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Original Article

Biomechanical analysis of a novel bone cement bridging screw system for the treatment of Kummell disease: a finite element analysis

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Abstract: When bone cement is used to strengthen the vertebrae in patients with Kummell disease (KD), loosening and displacement of cement are common complications that can cause poor results. We developed a bone cement bridging screw system to avoid this complication. This three-dimensional finite element study aims to analyze the biomechanical properties of the novel bridging screw system and compare it to single vertebroplasty and vertebroplasty combined with pediculoplasty. After the effective establishment of a KD three-dimensional finite element model, the stability of the bone cement in the five treatment methods was analyzed and compared on four aspects. According to the calculation results of the maximum von Mises stress of bone cement and the relative displacement ratio of bone cement, it was determined that the stability of the bone cement was significantly improved when combined with the bridging screw system or pediculoplasty. In addition, according to the calculation results of the maximum von Mises stress of the inferior endplate of T12 and the displacement load ratio of the bone cement, we further found that after using the bridging screw system, the bone cement in the vertebral body has the best stability, and the risk of bone cement loosening or displacement is the lowest. In conclusion, for treating KD with bone cement augmentation, the bone cement bridging screw system combined with vertebroplasty has better stability and safety than ordinary single vertebroplasty and vertebroplasty combined with pediculoplasty. This treatment approach has the most robust ability to avoid loosening and displacement of bone cement.

Keywords: Bone cement bridging screw system, finite element analysis, vertebroplasty, biomechanics, Kummell disease

Introduction

With the aging of the global population, the number of patients with spinal fractures, especially osteoporotic spinal fractures, is increasing year by year [1, 2]. Clinically, patients with Kummell disease (KD) are also showing an increasing trend. In KD, after a minor trauma, the patient experiences an asymptomatic period that may last for a few months or even years. Then, the patient develops severe pain at the site of the former trauma without experiencing any recurrent trauma. This gradually progresses to kyphosis deformity and even nerve damage. KD often occurs in elderly individuals, mostly in the thoracolumbar spine, especially in the T12 vertebrae, and the male to female ratio is approximately 1:10 [3, 4].

Intravertebral vacuum cleft (IVC) is the characteristic imaging manifestation of KD. Libicher et al. [5] found that IVC, as the most important diagnostic feature of KD, has up to 85% sensitivity and 99% specificity. However, IVC cannot be used as evidence for the final diagnosis since it is not only found in KD but also in the acute stage of vertebral fracture, vertebral infection, and primary or metastatic tumors of the vertebrae [6, 7]. An IVC is formed by the accumulation of gas or liquid in the vertebral body, most commonly in the anterior column of the vertebral body [8]. IVC progression leads to loss of vertebral stability, which is the underlying cause of the persistent pain and worsening of the symptoms [9]. Filling the IVC with bone cement is the best way to treat KD without neurological impairment. However, approximately

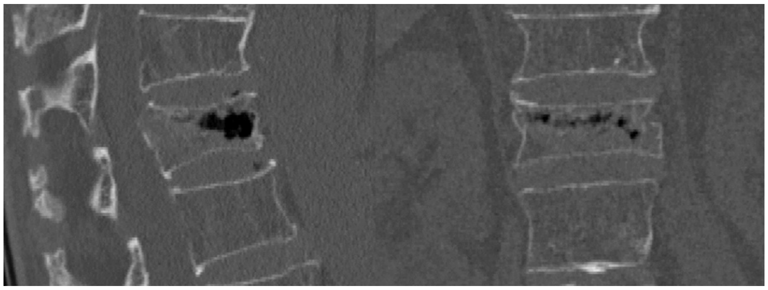

Figure 1. CT imaging of KD patient (Left: sagittal position; Right: coronal position).

25% of patients treated with bone cement alone may have cement loosening or displacement, resulting in the recurrence of pain symptoms [10].

To avoid cement loosening or displacement, the author's team innovatively developed a new bone cement bridging screw system combined with vertebroplasty for treating KD. This screw system can be used as a bridge to connect the bone cement in the IVC with the normal bone tissue to avoid the loosening and displacement of cement after vertebroplasty. To study the mechanical effectiveness of this new bone cement bridging screw further and to clarify the mechanical stability of the screw, we designed this three-dimensional finite element study to evaluate the mechanical strength of the new bridging screw for the treatment of KD compared to other treatment methods. The ultimate goal of this study was to provide information that can be used to guide clinical practice.

