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Research article

Reversed windshield-wiper effect leads to failure of cement-augmented pedicle screw: Biomechanical mechanism analysis by finite element experiment

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A R T I C L E I N F O

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A B S T R A C T

The failure mode of cement-augmented pedicle screw (CAPS) was different from common pedicle screw. No biomechanical study of this failure mode named as "reversed windshield-wiper effect" was reported. To investigate the mechanisms underlying this failure mode, a series of finite element models of CAPS and PS were modified on L4 osseous model. Nine models were created according to the cement volume at 0.5 mL interval (range: 1–5 mL). Pullout load and cranio-caudal loads were applied on the screws. Stress and instantaneous rotation center (IRC) of the vertebra were observed. Under cranio-caudal load, the stress concentrated on the screw tip and pedicle region. The maximal stress (MS) at the screw tip region was +2.143 MPa higher than pedicle region. With cement volume increasing, the maximal stress (MS) at the screw tip region decreased dramatically, while MS at pedicle region was not obviously affected. As dose increased to 1.5 mL, the MS at pedicle region became higher than screw tip region and the maximal stress difference was observed at 3.5 mL. IRC of the vertebra located at the facet joint region in PS model. While IRC in CAPS models shifted anteriorly closer to the vertebral body with the increasing of cement volume. Under axial pull-out load, the maximal stress (MS) of cancellous bone in CAPS models was 29.53–50.04% lower than that 2.228 MPa in PS model. MS in the screw-bone interface did not change significantly with cement volume increasing. Therefore, the possible mechanism is that anterior shift of IRC and the negative difference value of MS between screw tip and pedicle region due to cement augmentation, leading to the screw rotate around the cement-screw complex as the fulcrum point.

1. Introduction

The incidence of osteoporosis has been increasing significantly with a rapidly ageing population [1], especially in postmenopausal women, with a prevalence as high as 50% [2]. As a consequence, a growing number of osteoporosis patients with degenerative spinal

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diseases (DSD) need internal fixation to reconstruct spinal stability [3]. A considerable proportion of patients in need of surgery particularly underwent simultaneous bone fusion [4]. However, osteoporosis results in insufficient instant stability of the screw-bone interface, which would severely decline the stability of constructs and significantly increases the risk of implant failure [5].

A variety of methods have been used to improve the stability of pedicle screw (PS) in osteoporotic spine, such as reinforcement with lamina hook [6] or wire [7], cortical bone trajectory screw [8], expandable screw [9,10] and cement-augmented pedicle screw (CAPS) [11]. CAPS is widely accepted as the most effective method for augmentation of implant-bone interface [12]. Studies showed that CAPS could improve the pullout force by 95%–350% compared with PS and achieved better bone fusion rates [13–18]. Fixation failure of CAPS is less encountered than traditional PS, however, it would be more disastrous once happened. The revision surgery involving CAPS usually comprises of a much longer fixation and greater iatrogenic trauma than the index surgery [19,20].

For typical PS failure mode, the screw rotates in the bone with the pedicle as the fulcrum point [21,22]. The screw tips cut the cancellous bone most. Loosening begins at the screw tips, gradually spreading to the whole screw, which often presents as a “halo” sign on the X-ray or CT imaging. This typical fatigue failure mode of PS was named as “windshield-wiper effect” [21]. Recently, researchers have observed a rather different failure mode in CAPS with an incidence ranging from 42.9% to 44.2% [21]. CAPS failure sites were no longer located at the screw tip, but at the pedicle region [13,21–23]. The cortical bone may develop a fracture at the pedicle, that means, the screw perhaps rotated around the cement-screw complex in the vertebral body as the fulcrum point. We named the failure mode of CAPS as “reversed windshield-wiper effect”. However, the biomechanical mechanism of the “reversed windshield-wiper effect” remains unclear, and its potential clinical implication needs to be clarified.

To investigate the mechanism difference between the two failure modes, a biomechanical test was carried out with finite element (FE) analysis. We created a series of FE models that aid in observing the maximal stress under pull-out load and changes in instantaneous rotation center (IRC) and load distribution patterns under simulated physiological cranio-caudal loads. We have this hypothesis to be verified by the biomechanical tests: the transition of the failure mode attributes to the antedisplacement of IRC and significant changes of the stress distribution pattern in CAPS. The results may provide a theoretical basis for the improvement of CAPS in osteoporotic spine surgery.

