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Biomechanical study of space frame structure based on bone cement screw

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Abstract. Stability of space frame structures with bone cement screw reinforcement by biomechanical testing was analyzed. Seven complete human spine specimens with osteoporosis were selected. Three specimens were separated into 18 vertebral bodies. Nine vertebral bodies were randomly selected and bone cement screws were implanted on both sides. Bone cement was used to form a bridge at the front end of the two screws (single vertebral group A). The other nine vertebral bodies were implanted with cement screws on both sides, but the front ends of the two screws were not bridged (single vertebral group B). The remaining spine specimens were used for biomechanical testing of the overall stability of the three-dimensional frame. The four specimens were osteotomized, and then two specimens were randomly selected. Bone cement screws were implanted on both sides of the vertebral body, and a bone cement bridge was formed at the front end of the two screws to establish a three-dimensional frame structure (multi-vertebral group A). The other two spine specimens were implanted with cement screws on both sides of the vertebral body, but the front ends of the two screws were not bridged (multi-vertebral group B). A statistical difference was found between the extractive force of bridged and non-bridged specimens. Group B showed some loosening of screws after the test. The stability of the triangle structure screw, which was formed after the bridge was established at the front end of the single-vertebral bone cement screw, was significantly enhanced. Moreover, the stability was significantly improved after the three-dimensional frame structure was established in the multi-vertebral body group, providing a new method for clinical improvement of the stability and reliability of internal fixation in patients with severe osteoporosis and spinal disease.

Introduction

Osteoporosis is a common disease in the elderly, and its incidence continues to rise. With the aging of the population in China, there are increasing number of patients with osteoporosis. For spinal surgeons, internal fixation (1) is a routine treatment for osteoporosis requiring nerve decompression and instrumented fusion such as posterior lumbar interbody fusion (PLIF), which enables successful fusion of the spine. The posterior spinal instrumentation subjects the pedicle screw-bone interface to greater stress and affects the stability of the pedicle screw. A number of studies have shown that the stability of pedicle screws depends on the quality of the bone, so patients with osteoporosis are more prone to instrumentation failure (2-4). At present, fatigue tests and withdrawal force testing of screws at different bone densities indicate that the quality of the compact trabecular bone enhances firm fixation of the screws, and osteoporosis increases the failure rate of the internal fixation (5-10). The cement-reinforced [e.g. polymethylmethacrylate (PMMA) or calcium-based bone cement] pedicle screw technology can enhance the stability of the internal fixation system. However, after the bone cement is strengthened, loosening of the screws may occur again.

In order to address this problem, a new type of spine-expansion pedicle screw was invented by Lei and Wu (11). According to a large number of experimental studies on the biomechanics of animal vertebral specimens, it was found that the axial withdrawal force of the new expandable pedicle screws is significantly enhanced compared with the conventional pedicle screw. In a large number of intact animal experiments (12), the new expandable pedicle screws and bone formed a staggered structure, which increased the stability of the screw. This type of expansion screw has been shown to be safe, effective, and practical through biomechanical testing, imaging evaluation, and epidemiological investigation (13). The expansion screw has obtained a number of patents and is used in clinical practice (14). Following the development of the expansion screw, we also developed a composite screw-bone cement anchor bolt, and biomechanical and animal experiments have proven that this new bone cement screw has good fixation strength and low cement leakage rate (15), but it is not effective for complex osteoporosis. We therefore established a three-dimensional frame structure to ensure stability. This

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study analyzed the stability of a three-dimensional frame structure based on cemented screw reinforcement through biomechanical testing.

Materials and methods

Screws and augmentation materials. A composite threaded bone cement anchoring screw (Shandong Weigao Orthopedic Device Company) was used. The details of the screw: diameter 6.5 mm x length 45 mm, proximal 9 threads, distal 10 threads, total 19 threads. The thread density is increased at the proximal end. At the distal end the depth of the thread is increased, the pitch is increased, and a V-shaped nail is present. The screw is hollow with an inner diameter of 1.6 mm. The screw has a total of 6 side holes, with the side holes enlarged from the proximal end to the distal end. The two apertures are symmetrically distributed within one thread. Mendec Spine PMMA bone cement is produced by TECRES. Denture base material resin type II was used (self-curing denture acrylic: 100 g x 7 bottles and liquid for denture acrylic 500 ml x 1 bottle) Shanghai Medical Devices Co., Ltd. holding.