Methods

Establishment of the finite element model

An 85-year-old healthy male volunteer with an L1 KD was selected, with a height of 168 cm and a body weight of 60 kg. He had no history of severe thoracolumbar trauma and no history of chronic medical diseases. Fresh vertebral fractures, deformities, and degenerative diseases were excluded by imaging examination. The patient and his family agreed to participate in the experiment by signing the informed consent form. This study was approved by the biomedical research ethics committee of Hong Hui Hospital, Xi'an Jiaotong University (No. 202204004).

The selected patient CT data (**Figure 1**) were imported into Mimics 20 (Materialise Corporation, Belgium) image processing software. The structural information of the T12, L1 and L2 vertebral bodies and intervertebral discs were extracted, and the three-dimensional geometry was segmented. Then, the data were imported into 3-matic 11.0 (Material Corporation, Belgium) for smoothing, surface fitting and coating, and the bridging screw model was reconstructed by Creo 3.0 (Parametric Corporation, USA). Finally, the entity model was derived, and the meshing, material attribute definition, assignment, and constraint condition were defined in Workbench 19 (ANSYS, USA) software. The relevant finite element models of the vertebral segments (T12, L1 and L2, of which the KD model is on the L1 vertebral segment) were analyzed by workbench finite element software. The following five scheme models are shown in **Figure 2**: a) Unilateral novel bone cement bridging screw model; b) Bilateral novel bone cement bridging screw model; c) Vertebroplasty combined with unilateral pediculoplasty model; d) Vertebroplasty combined with bilateral pediculoplasty model; e) Vertebroplasty model.

Validation of the finite element models

The material parameters of the model were assigned according to the calculated density and modulus of elasticity in Mimics software. The validity of the model was verified according to the torque of 250 N and 50 N·m in the vertical direction according to the five directions of flexion, extension, left flexion, right bending and rotation. The calculation results are shown in **Figure 3**. Compared to the classic in vitro thoracolumbar biomechanical experimental results of Schuhz et al. [11], there was no significant difference in the degrees of freedom and activity of a single segment of the complete spine model established in this study, and the model was effective.

At present, there is no consensus on whether isotropy or anisotropy should be set for bone tissue properties. In this finite element calculation, referring to previous literature data on KD [12], T12, L1, and L2 are regarded as anisotropic materials, and the material parameters of the three segments are assigned. Other bone

