Biomechanical Analysis of Cortical Bone Trajectory Screw Versus Bone Cement Screw For Fixation In Porcine Spinal Low Bone Mass Model

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Research Article

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Abstract

Purpose: To compare the biomechanics of cortical bone trajectory screw(CBT) and bone cement screw(BC) in isolated porcine spinal low bone mass model.

Method: Ten porcine spines with 3 segments were treated with EDTA decalcification. After 8 weeks, all the models met the criteria of low bone mass. Ten specimens were randomly divided into two groups, one group was implanted with CBT screw(CBT group) and the other group was implanted with bone cement screw(BC group).The biomechanical material testing machine was used to compare the porcine spine activities of the two groups in flexion, extension, bending and axial rotation, and then insertional torque, pull-out force and anti-compression force of two groups were compared. Independent-sample t test was used for comparison between groups.

Result: Ten 3 segments porcine spine models with low bone mass were established, the bone mineral density of all models was lower than 0.75g/cm^2. The flexion, extension, bending and axial rotation angle of CBT group and BC group respectively were 7.1±1.3°,4.3±0.8°,3.4±0.8°,6.8±0.7°and 6.4±0.8°, 4.5±0.5°, 3.5±0.5°, 6.8±0.8°, there was no significant difference between the two groups,P＞0.05.However, there were significant differences between the two groups and the control group,P＜0.01.The insertional torque of the CBT group and BC group respectively were 0.43±0.09N-m and 0.30±0.07N-m (P=0.03), and the screw pull-out force were 462.67±72.51N and 325.60±77.27N (P=0.021), respectively. There were significant differences between the two groups. The anti-compression forces between the two groups were 3561.81±522.7N and 3586.80±607.42N, respectively, and there was no significant difference between the two groups (P =0.946).

Conclusion: The insertional torque and pull-out force of the CBT were higher than those of the BC in the isolated low bone porcine spine model, and the range of motion and anti-compression ability of model were similar between the two fixation methods.

Background

Pedicle screw internal fixation system has been widely used in the treatment of lumbar disorders[1], along with the ages, the number of osteoporotic patients with degenerative diseases of the lumbar spine and thoracolumbar fractures is increasing. Traditional pedicle screw internal fixation began to have disadvantages, screw loosening is easy to occur when screw fixation is not firm or the spine bears too much load after operation, or even the need for a second operation[2, 3]. Solution is commonly used of bone cement screw in current clinical, it can enhance screw holding force to avoid screw loose, but there is a risk of bone cement leakage, once bone cement leakage into the spinal canal will generate iatrogenic nerve injury, this kind of situation is very serious. Moreover, the complications of bone cement, such as toxic reactions, allergic reactions, and pulmonary embolism, etc.[4], also occur frequently. On the other hand, the cost of bone cement screws is too high for ordinary patients to afford[5, 6].

In recent years, a new idea has emerged, that is to change the existing traditional pedicle screw placement method to adopt a new screw placement method to obtain better screw and bone holding force. In 2009, Santoni et al. proposed the application of cortical bone trajectory technique in lumbar spine internal fixation, namely cortical bone trajectory screw fixation technique(CBT)[7]. At present, there is still controversy about the choice of internal fixation strategy for patients with osteoporosis. Is CBT superior to traditional bone cement screw for the fixation of vertebral bodies with osteoporosis? A literature search revealed a lack of research on this issue. The aim of this study was to compare the biomechanics of CBT screw technique and bone cement screw technique in isolated porcine spinal model with low bone mass, and to explore which internal fixation method was more advantageous for the osteoporotic vertebral body.

