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Research Article

Keywords: Lumbar Vertebra, Osteoporotic Vertebral Compression Fractures, Percutaneous kyphoplasty, Bone Cement, Biodynamics, Finite Element Analysis, Mechanical Loading.

Posted Date: May 5th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-450478/v1

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Is it necessary to link the bilateral cement during the process of Percutaneous kyphoplasty?

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Abstract

BACKGROUND:
To evaluate the clinical and biomechanical results of different types of bone cement distribution post bilateral percutaneous kyphoplasty (PKP) in patients with osteoporotic vertebral compression fractures (OVCF).

METHODS:
A retrospective study of 227 single-segment OVCF patients from May 2017 to November 2020 were operated with bilateral percutaneous kyphoplasty and injected with the same material and the same volume of bone cement. According to the postoperative imaging data of the patients, the patients were allocated into two groups according to whether the bilateral bone cement in the vertebral body was connected. Further, establishment of a three-dimensional finite element model to evaluate the mechanical property of vertebral bodies after percutaneous kyphoplasty. Loading the model in five motion states (compression, forward bending, backward extension, rotation and lateral bending) for force analysis, and compare the stress difference between the fractured vertebrae and adjacent vertebrae under the two cement distributions.

RESULTS:
Of the 227 patients, 217 eventually received an average follow-up of 22 months. The restoration rate of vertebral body height, the improvement of kyphotic angle and the degree of postoperative improvement of the visual analog scale for pain (VAS) of the two groups of patients were similar, and there was no significant difference between the groups (P>0.05). There was no significant difference in the rate of bone cement leakage between the two groups (P>0.05). But there was a significant difference in the incidence of recurrent vertebral fractures (new fractures of adjacent vertebral bodies and re-fractures of injured vertebrae) (P<0.05). There was a significant difference in the von Mises stress between the fractured vertebral body and the cranial adjacent vertebra under the same conditions between the two groups of vertebral body models (P<0.05)

CONCLUSION:
Administration of bone cement in the center of vertebrae without distribution to both edges may reduce the risk of re-collapse of the injured vertebrae and fracture of adjacent vertebral body on the cranial side.

KEYWORDS: Lumbar Vertebra; Osteoporotic Vertebral Compression Fractures; Percutaneous kyphoplasty; Bone Cement; Biodynamics; Finite Element Analysis; Mechanical Loading.
Background

Vertebral compression fracture (VCF) is one of the main health problems of the elderly. The annual incidence of vertebral compression fractures is 10/1000 for women, and that of men is 5/1000, which is one of the main causes of poor quality of life and an important burden on the national health care budget[1,2]. The elderly, especially those with osteoporosis, are more likely to suffer from osteoporotic vertebral compression fractures (OVCF). Particularly among women, there are approximately 1.5 million OVCF patients each year[3,4]. At present, there are surgical and non-surgical methods for the treatment of OVCF. Non-operative methods include taking painkillers, wearing back braces, bed rest to improve functional status and preventing future fractures of other vertebral bodies. However, they have limited efficacy and severe side effects (thrombosis, lung infection, etc.))[5,6]. At the same time, because of the high risk of surgical accidents in elderly patients with osteoporosis, traditional open surgery is generally not recommended[7]. Therefore, minimally invasive spinal surgery has been widely used for vertebral body expansion in OVCF patients, including percutaneous kyphoplasty (PKP) and percutaneous vertebroplasty (PVP)[8]. Data analysis shows that both PKP and PVP can achieve satisfactory clinical effects of OVCF treatment, but PKP has a lower cement leakage rate, better kyphotic angle, and better vertebral height recovery [9-11]. In general, PKP can greatly reduce pain, restore lost vertebral height, and improve the quality of life. Therefore, more and more surgeons choose PKP to treat OVCF patients.

The bone cement used in PKP is made of viscous polymethyl methacrylate (PMMA). The cytotoxic and febrile effects of PMMA can damage the bone peripheral nerves and stabilize micro-movements by strengthening the vertebral body[12]. However, PMMA has non-degradability and high biomechanical stress, which may cause re-collapse[13]. In addition, the actual position of cement in the vertebral body may be affected by the differences of surgeons’ surgical techniques, different choices of dilators, and changes in the anatomical structure of the puncture vertebral body. For example, when performing PKP surgery on the lateral pedicle, the bone cement on both sides may or may not be connected. At the same time, excessive injection of cement may cause some biomechanical changes. This may indicate that the most appropriate intravertebral cement volume should be used to obtain the best bone cement distribution in the vertebral body to achieve the best postoperative results. And some studies have confirmed that proper cement distribution and a small amount of cement can achieve good surgical results[14,15]. At the same time, several recent studies have shown that the reduced contact of polymethyl methacrylate (PMMA) with the upper and lower endplates is a risk factor for the re-collapse of the fractured vertebral body. Therefore, controlling the distribution of PMMA during surgery can reduce the risk of re-compression after vertebroplasty or kyphoplasty. And if the bone cement fully contacts the upper and lower endplates, it can better restore the strength of the vertebral body, maintain the height of the vertebral body, and reduce the risk of vertebral body re-compression and long-term pain[16-18]. Kim & Todd argue that if bone cement touches the two endplates, the pressure transmitted through the non-cemented area will be reduced[19]. Although there will be a stress shielding effect, (that is, when components with different elastic modulus bear the load in parallel, the component with higher elastic modulus bears more load and plays a stress shielding effect on the component with low elastic modulus), but the collapse of the non-cemented area caused by excessive
pressure will be reduced. but so far, almost no one has studied the effect of whether the two sides of the bone cement are connected or not in bilateral percutaneous kyphoplasty on the postoperative efficacy of patients. Therefore, this study analyzes the influence of whether the two sides of the bone cement are connected or not on the postoperative efficacy of patients through retrospective research and finite element analysis, and provide surgeons with more effective surgical methods and reduce as many complications as possible.