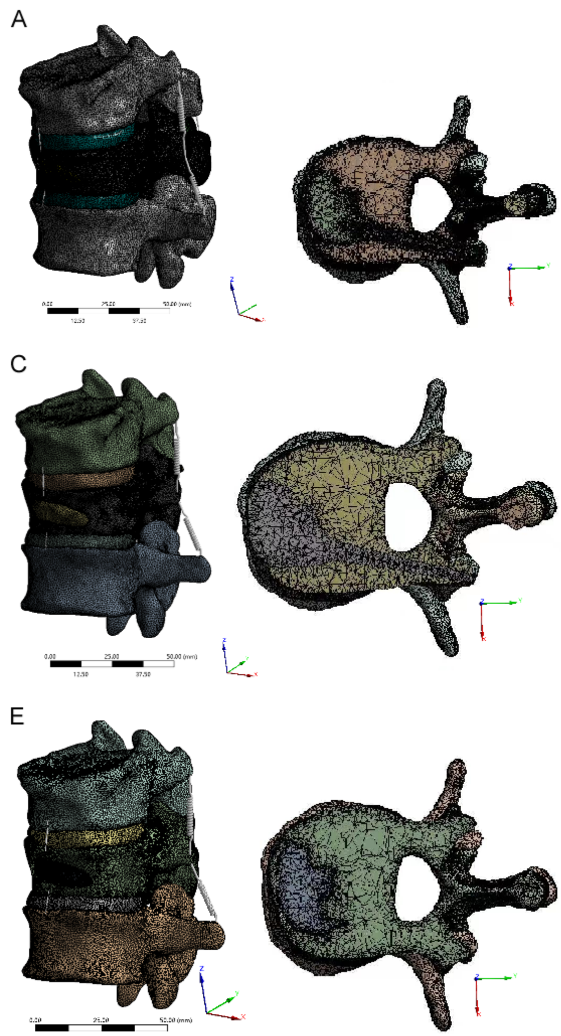

Figure 2. Five scheme models used in the experiment: (A) Unilateral novel bone cement screw model; (B) Bilateral novel bone cement screws model; (C) Percutaneous vertebroplasty combined with unilateral percutaneous pediculoplasty model; (D) Percutaneous vertebroplasty combined with bilateral percutaneous pediculoplasty model; (E) Percutaneous vertebroplasty model.

tissue structures can be regarded as isotropic materials, and their parameters are shown in **Table 1**.

All group models were fixed on the bottom of the L2 vertebral body (6 degrees of freedom is 0), and a 250 N vertical downward force was applied on the upper surface of the T12 vertebral body as a preload to simulate the upright state of the human thoracolumbar spine. the moments of forward flexion, backward extension, left flexion, right flexion and rotation, with a size of 50 N·m, were applied on the upper surface of the T12 vertebral body to simulate the load bending condition of the human body in different directions.

Main outcome measures

The main measurement items include the maximum Von-Mises of the inferior endplate of T12, the maximum Von-Mises of bone cement, the comparison of the relative displacement of bone cement, and the stability of bone cement.

The maximum Von-Mises of the inferior endplate of T12 can be used to observe the upper endplate stress on the L1 vertebrae. The lower the stress on the T12 lower endplate, the lower the stress on the L1 vertebrae, indicating improved stability of the L1 vertebrae. The stress of internal fixation is one of the indices used to evaluate the advantages and disadvantages of internal fixation methods. The smaller the maximum Von-Mises of bone cement, the lower the possibility of loosening and displacement of cement (**Figure 4A**). The relative displacement ratio and stability index of bone cement also reflect the stability of bone cement. A smaller relative displacement ratio of bone cement and a smaller displacement load ratio indicate better bone cement stability (**Figure 4B**).

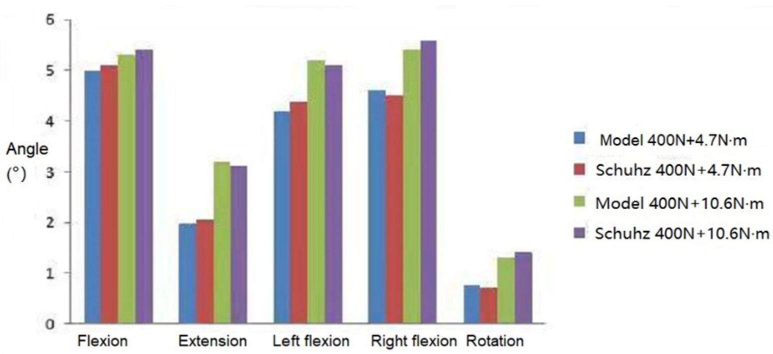

Figure 3. Activity statistical histogram of the complete model.

Table 1. Material properties of tissues

Material	Unit type	Yang's modulus (Mpa)	Poisson ratio
Bone cement	Solid 186	4000	0.33
Cartilage endplate	Solid 186	1000	0.2
Annulus fibrosus	Solid 186	8.4	0.45
Nucleus pulposus	Solid 186	8.4	0.45
Novel bone cement screw	Solid 186	145000.0	0.30