Method

1. The specimens

The lumbar vertebrae of slaughtered adult domestic pigs ,weighs 120–130 kg, were used in this experiment, and all specimens were collected from Shanghai Punan Agricultural and Sideline Products Wholesale Market (Address: No. 1098, Cheting Road, Songjiang District, Shanghai). Five freshly frozen porcine lumbar vertebrae, each containing 6 vertebrae, were soaked in formalin, and the surrounding muscle tissue, ligaments and periosteum were removed, each specimen was separated into 2 segments, each segment containing 3 vertebrae. After the above steps, a total of 10 specimens with 3 vertebrae were prepared. This experiment was approved by the Ethics Committee of Shanghai Tongren Hospital (approval number: 2016-35).

2. Internal fixation instruments and experimental instruments

Cortical bone trajectory screw, titanium alloy material, diameter 4.5mm, length 30 mm.Bone cement screw, titanium alloy material, diameter 5.0 mm, length 50 mm. The connecting rod, titanium alloy material, diameter 50 mm,the length can be cut according to the specific conditions of the experiment. A set of spinal internal fixation surgical instruments.The above internal fixation implants and surgical instruments were provided by Dabo Medical Devices. Bone cement (high viscosity bone cement) provided by Medtronic. Spine biomechanical material testing machine (SBM2000, Sanyou Medical Inc, Shanghai.). Dynamic Video Monitor (NDI, Ontario, Canada.).Torque meter (DB1.5N4; Tohnichi Mfg.Co., Ltd., Tokyo, Japan).

3. A low bone mass model of isolated porcine spine was established

The low bone mass model of isolated porcine spine was prepared according to Lee's method[8]. In vitro decalcification of porcine vertebrae with calcium chelating agent (0.5M EDTA solution, pH 7.4) to reduce bone mineral density. The specimens was immersed in 1000 mL of 0.5 M EDTA decalcification solution (pH 7.4; σ) at room temperature, EDTA solution was renewed weekly. Bone mineral density in the specimens was measured after 8 weeks (QDR 1000; Hologic, Inc) to confirm whether a low bone mass model has been established. Low bone mass was defined as mean lumbar bone mineral density less than 0.75g/cm^2. Dual energy X-ray absorptiometry from Shanghai Tongren Hospital was used for bone mineral density measurement. Secure the specimen in a square plastic tank and fill the tank with water until all specimens are completely submerged. All vertebral bodies were scanned one by one and bone mineral density was derived.

4. Implantation of internal fixation

The specimens were fixed by Erkan's methods of embedding fixation[9]. Firstly, 5 specimens were randomly selected as the control group for biomechanical test and data were recorded (see below for the method). Subsequently, the 10 specimens were randomly divided into two groups on average: cortical bone trajectory screw group(CBT) and bone cement screw group(BC), with 5 specimens in each group. Both the CBT group and BC group had 6 screws internal fixation. After the screws implantation, both sides were fixed and locked with connecting rods.All screws implantation operations were performed by Dr. Zhikun Li. After the internal fixation was completed, X-ray and CT were used to check the appropriate position of screw implantation.

(1) CBT group: CBT screws were used for fixation. The screw entry point was the intersection of the central vertical line of the inferior articular process of the upper vertebral body and the horizontal line 1 mm below the lower edge of the transverse process. The camber angle of the screw is 8°-9° and the tail-dip Angle is 25°-26°[10, 11].

(2) BC group: Bone cement screws were used for fixation, and the intersection point of the longitudinal midline of the facet joint and the transverse midline was the entry point, and the entry direction was perpendicular to the coronal plane of the vertebral body and at an Angle of 10°-15° to the sagittal plane of the vertebral body. After the implantation of bone cement screws, bone cement was prepared, and bone cement was injected into the vertebral body through a matching syringe assisted by C-arm machine[12].

5.Biomechanical testing

5.1 Lumbar range of motion: The specimens were placed in the spine biomechanical material testing machine, and infrared sensors were fixed in front of the upper and lower vertebral bodies of the specimens. 4 loading conditions (load ± 7.5N-m, 0.05Hz) : flexion, extension, left and right side bending, axial rotation. The motion state of each moving segment is recorded by a dynamic video monitor with accuracy (0.1mm, 0.1°). Each working condition lasted for 60 s, with each interval of 60 s. Three cycles of testing were carried out in each direction, and the data of the last cycle was recorded. According to the recorded data, flexion, extension, left and right side bending, and axial rotation of each movement segment of the specimen were obtained to evaluate the stability of fixation.