In addition, as an important research method of computational mechanics, finite element analysis has the characteristics of low cost and good repeatability. It is an effective, accurate and low-cost mechanical structure analysis method. It has been widely used in the research of spine biomechanics. It has been proven that the finite element model of the spine can be effectively used to assess spinal injury from the field of biomechanics[20]. At present, the use of finite element analysis is an important part of studying human biomechanics, and it is widely used in cervical spine, lumbar spine, joints and other directions[21,22]. Therefore, this study established the three-dimensional finite element model of the L2 ~ L4 vertebral body, set the L3 vertebral body as the fractured vertebral body and injected the ideal bone cement shape to simulate the compression, forward bending, backward extension, rotation and lateral bending of the lumbar spine. To study the effect of whether the bone cement distribution of bilateral PKP is connected or not on the structure of the injured vertebral body and adjacent vertebral body. The purpose of this study is to clarify the difference in the structural biomechanical properties of the vertebral body with different bone cement distribution after bilateral PKP, and to provide a theoretical basis for the surgeon to perform the operation effectively and reduce as many complications as possible.

Methods

Patients

This research plan is a retrospective investigation, and the research object is the data of 217 patients who received OVCF treatment in our hospital from May 2017 to November 2020. MRI-diagnosed single-level OVCF patients who matched the following criteria were enrolled in this retrospective investigation. In addition, the patients were divided into cement-connected group and bone-cement unconnected group according to the X-rays taken one day after the operation. If it is difficult to determine the patient, it is determined by Thin-slice CT scan (Fig.2) . Connection group: X-ray front and lateral radiographs show that the bone cement on both sides is connected. Unconnected group: X-ray front or lateral radiographs show that the bone cements on both sides are not connected. The inclusion criteria: (1) A single-level OVCF (2) 15% < collapse < 60% (3) 2 weeks < Symptom duration < 3 months (4) Visual Analogue Scale (VAS) > 5 (5) The score of bone mineral density (BMD) < -2.5 (6) 60 < age < 80 years old. The exclusion criteria: (1) Inability to give informed consent; (2) Poor general physical state; (3) Caused by malignant disease; (4) The pedicles or the back wall of the vertebra was broken; (5) Associated with spinal stenosis or disc herniation. (6) Fractures with lower limb symptoms.

Surgical procedures

The PKP procedure was performed by the same senior physician. Place the patient in the prone position, perform local anesthesia, and install a C-arm for guidance. Using a small incision, the working cannula is inserted into the vertebral body through the bilateral pedicle
approach. Through the working casing, the drill bit is advanced, creating a channel for the balloon. Depending on the size of the vertebral body (VB), a balloon with a diameter of 15 or 20 mm is used. The balloon is inserted into the cancellous bone of the vertebral body, and the contrast agent iohexol is injected through a high-pressure pump to slowly expand the balloon. Once a satisfactory Cobb angle and vertebral height relative to the preoperative level have been determined by C-arm radiography, the contrast agent is extracted and the balloon is deflated and removed. Perform the same operation on the other side of the vertebral body. Subsequently, PMMA was injected into the vertebral body under low pressure to fill the gap, and as far as possible to make the PMMA and the endplate fully contact. Finally, remove the working sleeve and close the skin entrance with a single suture. Record the operation time and bone cement injection data and compare them. The patient needs to rest in bed for 24 hours.

**Build a 3D model of the vertebral body and Finite element analysis**

Collecting CT imaging data of a volunteer, a total of 316 continuous cross-sectional CT images of 512 × 512 pixels were obtained, which were imported into Mimics software in DICOM standard format, and perform threshold segmentation on the vertebral body image to generate a mask of the bone part, edit the mask in multiple layers, repair its shape layer by layer, remove excess bone and fill in the pores. At the same time, the L2, L3, and L4 vertebral bodies are separated, and new masks are generated and three-dimensional calculations are performed. After reconstruction, the L2, L3, and L4 vertebral bodies are obtained and saved in STL format. Import the above STL files into the reverse engineering software Geomagic Studio at the same time for post-processing. Use commands such as manifold, remove features, delete nails, smooth noise reduction, and re-mesh to optimize the surface of the vertebral model. At the same time, the offset command was used for the L2, L3, and L4 vertebral body models, and the cancellous bone model was generated by offsetting 2 mm inward, and the surface was also optimized. Finally, edit the contour of the surface to construct a more accurate surface patch, and fit the solid model, and save the model in STP format. (Figure 1).