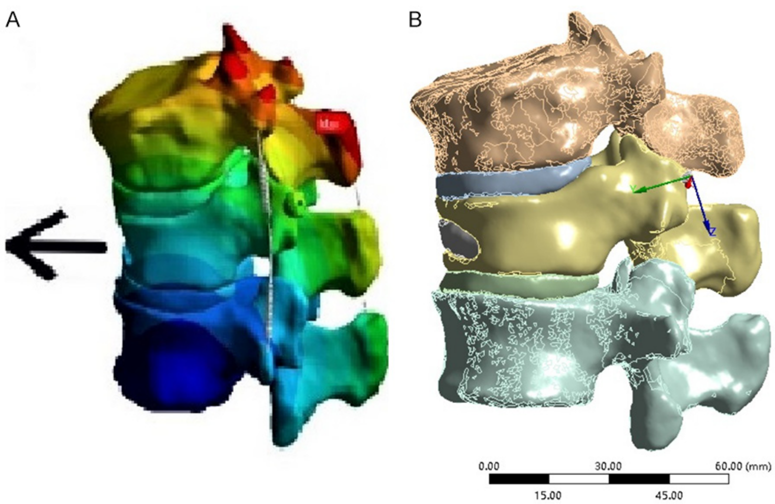

Figure 4. Schematic diagram of the displacement direction of bone cement: (A) Experiment on the relative displacement ratio of the bone cement; (B) Experiment on the stability of bone cement.

Results

Calculated results of the maximum Von Mises stress of the inferior endplate of T12

The maximum Von Mises stress cloud diagrams of the T12 inferior endplate in the different groups are shown in **Figure 5A**. The calculation results and statistical histogram after loading the same load are shown in **Figure 6A** and **Table 2**. According to these results, the 5 groups showed little difference in the stress distribution under the anteflexion, extension, left flexion, right flexion, and rotation conditions. In contrast, the maximum Von Mises stress values of the T12 inferior endplate in Groups a, b, and e were less than those of Groups c and d, which shows that the stress on the L1 vertebrae was slightly lower and the relative stability of the L1 vertebrae was better in Groups a, b, and e. In Group d, the maximum Von Mises stress values of the T12 inferior endplate were the highest, and the stability of the L1 vertebrae was the worst. The stress values were as follows: anteflexion 41.288 MPa, extension 53.380 MPa, left flexion 46.888 MPa, right flexion 41.850 MPa, left rotation 31.632 MPa, and right rotation 33.116 MPa.

Calculated results of the maximum Von Mises stress of bone cement

The stress on the implant is one of the most important indices to evaluate its stability. A smaller maximum Von Mises stress on the bone cement indicates a lower possibility of loosening and displacement of bone cement. The maximum Von Mises stress cloud diagram of the bone cement is shown in **Figure 5B**. The stress calculation results are shown in **Table 3**, and the statistical histogram is shown in **Figure 6B**.

According to the calculated results, the maximum Von Mises stress of bone cement in Group e was the largest, which was significantly larger than that in the other four groups, and the stress values were anteflexion 146.140 MPa,