5.2 Torque meter was used to detect the torque of each screw during implantation, and the maximum torque of each screw was recorded, which was the maximum torque value from the beginning to the end of screw implantation.Pull-out force and anti-compression force of screws: Two specimens from each group were randomly selected for the screw pull-out experiment. First, the bilateral connecting rods of the specimens were removed, and the screw pull-out force was measured using a material testing machine. The screw is first connected to the load arm using the nailer connecting rod. The device was loaded at a uniform speed of 5mm/min, and the screw pullout experiments were performed in the long axis direction of the pedicle screws and cortical bone screws until the screws were pulled out 5mm. The data of 24 screws were recorded. The remaining 6 specimens were then put into the material testing machine successively for static compression experiment, and the vertical dynamic arm was loaded with vertical load until the experiment was terminated. The termination of the experiment included the following three situations: fracture of the internal fixation, screw and connecting rod are displaced and sudden decrease of the stress curve.

6. Statistics

Statistical software SPSS 21.0 was used for data analysis. The measurement data was expressed as ±s, the comparison of activity between the control group, lumbar range of motion was compared between control group, CBT group and BC group using LSD test, and the comparison of weight, bone mineral density, insertional torque,pull-out force and anti-compression force between CBT group and BC group was performed by independent sample t test. $P < 0.05$ indicates that the difference is significant.

Result

1. Bone mineral density

Ten isolated porcine spinal spine models with low bone mass were established. Weight was 1.18 ± 0.17kg (0.91-1.40kg), BMD was 1.27 ± 0.11g/cm^2 (1.09-1.45g/cm^2) before soaking. BMD after immersion was 0.47 ± 0.074g/cm^2 (0.37-0.58g/cm^2), which all reached the predetermined low bone mass standard (less than 0.75g /cm^2). The vertebral body weight of CBT group and BC group were 1.14 ± 0.20kg and 1.22 ± 0.14kg, respectively. BMD were 1.27 ± 0.14g/cm^2 and 1.27 ± 0.8g/cm^2 before soaking, and 0.47 ± 0.07g/cm^2 and 0.47 ± 0.08g/ cm^2 after soaking, respectively. There was no significant difference between the two groups ($P > 0.05$), as shown in Table 1.

Table 1
Weight of a porcine spinal model and BMD before and after 8 weeks of EDTA immersion

NO.	Group	Weight(kg)	BMD before 8 weeks(g/ cm^2)	BMD after 8 weeks(g/ cm^2)
1	CBT	1.31	1.18	0.58
2	CBT	0.91	1.09	0.49
3	CBT	1.12	1.30	0.50
4	CBT	1.37	1.45	0.41
5	CBT	0.98	1.36	0.39
6	BC	1.25	1.20	0.55
7	BC	1.40	1.24	0.42
8	BC	1.26	1.31	0.55
9	BC	1.19	1.39	0.37
10	BC	1.01	1.20	0.45

2. Internal fixation model

Five CBT models and five BC models were successfully established.After implantation of internal fixation, both CBT group and BC group were examined by X-ray and CT to determine the correct position of screw implantation, as shown in Fig. 1.

3. The range of motion

The activity degree of CBT group and BC group was significantly lower than that of normal control group ($P < 0.05$), and there was no significant difference in activity degree between CBT group and BC group under different status ($P > 0.05$), as shown in Table 2 and Fig. 2.