Import the above optimized L2, L3, L4 cortical and cancellous bone STP models into Solid works software to convert them into parts (SLDPRT format), and then assemble them through the insert part command. The cancellous bone model in the vertebral body is subtracted by Boolean operation to generate cortical bone models of the L2, L3, and L4 segments. Next, use the features and segmentation commands to generate the intervertebral disc (the nucleus pulposus and the annulus fibrosus are segmented by the curve), the articular cartilage, and the isometric surface commands to segment the upper and lower endplates of the cone (1 mm). A cylinder is generated by Solid works software to simulate the injected bone cement, and it is assembled in the vertebral body by placing it in the middle of the L3 cone or dividing it into two semi-cylinders and placing them on both sides of the L3 cone. After removing the excess bones by Boolean operation, the bone cement model is assembled in the cavity of the L3 vertebral body, thereby obtaining a strengthened three-dimensional model of the vertebral body. Finally, save the assembled whole 3D model (corresponding structure including cortical bone, cancellous bone, bone cement, endplate, intervertebral disc nucleus pulposus and annulus fibrosus) in STP format, and import Ansys finite element analysis software for biomechanical analysis. And then, supplement the main ligaments such as the anterior longitudinal ligament, posterior longitudinal ligament, ligament flavum, interspinous ligament,
supraspinous ligament, etc., and use spring elements to simulate the above-mentioned ligament structure. The material properties and mechanical properties of ligaments and cortical bone are shown in Table 1. The elastic modulus of cortical bone, cancellous bone, and endplate is lower than that of normal bone, which represents a bone condition of osteoporosis. Reducing these moduli will result in a decrease in overall compression stiffness, which makes the vertebral body more prone to vertebral compression fractures[23].

The above structures are simplified to isotropic homogeneous materials. The meshes, nodes and elements are generated by software. The endplate, articular cartilage and intervertebral disc are divided into 1mm grids, and cortical bone, cancellous bone and bone cement are divided into 3mm grids. The connection between endplate and vertebral body, endplate and intervertebral disc, articular cartilage and bone is defined as binding, and the connection between articular cartilage and articular cartilage is defined as frictionless. By fixing the lower endplate of the L4 vertebral body, five different loads were applied from the upper endplate of the L2 vertebral body: compression, forward bending, backward extension, rotation and lateral bending. Then use two different strengthening models of bone cement distribution for finite element analysis. Since the purpose of this study is to evaluate the overall biomechanical changes of the vertebral body, the overall von Mises stress on the L2, L3, and L4 vertebral bodies was calculated to evaluate the effect of bone cement strengthening. The finite element analysis model of the L2-L4 cone under different loads is similar to the model published in the literature[24]. According to the published finite element analysis model of the thoracolumbar spine of human cadavers[25], the normal model was verified by ANSYS. Apply 500N compression, forward bending, backward extension and lateral bending loads, and 7.5N•m torque to simulate daily activities, and extract the stress distribution nephogram of the vertebral body model in five motion states: compression, forward bending, backward extension, rotation and lateral bending.

**Postoperative outcome measurement**

All patients obtained lateral X-ray pictures to measure the recovery rate of vertebral body height and the degree of improvement of kyphotic angle. The recovery rate of vertebral body height is calculated as follows: (postoperative vertebral body height-preoperative vertebral body height)/(predicted primary vertebral body height-preoperative vertebral body height) × 100% (Figure 4). The estimated height of the primary vertebral body is the average height of the two vertebral bodies adjacent to the injured vertebral body. On the lateral X-ray image, the Cobb angle was measured from the upper end plate of the first vertebra above the treatment vertebra to the lower end plate of the first vertebra below the treatment vertebra (Figure 3). The improvement of the kyphotic angle is calculated as follows: preoperative Cobb angle-postoperative Cobb angle. The degree of focal back pain was assessed by the visual analog scale (VAS) (0 = no pain, 10 = most severe pain). The calculation method of the improvement of the VAS score is as follows: preoperative VAS-postoperative VAS.

Cement leakage is defined as the presence of any extravertebral high cement signal observed by X-rays. Fractures of the vertebral body adjacent to the injured vertebrae after surgery are defined as treatment of adjacent vertebral body fracture

**Data Analysis**

SPSS21.0 software was used for data analysis. Numerical variables are expressed as the mean ± standard deviation ( \( \bar{x} \pm S \)) and percentage, and independent sample t-test or t'-test
Chi square test was adapted to analyze the Count data variable. The statistical significance was set as \( P < 0.05 \).

