Basic Science

Biomechanical properties of pedicle screw fixation augmented with allograft bone particles in osteoporotic vertebrae: different sizes and amounts

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Abstract

BACKGROUND CONTEXT: A persistent challenge in spine surgery is improving screw fixation in patients with poor bone quality. Augmenting pedicle screw fixation with allograft bone appears to be a promising approach.

PURPOSE: To evaluate the biomechanical properties of screws augmented or revised with allograft bone particles (ABPs) and the effect of different sizes and amounts of ABP on screw-fixation strength.

STUDY DESIGN: Biomechanical in vitro study.

METHODS: Sixty vertebrae were separated randomly into six groups. Groups A1 and A2: one pedicle of each vertebra was selected randomly to be the original pedicle and implanted with a screw. Then, biomechanical tests were performed. Subsequently, the failed trajectory was revised with 1 mm ABP, and the contralateral pedicle was augmented with the same size and amount of ABP. Groups B1 and B2: two pedicles of each vertebra were augmented with different amounts of 1 mm ABP. Groups C1 and C2: one pedicle of each vertebra was augmented with 1 mm ABP to the maximum. The contralateral pedicle of each vertebra was augmented with the same amount of 2 mm ABP. After augmentation and screw insertion, groups A1, B1, and C1 were subjected to the pullout test, whereas groups A2, B2, and C2 the cyclic fatigue test.

RESULTS: Groups A1 and A2: screw augmentation increased the pullout strength by 47%, cycles to failure by 31%, and failure loads by 21% compared with the screw in the original pedicle (p<.05). Screw revision obtained 79% pullout strength, 97% cycles to failure, and 98% failure loads of the screw in the original pedicle (p<.05). Groups B1 and B2: full (100%) trajectory augmentation increased the pullout strength by 39%, cycles to failure by 18%, and failure loads by 12% compared with half (50%) trajectory augmentation (p<.05). Groups C1 and C2: the values of the pullout strength, cycles to failure, and failure loads of the screw augmented with 1 mm ABP were all greater than those in the 2 mm ABP. However, no significant differences were observed between the two treatments (p>.05).

CONCLUSIONS: Trajectory augmentation with ABP can significantly increase the strength of the augmented screws. Full trajectory augmentation can provide greater strength compared with half trajectory augmentation. In patients with osteoporosis, we recommend using 1 mm ABP in full trajectory augmentation (0.3 g ABP for 5.5 mm×40 mm and 0.5 g ABP for 6.5 mm×45 mm) before trajectory fails. © 2019 Elsevier Inc. All rights reserved.

Keywords: Allograft; Biochemical phenomena; Bone transplantation; Osteoporosis; Pedicle screws; Bone mineral density; Spine

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Introduction

The incidence of osteoporosis (OP) is continually increasing, especially among the elderly population. For spine surgeons, pedicle screw fixation plays an important role in treating patients with OP. Successful fusion is likely possible with rigid internal fixation [1], and such posterior internal fixation systems undergo important internal constraints, resulting in high-load-bearing requirements for the pedicle screw−bone interface. However, reduction of bone mineral density (BMD) in patients with OP often results in poor holding strength of the pedicle screw [2]. Thus, additional stabilization should be considered [3].

To increase the stability of the internal fixation, many researchers have conducted a number of studies and suggested various methods, including the use of long and large-diameter screws, screws with uneven surface, and expandable screws and matchstick bone, absorbable polymers, and polymethyl methacrylate (PMMA) in screw augmentation [4−8]. Screw bone cement augmentation is an effective method of improving the fixation interface intensity in patients with OP [9,10]. Polymethyl methacrylate is widely used in screw bone cement augmentation and has been shown to significantly improve pedicle screw fixation [11]. However, it has several disadvantages, including the risk of thermal injury and intraspinal occupancy [12]. Meanwhile, other researchers have used calcium phosphate cement (CPC) in screw augmentation [13−15]. Unlike PMMA, CPC is biodegradable and hardens via a hydration reaction, which is endothermic. However, the use of CPC cannot completely avoid the risk of leakage. To find alternative bone cements, researchers have used allograft bone plugs, milled bones, and matchstick-shaped bones in screw augmentation and revision. However, these materials did not significantly increase the screw strength [6,12]. In these studies, the researchers did not make a clear definition of the size and amount of bone used. To our knowledge, the present study is the first to use allograft bone particles (ABPs) with uniform specification in screw augmentation and revision. Moreover, we evaluated the effect of different sizes and amounts of ABPs on screw-fixation strength.