2. Materials

2.1. Development of L4 vertebra with osteoporosis

A three-dimensional osteo finite element model (FEM) of the fourth lumbar vertebra was created with geometry based on the high-resolution computed tomography scan (slice thickness of 0.675 mm) of a healthy volunteer (33-year-old male; height: 182 cm; weight: 77 kg). Current FEM consisted of cortical bone and cancellous bone. The cortical bone was modeled with 3-node isotropic-elastic shell elements. The cancellous bone was modeled with 4-node isotropic-elastic tetrahedron elements. All soft tissue including cartilaginous endplate was excluded in the current model. The initial material properties were based on previous studies [24–26], and a moderate osteoporosis was simulated by assigning relative material properties to the bony structure as shown in Table 1.

2.2. Instrumentations and groups

Bilateral PS (Fig. 1) and CAPS insertion were simulated on the L4 FE model. Screws (diameter: 6.5 mm; length:45 mm) were parallel to the long axis of the pedicle with a medial converge angle of 20°. Screw-bone interface and screw-cement-bone interface were set as rigidly fixed. Nine CAPS models were established according to the dosage of bone cement per screw (ranged from 1 mL to 5 mL at a 0.5 mL interval).

The CAPS model in current study simulated the one has outflow channels at the apex and lateral anterior half of the screw which allows the cement to flow out more safely. According to experimental and clinical imaging observations from our team and others, bone cement flowed out mainly from the lateral channel and most of the bone cement seems like an ellipsoid at the anterior screws [16,27–30] (Fig. 2).

Convergence studies were performed to determine appropriate mesh densities. According to the convergence and our computing power, the grid size of 1.5 mm is finally selected.

2.3. Boundary and loading condition

Daily activity is complicated involving multiple loads. To investigate potential mechanism of reversed windshield-wiper effect,

Table 1
Material properties of the model components.

Name	Element Type	Material Model	Material properties	Reference
Cortical bone	S3	ISO elastic	E = 5600 MPa, μ = 0.3	Wheeldon et al. [25]
Cancellous bone	C3D4	ISO elastic	E = 24 MPa, μ = 0.3	Wheeldon et al. [25]
Cement	C3D4	ISO elastic	E = 1500 MPa, μ = 0.3	Hussain et al. [26]
Instrumentations	C3D8	ISO elastic	E = 110,000 MPa, μ = 0.3	Hussain et al. [26]

E, young modulus; μ, passion’s ratio; ISO elastic: isotropic.

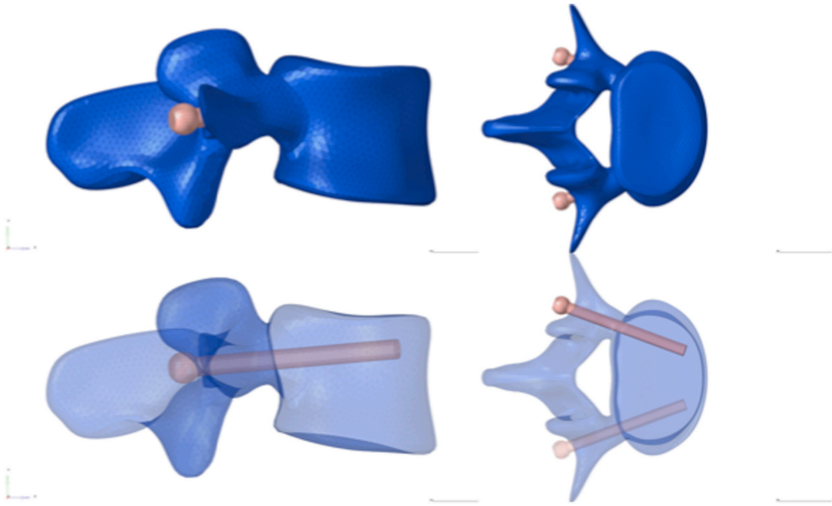

Fig. 1. Finite element models of L4 vertebra with PS insertion (left: lateral view; right: top view).

pullout load and cranio-caudal loads were applied in current test, respectively (Fig. 3). All loads in these two tests were applied in a quasi-static loading rate.

2.4. Axial pullout test

500 N pullout force was applied on the screw tail along the longitudinal axis of screw [21,31,32]. The inferior ends of L4 endplate were fixed all six degrees of freedom (DOF) [32] (Fig. 3A).

2.5. Cranio-caudal loading test

500 N cranio-caudal load was applied perpendicular to the superior surface of the L4 vertebra. The ends of the bilateral pedicle screws were rigidly constrained for all 6 DOF [32] (Fig. 3B).