**Results**

**General Information of Patients**

The demographic and parameter measurement study ultimately included 217 patients, 96 in the connection group and 121 in the unconnected group. For the connection group, there were 39 males and 57 females, with an average age of 69.9±7.8 years. The average bone mineral density T score was -3.2±0.6. For the non-connected group, there were 48 males and 73 females, with an average age of 70.4±9.2 years. The average bone mineral density T score was -3.0±0.7. In terms of patient demographics, there was no significant difference between the two groups \( (P>0.05) \) (Table 2).

**Surgical results and complications**

All patients successfully received PKP. The imaging shows that the injection of bone cement can effectively restore the height of the vertebral body, the kyphotic angle and the integrity of the endplate. The operation time, bone cement injection amount, improvement degree of kyphotic angle, vertebral height recovery rate, and VAS score of the two groups were not statistically significant \( (P>0.05) \). The operation time of the connected group was 36.2±5.8 minutes, the cement injection volume was 3.8±1.2 ml, and the unconnected group was 37.1±6.3 minutes, and the cement injection volume was 4.0±1.1 ml \( (P>0.05) \) (Table 3). There were 11 cases (5.1%) and 16 cases (7.4%) of patients with cement leakage and re-fracture of the injured vertebral body, respectively, and 23 cases (10.59%) of patients had fractures of adjacent vertebral bodies. There was no significant difference in the amount of bone cement leakage between the two groups \( (P>0.05) \), and there were significant differences in the incidence of re-fracture of the injured vertebrae and adjacent vertebral body fractures \( (P<0.05) \) (Table 4).

**Stress changes of fractured vertebral body**

As shown in Figure 5, comparing the stress distribution nephogram of two sets of vertebral models in the state of compression, forward bending, backward extension, lateral bending, rotation, it can be found that when compression, forward bending, backward extension, lateral bending, rotation, the stress distributions of the L2 and L3 vertebrae in the cement-connected group on both sides are more concentrated than those in the non-cemented group on both sides. In addition, the average stress of L2 and L3 vertebrae in the cement connection group on both sides is greater than the average stress of the cement unconnected group on both sides, and there is a significant difference between the stresses of the L2 and L3 vertebrae of the two vertebral body models under the same conditions. \( (P<0.05) \) (e.g. Table 5). At the same time, there is no significant difference in the stress distribution of the L4 vertebrae of the two groups of models in compression, forward bending, backward extension, rotation and lateral bending. There is also no significant difference between the stresses of the L4 vertebral bodies under the same conditions \( (P>0.05) \) (e.g., Table 5). All of this shows that under the same load, the stress of the fractured vertebral body and the adjacent vertebral body on the cranial side in the bone cement connection group is more concentrated. And there is a significant difference between the stress of the bone cement...
unconnected group, which may be one of the factors that cause the re-fracture of the fractured vertebrae and the new fracture of the adjacent vertebrae.

**Discussion**

Vertebral compression fractures often occur in the thoracolumbar vertebrae of the spine. It is one of the common complications of osteoporosis. It is more common in the elderly, especially in postmenopausal women[1,26]. The patient not only has persistent pain at the fracture site, but also accompanied by loss of vertebral body height, spinal instability and kyphosis, which seriously affects the quality of life[27]. Therefore, with the development of minimally invasive spinal surgery techniques, percutaneous kyphoplasty (PKP) has been widely used in the surgical treatment of OVCF patients. However, with the widespread application of PKP technology, the increased risk of adjacent vertebral fractures, re-collapse of the strengthened vertebral body, and high economic costs have gradually attracted people's attention[28-30]. Therefore, how to use PKP to treat osteoporotic vertebral compression fractures (OVCF) more efficiently to reduce the suffering of patients, obtain a better quality of life and reduce the economic burden of national medical insurance is the focus of our research.