Axial pullout test and insertional torque measurement are widely used in biomechanical studies as they are good predictors of screw strength [16]. However, the clinical relevance of pullout test for pedicle screw testing is debated because pullout has rarely been reported clinically as a failure mechanism [17,18]. Furthermore, fatigue failure of the bone under cyclic toggling loading is clinically relevant [19,20]. Construct failure of internal spinal fixation mainly occurs due to the patient's daily activity over a substantial period of time postoperation [21]. Pedicle screws undergo a "teeter−tauter effect" with the pedicle screws acting as a fulcrum and the surrounding trabecular bone being pushed away from the screw. Cyclic loading is a critical factor that significantly affects screw−bone construct stiffness and may lead to acute screw loosening. This mechanism of failure has been called "hubbing." Thus, in the present study, we selected insertional torque, axial pullout test, and cyclic fatigue test as the evaluation criteria for the biomechanical properties of the pedicle screw augmented or revised by ABP.

The objectives of this study were to evaluate the biomechanical properties of the screw augmented or revised by ABP and the effect of different sizes and amounts of ABP on screw-fixation strength. The results of our work may provide a theoretical basis for the clinical application of ABP in pedicle screw augmentation.

Material and methods

Specimens

This study was performed using osteoporotic human lower thoracic vertebrae and lumbar vertebrae obtained through the Department of Human Anatomy of our university. After receiving ethics approval, 60 vertebrae (T10−L5) were harvested from 10 adult cadavers (five males and five females, average age: 65.63±10.35 years, age range: 53−83 years). Each vertebra was separated carefully from its neighbors and dissected free of all soft tissues. Directly after harvesting, the vertebrae were sealed in plastic bags and stored at −20°C. Radiograms of the vertebrae were obtained to rule out any bony abnormalities, such as fracture, tumor, and severe degeneration, which could affect the mechanical properties of the spine. Before the test, the vertebrae were taken out of the refrigerator and thawed at room temperature for 24 hours.

Determination of BMD

The BMD of the vertebral body of specimens was measured using dual-energy X-ray absorptiometry (Lunar Prodigy; General Electric, Fairfield, CT, USA) and quantitative computed tomography (QCT, SOMATOM Spirit; SIEMENS). The threshold value of the osteoporotic vertebrae was based on the guidelines of the American college of radiology which defined a QCT trabecular spine BMD range which is approximately equivalent to the World Health Organization diagnostic category: normal: BMD>120 mg/mL; osteopenia: 80 mg/mL≤BMD≤120 mg/mL; OP: BMD<80 mg/mL [42]. In this study, the average BMD of all vertebrae was under 80 mg/mL. As reference, a BMD lower than 0.8 g/cm^2 or a T-score of −2.5 or less was classified as the osteoporotic human cadaveric vertebrae [22].

Pedicle screw and ABPs

Before the start of the formal experiment, we conducted a pre-experiment to explore the test conditions to debug the test equipment. According to the three-dimensional computed tomography (CT) measurement results of the