Specimen. Seven intact human spine specimens (T12-L5) from people with an average age of 72 years were used. The bone mineral density of the specimens was detected by dual energy X-ray absorptiometry (DEXA method). The test results showed that all of the specimens were osteoporotic.

The study was approved by the Ethics Committee of Xijing Hospital (Xi'an, China), and written informed consents were signed by the patients and/or the guardians.

Experimental apparatus. Screw insertion devices including hole openers, hand drills, nail holders, staple handles and other instruments were provided by Shandong Weigao Orthopedic Device Co., Ltd. Digital X-ray machines (Philips) and 64-row spiral CT (Picker PQ6000) were provided by the Department of Radiology of the Fourth Military Medical University. The biomechanical experimental instrument was a microcomputer-controlled electronic universal testing machine, provided by the Mechanics Laboratory of the Mechanical College of Xi'an Jiaotong University.

Methods

Experimental grouping. Three specimens were separated into 18 vertebral bodies for the biomechanical testing of a single screw. Nine vertebral bodies were randomly selected and bone cement screws were implanted on both sides. Bone cement was used to form a bridge at the front end of the two screws (single vertebral group A).

The other nine vertebral bodies were implanted with cement screws on both sides, but the front ends of the two screws were not bridged (single vertebral group B).

The remaining spine specimens were used for biomechanical testing of the overall stability of the three-dimensional frame.

The four specimens were osteotomized, then two specimens were randomly selected. Bone cement screws were implanted on both sides of the vertebral body, and a bone cement bridge was formed at the front end of the two screws to establish a three-dimensional frame structure (multi-vertebral group A).

Table I. Experimental grouping.

Group	Group A	Group B
Single vertebral	9 (triangular stable structure)	9
Multi-vertebral	2 (three-dimensional frame)	2

The other two spine specimens were implanted with cement screws on both sides of the vertebral body, but the front ends of the two screws were not bridged (multi-vertebral group B) (Table I).

Screw placement. According to the standard surgical procedure for this clinical operation, following the herringbone crest vertex technique, the specimen was first fixed, and an open cone was used to punch the vertex of the specimen at the Herringbone crest vertex. A nail path was prepared with a depth of 40 mm and perpendicular to the side of the specimen. A composite threaded bone cement anchoring screw was inserted into the cancellous bone of the specimen at an angle to the vertebral specimen until the screw was fully screwed into the specimen. During the screw placement process, the vertebral specimen should be prevented from moving as that would destroy the structure. The experimental vertebral specimens could not be pre-tapped to avoid affecting the stability of the screws. The PMMA bone cement powder and the water agent were uniformly mixed in the formulated ratio, and the mixture was injected into the injection device during the spinning period. During the cement injection process, the bone cement flows out from the side holes and diffuses into the cancellous bone around the screw. Attention should be paid to the presence or absence of bone cement leakage from the rear end of the screw. The above operations of screw placement were performed by a clinically experienced spine surgeon. Following the methodology of a previous study, all vertebral bodies were infused with 2.5 PMMA for intensification, and the amount of bone cement in the hollow part of the screw was subtracted (Fig. 1).

Radiographic evaluation. When the bone cement screw placement and bone cement filling of the vertebral body specimens was completed, the vertebral body specimens were allowed to stand at room temperature for 24 h. After the bone cement in the vertebral body specimen was completely solidified, CT scanning was performed using an X-ray machine and 64-slice spiral CT (parameter: 200 mA, 130 KV, 1 mm slice thickness). In the later stage of the experiment, the three-dimensional reconstruction of the bone cement screw and the bone cement was performed using Mimics software, and the positional relationship of the bone cement screw, the bone cement and the cancellous bone of the vertebral body specimen was observed. In this way, the shape of the bone cement in the vertebral body, the position of the cement screw, and whether the bone cement screw and the bone cement formed a bridge were studied.