2.6. Indicators

In axial pullout test, the stress distribution and the maximal stress value (MS, von Mises stress) were recorded. In cranio-caudal loading test, stress distribution, MS and IRC of fixation configuration were recorded. IRC was recorded based on the motion of anterior and superior apex of L4 vertebra, ignoring the deformation of all bone tissue. IRC shift on sagittal plane were recorded and compared in ten models.

2.7. Software

Amira (5.3.3, Visage Imaging, Carlsbad, CA) was used for checking the quality of segmentation and surface smoothing. The acquired surface files were processed in HyperMesh (V12.0, Altair, Michigan, America) for meshing. Simulations were conducted using ABAQUS (Simulia, Providence, RI).

3. Results

3.1. Axial pullout test

Throughout all groups, the stress concentrated on the screw-bone and/or cement-bone interface (Fig. 4A). In PS model, the stress distributed approximate averagely at the whole screw-bone interface, with a MS of 2.228 MPa (MPa).

In CAPS models, the stress distribution pattern changed significantly: stress of screw-bone interface decreased dramatically due to cement augmentation at the screw tip region; MS decreased as well (ranged from 29.53% to 50.04% of PS), with the stress concentration region locating at the cranial boundary of cement-bone interface.

A gradual increase of cement volume leaded to progressive decrease of MS. Whereas, MS decrease was basically in line with a trend of linear increase of volume, which was distinguished from the PS model. However, MS did not vary obviously among the nine CAPS models (Fig. 4B). MS value was reduced only by 0.457 MPa in 5 mL model compared with 1 mL model, while the difference was 1.113 MPa between 0 mL and 1 mL model. This was basically consistent with the experimental results of the classical specimen mechanics

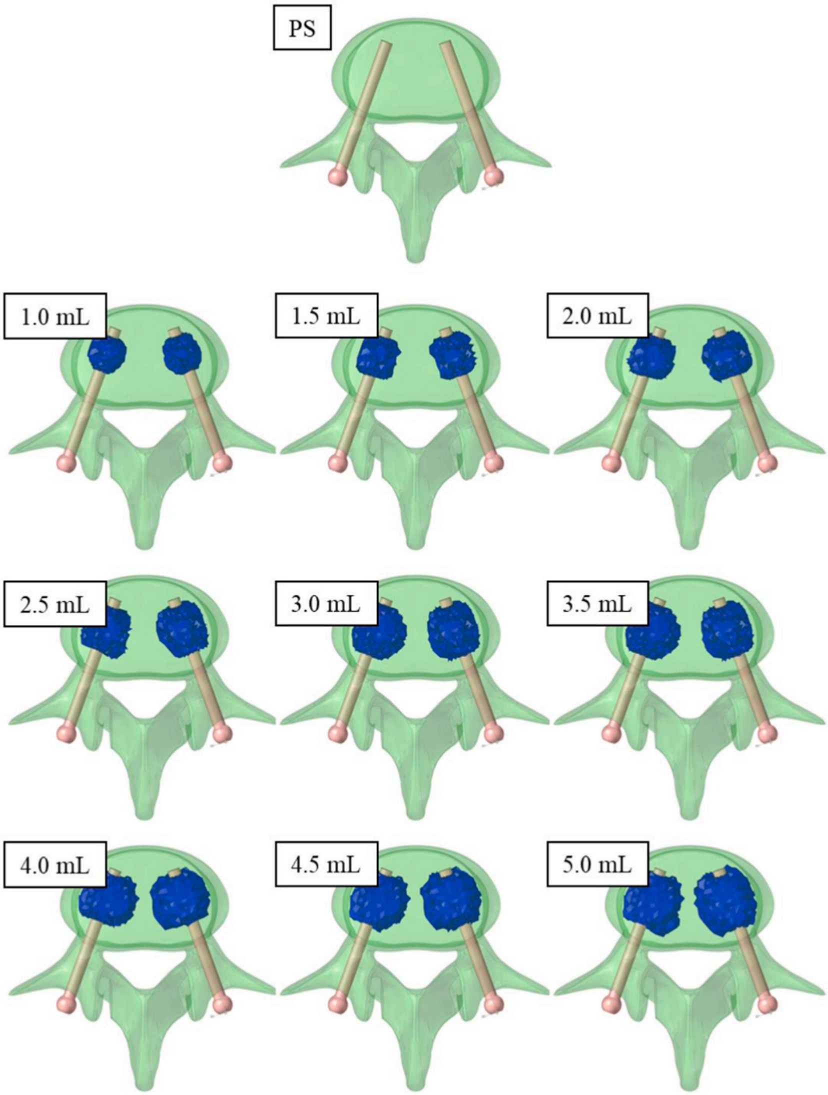

Fig. 2. Finite element models of L4 vertebra with PS and CAPS insertion (top view).