specimen, we selected 5.5 mm×40 mm pedicle screw (U Spine II, Libeier Bio-engineering Institute, Beijing, China) for the lower thoracic vertebrae and 6.5 mm×45 mm pedicle screw for the lumbar vertebrae. The 5.5 mm×40 mm and 6.5 mm×45 mm pedicle screws had minor diameters of 3.5 and 3.8 mm, respectively. As for the trajectory bone graft, we used a delivery tube with an inner diameter of 3 mm. This tube is commonly used in kyphoplasty technique in current clinical applications (Fig. 1). Using a delivery tube in the trajectory bone graft can allow the bone particles to be evenly and fully distributed in the trajectory compared with forceps. The delivery tube mentioned above was made by Medtronic, Inc. We selected 1 and 2 mm sizes of ABP (Xin Kang Chen Medical Technology Development, Beijing, China) to be used in trajectory augmentation and revision because of the minor diameter of the pedicle screw and the inner diameter of the delivery tube. We found that bone particles greater than 3 mm could not unimpededly pass through the delivery tube. The average BMD of ABP was 0.45 g/mL for 1 mm ABP and 0.28 g/mL for 2 mm ABP (Fig. 2). In the pre-experiment, we measured the amount of bone particles needed to fully fill the trajectory and found that 0.3 and 0.5 g of ABP were needed for 5.5 mm×40 mm and 6.5 mm×45 mm trajectories, respectively. After trajectory bone graft, CT scan was performed on the augmented vertebrae. The entire trajectory was evenly full of ABP (Fig. 3).

Experimental groups

Sixty vertebrae were separated randomly into six groups (Table 1), each containing 10 vertebrae. Groups A1, B1, and C1 were subjected to the pullout test, whereas groups A2, B2, and C2 the cyclic fatigue test.

Original, augmentation, and revision

Groups A1 and A2: one pedicle of each vertebra was selected randomly as the original pedicle. In the original
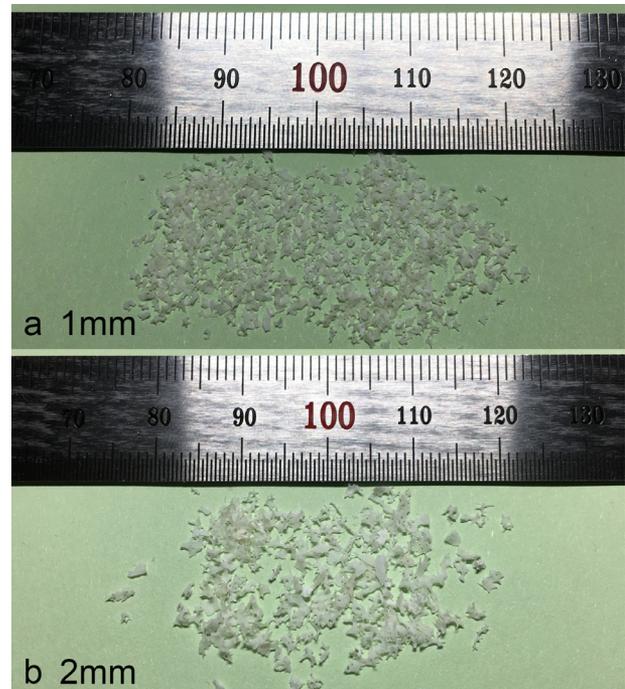

Fig. 2. ABP used in this study. The upper ABP are 1 mm in diameter (a) and the lower ABP are 2 mm in diameter (b).

pedicle, the screw was inserted into the virgin trajectory, and biomechanical tests (torque, axial pullout test, or cyclic fatigue test) were conducted directly. After finishing the biomechanical tests, the screw in the original pedicle was removed. Then, the failed trajectory (revision pedicle) and the contralateral pedicle (augmentation pedicle) were fully filled with ABP. The same size and amount of ABP were used in augmentation and revision pedicles. After trajectory bone graft, the screws were inserted, and biomechanical tests were conducted.

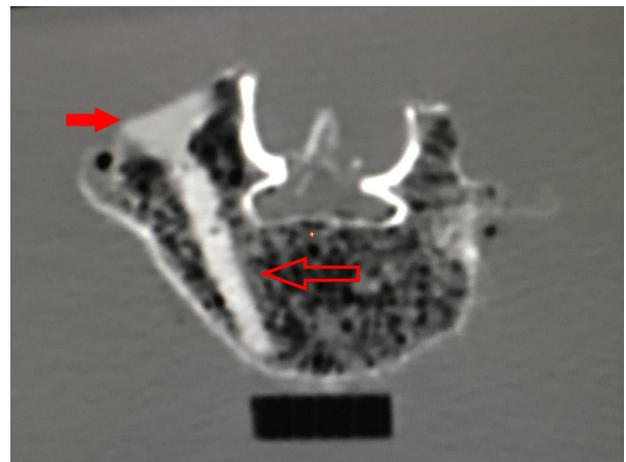Fig. 1. Delivery tube used in bone graft made by Medtronic, Inc.