Table 2
Comparison of range of motion in three groups under different conditions

Group	Flexion(°)	Extension(°)	Bending(°)	Rotation(°)
Control□	13.3 ± 1.9	12.6 ± 0.8	22.9 ± 1.8	20.5 ± 1.1
CBT□	4.3 ± 0.8	3.4 ± 0.8	7.1 ± 1.3	6.8 ± 0.7
BC□	4.5 ± 0.5	3.5 ± 0.5	6.4 ± 0.8	6.8 ± 0.8
□and□	t = 9.747 P□0.01	t = 18.208 P□0.01	t = 15.753 P□0.01	t = 23.331 P□0.01
□and□	t = 9.993 P□0.01	t = 20.722 P□0.01	t = 18.778 P□0.01	t = 21.786 P□0.01
□and□	t=-0.579 P = 0.582	t=-0.338 P = 0.744	t = 0.908 P = 0.390	t=-0.041 P = 0.968
Note:□and□,□and□,□and□represents a comparison between the two groups.				

4. Biomechanical analysis

There were significant differences in the insertion torque (P = 0.03) and screw pull-out force (P = 0.021) between the CBT screw and the bone cement screw. There was no significant difference in anti-compression force between the two groups (P = 0.946). See Table 3 and Fig. 3.

Table 3
Comparison of insertional torque,pull-out force and anti-compression force between CBT group and BC group

Group	Insertional torque(N-m)	Pull-out force(N)	Anti-compression force(N)
CBT	0.43 ± 0.09	462.67 ± 72.51	3561.81 ± 522.7
BC	0.30 ± 0.07	325.60 ± 77.27	3586.80 ± 607.42
t	2.636	2.878	-0.070
P	0.030	0.021	0.946

Discussion

1. Background and significance

With the aggravation of aging society, the incidence of osteoporosis is gradually increasing. Patients with lumbar diseases often have osteoporosis, such as disc herniation, spinal stenosis, or a lumbar fracture and so on. These patients have spinal cord or nerve root compression, lower limb pain, dysphagia and other serious complications that require surgical treatment for posterior lumbar laminectomy. After the decompression of the lamina, it is necessary to implant an internal fixation device to stabilize the vertebral body. However, the bone strength of the vertebral body is reduced in patients with osteoporosis, and the use of conventional pedicle screws is prone to internal fixation failure[13]. Therefore, it is a difficult problem to choose what internal fixation strategy to stabilize the osteoporotic lumbar spine.

For the internal fixation strategy of osteoporotic vertebral body, scholars have conducted a large number of studies. Generally speaking, there are the following methods. The first is the most commonly used method in clinical practice: bone cement screws. This method follows the original method of pedicle screw implantation and can prevent screw loosening by strengthening with bone cement. In the beginning, bone cement injection was followed by screw implantation. With the development of internal fixation devices, there are now specialized bone cement screws. After the screw is implanted, the bone cement is injected into the vertebral body through the lateral hole of the screw through a specially fitted injection device. However, the research shows that the former screw pull-out force is higher than the latter[2]. However, there are some shortcomings with bone cement screws. For example, in the use of bone cement, there are problems such as high temperature release, monomer toxicity, bone cement fatigue fracture, bone cement leakage, embolism and unable to metabolic, etc., which often need to extend the spinal fixation segment, thus increasing the operation cost, operation time, blood loss and complications[14]. Therefore, the clinical use of bone cement screws is limited. The second is to change the placement and direction of screws, and CBT screws are the most commonly used. Many studies have shown that the pull-out force of CBT screws is better than that of traditional pedicle screws[15], and compared with cemented screws, CBT screws avoid the complications related to bone cement strengthening. At the same time, the insertion point of CBT screws is medial, and there is less muscle dissection during the operation, which can reduce the articular process injury and indirectly reduce the intraoperative bleeding and operation time. The third is to use thicker diameter and longer length screws to increase the pull-out force of the screws. This approach is effective with both conventional pedicle screws and CBT screws. Keitaro et al. found that the fixation strength of CBT screws varies with different screw sizes. The ideal screw size for CBT screws is greater than 5.5 mm in diameter and greater than 35mm in length, and the screw should be sufficiently deep into the vertebral body[16]. Each of these methods has its own disadvantages, so scholars are still debating which internal fixation strategy to choose. The purpose of this study was to determine the appropriate internal fixation strategy for patients with osteoporosis.

