Pullout strength of adjusting pedicle screw with or without self-bone grafting in the previous trajectory using an osteoporotic human vertebral body

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Abstract

Objectives The aim of this study is to explore the pullout strength of adjusting pedicle screw with or without self-bone grafting in the previous trajectory using an osteoporotic human vertebral body. Methods Thirty vertebrae from six cadavers were collected and all of the vertebrae were divided into two groups according to bone mineral density: control group with normal bone mineral density; osteoporosis group with osteoporosis. The osteoporosis group was randomly and evenly divided into five subsamples according to direction of reinsert pedicle screw: the normal angle, sagittal angle, sagittal bone grafting, horizontal angle, horizontal bone grafting. Axial pullout strength testing of the pedicle screw was performed and the maximum axial pullout force (Fmax) was applied to analyse. Result The bone mineral density of the control group was 1.115±0.065 g/cm3, and the bone mineral density of the osteoporosis group was 0.678±0.055 g/cm3, presenting significantly different between the two group (P<0.001). Compared with the control group, the Fmax of the normal angle group was smaller (600.64±43.10 vs 1100.74±49.08 N, P<0.001). Compared with the normal angle group, the Fmax of the sagittal angle group (339.13±38.90 vs 600.64±43.10 N, P<0.001) and the horizontal angle group (342.06±33.01 vs 600.64±43.10 N, P<0.001) were smaller. The Fmax in sagittal bone grafting group was higher than that with non-implanted bone in primary screw canal (492.30±42.06 vs 342.06±33.01 N, P<0.001), and the Fmax of the horizontal bone grafting group was higher than that with non-implanted bone in primary screw canal (502.02± 50.26 vs 342.06±33.01 N, P<0.001). Conclusion The pullout strength of adjusting pedicle screw is seriously decreased in osteoporotic human vertebral body and self-bone grafting in the previous trajectory is an effective remedial measure.

Introduction

Since the introduction of the pedicle screw internal fixation by Boucher in 1950s. Pedicle screw instrumentation has recently been an increasingly popular surgical procedure to treat spinal pathology, such as spinal degenerative diseases, fractures, tumors, and deformities [1–3]. Numerous studies have proved that pedicle screw fixation provided reliable stability for spinal segment to achieve safe and successful outcomes [4, 5]. However, it showed the challenges in controlling the incidence of screw loosening which is between 0.6% and 11% and may cause the fusions to become unstable, especially for the aged population with osteoporosis [6–8]. Osteoporosis is characterized by low bone mineral density (BMD) and deterioration of bone microarchitecture, which can affect quality of life dramatically for patients and still have high difficulties and increased risk for surgery. Osteoporosis-related complications, like fragility fractures, screws loose, instrumentation collapse, symptom return, are the principal concern of performing surgery and must be carefully monitored and managed during intra-and post-operative to avoid potential reoperation. For the osteoporotic spine especially with vertebral instability, fracture, spinal deformity, tumor, multi-segment lumbar spinal stenosis and so on, the maintenance of postoperative stability is vital to ensure its rapid recovery. Therefore, until the methods to enhance fixation can be aggressively improved for surgeons, pedicle screw fixation will still be the most commonly used fixation method in the aging spine. To pursue better methods, some authors have raised a series of studies on the influencing factors of the pullout strength of pedicle screw in normal and osteoporotic spine [9–10]. Various parameters based on screw design including material, thread, pitch, diameter and length; screw insertion including direction and location; vertebral body including bone mineral density, trabecular structure, cement augmentation, have been described in relation to the pullout strength of pedicle screws in osteoporotic vertebral bodies. Nevertheless, to date studies on influencing factors of the pullout strength prove to be inadequate in which few studies have looked at remedies for failed screw placement. In clinical practice, the elderly patients complicated with kyphosis, lateral bending and other spine malformations, increased the difficulty of screw placement and might involve secondary or even multiple insertions. Reinsertion of pedicle screw will not only lead to the loss of bone in the pedicle and vertebral body but also further reduce the holding force of pedicle screw in osteoporotic spine. Previous studies have shown that tapping prior to placing a pedicle in osteoporotic bone could reduce the pullout force by 52% [11] and have found that if the screw was not inserted in the ideal position once, the torque could reduce by 34% compared with the previous one. In previous studies, there was few report on the secondary adjustment and remedial measures for failed screw placement. Thus, this study aimed to introduce the procedure of self-bone grafting in trajectory as a new remedial method for failed screw placement and compare pullout strength of adjusting pedicle screw with or without self-bone grafting in the previous trajectory using an osteoporotic human vertebral body to explore the feasible measures of adjusting screw in the osteoporotic vertebral body.