Fig. 3. CT scan shows that ABP evenly distribute in trajectory (hollow arrow). Plasticine was used to seal the portal of trajectory (solid arrow).

Table 1
Information of the experimental groups and average BMD of each group (averages±deviation)

Group	Treatments	Mechanical testing	n	BMD QCT(mg/mL)	BMD DXA(g/cm^2)
A1	Original/Revision/Augmentation	Axial pullout	10	65.29±6.12	0.61±0.08
B1	50% vs. 100%	Axial pullout	10	71.69±5.35	0.60±0.08
C1	1 mm vs. 2 mm	Axial pullout	10	63.61±3.84	0.57±0.06
A2	Original/Revision/Augmentation	Cyclic fatigue loading	10	71.36±5.56	0.71±0.24
B2	50% vs. 100%	Cyclic fatigue loading	10	66.03±5.35	0.62±0.09
C2	1 mm vs. 2 mm	Cyclic fatigue loading	10	71.31±5.11	0.68±0.11

Different amounts of 50% vs. 100%

Groups B1 and B2: one pedicle of each vertebra was selected randomly as the 100% pedicle. In the 100% pedicle, the ABPs were placed into the screw trajectory to the maximum before screw insertion. On the contralateral side (50% pedicle), the amount of ABP used in screw trajectory augmentation was half that of the 100% pedicle (0.15 g in 5.0 mm×40 mm trajectory and 0.25 g in 6.5 mm×45 mm trajectory). The ABPs used in both pedicles had the same diameter (1 mm). After the augmentation was completed, the screws were inserted, and biomechanical tests were carried out.

Different sizes of 1 mm vs. 2 mm

Groups C1 and C2: one pedicle of each vertebra was selected randomly as 1 mm pedicle. In this pedicle, before screw insertion, the 1 mm ABPs were used in screw trajectory augmentation to the maximum. On the contralateral side (2 mm pedicle), the 2 mm ABPs were used in screw trajectory augmentation. The amounts of ABP used in both pedicles of each vertebra were the same. Then, screw insertion and biomechanical tests were carried out.

Trajectory augmentation and screw insertion

Each vertebra was thawed overnight to room temperature before augmentation and testing. The laminar cortex overlying the pedicle screw entry point was broached with a starter awl, and a pilot hole for the pedicle screw was prepared according to the method of Ebraheim et al. [23,24]. For the lower thoracic vertebra, the entry point was located at the intersection of the vertical line along the middle of the superior articular process and the horizontal line through the top of the transverse process. The screws should be placed parallel to the superior end plate with an angulation of 7˚−10˚ toward the midline. For the lumbar vertebra, the entry point was located at the intersection of the vertical line along the lateral edge of the superior articular process and the horizontal line through the middle of the transverse process. The screws should be placed parallel to the superior end plate with an angulation of 15˚−25˚ toward the midline [25]. The trajectory of the pilot hole was coaxial with the individual pedicle, and the pilot hole did not cross the midline of the vertebral body or penetrate the vertebral cortex. The pilot hole was tapped with a tap (5.5 mm for lower thoracic vertebrae and 6.5 mm for lumbar vertebrae). After trajectory augmentation and revision, the screws were inserted. In the revision pedicle, the screws were inserted to their original depth.

Insertional torque measurement

A screwdriver connected with a torque meter (DB1.5N4; Tohnichi, Tokyo, Japan) was used for screw insertion to determine the torque generated (Fig. 4). The maximum torque was recorded after the screws were inserted. Each screw was placed at a depth that was not connected to the entry point cortex with the screw head because the insertional torque increases rapidly when the screw head comes in contact with the near cortex during the last phase [26].