The axial withdrawal force test. The axial pull-out force experiment was performed on a single vertebral specimen with the help of a microcomputer-controlled electronic universal testing machine. The vertebral body specimen was attached to a special fixture, which was then fixed to the base

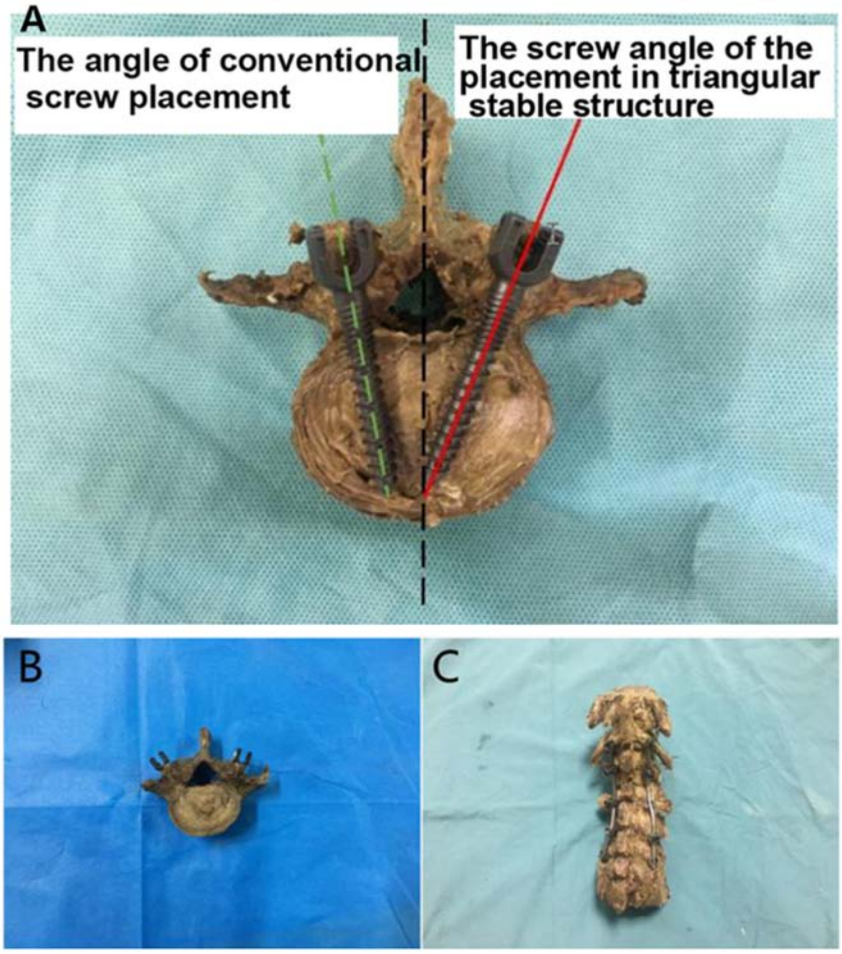

Figure 1. Screw placement. (A) Forming a triangular stable structure with a larger nail angle than the conventional nail angle (the red solid line). (B) Specimen of a single vertebral group. (C) Specimens of multiple vertebral bodies.

of the testing machine. The direction of the specimen was adjusted so that the long axis direction of the bone cement screw was consistent with the direction of the robot arm of the testing machine. The arms and screw tails were secured by the upper clamp. The extraction rate of the cement screw was set to a constant rate of 5 mm/min, and continued until the pull-out force decreased, indicating that the cement screw was completely withdrawn. The computer automatically recorded the load signal data of the test machine and generated the load-displacement curve. The maximum pullout strength (Fmax) of the cement screw was calculated by the corresponding computer software (Fig. 2).