Materials And Methods

Specimen preparation of osteoporotic human vertebral body

Thirty lumbar vertebrae from L1-L5 levels of six embalmed cadavers were collected for the assessment of pullout strength of pedicle screw and all specimens were provided by the anatomy laboratory of hebei medical university. The specimen age was range from 55 to 75 years old. All vertebra underwent roentgen graphic examination to exclude gross defects, congenital deformities, fractures and tumors. Specimen preparation was accomplished by performing the following steps: (1) Dissect Lumbar spine specimen from the embalmed cadavers. (2) Carefully remove the soft tissues attached to the surface of the lumbar such as the fat, fascial, muscles, periostea, ligaments and so on. (3) Severe junctions including intervertebral disc and Facet joint between vertebrae to harvest disarticulated vertebral bodies cleaned of all soft tissue. (4) Finally, store at -20 degrees for testing. Ethics Committee of The First Hospital of Hebei Medical University approved this study

Measurement of bone mineral density

Dual energy X-ray absorptiometry (Lunarprodigy, GE, USA) was used to evaluate the bone mineral density (BMD) of specimen. According to the t value of BMD, the degree of osteoporosis was divided into three grades, normal: $t > -1SD$, bone mass reduction: $1SD < t \leq 2.5SD$; osteoporosis: $t < -2.5SD$. The diagnostic criteria of osteoporosis was defined by a loss of BMD greater than 2.5 standard deviations (SD) below average peak BMD of young adult.

Experimental procedures

All of the vertebrae were divided into two groups according to bone mineral density：control group，including 10 vertebrae（L1~L5) with 20 pedicles harvested from 2 cadavers and confirmed as normal bone mineral density; osteoporosis group, including 20 vertebrae（L1~L5) with 40 pedicles harvested from 4 cadavers and confirmed as osteoporosis. The 6.5 mm diameter, 45 mm long, fixed-head pedicle screws were used in all mechanical pullout strength tests. The osteoporosis group was divided into five subsample randomly and averagely according to direction of pedicle screw: normal angle, sagittal angle, sagittal bone grafting, horizontal angle, horizontal bone grafting. The normal angle was defined as more than half of the vertebral body in depth，parallel to the superior end plates and 15° abduction angle. The sagittal angle group was treated as 20 degrees pedicle screw placement relative to the end plate based on normal angle placement of pedicle screw. The sagittal bone-grafting group was treated as self-bone grafting in the previous trajectory prior to insert a 20 degrees pedicle screw relative to the end plate based on normal angle placement of pedicle screw. The horizontal angle was treated as 30 degrees pedicle screw placement in horizontal plane based on normal angle placement of pedicle screw. The horizontal bone-grafting group was treated as self-bone grafting in the previous trajectory prior to insert a 30 degrees pedicle screw in horizontal plane based on normal angle placement of pedicle screw. We evaluated load to failure of screws placed in human vertebral body with or without osteoporosis as well as after adjusting trajectory of screw insertion. Then we evaluated load to failure of screws placed in osteoporotic human vertebral body with self-bone grafting in the previous trajectory prior to a screw reinsertion. A custom pulling jig used to assure only normal axial forces were applied during testing and pedicle screws from various design were loaded until failure. The maximum axial pullout strength was determined to be the max load sustained before failure.

Screw Insertion and Self-bone Grafting

The 6.5 mm diameter, 45 mm long, fixed-head pedicle screws (AFJ129, Tianjin, China) were used in all mechanical pullout strength tests. For the insertion of screws in the normal angle, the entry point was located at the tip of V-shape crest which was defined as the junction of lateral of isthmus and the base of the transverse process at posterior aspect of the pedicle. The posterior cortex of tip of V-shape crest was removed with a rongeur to facilitate direction control. A 3.5 mm diameter drill was advanced by various angles medially as described to create a pilot hole. The direction of sagittal angle group aimed toward the anterior-inferior edge of inferior end plate with 20 degrees relative to the end plate based on normal angle placement of pedicle screw. The direction of horizontal angle group aimed toward the anterior-middle edge of vertebrae with 30 degrees in horizontal plane based on normal angle placement of pedicle screw, as shown in figure 1.

