinical randomized controlled trial to validate our findings. Lastly, it is crucial to acknowledge that the professional expertise of surgeons could influence the efficacy of PKP treatment. Therefore, efforts must focus on enhancing the PKP surgical skills of physicians within the hospital through training initiatives, thereby further ensuring optimal patient prognosis.

## CONCLUSION

In conclusion, PKP demonstrates favorable clinical outcomes in the treatment of OSF across varying bone mineral densities. Notably, lower BMD-T is associated with more pronounced postoperative correction of vertebral height and kyphosis. However, it comes with an increased risk of bone cement leakage. Therefore, careful consideration is warranted in surgical decision-making. Furthermore, age, bone cement leakage, BMD-T, bone cement injection volume, Ca, Mg, and Zn emerge as important factors influencing the occurrence of post-PKP re-fracture in OSF patients. These indicators demand diligent attention in follow-up clinical interventions to provide a robust foundation for enhanced patient prognosis.

## ETHICAL APPROVAL

Not applicable.

## COMPETING INTERESTS

The authors report no conflict of interest.

## AUTHORS' CONTRIBUTIONS

Yongxia Li conceptualized and designed the study, as well as drafted the manuscript. Qinglin Jing collected and generated the data. Feng Chen performed data analysis. Yong Xu contributed to the manuscript revisions. All authors provided final approval of the version to be published and agreed to be accountable for all aspects of the work.

## AVAILABILITY OF DATA AND MATERIALS

The data that support the findings of this study are available from the corresponding author upon reasonable request.

## FUNDING

This research received support from the Applied Basic Research Program of Qinghai Provincial Department of Science and Technology (Grant Title: "*The Correlation Between T-Value and Local Calcium, Phosphorus, and Magnesium in Patients with Osteoporotic Fractures and Its Influence on Clinical Treatment Effect and ODI Score*," Grant Number: 2022-zj-777).

## ACKNOWLEDGEMENTS

Not applicable.