Cyclic loading test. Four spine specimens of multiple vertebral bodies were embedded, and the lower end of the spine specimen was trimmed, keeping the specimen erect and slightly forward. The specimen was placed in an 8.6 cm-diameter embedding tank, and embedded in a ratio of 2:1 with 100 g of a foundation base material resin type II (self-curing denture acrylic) and 100 ml of liquid for denture acrylic. The specimen was kept up and down horizontally for self-condensation. The specimen was then fixed on a LETRY biomechanical fatigue testing machine. The upper end of the specimen was fixed to the center of the groove of the embedding block to provide an anterior flexion load for the test, and the angle of the vise was adjusted to form the flexion angle required for the cyclic load test. The fatigue testing machine was set to a cyclic loading state with the following loading schedule: 3 h total, cycle of 60/min, 10,000 revolutions, initial pressure of 300 N, peak pressure of 3,000 N, front flexion of 8° (Fig. 3).

Statistical analysis. The axial withdrawal force and cyclic load experimental data were analyzed by SPSS 13.0 statistical software. The measurement data were expressed as average ± standard deviation (mean ± SD). Two independent sample t-tests were used for comparison between groups. $P<0.05$ was considered statistically significant.

Results

Imaging results. Through imaging analysis, all 9 specimens of the single vertebral body group A were seen to have formed a triangular stable structure by increasing the angle during the process of screw placement. Nine specimens of the single vertebral body group B were prepared according to the conventional screw placement and did not have a front end bridge. In the multi-vertebral group A (stereoscopic frame structure), the three-dimensional frame structure was observed. The absence of obvious bone cement leakage was confirmed by X-ray and CT three-dimensional reconstruction. The multi-vertebral group B did not have a three-dimensional frame structure (Fig. 4).

Figure 2. Axial pullout force test. The pull-out force is coaxial with the screw. The extraction rate of the cement screw was set to a constant rate of 5 mm/min, and continued until the pull-out force decreased, indicating that the cement screw was completely withdrawn.

The result of maximal axial pull-out strength test. The maximal pull-out force of the single-vertebral group A, the screw front-end bridging group, was experimentally measured as 1395.693±85.775. The maximal pull-out force of the single-vertebral group B was 889.62±63.5. A statistically significant difference ($P<0.05$) was found. The triangular structure of the single vertebral body group A was stable, so the maximum extraction force of the pedicle screw was higher.

The result of cyclic loading test. After the cyclic load test, the strain and displacement of both groups increased, the stiffness decreased, and the stability of the entire lumbar vertebra decreased. However, by comparing the two groups, it was found that the screws of multi-vertebral group A (stereoscopic frame) did not loosen (Fig. 4I), while screw loosening occurred in multi-vertebral group B (Fig. 4J). When compared with multi-vertebral body group B, the stability of the spine in multi-vertebral group A is better. As the cyclic loading force increases, this trend tends to be obvious. The reason may be that an osteotomy specimen is used for testing, which can more realistically simulate the clinical situation. The biomechanical effects of the specimens are less pronounced when subjected to smaller cyclic loads. As the cyclic load increases, the influence becomes increasingly obvious, resulting in the biomechanical instability of the spine and screw loosening.

Figure 3. Cyclic load test. Cyclic compressive loading was performed vertically aligned along the vertebral axis. The fatigue testing machine was set to a cyclic loading state with the following loading schedule: 3 h total, cycle of 60/min, 10,000 revolutions, initial pressure of 300 N, peak pressure of 3,000 N, front flexion of 8˚.

Discussion

An increasing challenge in spinal surgery is to achieve optimal fixation of pedicle screws in poor bone conditions, such as severe osteoporosis.

The restricted area is still a problem for some patients with complex osteoporosis. In this study, the theory of triangular stability of the single vertebral body was proposed, and a three-dimensional framework structure was used to solve this medical problem.

Studies have shown that under normal physiological conditions, the various structures of the spine maintain their normal positional relationship with each other and do not cause compression and damage to the spinal cord or spinal nerve roots, which is called 'clinical stability'. When the spine loses this function, it is termed 'clinical instability'. The common method of internal fixation cannot be used to sustain the stability of a spine that is destroyed through serious osteoporosis and spinal deformity.