Self-bones for grafting came from spinous process and soft tissue on the surface was removed. The bone-grafting group was treated as self-bone grafting in the previous trajectory prior to insert a various degrees pedicle screw as described.

Pullout Strength Measurements

A custom pulling jig used to assure only normal axial forces were applied during testing (Figure 2). Pedicle screws from various designs were loaded until failure using the 8874 Universal Testing Machine Shimadzu AG-A20000, Shanghai, China). The failure load was measured by a preload of 50 N and speed of 10 mm/s in the long axis direction of the pedicle screw. The data was collected every 0.005s. Pedicle screws from various design were loaded until failure. The ultimate maximum axial pullout strength was determined to be the max load sustained before failure and marked as "Fmax". All data were recorded and analyzed by the computer [12, 13].

Statistical Analysis

All statistical analyses were performed used SPSS software version 13.0 (SPSS, Inc., Chicago, IL). The results were expressed as the mean ± standard deviation (SD). One-way analysis of variance (ANOVA) was used for the analysis of bone mineral density and maximum axial pullout strength, followed by Student-Newman-Keuls test for significant pairwise differences between subsamples. The statistical significant value was set at $p<0.05$ in the univariate analyses.

Result

Thirty lumbar vertebrae from L1-L5 levels of six embalmed cadavers were included in this study. The 10 vertebrae were included in control group and 20 in osteoporosis group. The result of bone mineral density shown as follow: The bone mineral density of the control group was 1.115±0.065 g/cm3, and the bone mineral density of the osteoporosis group was 0.678±0.056 g/cm3, presenting significantly different between the two group ($P<0.001$) (Table 1). The bone mineral density of normal angle group, sagittal angle group, sagittal bone grafting group, horizontal angle group and horizontal bone grafting group were 0.675±0.043 g/cm3, 0.673±0.049 g/cm3, 0.689±0.062 g/cm3, 0.646±0.081 g/cm3, 0.651±0.042 g/cm3, individually and no difference was found between them ($P>0.05$), as shown in table 2.

All of pedicle screws were treated as described in the "Materials and methods" section and the results of CT scanning presented in figure 3. At the CT scanning level, the control group displayed normal morphology and signal in the vertebrae. However, abnormal morphology and signal, a loss of well-distributed pattern, as well as a gradual reduction in the number of solidity bone tissue with some areas of disintegration, were clearly observed in the osteoporosis group on the CT scanning, testifying to the bone tissue's degradation. Moreover, the following specific changes were observed: the percentage of normal bone decreased significantly; the shapes of bone tissue were irregular and some of them were defected; the previous trajectory without self-bone grafting was clear and the blurry edge of previous trajectory could be seen in self-bone grafting group.

Compared with the control group, the Fmax of the normal angle in osteoporosis group was marked smaller (600.64±43.10 vs 1100.74±49.08 N, $P<0.001$). Compared with the normal angle group, the Fmax of the sagittal angle group (339.13±38.90 vs 600.64±43.10 N, $P<0.001$) and the horizontal angle group (342.06±33.01 vs 600.64±43.10 N, $P<0.001$) presented individually significant smaller. The Fmax in sagittal bone grafting group was higher than that with non-implanted bone in sagittal angle group (492.30±42.06 vs 342.06±33.01 N, P<0.001), and the Fmax of the horizontal bone grafting group was higher than that with non-implanted bone in horizontal angle group (502.02± 50.26 vs 342.06±33.01 N, P<0.001), as shown in table 3 and figure 4.

Discussion

In recent years, increased attention has been given to the effects of chronic neck or lower back pain (LBP) which can not only bring about physical and psychological pain to the patients but also result in numerous socio-economic burdens. In natural populations, up to 70–80% of adults have experienced at least one incident of LBP in their lifetime [14]. For severe LBP with spinal degenerative diseases, fractures, tumors and deformities, surgical treatment, intervertebral fusion combined with screw fixation is often considered a reasonable indication and can obtain satisfactory clinical outcome. However, among elderly patients with osteoporosis, as the perioperative complication, failure or dissatisfaction of instrumentation is relatively often and clinically worrisome. Malposition and loosening of pedicle screw are main reasons of failure of internal fixation. The reported rate of pedicle screw malposition is 5–41% [15-17]. Numerous studies have proved the influencing factors of the pullout strength [18-19]. Nevertheless, few studies have looked at remedies for failed screw placement. Thus, this study has introduced the procedure of self-bone grafting in trajectory as a new remedial method for failed screw placement and compare pullout strength of adjusting pedicle screw with or without self-bone grafting in the previous trajectory using an osteoporotic human vertebral body to explore the feasible measures of adjusting screw in the osteoporotic vertebral body.