Retrieval of literature found that lack of biomechanical research of CBT screw compared with bone cement screw in osteoporosis vertebral body, this study established in vitro low bone mass porcine vertebral body model, the biomechanical properties of CBT screws and bone cement screws in osteoporotic vertebral bodies were compared, to provide theoretical basis for clinical treatment strategies.

2. Results and analysis

In this study, there was no significant difference in the range of motion in flexion, extension, bending and axial rotation between CBT group and BC group (P > 0.05), but the range of motion in the two groups were significantly lower than that in the control group (P < 0.01). Oshino et al. compared the biomechanical stability of CBT screw and conventional pedicle screw fixation. The results showed that there was no significant difference between the traditional pedicle screw group and the CBT screw group in the range of motion in the direction of flexion, extension, bending and axial rotation (P > 0.05)[17]. In addition, the studies of Perez-Oribo et al. [18] also have similar conclusions, which are similar to the results of this study. Other scholars have different views. Zhang et al. [18] compared the biomechanics of CBT screws and traditional pedicle screws through finite element analysis, and found that the ROM (range of motion) of adjacent segments in the CBT group was higher than that in the traditional pedicle screws group (TT group), and the screw stress in the CBT group was better than that in the TT group. In addition, compared with the TT group, the facet joint and endplate stress at the fixed segment was lower in the CBT group, while the stress at the adjacent segment was higher[19].

On the other hand, the results of this study showed that insertional torque and pull-out force in CBT group were significantly higher than those in BC group (P < 0.01), but there was no significant difference in anti-compression force between the two groups (P > 0.05). Santoni et al. also confirmed that the pullout force of CBT screws in osteoporotic lumbar specimens was significantly higher than that of traditional pedicle screws, and there was no difference in fatigue test and structural stability between the two groups[7]. Because the CBT screw is double thread screw, the proximal end of the screw is tight cortical bone thread, the distal end of the screw is sparse cancellous bone thread, this double thread screw structure leads to the insertional torque and pull-out force increased. Matsukawa et al. [15] researched that screw insertion resistance during the insertion of CBT screws was measured in real time, and the results showed that the screw insertion resistance was about 1.7 times that of traditional pedicle screw placement. In the resistance curve, both techniques gradually increased in the initial stage. With screw development, the screw insertion resistance of the traditional pedicle screw quickly reached a plateau, while the resistance of the CBT screw increased throughout. Studies have confirmed that the axial pullout force of the CBT screw is 30% higher than that of the traditional pedicle screw, and the maximum torque is increased by about 99%, with no significant difference in structural stability between the two groups[18]. Another study showed that this CBT screw, applied to thoracolumbar specimens from osteoporotic cadavers, had greater torque than conventional pedicle screws and the same pull-out strength[20]. The biomechanical comparison between bone cement screws and CBT screws was used in this study. Due to the addition of bone cement, bone cement screws anchored together with the vertebral body, and insertional torque and pull-out force were stronger than that of pedicle screws alone. However, the bone cement screw is not in direct contact with the bone, but makes the screw link with the bone through the bone cement, so that insertional torque and pull-out force of the screw are weakened. In addition, osteoporosis vertebral bone trabecula sparse, bone strength decreased, once the bone cement and bone bonding is not tight, easy to appear internal fixation loosening. However, CBT screws are in direct contact with the bone cortex, and the hardness of the bone cortex is much higher than that of the bone cancellous. Therefore, compared with the traditional pedicle screw fixation, insertional torque and pull-out force between the screw and bone interface is increased, thus improving the fixation stability of the screw internal fixation[10, 17].