This study proposes a theory that the triangular stability of a single vertebral body and the three-dimensional frame structure of multiple vertebral bodies can achieve the stability of spinal internal fixation. The structure of internal fixation used in clinical practice has been considered as a quadrilateral structure of a single vertebral body. However, a triangle is more stable compared with a quadrilateral when the edge length and three angles of the triangle are fixed. As early as 1303, Zhu Shijie, an outstanding Chinese mathematician, published this famous theory of triangles in his writing named Jade Mirror of the Four Unknowns. When the two edges of a triangle are selected randomly and the non-common endpoints of the two edges are connected by the third side that is not flexible or bent,

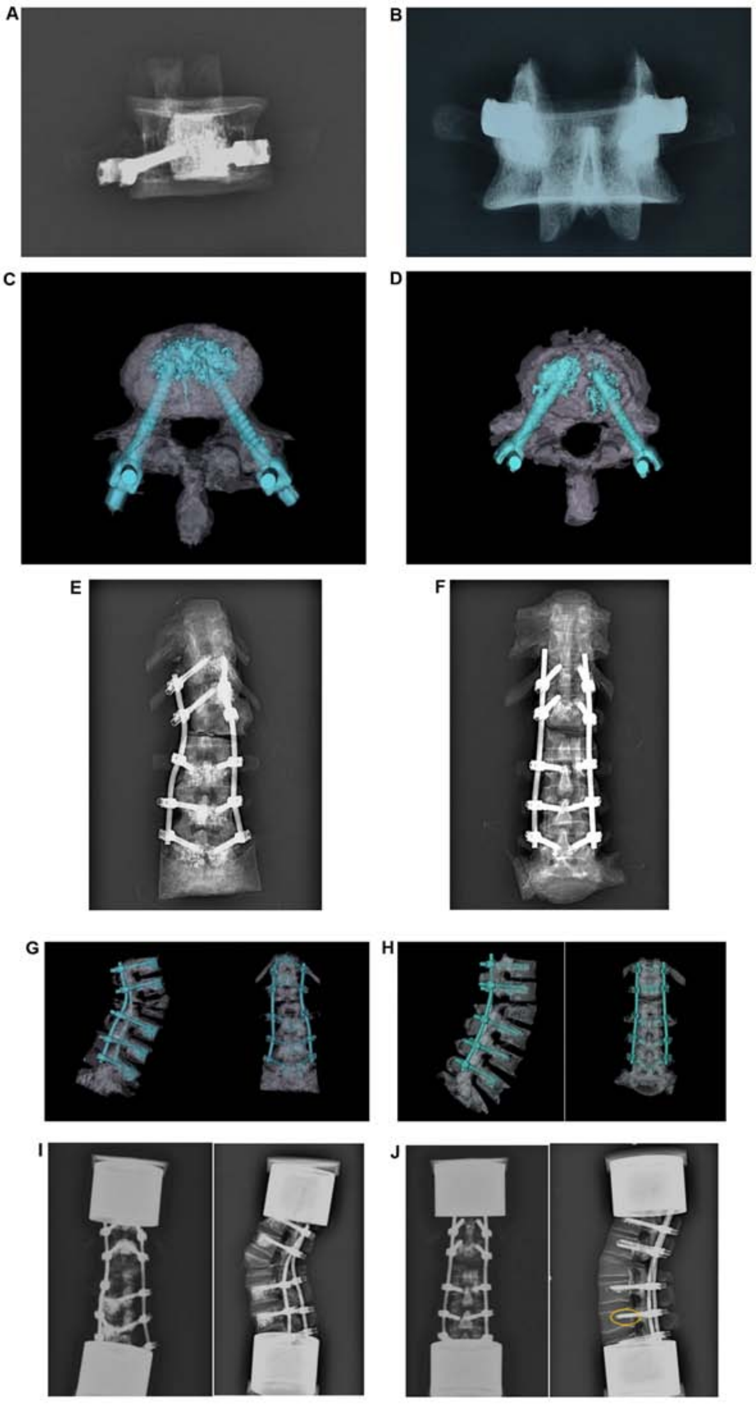

Figure 4. Imaging analysis. (A) Single vertebral body without triangular stabilizing structure (increase the angle of the nail). The X-ray film shows the bone cement at the front of the screw to establish the bridge. (B) Single vertebral body without triangular stabilizing structure (screw placement in conventional angle). The X-ray shows that the cement at the front of the screw does not establish a bridge. (C) The end of screw front with bridge CT. The results showed that a bridge was built on the front end of 2 screws. (D) The end of screw front without bridge CT. The results showed that the front end of 2 screws was not bridged. (E) Multi-vertebral group A. X-ray examination was performed after osteotomy and screw placement, and it was found that the bone cement at the front of each group of screws established a bridge and formed a three-dimensional frame structure. (F) Multi-vertebral group B. X-ray examination after osteotomy and screw placement showed that no bridging was established at the front of each group of screws and no stereoscopic frame structure was formed. (G) Multi-vertebral group A. After osteotomy and screw placement, CT 3d reconstruction was performed, and no bone cement leakage was observed after 3d reconstruction. The bone cement at the front end of each screw was bridged to form a three-dimensional frame structure. (H) Multi-vertebral group B. CT 3d reconstruction was performed after osteotomy and screw placement, and no bone cement leakage was observed after 3d reconstruction. No bridge was established at the front end of each group of screws, and no three-dimensional frame structure was formed. (I) Multi-vertebral group A. The results of the cyclic load experiment showed no screws loosening. (J) Multi-vertebral group B. The results of the cyclic load experiment showed that the screw was loose after cyclic loading, as shown, radiolucency appeared around the screw at the yellow circle.