Osteoporosis is widely recognized in the scholarly literature as a premise and foundation of fragility fractures, which is most common in older people and needs to be corrected by surgery [20-21]. For the osteoporotic spine especially with vertebral instability, fracture, spinal deformity, tumor, multi-segment lumbar spinal stenosis and so on, fixation of pedicle screw is vital to maintain postoperative segment stability and ensure its rapid recovery [22-24].

Weinstein et al. [25] reported a biomechanical experiment of pedicle screws and found that 60% of the fixation strength required for pedicle screw was provided by pedicle, 15-20% by interaction of screw with cancellous bone, and another 20-25% by penetrating contralateral cortical bone. Many studies reported that osteoporosis could lead to the decrease of anchoring force of pedicle screw and the pedicle screw often loosen. Based on the results, we found that BMD had a high correlation with pedicle screw axial pullout force, which presented downward trends in osteoporotic vertebrae and was comparable with those by other authors [26, 27]. From CT scanning of lumbar vertebrae, exhibited signs of osteoporosis testifying to the bone tissue's degradation were clearly observed in the osteoporosis group, which shown specificity as abnormal morphology and signal, a loss of well-distributed pattern, as well as a gradual reduction in the number of solidity bone tissue with some areas of disintegration. Moreover, the following specific changes were observed: the percentage of normal bone decreased significantly; the shapes of bone tissue were irregular and some of them were defected. We think it may be associated with the decrease of Minerals, like inorganic calcium and phosphorus and the disorder of bone trabecular structure. Varghese et al. found that BMD was an important factor affecting the fixation strength of pedicle screw, of which the greatest impacts on it involved insertion torque of screw (82%). The maximum pullout force (76%), stiffness (46%) and strain energy (85%), when synthetic osteoporotic cancellous bone block models with 3 different BMD of 80 kg/m-3, 160 kg/m-3, 240 kg/m-3 were utilized [28]. Ruffoni et al. through describing the three-dimensional lattice model of bone trabeculae found that the thinness degree of bone trabeculae mainly affected the pullout strength of screws, while the loss of bone trabeculae mainly affected the stiffness of screw [29]. As the similar results, we imagine that normal structure and function of bone trabeculae cannot be enough to maintained and lead to disintegration of internal structure, the decline of the ability to resist external forces and even the occurrence of micro fractures occur, once the loss of minerals to a certain extent.

In clinical practice, the elderly patients complicated with kyphosis, lateral bending and other spine malformations, increased the difficulty of screw placement and might involve secondary or even multiple insertions. Many studies reported that the biomechanical strength of a redirected pedicle screw is less than that of a correctly placed screw [30-32]. In the present study, we found that the pullout strength of reinserted pedicle screw seriously decreased by more than 40% in osteoporotic vertebral compared with inserted one time. This reduction in the pullout strength of the reinserted pedicle screw might be related to the compression of bone tissue in the pedicle and the loosening of the microstructure such as bone trabecula. Ferris et al. et al had preformed a study of evaluating the effect of various screw designs on the screw fixation strength and found that tapping a pilot hole does not increase pullout strength in bone with densities near 20 lb/ft3, which correlates with low-density cancellous or osteoporotic bone [33]. Purvi et al. found that pullout strength was obviously rising with the increased angle of the screw axis with the axis of pullout force for 10°, 20°, 30° and 40°, which might be related to the increased compressed resistance of the screw to the bone tissue above it [34]. The results, in our study, indicated that there was no significant difference in pedicle screw axial pullout strength between sagittal angle and axial angle reinserted, which could be related to the axial pullout of the screw. Axial pullout of the screw only needed to overcome the resistance of the screw thread trajectory without shear force. The results indicated that the use of the universal screw and crossbar might have a positive effect to avoid the axial pull-out of the screw, Inserted pedicle screws at the the first time formed a thread track matching the screw and the connection with the bone tissue was tight and firmly fixed. Inserted pedicle screws using the previous entry point easily caused compression and dissociation of previous trajectory due to too much spongy bone tissue decreased and the bone tissue around pedicle screw does not fit closely due to previous thread track broken down. At the same time, it speculated that the compression of the bone tissue surrounding screw resulted in uneven distribution of osteoporotic bone tissue and reduction of contact area of thread and bone, which needed to be confirmed in our future research.