Chen et al. through the inclusion of 8 eligible meta-analysis showed that unilateral and bilateral PKP can obtain similar good clinical and radiological results[31]. Zhang et al. through a retrospective study found that unilateral and bilateral PKP can improve the clinical symptoms of OVCF, and the vertebral body height can be effectively restored within at least 18 months after surgery[32]. JIN et al. found that only 30% of the amount of bone cement can restore the compressive stiffness of the osteoporotic vertebral body to the normal range. As the volume of bone cement exceeds 30%, the hardness further increases, but it may cause subsequent fractures of adjacent vertebral bodies, and most likely to occur on the cranial side[33]. This is consistent with the conclusion drawn in this study. Michael et al. also believe that a large filling volume may not be the best biomechanical configuration. Overfilling may cause the vertebral body to be more sensitive to bone cement, which can be improved by using a symmetrically placed lower cement volume[34]. That is to say, the amount of bone cement has a significant impact on the occurrence of subsequent vertebral body fractures after vertebroplasty. Although the increase in the amount of bone cement may help the recovery of vertebral body height, it may also be a risk factor for adjacent vertebral body fractures. He & Li et al. found that a small cement volume with a wide distribution has the same restoration effect as a large cement volume with a limited distribution. When the volume of the bone cement does not change, the wide bone cement distribution can effectively improve the kyphosis angle and the height of the vertebral body, and Will not cause bone cement leakage or adjacent vertebral fractures[15]. Kim & Todd believe that if bone cement touches the two end plates, the pressure transmitted through the non-cemented area will be reduced[19]. These findings support the basic idea of load sharing. Therefore, in this study, without causing bone cement leakage, the bone cement should be distributed as evenly and symmetrically as possible, and in contact with the upper and lower endplates. A biomechanical study showed that as the load of the vertebral body continues to increase, the maximum point of vertebral body collapse is always located in the center of the vertebral body, and is usually the strongest in the center of the cranial endplate[35]. Studies have also shown that the cranial endplates are more susceptible to
compression injuries than the caudal endplates because they are thinner and are supported by lower density trabecular bone\[36\]. Hou et al.'s study on the structure of the endplate showed that the peripheral cortex of the lumbar endplate is thicker than the central cortex, forming a ring-shaped protrusion, and the central area is a porous structure, that is, the central endplate is the weakest area, and in the upper lumbar spine endplate and the lower lumbar spine endplate, there are significant differences between the lumbar spine segments, from L1 to L5, the failure load tends to increase \[37\]. In this study, on the basis of full contact between the bone cement and the endplate, if the bilateral bone cement is symmetrically distributed on both sides of the vertebral body, the pressure on the vertebral body will be transmitted to the lower lumbar spine through the bone cement on both sides, thereby reducing the pressure in the central area, protecting the weak area in the center of the endplate, and reducing the risk of the injured vertebrae collapsing again.

In the study of bone biomechanics, the finite element method can simulate and analyze human bones, muscles, ligaments and other tissues, especially in the stress and strain analysis of the internal structure of the bone under load, which effectively makes up for the shortcomings of traditional biomechanical methods. It has deepened people's understanding of the biomechanical behavior of the spine and has incomparable advantages\[20,38,39\]. But as a computer-simulated biomechanical experiment, it has its inherent shortcomings, such as excluding differences in soft tissue anatomy and complex movements of the spine, etc., and this study simplifies the nonlinear characteristics of ligaments, and excludes the effects of skin and fat.

All in all, the purpose of this study is to evaluate the relationship between the different distribution of bilateral bone cement in bilateral PKP surgery and the outcome of the operation and postoperative complications. A total of 217 patients were eventually included in the study. The difference between the two groups of patients before and after the VAS score, the recovery rate of vertebral body height and the recovery of Cobb angle were not statistically significant (P>0.05) In the case of no significant difference in the bone cement exudation rate between the two groups of patients, the risks of re-collapse of the injured vertebrae and adjacent vertebral fractures are significantly different. This has attracted our attention. Therefore, this study constructed three-dimensional models of L2~L4 vertebral bodies, and under the ideal distribution of bone cement, the five motion states of compression, forward bending, backward extension, rotation and lateral bending of the two groups of bilateral PKP postoperative three-dimensional finite element vertebral body models were simulated respectively. Then, the stress of the two groups of fractured vertebrae and adjacent vertebrae were measured respectively, and it was found that under these five motion states, the stress distributions of the L2 and L3 vertebrae in the cement-connected group on both sides are more concentrated than those in the non-cemented group on both sides. In addition, the average stress of L2 and L3 vertebrae in the cement connection group on both sides is greater than the average stress of the cement unconnected group on both sides, and there is a significant difference between the stresses of the L2 and L3 vertebrae of the two vertebral body models under the same conditions. (P<0.05). At the same time, there is no significant difference in the stress distribution of the L4 vertebrae of the two groups of models in compression, forward bending, backward extension, rotation and lateral bending. There is also no significant difference between the stresses of the L4 vertebral bodies under the same conditions (P>0.05).
The above results all indicate that when performing bilateral kyphoplasty, connecting bilateral cement will increase the stress of the original fractured vertebral body and the adjacent vertebral body on the cranial side, thereby increasing the risk of recurrent vertebral body fractures. Therefore, there is no significant effect on the connection of bilateral bone cement in the clinical operation to reduce the patient's pain, improve the recovery of the vertebral body height and the recovery of the Cobb angle (P>0.05), but if we want to avoid as much as possible for re-collapse of the vertebral body and new fractures of the adjacent vertebral body, the bilateral cement should be in full contact with the upper and lower endplates of the vertebral body as much as possible. But if we want to avoid re-collapse of the original fractured vertebral body and new fractures of the adjacent vertebral body as much as possible, we should make the bilateral cement fully contact with the upper and lower endplates of the vertebral body respectively, so as not to create a connection, then the pressure transmitted through the non-cemented area will be reduced, which will produce The stress shielding effect and then the collapse of the non-cemented area caused by the excessive pressure will be reduced, so as to reduce the risk of re-collapse of vertebral body and achieve better surgical results.