[33].

3.2. Cranio-caudal loading test

Both PS and CAPS models showed the similar stress distribution pattern under cranio-caudal loads (Fig. 5A): stress concentrated on the screw tip and pedicle region, respectively. In PS model, MS of screw tip region (5.917 MPa) was much higher than that of pedicle (3.774 MPa), and Δstress, which was defined as the difference value between the former and the latter, was +2.143 MPa. With cement-augment and the volume increasing, MS of screw tip decreased significantly (from 4.068 MPa in 1 mL model to 1.426 MPa in 5 mL model), while MS of pedicle region (from 3.772 MPa in 1 mL model to 3.149 MPa in 5 mL model) kept relative stable regardless of cement-augment and/or increase of volume (Fig. 5B). Δstress of CAPS model with 1 mL cement was positive as +0.296 MPa, and those of models with 1.5 mL and more cement were negative (range of −0.408 MPa to −1.769 MPa), of which the maximum change was observed at the 3.5 mL model. It implied that the major stress concentration transited from screw tip to pedicle with the cement-augmentation more than 1.5 mL.

3.3. Shift of IRC under cranio-caudal loads

Under cranio-caudal loads, IRC of all models located on the midsagittal plane (Fig. 6A and B). In the top view, IRC located in the facet joint region in PS model. IRC shifted anteriorly following cement augmentation. With 1 mL cement, anterior shift of IRC was 4.0

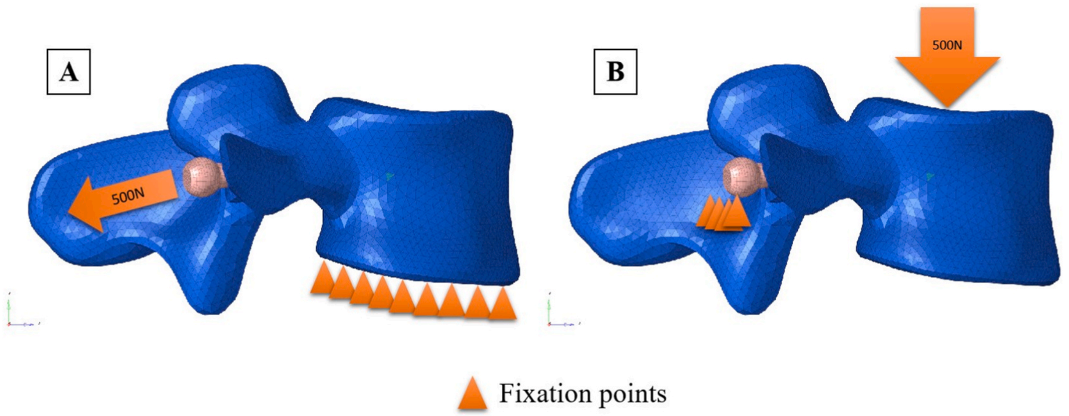

Fig. 3. Loading and boundary conditions of pullout and cranio-caudal tests. Yellow arrows showed the loading direction and yellow triangles showed fixation points. A: Pullout test. B: Cranio-caudal test. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