Many studies have tried to solve the problem. Bone cement augmentation is considered an effective measure to improve the pullout strength in osteoporotic cancellous bone [35, 36]. However, when the screw position needs to be adjusted, it is very difficult to judge the integrity of the cortical bone as the poor bone quality. it is possible for the screw canal to communicate with the adjacent canal. There exists potential risks that redundant bone cement may be extruded and uncontrolled, resulting in bone cement leakage and nerve injury. Matsukawa et al. reported that in osteoporotic bone, increasing the diameter of pedicle screw larger than 5.5mm did not significantly increase the strength of screw fixation related to the thinning of bone in pedicle caused by osteoporosis, on the contrary, larger screw diameter might cause the risk of cortical fracture around pedicle [37]. Therefore, bone cement augmentation and increasing the diameter for reinserted pedicle screw may not be the best indication in osteoporotic vertebral body. We used the method of autologous spinous process replaced into the previous trajectory, which shown that the reduction of screw fixation strength caused by adjustment of trajectory could be effectively compensate by additional thread resistance from the self-bone grafting. In addition, the self-bone does not cause the rejection reaction and embolism. To self-bone grafting, the material is convenient to obtain and is relatively safe, and meanwhile, the operation time and the operation cost caused by the temporary change of treatment can be avoided.

There are still some limitations in this study. First, pullout force at certain angles to the screw axial direction was not involved, which may be more close to the biomechanical of the actual pedicle screw in vivo. Then, the adjustment of screw involved only two directions and optimal adjustment angle needed to be further explored. Finally, it is necessary to increase the sample size and expand the experimental conditions for further analysis.

Conclusion

The pullout strength of adjusting pedicle screw is seriously decreased in osteoporotic human vertebral body and self-bone grafting in the previous trajectory is an effective remedial measure.

Declarations

Ethics approval and consent to participate- The study was approved and consented by Ethics Committee of The First Hospital of HeBei Medical University.

Consent for publication- Not applicable.

Availability of data and materials- The datasets generated and analysed during the current study are availabled from the corresponding author on reasonable request.

Competing interests- The authors declare that they have no competing interests.

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Authors' contributions- conceived and designed the study: GBL; collected

data: S.L, J.L, HYG; analyzed the data: W.W, F.Z, S.L; wrote the paper: Sen Liu

All authors declare that we have no conflict of interest regarding this study. All authors read and approved the final manuscript

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Tables

Table 2 Comparison of bone mineral density (BMD) between the subsample groups of osteoporosis

There were no statistically significant differences in BMD between the subsample groups of osteoporosis ($P > 0.05$)

Table 1 Comparison of bone mineral density (BMD) between the groups of control and osteoporosis

Group	BMD（g/cm3）			t-Value	P-Value
	Minimum	Maximum	mean ±SD		
Control	1.00	1.23	1.115±0.065	26.89	<0.001*
Osteoporosis	0.59	0.79	0.678±0.056		

"*" indicates that there was a statistically significant difference in BMD between the two groups ($P<0.001$)

Group	BMD（g/cm^3）			F-Value	P-Value
	Minimum	Maximum	mean ±SD		
Normal angle	0.60	0.77	0.675±0.043	0.492	0.742
Sagittal angle	0.59	0.75	0.673±0.049		
Sagittal bone grafting	0.60	0.77	0.689±0.062		
Horizontal angle	0.59	0.79	0.646±0.081		
Horizontal bone grafting	0.62	0.72	0.651±0.042		

Table 3 comparison of maximum pullout strength (Fmax) between the groups

Group	Fmax（N，mean ± SD）	t-Value	P-Value
Control VS Normal angle	1100.74±49.08 VS 600.64±43.10	25.14	<0.001*
Normal angle VS Sagittal angle	600.64±43.10 VS 339.13±38.90	12.74	<0.001*
Sagittal angle VS Sagittal bone grafting	339.13±38.90 VS 492.30±42.06	-7.56	<0.001*
Normal angle VS Horizontal angle	600.64±43.10 VS 342.06±33.01	13.47	<0.001*
Horizontal angle VS Horizontal bone grafting	342.06±33.01 VS 502.02± 50.26	-7.52	<0.001*