This research still has some shortcomings: 1. The three-dimensional finite element model of the lumbar spine failed to fully simulate the real changeable distribution of bone cement. This study only analyzed the stress changes under the standard distribution of bone cement. 2. It is impossible to avoid the influence of bone hyperplasia and degenerative diseases on modeling and analysis in elderly patients, and the above-mentioned diseases are common and different in elderly patients with osteoporosis, so it cannot completely simulate the stress of the original fractured vertebral body and adjacent vertebral bodies after vertebroplasty, which has certain limitations. 3. This study did not measure the stress changes of non-adjacent segments, and did not perform real human specimen measurement verification, which can be improved in the next study. 4. The vertebral body and the stress condition of the human body in each movement state in daily life cannot be accurately simulated, only the stress analysis of the specific motion state is carried out in the ideal condition, which has some limitations.

Conclusion

Whether the bilateral bone cement is connected or not, bilateral percutaneous kyphoplasty treatment of OVCF can provide better vertebral strength, vertebral height restoration rate and Cobb angle improvement, reduce patient suffering, and improve patient survival quality. However, under the condition of no cement leakage during bilateral PKP surgery, the bilateral bone cement should be in full contact with the upper and lower endplates, and they should be located on both sides of the vertebral body, so as not to produce connections, so as to reduce the probability of re-collapse of the injured vertebrae and the risk of fractures of the adjacent vertebral body on the head side to achieve better postoperative results.

Abbreviations

PKP: percutaneous kyphoplasty; OVCF: osteoporotic vertebral compression fractures; BMD: bone mineral density; PMMA: polymethyl methacrylate; PVP: percutaneous vertebroplasty.
Acknowledgements
Not Applicable.

Authors’ contributions
ZY analyzed, and interpreted the data and wrote the draft. LD, ZXY collected the data and made the chart, LZY, SH, MXS performed a mechanical analysis. FLH, SQC, SZB performed the surgery, designed the protocol, revised the draft. All the authors have read and approved the final manuscript.

Funding
The present study was funded by the National Natural Science Foundation of China, (grant no. 82002311).

Availability of data and materials
The datasets used during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate
After providing all the enrolled patients with detailed information about the surgical procedure, their written informed consent was obtained. All procedures are carried out in accordance with the "Helsinki Declaration" of the World Medical Association. The study was approved by the Medical Ethics Committee of Xi’an Jiao tong University.

Consent for publication
Not Applicable.

Competing interests
There is no conflict of interest in this article.

Reference
1. Johnell O, Kanis J. Epidemiology of osteoporotic fractures. Osteoporos Int 2005;16 Suppl 2:S3-7.
2. Lange A, Zeidler J, Braun S. One-year disease-related health care costs of incident vertebral fractures in osteoporotic patients. Osteoporosis International 2014;25(10):2435-43.
3. Bonnick SL. Osteoporosis in men and women. Clinical cornerstone 2006;8(1):28-39.
4. Jackson A, Wasfie T, Brock C, Galovska S, Smalley M, Grundman K, et al. Fragility Vertebral Compression Fractures in Postmenopausal Women: The Role of a Fracture Liaison Service Program. American Surgeon 2020;86(12):1636-39.
5. Kim B, Kim J, Jo YH, Kang SH, Lee YJ, Lee JH, et al. Risk of Pneumonia After Vertebral Compression Fracture in Women With Low Bone Density: A Population-Based Study. Spine (Phila Pa 1976) 2018;43(14):E830-E35.
6. Huang CH, Wang WH, Kor CT, Hsiao CH, Chang CC. Risk of venous thromboembolism in elderly patients with vertebral compression fracture: A population-based case-control study.
7. Bo M, Cacello E, Ghiggia F, Corsinovi L, Bosco F. Predictive factors of clinical outcome in older surgical patients. Arch Gerontol Geriatr 2007;44(3):215-24.

8. Garfin SR, Yuan HA, Reiley MA. New technologies in spine - Kyphoplasty and vertebroplasty for the treatment of painful osteoporotic compression fractures. Spine 2001;26(14):1511-15. [English].

9. Chen AT, Cohen DB, Skolasky RL. Impact of nonoperative treatment, vertebroplasty, and kyphoplasty on survival and morbidity after vertebral compression fracture in the medicare population. J Bone Joint Surg Am 2013;95(19):1729-36.

10. Lee JK, Jeong H-w, Joo I-H, Ko Y-I, Kang C-N. Percutaneous balloon kyphoplasty for the treatment of very severe osteoporotic vertebral compression fractures: a case-control study. The Spine Journal 2018;18(6):962-69.

11. Yang H, Chen L, Zheng Z, Yin G, Lu W, Wang G, et al. Therapeutic effects analysis of percutaneous kyphoplasty for osteoporotic vertebral compression fractures: A multicentre study. Journal of orthopaedic translation 2017;11:73-77.

12. Lieberman IH, Togawa D, Kayanja MM. Vertebroplasty and kyphoplasty: filler materials. Spine J 2005;5(6 Suppl):305S-16S.

13. Yu W, Xu W, Jiang X, Liang D, Jian W. Risk Factors for Recollapse of the Augmented Vertebrae After Percutaneous Vertebral Augmentation: A Systematic Review and Meta-Analysis. World Neurosurgery 2018;111:119-29.