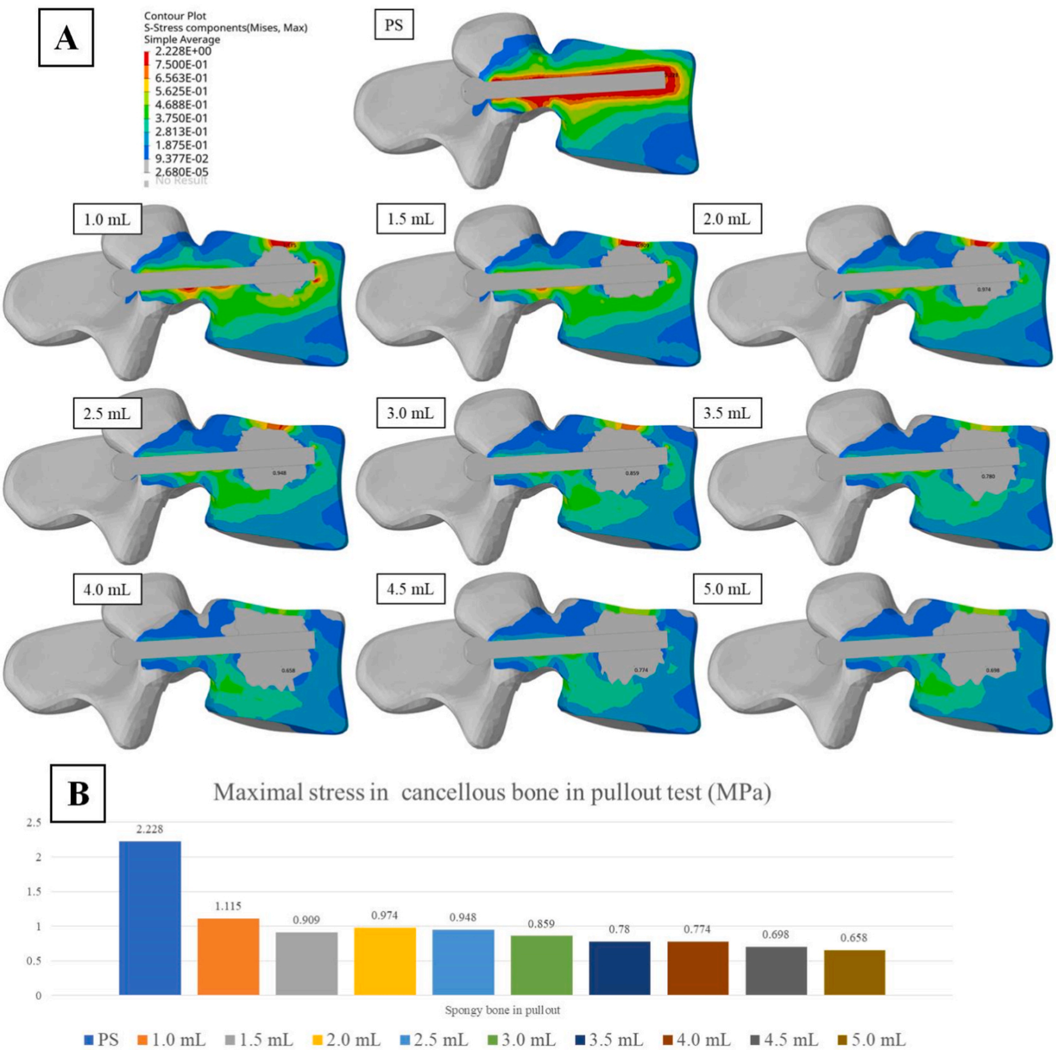

Fig. 4. Stress distribution and maximal stress in pullout test. A: Internal stress distribution of cancellous bone in ten models. B: Histogram of maximum stress in screw tip area.