"*" indicates that there were statistically significant differences in maximum pullout strength between the groups ($P<0.001$)

Figures

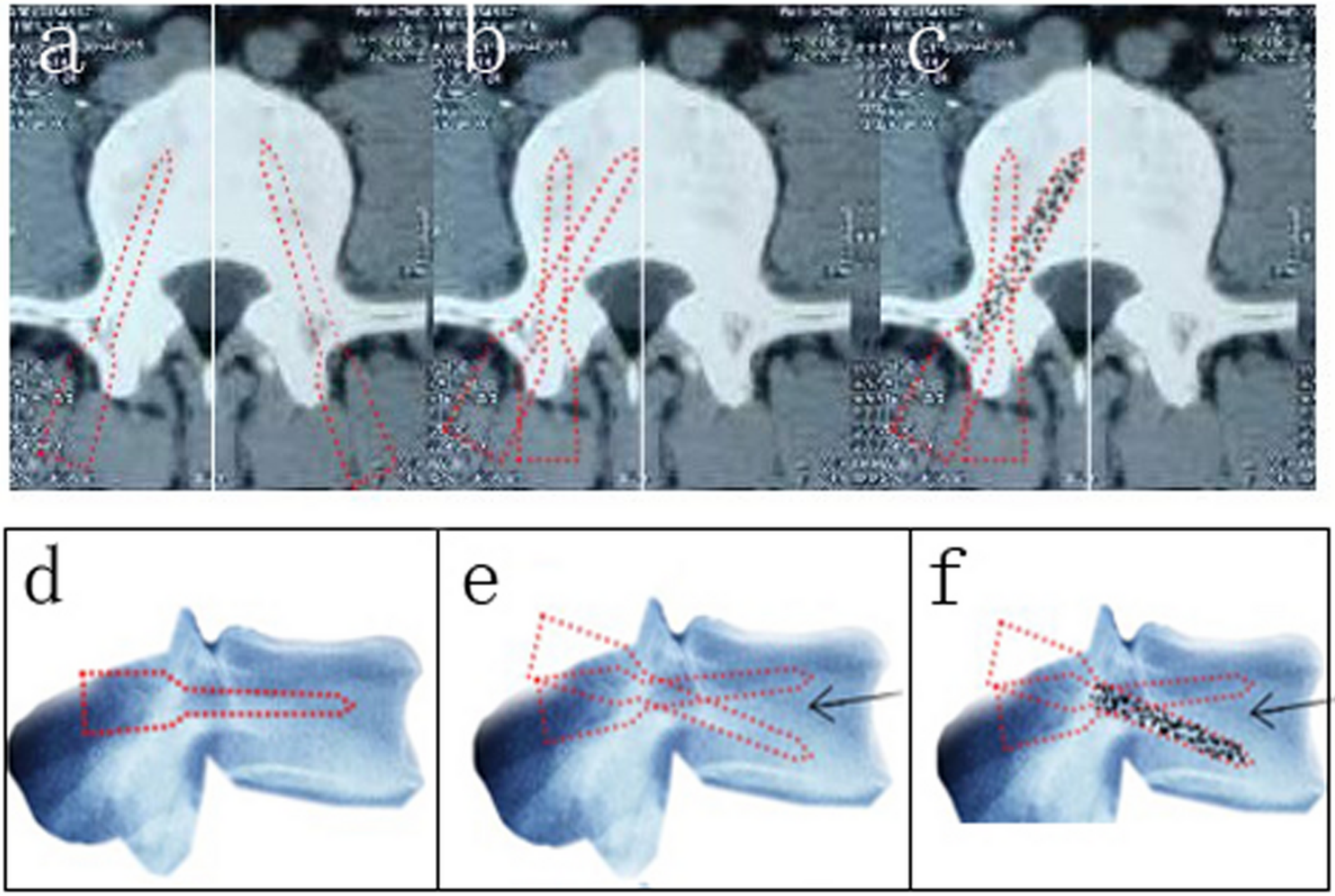

Figure 1

Sketches of pedicle screw placement. a and d: The normal angle was defined as more than half of the vertebral body in depth parallel to the superior end plates and 15° abduction angle. b: The sagittal angle group was treated as 20 degrees pedicle screw placement relative to the end plate. c: The sagittal bone-grafting group was treated as self-bone grafting in the previous trajectory prior to insert a 20 degrees pedicle screw relative to the end plate. e: The horizontal angle was treated as 30 degrees pedicle screw placement in horizontal plane. f: The horizontal bone-grafting group was treated as self-bone grafting in the previous trajectory prior to insert a 30 degrees pedicle screw in horizontal plane.