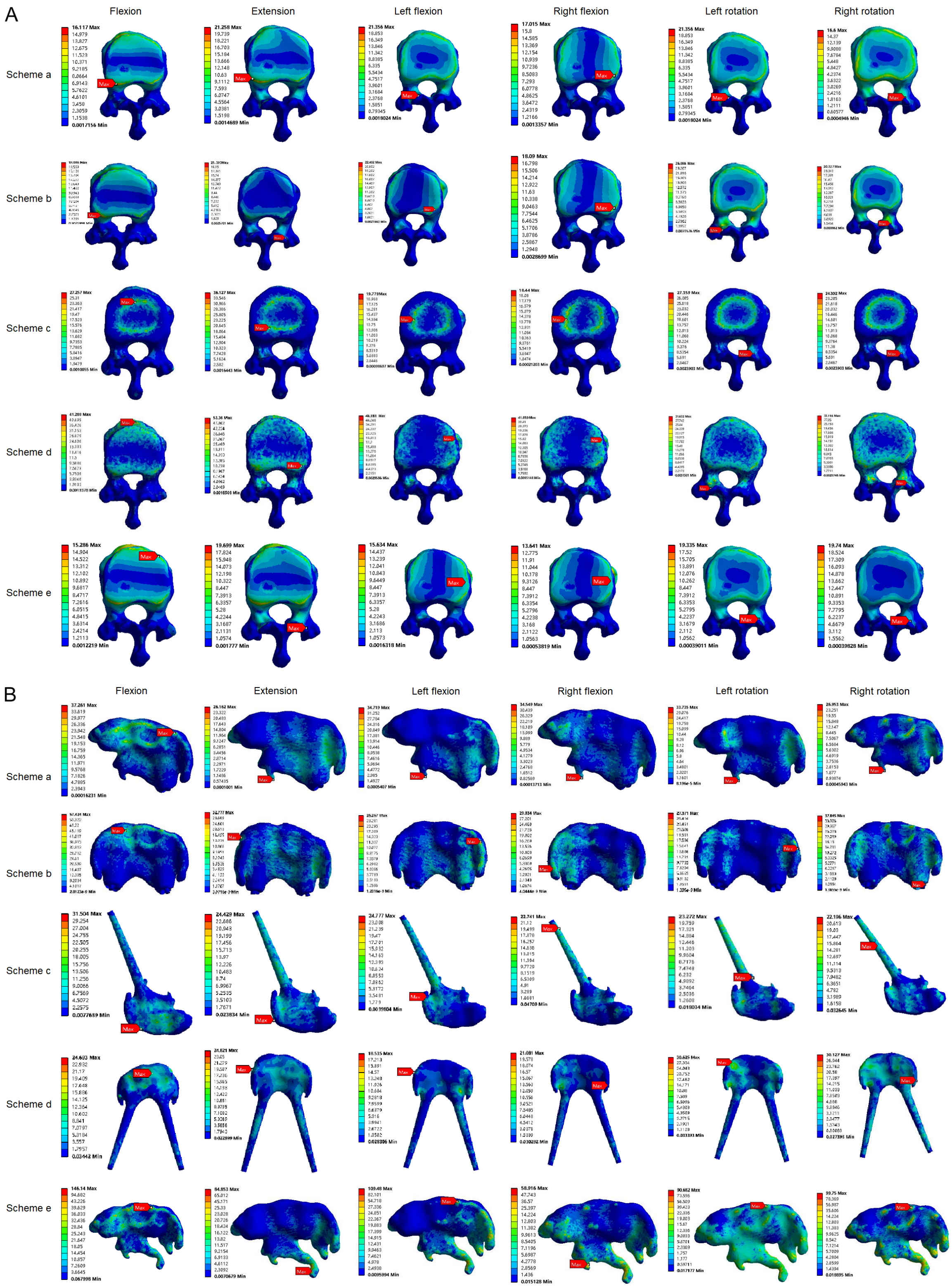

Figure 5. Stress cloud diagram under different working conditions of each group of models: (A) Inferior endplate of T12 vertebral body; (B) Bone cement.

extension 84.853 MPa, left flexion 109.480 MPa, right flexion 58.916 MPa, left rotation 90.682 MPa, and right rotation 99.750 MPa. This shows that the risk of cement loosening or

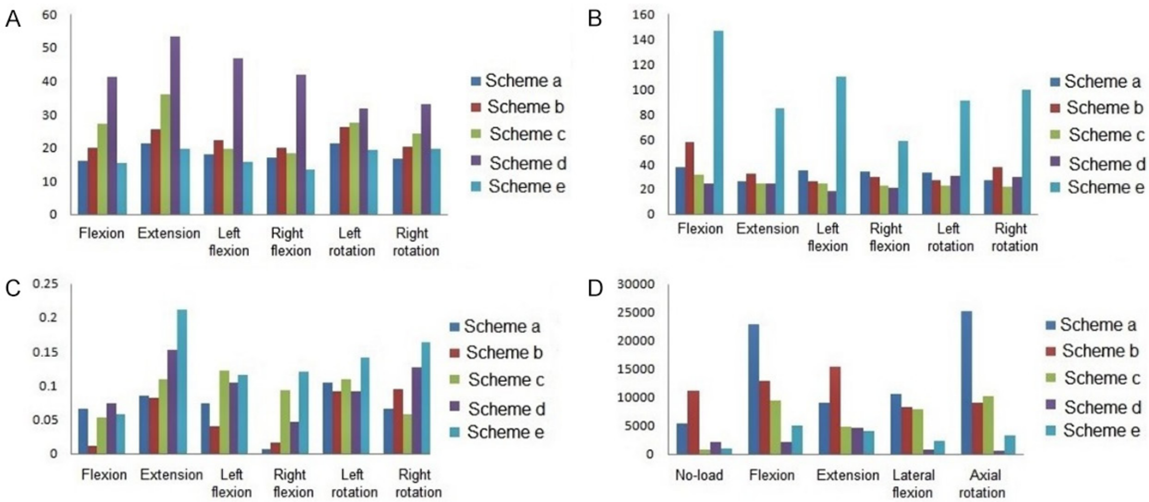

Figure 6. Statistical graphs of results under different experiments: (A) T12 maximum Von-Mises statistical bar chart of each repair model under different working conditions; (B) Bone cement maximum Von-Mises statistical bar chart of each repair model under different working conditions; (C) Statistical histogram of bone cement relative displacement under different working conditions; (D) Statistical histogram of displacement load ratio of bone cement of each repair model under different working conditions.