In vitro animal models of osteoporosis are often used for biomechanical analysis of orthopedic instruments because of their advantages such as short modeling time, low cost and large-scale promotion.First, the shape and structure of the animal model should be similar to that of the human spine to reduce the differences in mechanical results.In a review of the literature, the applicability of different animal models in biomechanical studies of osteoporosis has been identified, for example, large animal models such as pigs, sheep, and dogs are required for biomechanical studies[21]. The porcine vertebral body was chosen as the study object because its vertebral body size and the ratio of cortical bone to cancellous bone microstructure are similar to human vertebral bodies.In addition, the shape of the thoracolumbar spine is the most similar to the human spine, and is the most appropriate segment of all spinal segments. Through CT examination, Teo et al. found that the thickness, number and space of bone trabeculae in porcine spine and human spine were very similar[21], as shown in Table.4. In addition, the study of Zhang et al. used spinal specimens of human with osteoporosis, and the results of maximum insertional torque and pullout load were similar to those of this study[22], as shown in Table.5. On the other hand, rapid decalcitration of porcine spine with EDTA solution is also a common method, which can be used to prepare a reproducible in vitro model of osteoporotic animal vertebral body in a simple and rapid manner[8].

Table.4 Comparison of selected microarchitectural parameters with porcine cancellous bone*

Microarchitectural Parameter	Human Lumbar Cancellous Bone	Porcine Cancellous Bone, Nondecalcified
trabecular thickness (mm)	0.06 ± 0.02	0.19 ± 0.01
trabecular no. (mm^{-1})	1.30 ± 0.23	1.26 ± 0.04
trabecular separation (mm)	0.65 ± 0.16	0.87 ± 0.01

* These data are an updated version of data published by Teo et al

Table.5 Comparison of porcine lumbar and human lumbar with BMD,maximum insertional torque and pullout load

Osteoporosis model	Human lumbar*	Porcine lumbar
BMD,g/cm^2	0.47±0.074	0.571 ± 0.098
Maximum insertional torque, N-m	0.30±0.07	0.35 ± 0.25
Pullout load, N	325.60±77.27	396.0 ± 190.0

* These data are an updated version of data published by Zhang et al

3.Advantages and disadvantages

In this study, the biomechanics of CBT screws and bone cement screws in isolated vertebral body models of osteoporosis were compared to provide a theoretical basis for selecting a more appropriate internal fixation for patients with osteoporosis. Literature search found that no similar studies have been conducted by scholars. The results of this study are of guiding significance for clinical practice, but there are already the following shortcomings.(1) Selection of model: The animal model in this study selected the isolated porcine spine model. Although it has the advantages of short modeling period, low price and good homogenization, cadavers are still the best model for biomechanical research.(2) Sample in vitro: Most of the ligaments and muscles around the isolated porcine spinal model were removed, greatly reducing the advantages of CBT screws for lumbar stability.(3) Sample size: Due to limited funding, the sample size of the model was small, but the biomechanical differences between CBT screws and bone cement screws have been preliminarily demonstrated.

4.The further study

CBT screws provide an alternative fixation technique for the thoracolumbar spine that not only provides adequate fixation strength, but also reduces intraoperative dissection of the muscle, with good patient satisfaction[4, 23]. Therefore, CBT screws provide an additional fixation option for orthopedic surgeons, not only for patients with osteoporosis, but also for revision cases[24–26]. The results of this study showed that insertional torque and pull-out force of CBT screws was better than that of pedicle bone cement screws. In the future, we will use CBT screws in the clinical treatment of patients with osteoporotic thoracolumbar disease with neurological symptoms, and compare the clinical efficacy of the two internal fixation strategies.

Conclusion

The insertional torque and pull-out force of the CBT were higher than those of the BC in the isolated low bone porcine spine model, and the range of motion and anti-compression ability of model were similar between the two fixation methods.

Abbreviations

BMD: Bone mineral density; CBT:cortical bone trajectory; BC: bone cement

EDTA: Ethylene Diamine Tetraacetic Acid; CT: computerized tomography

Declarations

Acknowledgements

Yifan Li and Wei Xu are co-first authors

Authors' contributions

LZK, XW, and LYF conceived and designed the study. WSL, CLW, and SZP measured and recorded the data. LZK and LYF wrote the paper. XW, LZK, and YXJ reviewed and edited the manuscript. All authors read and approved the manuscript.