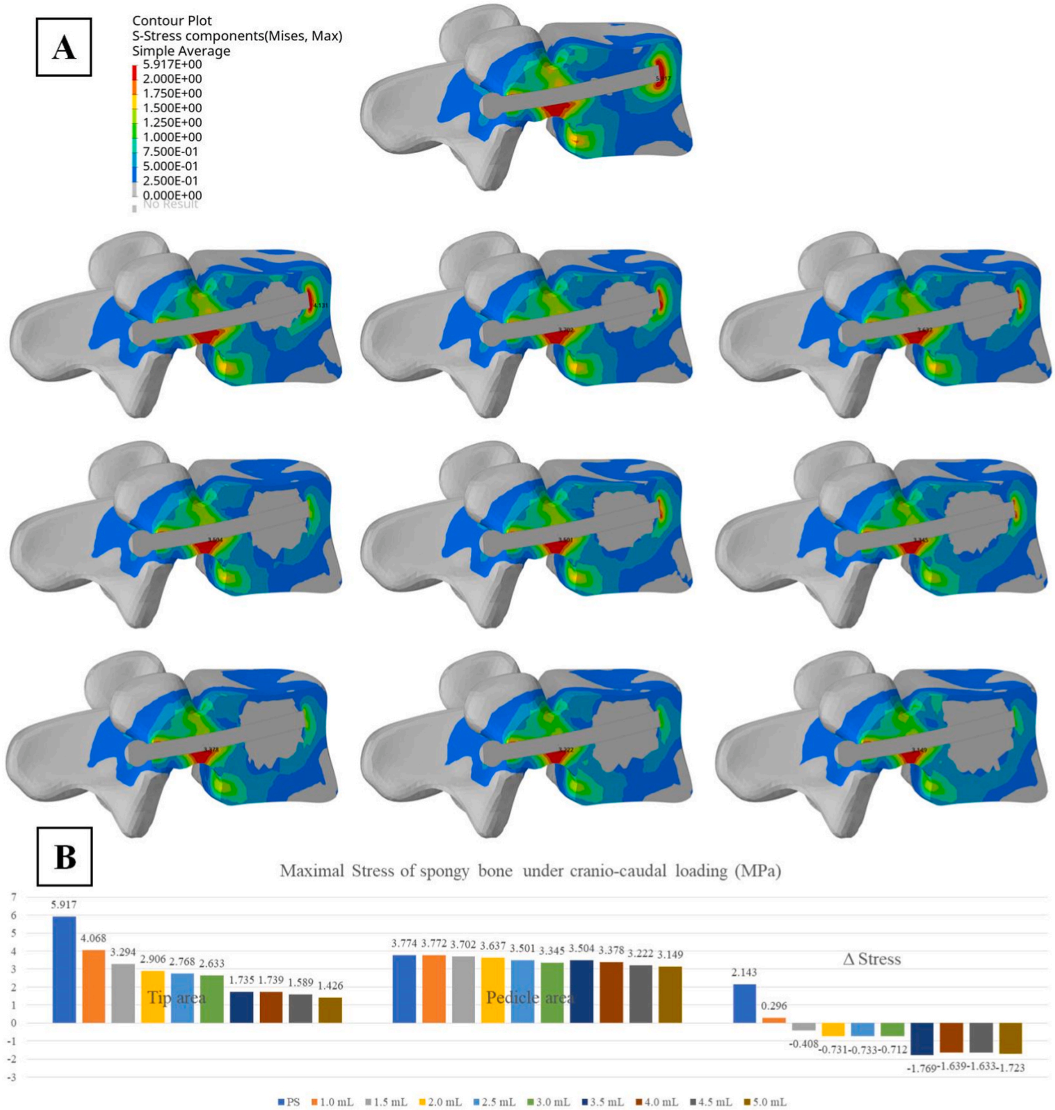

Fig. 5. Stress distribution and maximal stress under cranio-caudal loads. A: Internal stress distribution of cancellous bone in ten models. B: Histograms of maximum stress in screw tip and pedicle area (the first two histograms), and the difference between these two values (Δstress, the third histogram).

mm in distance, compared with PS model. The distance increased with the volume increase, and in the 5 mL model, the distance was 5.5 mm (Fig. 6B).

4. Discussion

To our knowledge, the present study is the first biomechanical experiment to elucidate the failure mechanism of CAPS. It shows the internal responses to mechanical loads are quite different in PS and CAPS models. In the classical pullout test, stress distribution pattern of the implant-bone interface was significantly altered due to intervention of cement augmentation, which included MS regions distribution was quite different from PS models and MS values kept decreasing due to cement volume increase. Cranio-caudal loading test is designed to simulate the axial loads from trunk in daily life activity, which is more similar to the scenario of postoperative status than pullout test. Under axial load, stress distribution patterns of the implant-bone interfaces were similar in PS and CAPS models: stress concentrated both on screw tip and pedicle regions. However, Δstress (difference MS value between the screw tip and pedicle) changed with the cement application: the value was +2.143 MPa in PS model, and it kept positive although decreased nearly to zero with 1 mL cement augmentation; with 1.5 mL and more cement, it kept negative. It suggested that a significant transition of the stress concentration from the screw tip to the pedicle and simultaneous anterior shift of IRC occurred due to cement augmentation, which induced the ultimate failure behavior of CAPS as "reversed windshield-wiper effect".