Table 2. T12 von Mises calculation results of five schemes (MPa)

	Flexion	Extension	Left flexion	Right flexion	Left rotation	Right rotation
Scheme a	16.117	21.258	18.090	17.015	21.356	16.600
Scheme b	19.986	25.393	22.402	20.150	26.086	20.327
Scheme c	27.257	36.127	19.779	18.440	27.359	24.302
Scheme d	41.288	53.380	46.888	41.850	31.632	33.116
Scheme e	15.286	19.699	15.634	13.641	19.335	19.740

displacement in Group e is much higher than that in the other four groups. In addition, in the stress cloud diagram, the stress distribution in Group e is not uniform, indicating that the local stress on the bone cement is greater than that of the other groups, and the probability of local complications is higher. However, the stress values of the other four groups under the six dimensions are almost the same, indicating that the stabilities of bone cement in these four groups are similar.

Calculated results of the relative displacement ratio of bone cement

The relative displacement ratio of bone cement also reflects the its stability. The smaller the relative displacement ratio is, the better the stability of the bone cement. In this experiment, the displacement of bone cement in the L1 vertebral body relative to its initial position was calculated, shown in **Figure 4A**. The calculated results and statistical histogram of the relative displacement ratio of bone cement in different groups are shown in **Figure 6C** and **Table 4**. Under the same load, Group a and Group b showed better cement stability than the other groups in anteflexion, extension, and left and right lateral flexion. Their cement displacement was the smallest, anteflexion 0.06610 mm and 0.01241 mm, extension 0.08456 mm and 0.08190 mm, left flexion 0.07435 mm and 0.04071 mm, and right flexion 0.00659 mm and 0.01723 mm. In terms of left and right rotation, there was little difference between the measured results of Groups a to d. The evaluation results indicated that the bone cement stability in Group e was the lowest, with the highest relative displacement ratio of bone cement.

Calculated results of the displacement load ratio of bone cement

The displacement load ratio of bone cement reflects its stability. The greater its value, the

Table 3. Bone cement von Mises calculation results of five schemes (MPa)

	Flexion	Extension	Left flexion	Right flexion	Left rotation	Right rotation
Scheme a	37.261	26.162	34.719	34.549	33.735	26.953
Scheme b	57.424	32.777	26.267	29.934	27.371	37.845
Scheme c	31.504	24.429	24.777	22.741	23.272	22.196
Scheme d	24.693	24.821	18.535	21.081	30.625	30.127
Scheme e	146.140	84.853	109.480	58.916	90.682	99.750

Table 4. Calculation results of relative displacement of bone cement in five schemes (mm)

	Flexion	Extension	Left flexion	Right flexion	Left rotation	Right rotation
Scheme a	0.06610	0.08456	0.07435	0.00659	0.10394	0.06615
Scheme b	0.01241	0.08190	0.04071	0.01723	0.09193	0.09432
Scheme c	0.05310	0.10947	0.12205	0.09341	0.10956	0.05887
Scheme d	0.07360	0.15264	0.10519	0.04659	0.09158	0.12645
Scheme e	0.05750	0.21109	0.11552	0.12106	0.14146	0.16433

Table 5. Calculation results of displacement load ratio of bone cement for five schemes (N/mm)

	No-load	Flexion	Extension	Lateral flexion	Axial rotation
Scheme a	5340.48	22927.62	8986.65	10703.81	25176.94
Scheme b	11255.98	12921.04	15385.16	8391.96	9121.89
Scheme c	767.51	9510.92	4906.55	7946.92	10308.95
Scheme d	2146.16	2267.35	4708.64	896.86	621.23
Scheme e	1113.92	5115.20	4152.69	2401.10	3268.25

more unlikely it is that the bone cement will loosen or be displaced, and the better its stability. This part of the experiment is based on the coordinate system shown in **Figure 4B**, constraining the 6 degrees of freedom of the L2 lower surface and applying a pull-out strength in the Y direction to the bone cement. The relative displacement in the Y direction of the bone cement represents the displacement of the outer surface of the bone cement relative to the inner surface of L1. The displacement load ratio of the bone cement is calculated as the strength of the bone cement displacement per 1 mm in the Y direction (N/mm).