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Availability of data and materials

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

Ethics approval and consent to participate

This retrospective study was approved and consented to participate by the Ethics Committee.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Figures

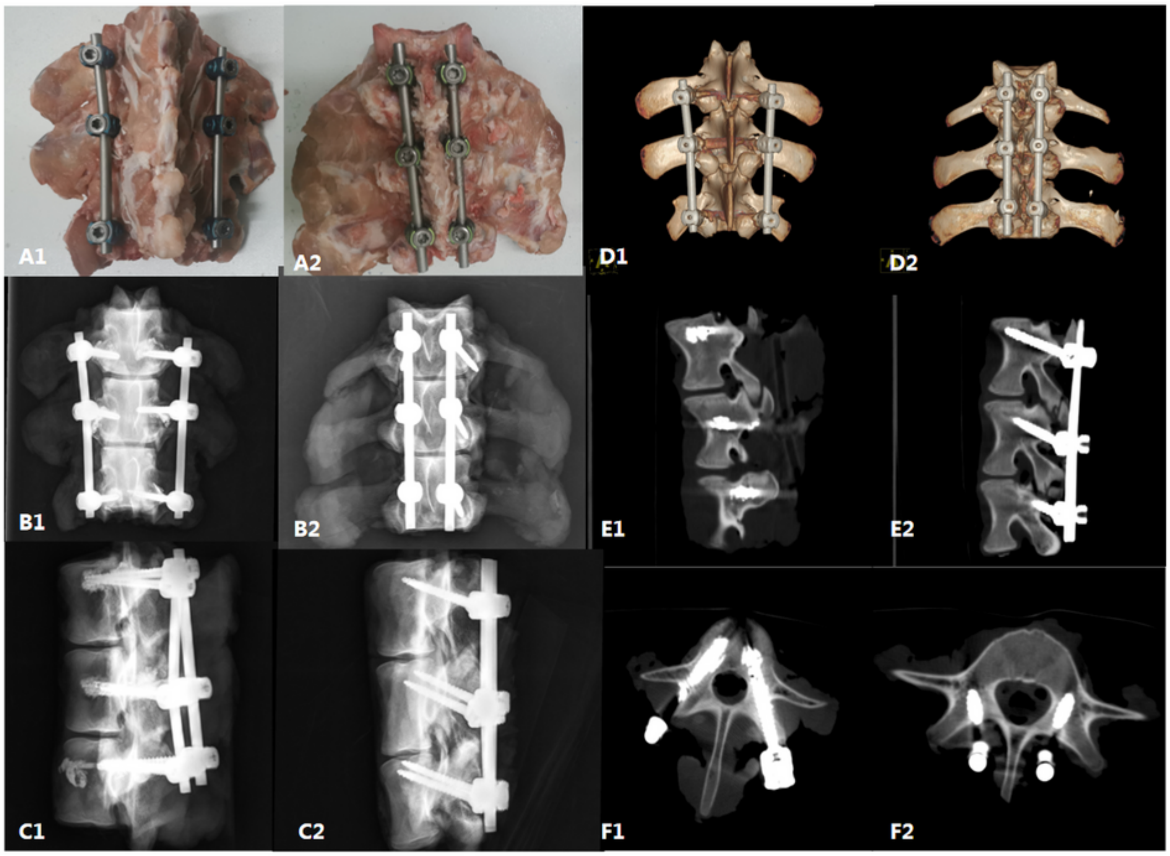

Figure 1

Five CBT models and five BC models were successfully established.After implantation of internal fixation, both CBT group and BC group were examined by X-ray and CT to determine the correct position of screw implantation, as shown in Figure