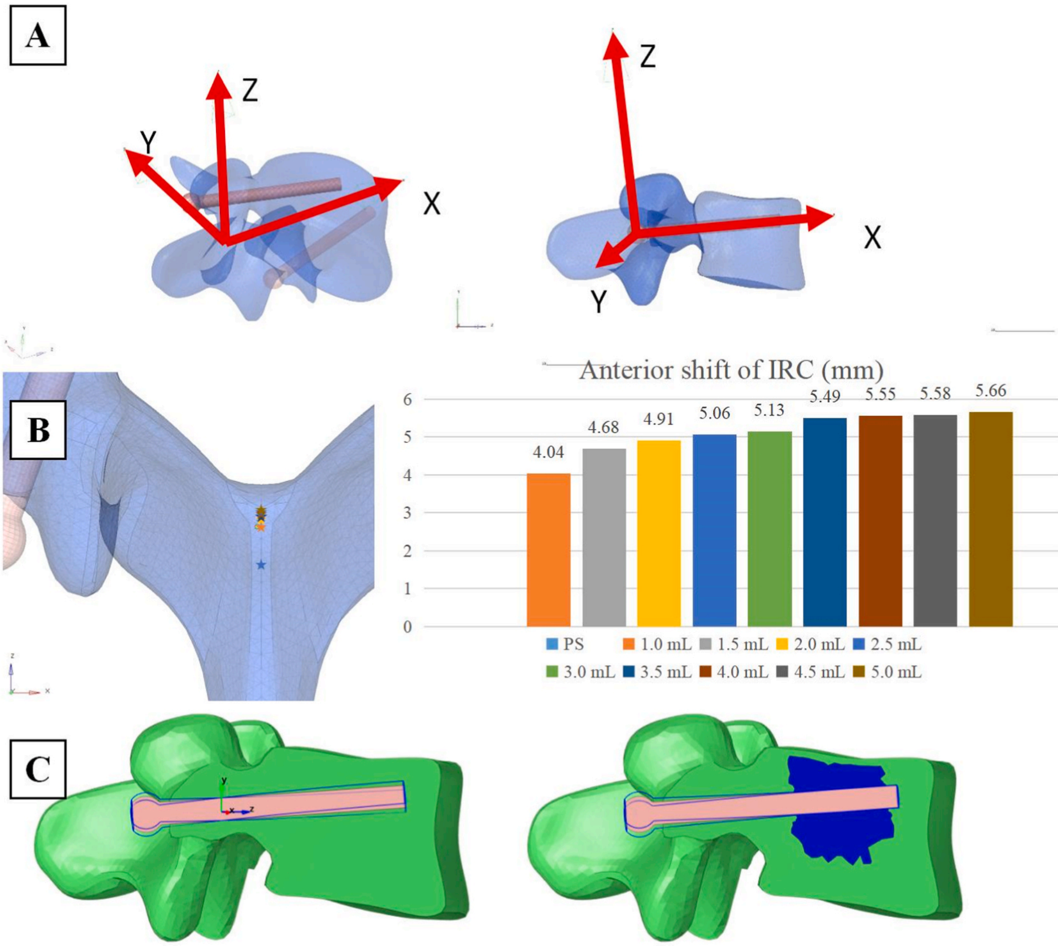

Fig. 6. Instantaneous rotation center in PS and CAPS models under cranio-caudal loads. A: Schematic diagrams of coordinate axis (the coordinate origin is defined as the instantaneous rotation center of PS). B: Location of instantaneous rotation center (left, the top view) and the histogram of displacement (right) for all groups. C: Schematic diagram of reversed windshield-wiper effect.

According to in vitro axial pullout test, the stability of implant-bone interface improved with the increase of cement volume [34–37]. The present study supported the viewpoint indirectly, as the stress distribution pattern significantly altered even with 1 mL cement augmentation, and MS value kept decreasing with cement volume increasing. However, the loads to which the spine is subjected are always complicated than a pullout one. Fatigue cranio-caudal loads are much more common reason for screw loosening [21, 38–40]. Accordingly, we chose cranio-caudal loading in the study to simulate daily activities and the outcomes might provide more reasonable mechanism of typical CAPS failure mode reported in clinical application.

Two major kinds of load and boundary conditions were used for the cranio-caudal loading test. For the frequently used protocol, one or more FSU (functional spinal unit, which contains at least two vertebrae and one intervertebral disc) were used in the test (short for FSU protocol). Compressive or bending moment were applied on the one side of spine. Another, one vertebral body was fixed, and cranio-caudal loading was applied on the screw tail (short for one vertebrae protocol). Usually, the vertebral body were embedded and firmly fixed by methyl methacrylate resin. In current study, the load and boundary condition were modified based on the one vertebrae protocol. The FSU protocol generated much more motion than one vertebrae protocol. Most of the motion generated in FSU protocol was from the intervertebral motion. In our preliminary experiments, we found that the stress distribution pattern of the bone and the movement characteristics of the screw in the bone receive different dosage-related effect of bone cement. We speculated that these are the mechanics of the "reversed windshield-wiper effect". The intervertebral motion plays a more distractions, confounding role in current study. So, we chose the one vertebrae protocol. In the cranio-caudal load, we fixed the screw tail and applied cranio-caudal load on the endplate. It is a little different with the typical protocol (fixed vertebral body and applied load on the screw tail). The screw is much stronger than the bone, which means choosing the screw fixed protocol brings a more stable coordinate system. It brings convenience to motion analysis. In the meantime, it is nearly equivalent in stress distribution analysis between these protocols.

Bostelmann et al. [21] described the "windshield-wiper-effect" as a screw cut out through the superior endplate as a result of cyclic loading, typically found in non-augmented screws or CAPS that are fixed only with a small dosage of cement. The present study showed MS of screw tip region was much higher than that of pedicle under cranio-caudal loads in PS model. Moreover, as the fatigue resistance of cancellous bone next to screw tip was weak [41] than that of pedicle, the failure of PS initiated from the tip and expanded posteriorly. During flexion-extension motion of spine, cranio-caudal loads accumulate into a significant amount of force which eventually results in minute motions turning into significant toggling upon the screw tip [22]. Screws rotated around the pedicle as the IRC of motion (Fig. 6C).