According to this calculation method, the results and statistical histogram of the displacement load ratio of the bone cement in different groups are shown in **Figure 6D** and **Table 5**. These results show that the displacement load ratio of the bone cement in Group a and Group b is the largest in all dimensions, indicating that these two groups have the most stable cement and are not prone to postoperative loosening or displacement of the bone cement. The specific measured values are no-load 5340.48 N/mm and 11255.98 N/mm, anteflexion 22927.62 N/mm and 12921.04 N/mm, extension 8986.65 N/mm and 15385.16 N/mm, lateral flexion 10703.81 N/mm and 8391.96 N/mm, rotation 25176.94 N/mm and 9121.89 N/mm.

Discussion

Kummell's Disease (KD) was originally proposed by Dr. Hermann Kummell in 1891 as a type of delayed posttraumatic vertebral collapse, which is a clinical phenomenon. That is, patients with mild trauma tend to develop aggravation of pain symptoms and progressive angular kyphosis after an asymptomatic period that can last for a few months to years [13]. It was first believed that conservative treatments, such as bed rest, nonsteroidal anti-inflammatory drugs, and orthotics, could be given priority when KD patients do not have neurological damage [14-17]. However, the existence of an IVC may lead to progressive vertebral collapse that does not respond well to conservative treatment. Lim et al. [18] reported that approximately 40% of KD patients were resistant to conservative treatment, while the remaining 60% could only achieve pain relief for up to 3 months. With further research on KD in recent years, an increasing number of scholars believe surgical intervention is the best choice to eliminate the IVC, reconstruct the height of the diseased vertebra, and restore the curvature of the spine.

With the rapid development of minimally invasive spinal surgery, the use of bone cement to fill a disease-causing IVC has the advantages of less trauma, good patient tolerance, fast pain relief, and effective deformity correction, and it has become the main way to treat KD without neurological impairment [14, 19-23]. Although the use of bone cement augmentation has achieved satisfactory clinical efficacy, the loosening of cement after the operation can lead to the recurrence of pain symptoms and even the catastrophic complication of cement displacement. Even if the patient's curative effect is satisfactory, the surgeons will inevitably worry about the loosening or displacement of cement during the follow-up period. In the event of bone cement displacement, open revision surgery through posterior, anterior, or even combined approaches may be necessary to remove the displaced cement, reconstruct the spinal stability, and restore the spinal sequence. As a result, some surgeons use short-segment or long-segment screw fixation combined with vertebroplasty to treat KD to avoid cement complications. However, these treatments have disadvantages such as large surgical trauma, loss of spinal mobility, increased risk of postoperative cardiovascular and cerebrovascular accidents, and high economic cost [14, 25-30].

To retain the advantages of cement augmentation and avoid complications of bone cement loosening or displacement, for the first time, we developed a novel bone cement bridging screw system combined with vertebroplasty to treat KD. In principle, the bridging screw system tightly connects the bone cement to the vertebral pedicle, which has the highest vertebral strength, enhances the stability of the bone cement in the vertebrae, and avoids cement loosening and displacement. We have preliminarily verified the effectiveness of the bridging screw system through clinical observation of 27 KD patients [31]. After a follow-up of 40.2 ± 3.7 months, none of the 27 patients had cement loosening or displacement. The vertebral body index, vertebral body angle, two-segment Cobb angle, visual analog scale, and Oswestry disability index of all of the patients were significantly improved. Finally, according to the Odom criteria, 19 cases were excellent, 7 cases were good, 1 case was fair, and 0 cases were poor, with an excellent or good rate of 96.3%.