14. Lv B, Ji P, Fan X, Yuan J, Xu T, Yao X, et al. Clinical Efficacy of Different Bone Cement Distribution Patterns in Percutaneous Kyphoplasty: A Retrospective Study. Pain physician 2020;23(4):E409-E16.

15. He X, Li H, Meng Y, Huang Y, Hao D, Wu Q, et al. Percutaneous Kyphoplasty Evaluated by Cement Volume and Distribution: An Analysis of Clinical Data. Pain Physician 2016;19(7):495-506.

16. Wang C, Zhang X, Liu J, Shan Z, Li S, Zhao F. Percutaneous kyphoplasty: Risk Factors for Recollapse of Cemented Vertebrae. World neurosurgery 2019;130:e307-e15.

17. Yu WB, Jiang XB, Liang D, Xu WX, Ye LQ, Wang J. Risk factors and score for recollapse of the augmented vertebrae after percutaneous vertebroplasty in osteoporotic vertebral compression fractures. Osteoporos Int 2019;30(2):423-30.

18. Tan L, Wen B, Guo Z, Chen Z. The effect of bone cement distribution on the outcome of percutaneous Vertebroplasty: a case cohort study. BMC Musculoskelet Disord 2020;21(1):541.

19. Kim MJ, Lindsey DP, Hannibal M, Alamin TF. Vertebroplasty versus kyphoplasty: Biomechanical behavior under repetitive loading conditions. Spine 2006;31(18):2079-84.

20. El Bojairami I, El-Monajjed K, Driscoll M. Development and validation of a timely and representative finite element human spine model for biomechanical simulations. Sci Rep 2020;10(1):21519.

21. Kim YH, Khuyagbaatar B, Kim K. Recent advances in finite element modeling of the human cervical spine. J Mech Sci Technol 2018;32(1):1-10. [English].

22. Xu M, Yang J, Lieberman I, Haddas R. Lumbar spine finite element model for healthy subjects: development and validation. Computer methods in biomechanics and biomedical engineering 2017;20(1):1-15.
23. Polikeit A, Nolte LP, Ferguson SJ. The effect of cement augmentation on the load transfer in an osteoporotic functional spinal unit - Finite-element analysis. Spine 2003;28(10):991-96. [English].

24. Zhang L, Yang G, Wu L, Yu B. The biomechanical effects of osteoporosis vertebral augmentation with cancellous bone granules or bone cement on treated and adjacent non-treated vertebral bodies: a finite element evaluation. Clin Biomech (Bristol, Avon) 2010;25(2):166-72.

25. Xu G, Fu X, Du C, Ma J, Li Z, Ma X. Biomechanical effects of vertebroplasty on thoracolumbar burst fracture with transpedicular fixation: a finite element model analysis. Orthop Traumatol Surg Res 2014;100(4):379-83.

26. Jordan KM, Cooper C. Epidemiology of osteoporosis. Best Pract Res Clin Rheumatol 2002;16(5):795-806. [English].

27. Adachi J, Ioannidis G, Olszynski W, Brown J, Hanley D, Sebaldt R, et al. The impact of incident vertebral and non-vertebral fractures on health related quality of life in postmenopausal women. BMC musculoskeletal disorders 2002;3:11.

28. Feng L, Feng C, Chen J, Wu Y, Shen JM. The risk factors of vertebral refracture after kyphoplasty in patients with osteoporotic vertebral compression fractures: a study protocol for a prospective cohort study. BMC Musculoskeletal Disorders 2018;19(1):195.

29. Lee BG, Choi J-H, Kim D-Y, Choi WR, Lee SG, Kang C-N. Risk factors for newly developed osteoporotic vertebral compression fractures following treatment for osteoporotic vertebral compression fractures. The Spine Journal 2019;19(2):301-05.

30. Yang D, Zhang Y, Ma X, Huo L, Li L, Gao Y. Resources utilisation and economic burden of percutaneous vertebroplasty or percutaneous kyphoplasty for treatment of osteoporotic vertebral compression fractures in China: a retrospective claim database study. BMC Musculoskeletal Disorders 2020;21(1):255.

31. Chen X, Guo W, Li Q, Ou Z, Lao Z, Liu Y, et al. Is Unilateral Percutaneous Kyphoplasty Superior to Bilateral Percutaneous Kyphoplasty for Osteoporotic Vertebral Compression Fractures? Evidence from a Systematic Review of Discordant Meta-Analyses. Pain Physician 2018;21(4):327-36.

32. Zhang B, Dai M, Tang YM. Unilateral Versus Bilateral Kyphoplasty for Osteoporotic Vertebral Compression Fractures. Advanced Materials Research 2011;393-395:1064-68.

33. Kim J-M, Shin DA, Byun D-H, Kim H-S, Kim S, Kim H-I. Effect of Bone Cement Volume and Stiffness on Occurrences of Adjacent Vertebral Fractures after Vertebroplasty. Journal of Korean Neurosurgical Society 2012;52(5):435.