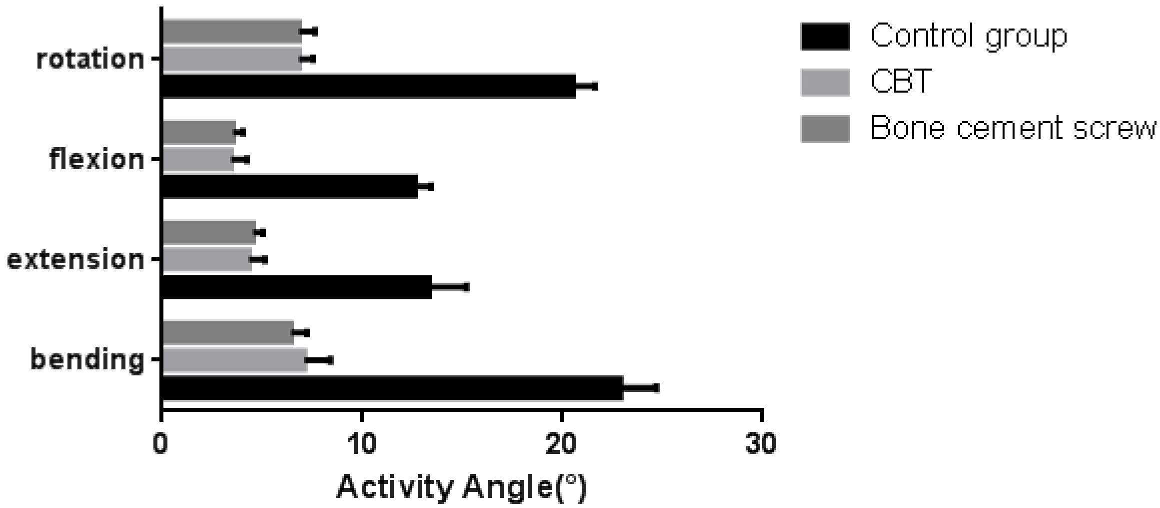

Figure 2

The activity degree of CBT group and BC group was significantly lower than that of normal control group (P < 0.05), and there was no significant difference in activity degree between CBT group and BC group under different status (P > 0.05), as shown in Table 2 and Figure

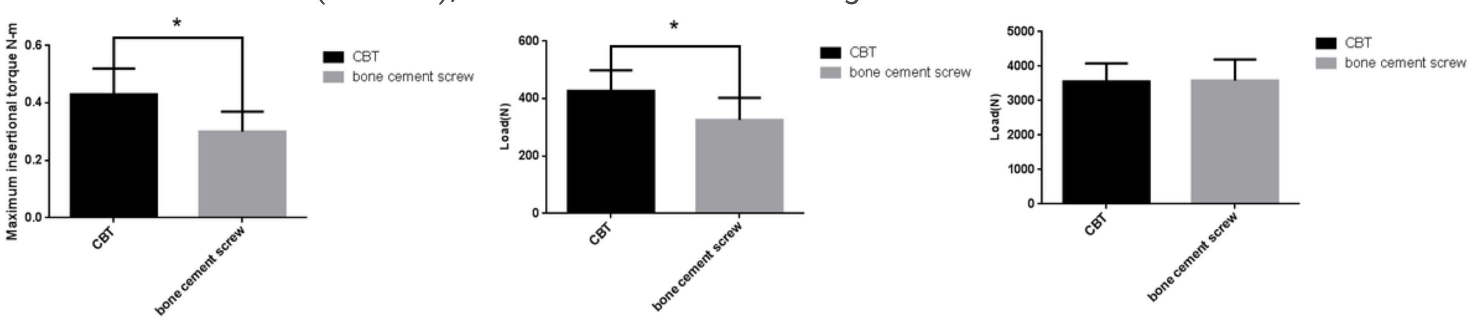

Figure 3

There were significant differences in the insertion torque (P=0.03) and screw pull-out force (P=0.021) between the CBT screw and the bone cement screw. There was no significant difference in anti-compression force between the two groups (P =0.946). See Table 3 and Figure