However, the mechanical properties of this screw system need to be further studied. In this study, according to the research of Erdem et al. [32], we established five three-dimensional finite element models of T12-L2 segments for the different treatment approaches to KD and used four methods to analyze and evaluate the stability of the bone cement, including calculations of the maximum von Mises stress on the inferior endplate of T12, the maximum von Mises stress on the bone cement, the relative displacement ratio of the bone cement, and the displacement load ratio of the bone cement.

According to the calculated results of the maximum von Mises stress of bone cement and its relative displacement ratio, we found that its stability was significantly improved when combined with the bridging screw system or pediculoplasty. In addition, according to the calculated results of the maximum von Mises stress of the inferior endplate of T12 and the displacement load ratio of bone cement, it was further confirmed that after using the bridging screw system, the bone cement in the vertebral body had the best stability, and the risk of bone cement loosening or displacement was the lowest.

A higher maximum von Mises stress on the inferior endplate of T12 will place greater pressure on the L1 vertebrae, which is more likely to lead to stress-related complications after bone cement augmentation of the diseased vertebrae. Compared to vertebroplasty combined with unilateral or bilateral pediculoplasty, the maximum von Mises stress on the T12 inferior endplate of the bridging screw system was smaller in the items of anteflexion, extension, left and right lateral flexion, and left and right axial rotation. This means that the use of a bone cement bridging screw system can greatly reduce the overload stress on the Kummell diseased vertebrae caused by vertebroplasty combined with pediculoplasty and reduce the probability of bone cement-related complications, diseased vertebral instability, pain, and lumbar dysfunction caused by the overloaded stress.

The working stress of implants is one of the most important indicators to evaluate the efficacy of implant methods. The smaller the maximum von Mises stress of bone cement is, the lower the possibility of its loosening and displacement. Based on the analysis of the maximum von Mises stress of bone cement that compared to vertebroplasty alone, its combination with the bridging screw system or pediculoplasty can reduce the stress on the bone cement, and then the possibility of cement loosening or displacement will be greatly reduced.

Under the same experimental conditions, after the application of the bone cement bridging screw system, the value of the bone cement relative displacement ratio is the lowest, and the value of the bone cement displacement load ratio is the highest, indicating that this treatment approach has the best ability to resist cement loosening and displacement. Especially for the items of anteflexion, extension and lateral flexion, the screw system can lock the bone cement more stably, which is significantly better than using pediculoplasty; however, for the item of rotation, there is no significant difference between the two approaches. Although the rotational stability of bone cement using the two approaches is better than that of single vertebroplasty, to retain more motor function of the spine, the two surgical approaches (the bridging screw system and pediculoplasty) are not affected by the rotation of the vertebrae. This means there is little difference in the rotational stability of cement between the two approaches.

Through this three-dimensional finite element biomechanical comparison study of five different approaches, we showed that for KD, the bone cement bridging screw system combined with vertebroplasty has better stability and safety than ordinary single vertebroplasty or vertebroplasty combined with pediculoplasty. The cement bridging screw system can take into account the advantages of single vertebroplasty and vertebroplasty combined with pediculoplasty; that is, it can reduce the maximum von Mises stress on the T12 inferior endplate and the pressure on the L1 vertebrae like vertebroplasty and reduce the maximum von Mises stress of bone cement like vertebroplasty combined with pediculoplasty. Most importantly, under the same conditions, using the cement bridging screw system will maximize the stability of the bone cement and significantly reduce the risk of cement displacement. At present, the lack of experimental verification on animal and cadaver specimens is a deficiency. Therefore, more biomechanical tests and clinical trials need to be carried out in the future. Although there are some limitations, this three-dimensional finite element study compares the mechanical efficiency of the five treatment approaches well, and the experimental values obtained have reliable and practical value, which provides a reliable basis for the next steps of biomechanical testing and clinical trials.

For treating KD with bone cement augmentation, the bone cement bridging screw system combined with vertebroplasty has the best stability and safety compared with ordinary single vertebroplasty and vertebroplasty combined with pediculoplasty. Because the bone cement has the best biomechanical stability, this treatment has the most robust ability to avoid the loosening and displacement of bone cement.

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Disclosure of conflict of interest

None.

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