the distance between the two ends and the angle between the two edges is fixed. This is the explanation for the stability of a triangle. If two adjacent edges of an n (n≥4)-sided polygon are selected randomly, the non-common endpoints of the two sides are connected by more than one edge. Therefore, the distance between the two endpoints and the angle between the two edges is not fixed, indicating that the n (n≥4)-sided polygon is unstable. In real life, there are numerous buildings, designs and equipment using triangles to achieve better stability. The frame of a bicycle, fixing of doors and windows and the construction of buildings and bridges, have all used the stability of triangles. In this study, the triangular stability is used in the field of spinal internal fixation to propose a theory of the triangular stability of a single vertebral body and the three-dimensional frame structure of multiple vertebral bodies.

The model was established through imaging analysis of single vertebral triangular stability models and multiple vertebral three-dimensional frame structure models, and the safe dose of bone cement injection that was calculated using the finite element model from previous experiments. By examining the X-ray and CT three-dimensional reconstruction of the model, it could be seen that the two bone cement screw front ends of the single vertebral body were bridged and the multiple vertebral spine model had established a three-dimensional frame structure, indicating that the model was constructed successfully.

Patients with complex osteoporosis cannot be operated on because of the loosening of screws. In addition, the maximum axial pull-out strength of the spine is an important indicator. Kiner *et al* (16) compared the application of 8 mm diameter pedicle screws with PMMA-enhanced 6 mm diameter pedicle screws in the vertebral body by cyclic constant loading test. They found that the initial and final stiffness of the larger diameter screws increased after cyclic constant loading test. However, the 8 mm diameter pedicle screws may be difficult to implant into all vertebral segments. Similarly, Frankel *et al* (17) tested the reconstructed thoracolumbar osteoporotic vertebral internal fixation, and found that the cementation resulted in a 1.6-fold increase in axial pull-out force. In addition, Moore *et al* (18) and Renner *et al* (19) both found that PMMA screw reinforcement increased the axial pull-out force to 1.5 times the normal pull-out force.

These studies have shown that there are two methods to increase the axial pull-out strength of the screw. One is to increase the diameter of the screw, which can make it difficult to implant into all spinal segments. The other is to inject PMMA, which can increase the maximum pull-out strength of the screw. However, there is a risk of leakage if the amount of bone cement is increased, and the pull-out strength of the screw will plateau when the amount of bone cement reaches a certain dose value.

In this study, the front ends of the two screws were bridged by controlling the angle of screw implantation and the amount of bone cement. According to the experimental results, the maximum pull-out strength of the single-vertebral group A, that is the screw front-end bridging group, was 1395.693±85.775, and the maximum pull-out strength of the single-vertebral group B was 889.62±63.5. The difference between the two groups was statistically significant ($P<0.05$). The single vertebral body group A was triangular stable, and the maximum pull-out strength of the pedicle screw was stronger than that of group B, which made the screw more stable.