## REFERENCES


1. Johnston CB, Dagar M. Osteoporosis in Older Adults. *Med Clin North Am*. 2020;104(5):873-884. doi:10.1016/j.mcna.2020.06.004
2. Hollensteiner M, Sandriesser S, Bliven E, von Rüden C, Augat P. Biomechanics of Osteoporotic Fracture Fixation. *Curr Osteoporos Rep*. 2019;17(6):363-374. doi:10.1007/s11914-019-00535-9
3. Yang Z, Zhang W, Ren X, Tu C, Li Z. Exosomes: A Friend or Foe for Osteoporotic Fracture? *Front Endocrinol (Lausanne)*. 2021;12:679914. doi:10.3389/fendo.2021.679914
4. Prost S, Pesenti S, Fuentes S, Tropiano P, Blondel B. Treatment of osteoporotic vertebral fractures. *Orthop Traumatol Surg Res*. 2021;107(1S):102779. doi:10.1016/j.otsr.2020.102779
5. Ohara Y, Hara T, Abe E. [How to Treat Osteoporotic Vertebral Fracture?]. *No Shinkei Geka*. 2021;49(6):1286-1297.
6. Liu JY, Wang JX, Xu L, Deng FY. Potential Biomolecules Capable of Assessing Risk of Osteoporotic Fracture: A Scoping Review. *Chin Med Sci J*. 2021;36(2):135-149.
7. Xin J, Liu X, Jing X, et al. Multifactor Analysis of Costal Pain in Osteoporotic Fracture of Thoracic Vertebra. *Pain Physician*. 2021;24(6):E795-E802. doi:10.36076/ppj.2021.24.E795
8. Afarideh M, Sartori-Valinotti JC, Tollefson MM. Association of Sun-Protective Behaviors With Bone Mineral Density and Osteoporotic Bone Fractures in US Adults. *JAMA Dermatol*. 2021;157(12):1437-1446. doi:10.1001/jamadermatol.2021.4143
9. Black DM, Bauer DC, Vittinghoff E, et al; Foundation for the National Institutes of Health Bone Quality Project. Treatment-related changes in bone mineral density as a surrogate biomarker for fracture risk reduction: meta-regression analyses of individual patient data from multiple randomised controlled trials. *Lancet Diabetes Endocrinol*. 2020;8(8):672-682. doi:10.1016/S2213-8587(20)30159-5
10. Topaloğlu US, Erol K. Bone mineral density and fracture risk in prediabetes: a controlled cross-sectional study. *Acta Reumatol Port*. 2021;46(1):32-39.
11. Kanis JA, Cooper C, Rizzoli R, Reginster JY; Scientific Advisory Board of the European Society for Clinical and Economic Aspects of Osteoporosis (ESCEO) and the Committees of Scientific Advisors and National Societies of the International Osteoporosis Foundation (IOF). European guidance for the diagnosis and management of osteoporosis in postmenopausal women. *Osteoporos Int*. 2019;30(1):3-44. doi:10.1007/s00198-018-4704-5
12. Fairbank JC, Pynsent PB. The Oswestry Disability Index. *Spine*. 2000;25(22):2940-2952. doi:10.1097/00007632-200011150-00017
13. Faiz KW. [VAS--visual analog scale]. *Tidsskr Nor Laegeforen*. 2014;134(3):323. doi:10.4045/tidsskr.13.1145
14. Mahoney FI, Barthel DW. Functional Evaluation: The Barthel Index. *Md State Med J*. 1965;14:61-65.
15. Alarkawi D, Bliuc D, Tran T, et al. Impact of osteoporotic fracture type and subsequent fracture on mortality: the Tromsø Study. *Osteoporos Int*. 2020;31(1):119-130. doi:10.1007/s00198-019-05174-5
16. Adami G, Giollo A, Rossini M, et al. Different fracture risk profile in patients treated with anti-osteoporotic drugs in real-life. *Reumatismo*. 2020;72(2):71-74. doi:10.4081/reumatismo.2020.1267
17. Louvois M, Ferrero S, Barnetche T, Roux CH, Breuil V. High risk of osteoporotic fracture in Parkinson's disease: Meta-analysis, pathophysiology and management. *Rev Neurol (Paris)*. 2021;177(6):660-669. doi:10.1016/j.neurol.2020.07.015
18. Ma X, Xia H, Wang J, et al. Re-fracture and correlated risk factors in patients with osteoporotic vertebral fractures. *J Bone Miner Metab*. 2019;37(4):722-728. doi:10.1007/s00774-018-0974-4
19. Issayeva S, Lesnyak O, Zakroyeva A, et al. Epidemiology of osteoporotic fracture in Kazakhstan and development of a country specific FRAX model. *Arch Osteoporos*. 2020;15(1):30. doi:10.1007/s11657-020-0701-3
20. Nguyen TV. Personalized fracture risk assessment: where are we at? *Expert Rev Endocrinol Metab*. 2021;16(4):191-200. doi:10.1080/17446651.2021.1924672
21. Morin SN, Yan L, Lix LM, Leslie WD. Long-term risk of subsequent major osteoporotic fracture and hip fracture in men and women: a population-based observational study with a 25-year follow-up. *Osteoporos Int*. 2021;32(12):2525-2532. doi:10.1007/s00198-021-06028-9
22. Chen L, Lu Q, Wang X, Zhu Y, Zhang D. Ultrasound-assisted Percutaneous Vertebroplasty in Upper and Mid-thoracic Osteoporotic Fracture. *J Coll Physicians Surg Pak*. 2021;31(3):330-333. doi:10.29271/jcpsp.2021.03.330
23. Wysham KD, Baker JF, Shoback DM. Osteoporosis and fractures in rheumatoid arthritis. *Curr Opin Rheumatol*. 2021;33(3):270-276. doi:10.1097/BOR.0000000000000789
24. Malle O, Borgstroem F, Fahrleitner-Pammer A, Svedbom A, Dimai SV, Dimai HP. Mind the gap: incidence of osteoporosis treatment after an osteoporotic fracture - results of the Austrian branch of the International Costs and Utilities Related to Osteoporotic Fractures Study (ICUROS). *Bone*. 2021;142:115071. doi:10.1016/j.bone.2019.115071
25. Kendler DL, Chines A, Brandi ML, et al. The risk of subsequent osteoporotic fractures is decreased in subjects experiencing fracture while on denosumab: results from the FREEDOM and FREEDOM Extension studies. *Osteoporos Int*. 2019;30(1):71-78. doi:10.1007/s00198-018-4687-2
26. Blanchette PS, Lam M, Le B, et al. The association between endocrine therapy use and osteoporotic fracture among post-menopausal women treated for early-stage breast cancer in Ontario, Canada. *Breast*. 2021;60:295-301. doi:10.1016/j.breast.2021.09.010
27. Chen Z, Song C, Chen M, Li H, Ye Y, Liu W. What are risk factors for subsequent fracture after vertebral augmentation in patients with thoracolumbar osteoporotic vertebral fractures. *BMC Musculoskelet Disord*. 2021;22(1):1040. doi:10.1186/s12891-021-04946-7
28. Wu X, Wang Z, Li H, Li Y, Wang H, Tian W. Biomechanical evaluation of osteoporotic fracture: metal fixation versus absorbable fixation in Sawbones models. *Injury*. 2019;50(7):1272-1276. doi:10.1016/j.injury.2019.05.023
29. Yang Z, Feng L, Wang M, et al. Sesamin Promotes Osteoporotic Fracture Healing by Activating Chondrogenesis and Angiogenesis Pathways. *Nutrients*. 2022;14(10):2106. doi:10.3390/nu14102106
30. Kim EG, Bae G, Kwon HY, Yang H. Aging and direct medical costs of osteoporotic fractures. *J Bone Miner Metab*. 2021;39(4):589-597. doi:10.1007/s00774-020-01192-0
31. Ji C, Rong Y, Wang J, et al. Risk Factors for Refracture following Primary Osteoporotic Vertebral Compression Fractures. *Pain Physician*. 2021;24(3):E335-E340.
32. Pickering ME, Millet M, Rousseau JC, et al. Selected serum microRNA, abdominal aortic calcification and risk of osteoporotic fracture. *PLoS One*. 2019;14(5):e0216947. doi:10.1371/journal.pone.0216947
33. Erhan B, Ataker Y. Rehabilitation of Patients With Osteoporotic Fractures. *J Clin Densitom*. 2020;23(4):534-538. doi:10.1016/j.jocd.2020.06.006