34. Liebschner M, Rosenberg W, Keaveny T. Effects of bone cement volume and distribution on vertebral stiffness after vertebroplasty. Spine 2001;26(14):1547-54.

35. Lu Q, Liu C, Wang D, Liu H, Yang H, Yang L. Biomechanical evaluation of calcium phosphate-based nanocomposite versus polymethylmethacrylate cement for percutaneous kyphoplasty. The Spine Journal : official journal of the North American Spine Society 2019;19(11):1871-84.

36. Zhao FD, Pollintine P, Hole BD, Adams MA, Dolan P. Vertebral fractures usually affect the cranial endplate because it is thinner and supported by less-dense trabecular bone. Bone 2009;44(2):372-9.

37. Hou Y, Luo Z. A Study on the Structural Properties of the Lumbar Endplate Histological
38. Goel VK, Kong WZ, Han JS, Weinstein JN, Gilbertson LG. A COMBINED FINITE-ELEMENT AND OPTIMIZATION INVESTIGATION OF LUMBAR SPINE MECHANICS WITH AND WITHOUT MUSCLES. Spine 1993;18(11):1531-41.

39. Dietrich M, Kedzior K, Zagajek T. A biomechanical model of the human spinal system. Proceedings of the Institution of Mechanical Engineers Part H, Journal of engineering in medicine 1991;205(1):19-26.
**Figure legends:**

**Fig.1:** Establish finite element model. A, the three-dimensional model of the spine (L2, L3, L4); B, the model of the vertebral body model divided by finite element cells; C, the schematic diagram of the bilateral bone cement unconnected group and bone cement connection group. The unit consists of three segments (L2, L3, L4) and bone cement is inserted into L3.

**Fig2:** Postoperative X-ray and CT Imaging. A and B, the bilateral cement-connected group; D and E, the bilateral cement-unconnected group; C, the CT imaging of the bilateral cement connected group; D, the CT imaging of the bilateral cement-unconnected group.

**Fig3:** Measure the Cobb angle. Line A is the parallel line of the upper end plate of the first vertebra above the fracture vertebra and Line B is the parallel line of the lower end plate of the first vertebra below the fracture vertebra. The Cobb angle is the angle between A and B.

**Fig4:** Measurement of vertebral height recovery. Calculate the vertebral height recovery rate, B2 and C2 are equal to (B1+B3)/2 and (C1+C3)/2, which represent the preoperative vertebral height and postoperative vertebral height, respectively. The vertebral height recovery rate is calculated as follows: (Postoperative vertebral body height-preoperative vertebral body height) / (predicted primary vertebral body height-preoperative vertebral body height) x 100%. The predicted height of the primary vertebral body is the average of the heights of the two vertebral bodies adjacent to the injured vertebra.

**Fig5:** The stress distribution nephogram of L2, L3, and L4. A, the stress distribution nephogram of L2, L3, and L4 when simulating compression, forward bending, backward extension, rotation and lateral bending under the condition of bilateral cement connection; B, the stress distribution nephogram of L2, L3, and L4 when simulating compression, forward bending, backward extension, lateral bending, and rotation motion states when the bilateral bone cement is not connected.
Figure 1

Establish finite element model. A, the three-dimensional model of the spine (L2, L3, L4); B, the model of the vertebral body model divided by finite element cells; C, the schematic diagram of the bilateral bone cement unconnected group and bone cement connection group. The unit consists of three segments (L2, L3, L4) and bone cement is inserted into L3.
Figure 2

Postoperative X-ray and CT Imaging. A and B, the bilateral cement-connected group; D and E, the bilateral cement-unconnected group; C, the CT imaging of the bilateral cement connected group; D, the CT imaging of the bilateral cement-unconnected group.
Figure 3

Measure the Cobb angle. Line A is the parallel line of the upper end plate of the first vertebra above the fracture vertebra and Line B is the parallel line of the lower end plate of the first vertebra below the fracture vertebra. The Cobb angle is the angle between A and B.
Figure 4

Measurement of vertebral height recovery. Calculate the vertebral height recovery rate, B2 and C2 are equal to \((B1+B3)/2\) and \((C1+C3)/2\), which represent the preoperative vertebral height and postoperative vertebral height, respectively. The vertebral height recovery rate is calculated as follows: \((\text{Postoperative vertebral body height} - \text{preoperative vertebral body height}) / (\text{predicted primary vertebral body height} - \text{preoperative vertebral body height}) \times 100\%\). The predicted height of the primary vertebral body is the average of the heights of the two vertebral bodies adjacent to the injured vertebra.

Figure 5

The stress distribution nephogram of L2, L3, and L4. A, the stress distribution nephogram of L2, L3, and L4 when simulating compression, forward bending, backward extension, rotation and lateral bending under the condition of bilateral cement connection; B, the stress distribution nephogram of L2, L3, and L4 when simulating compression, forward bending, backward extension, lateral bending, and rotation motion states when the bilateral bone cement is not connected.