Figure 2

a: bone self-transplant. B: a 6.5 mm diameter, 40 mm long, fixed-head pedicle screws were used in all mechanical pullout strength tests and pedicle screws from various design were loaded until failure. c and d: a custom pulling jig used to assure only normal axial forces were applied and the maximum axial pullout strength was determined to be the max load sustained before failure.

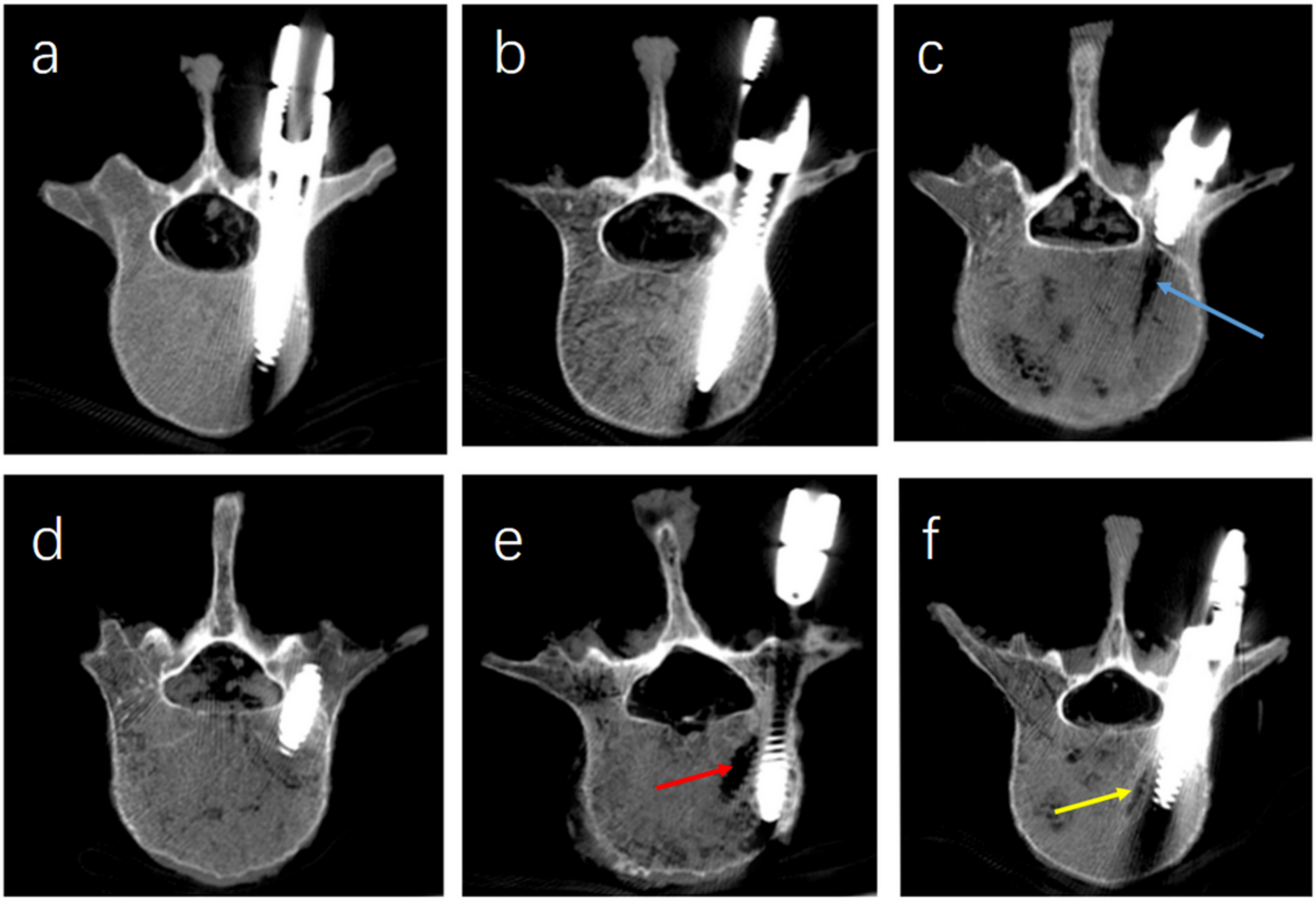

Figure 3

a: Control group with normal bone mineral density. b: Primary pedicle screw placement group. c and e: Sagittal angle group and horizontal angle group. The previous trajectories are visible as indicated by the blue arrow and red arrow in the figure. d and f: Sagittal bone grafting group and horizontal bone grafting group. The edges of previous trajectory are not obvious.