Recently, a distinct different failure mode was observed in CAPS [13,21–23]. The incidence of CAPS failure ranged from 42.9% to 44.2%, which was much higher than we anticipated. The related reports involved small samples of CAPS (range: 21–43 screws). In spite of failure, the cement remained attaching to screws, which suggested the failure occurred at the cement-bone interface instead of screw-cement one. Choy [22] speculated the mechanism of CAPS failure in a case report. In his assumption, the screw tip is rigidly fixed to cancellous bone in anterior column of vertebral body by cement binding. Therefore, cement-screw tip complex served as a fulcrum where subtle motion and torsion would cause the screw body to flip within the pedicle during flexion-extension motion. Results of our study supported this assumption and further unmasked the potential mechanism of CAPS failure: stress concentration shift from screw tip region to pedicle. The anterior shift of IRC induced by cement augmentation leaded to the rotating fulcrum transited from the pedicle region in PS model to the cement-screw complex in CAPS models. Repeated loading transformed the subtle motions to a significant togging in pedicle region by gradual bone stock loss of pedicle, even pedicle cortical breach and weakened purchase of screws [42].

Clinicians usually regarded the stability of the CAPS improved linearly with the increase of cement volume. Studies have shown a linear positive correlation between the cement dosage and the maximal pullout force of screw in vertebral specimens, when the dosage was less than 3 mL [35–37], which was in accordance with our FE analysis. Therefore, some clinicians pursue to inject cement as much as possible within the allowable range. However, an interesting phenomenon was observed in the present study: Δstress changed to negative in the 1.5 mL cement augmented model, kept relative steady (approximate −0.7 MPa) in the volume range of 2.0–3.0 mL, and abruptly reached to a maximum negative value of −1.769 MPa in the 3.5 mL cement augment CAPS models. It suggested that the cement augmentation more than 3 mL would increase the risk of CAPS failure. Combing with the fact that cement augmentation more than 3 mL would not significantly decrease MS in screw tip area, therefore, we speculate that augmentation with such big volume or more would benefit neither the safety nor the efficient of implants. The trends of Δstress explained perfectly the results of Liu Da et al. [37] and Frankel's [34], in which they found that when the dosage exceeded a certain value, the fatigue resistance of the CAPS was no longer improved dramatically in cranio-caudal direction. Consequently, we suggest that 1.5–3.0 mL of cement might be the ideal dosage for CAPS because the stress could be shared relative evenly. We believe that the most reasonable method for CAPS should be that all parts of the component are under comparatively uniform stress distribution, and there is no significant stress concentration in any certain part. This perhaps could not be achieved in the present available CAPS, indicating new-designed implants needed.

Our study has several limitations. First, the distribution characteristics of bone cement, the detailed structure of screws, and the specific distribution of bone cortex were simplified in current study. Second, the spine was also exposed to shear, lateral bending and axial rotational loads, only compressive loads and pullout load could not fully represent in vivo conditions. Third, the mechanical data of the specific cement dosage will change somewhat in different human bodies and in different external environments. In this study, the biomechanical characteristics of CAPS and PS are still fairly specific. However, this study includes such a knowledge, which readers should always be aware of, that the interpretation of data derived from simplified and simulated experiments are primarily based on inter-group trends, rather than specific values.

5. Conclusions

Controversy to the failure mode of pedicle screw, the reversed windshield-wiper effect was presented as the failure mode of cement-augmented pedicle screw. Anterior shift of IRC and the negative difference value of maximum stress between screw tip and pedicle region due to cement augmentation, lead to the screw rotate around the cement-screw complex as the fulcrum point. The optimal cement dosage for CAPS ranges between 1.5 mL and 3.0 mL.

Author contribution statement

Zhong Wang: Performed the experiments; Contributed reagents, materials, analysis tools or data.
Peng Liu: Conceived and designed the experiments.
Ming-yong Liu, Jian-hua Zhao: Performed the experiments.
Xiang Yin, Liang Zhang: Analyzed and interpreted the data.
Yi-bo Gan: Performed the experiments; Wrote the paper.
Ke-yu Luo, Qiang Zhou: Analyzed and interpreted the data; Wrote the paper.
Yao-yao Liu: Conceived and designed the experiments; Contributed reagents, materials, analysis tools or data.

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Data availability statement

Data will be made available on request.

Declaration of interest's statement

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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