The reason for patients with severe spinal deformity having a surgical exclusion zone is that there is no strong, stable internal fixation system to support the spine after surgery, and structural stability is difficult to establish. Chiang *et al* (20) isolated the lumbar vertebrae and fractured vertebral bodies of three cadavers, and performed vertebroplasty on the injured vertebral body alone or on the upper level, applying cyclic compression force. When prophylactic vertebroplasty was not performed in the vertebral segment, greater height loss was observed in its vicinity. The authors hypothesized that the non-reinforced vertebral body deformed more than the articular surface, which resulted in increased bending moments and greater height loss. Kebaish *et al* (21) used 18 spine specimens and managed T10-L5 with internal fixation. In one group, the first fixed segment of the uppermost of the segments to be internally fixed was reinforced. The first fixed segment and the upper vertebral body of the segment requiring internal fixation were cemented with bone cement in all specimens. The reinforced and non-reinforced groups were then compared, with vertical compression applied to both experimental groups until the internal fixation failed. In the non-reinforced group, the fracture rate at the proximal junction was reduced by 33%. In the reinforced group, the fracture rate of the proximal joint was reduced by 83%. In another study on internal fixation biomechanics, Tan *et al* (22) confirmed that cement augmentation of pedicle screws resulted in the most stable vertebral reconstruction compared to a separate posterior screw-rod system, while flexible rod extension minimized changes in range of motion at both adjacent rod extension and distal non-instrumented levels. Finally, in a finite element model of the posterior-lateral pedicle screw structure of the short segment around a thoracolumbar burst fracture, vertebroplasty reduces the stress applied to the screws and rods (23).

Cement-reinforced pedicle screws clearly have an effect on the vertebral body and biomechanical studies on the spine. In addition to simple screw fixation, the factors of total spinal stability should also be considered. It is important not only to stabilize the pedicle screw of a single centrum, but also to establish an effective internal fixation frame structure. This study proposes a multi-vertebral space frame structure. A three-dimensional frame spine model was established and a controlled cyclic loading experiment was performed on a LETRY biomechanical fatigue testing machine. In this study, the three-dimensional frame spine model was subjected to cyclic loading to simulate the daily stress of human spine, including axial and buckling load external forces, in order to validate the multiple vertebral three-dimensional frame structure. The results showed that the height of intervertebral discs in both groups decreased after cyclic constant loading test. An increase in displacement, and a decrease in stiffness and the stability of the whole lumbar spine also occurred in both groups. However, the stability of the spine in group A was higher than that in group B. With the increase of cyclic constant loading strength, the stability of the spine in group A improved. This may be due to the use of osteotomy specimens in the cyclic constant loading test, which was more realistic in simulating the clinical situation. The effect of biomechanics is not obvious when the specimens are subjected to small cyclic constant loading strength, but it becomes more obvious with the increase of cyclic constant loading strength, which leads to a biomechanical instability of the spine.

We verified the triangular stability of a single vertebral body and the availability of three-dimensional frame theory through imaging evaluation, pull-out strength test and cyclic constant loading test, which can provide a novel treatment for patients with serious osteoporotic spinal diseases.

In conclusion, the results showed that the stability of screws was significantly improved after the cement screw front ends of the single vertebral body were bridged, and the stability of a multiple vertebral spine was significantly improved after a three-dimensional frame structure was established. This study can provide a new method to improve the stability and reliability of internal fixation in patients with serious osteoporotic spinal diseases.

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Availability of data and materials

The datasets used and/or analyzed during the present study are available from the corresponding author on reasonable request.

Authors' contributions

JX wrote the manuscript. JX and TB performed Axial Withdrawal Force Test. YY and ZW were responsible for Cyclic Loading Test. ZY and WL contributed to observation indexes analysis. The final version was read and adopted by all the authors. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study was approved by the Ethics Committee of Xijing Hospital (Xi'an, China) and written informed consents were signed by the patients and/or guardians.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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