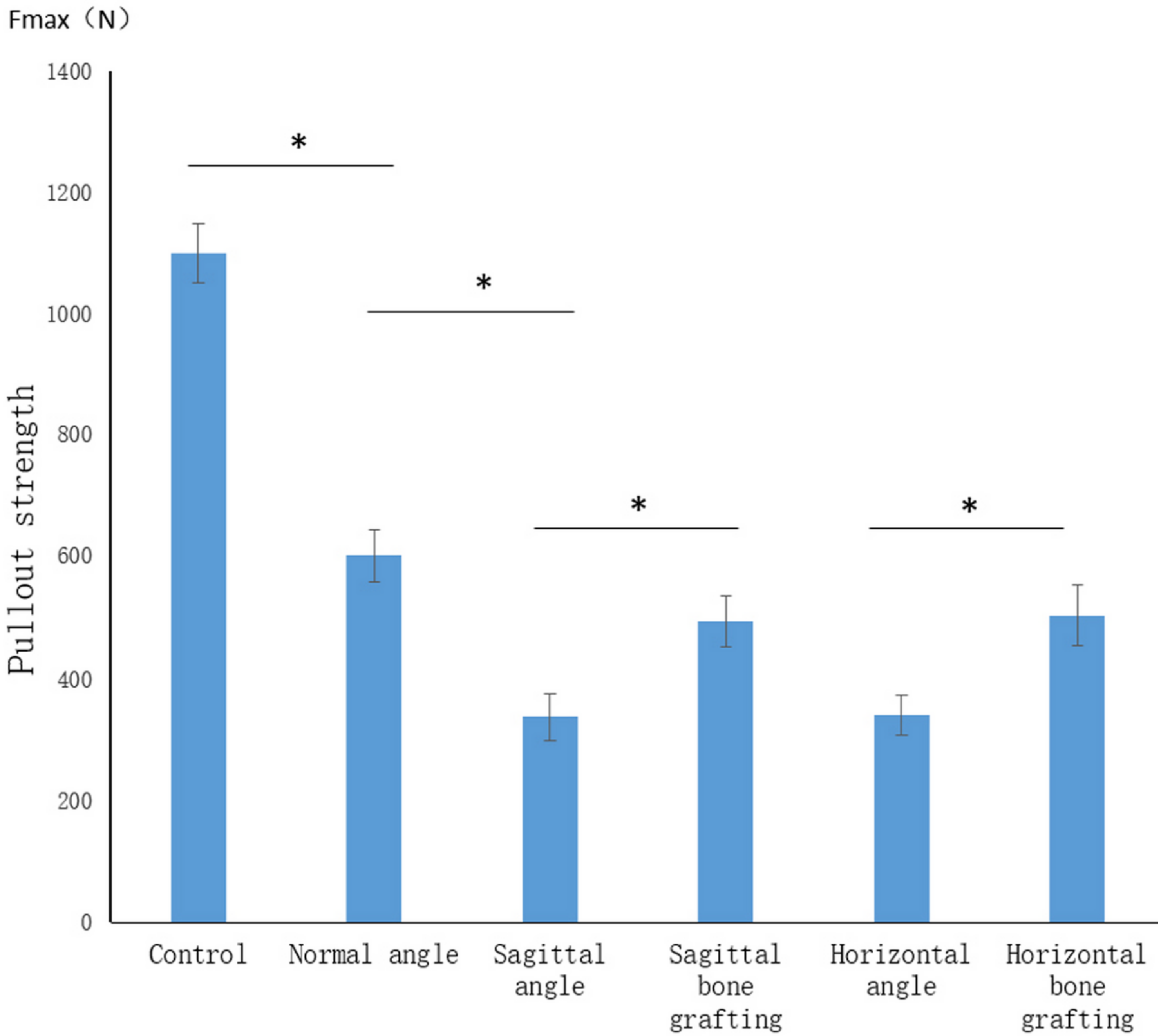

Figure 4

Comparison of maximum pullout force (Fmax) between the groups. “*” indicates there is a statistical difference.