Mechanical testing

After screw insertion, the vertebrae were embedded in a custom-made fixture with a denture base resin. The orientation of the vertebral body was perpendicular to the bottom surface of the fixture. Then, we waited for 8 hours for the denture base resin to solidify. The denture base resin surrounded the anterior vertebral body and partially filled the spinal canal, thereby leaving the pedicles exposed bilaterally. Any vessel penetration site was covered with a thin-filling material to prevent the denture base resin from coming in contact with the bone. Subsequently, a vertebra in fixture was selected and then fixed into a custom-made fixation device mounted to the base of the servohydraulic, biaxial material-testing machine (Instron 8874, Canton, MA, USA). In axial pullout testing, the fixation device could help each screw to become coaxial with the load cell (Fig. 5a). In the cyclic fatigue test, the fixation device could help each vertebra to assume a perpendicular position relative to the load cell motion axis (Fig. 5b).

Pullout testing

A screwdriver was used to connect the screw with the load cell. Then, the fixture holding the vertebra was tightly mounted onto the fixation device to make the long axis of the screw coaxial with the Instron pullout ram. Axial pullout testing was performed at a rate of 5 mm/min until the

Fig. 4. Insertional torque was measured using a torque meter with an especially designed connector.

screw was 5 mm out. The maximum load encountered during testing was defined as the peak load at failure (pullout strength). The order of the testing of the left and right pedicles was alternated with each specimen to eliminate any effects of testing order.

Cyclic fatigue testing

The testing vertebra was tightly fixed into the fixation device mounted to the base of the material-testing machine. We orientated the vertebral body parallel to the base of the material-testing machine and ensured that the screw head was on the load cell motion axis. Then, we connected the screw head with the load cell using a 5.5×90 mm titanium rod [27], which enables the applied load cell to become perpendicular to the long axis of the screw, with the intention of simulating the physiological loads seen in the immediate
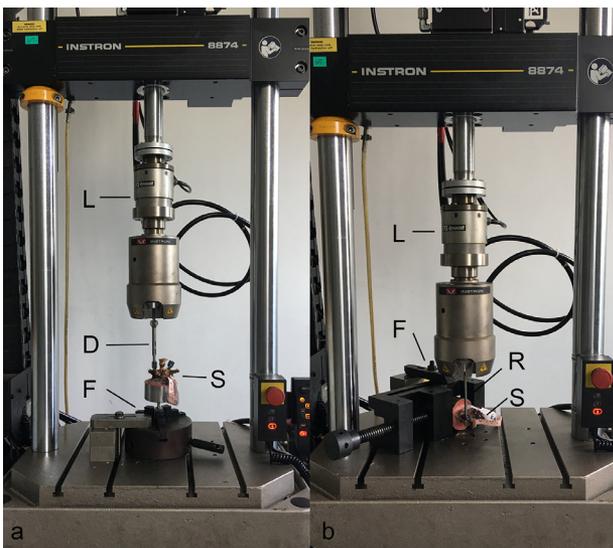

Fig. 5. Test setups of pullout test (a) and cyclic fatigue test (b). Load cell (L), screwdriver (D), fixation device (F), specimen (S), and 5.5×90 mm titanium rod (R).

postoperative phase before successful fusion. The loading of this experimental setup was similar to the loading in the ASTM F1717 norm [28].

Fatigue testing was performed by implementing a sinusoidal, cyclic (1 Hz) force. For the initial cycle, the load ranged from −150 N to 150 N, which is the minimum force that enables the material-testing machine to run in a steady state. This range is similar to the load range during physiological walking [29]. The compressive force was increased stepwise by 25 N every 500 cycles to accelerate failure. Testing was stopped when the cranial−caudal displacement of the load cell at the testing machine reached 5 mm [30]. In addition, the number of cycles and the linearly related maximum force (failure load) until the end of the test were recorded.

Repeat pullout testing of unaugmented pedicle screws

Ten remaining vertebrae (average DXA-BMD: $0.65\pm$ 0.08 g/cm^2 and QCT-BMD: 68.90 ± 7.58 mg/mL) were selected for the repeat pullout test. Each vertebra was implanted with pedicle screws without any revision, and pullout tests were conducted. After the screws were pulled out for 5 mm, the screws were reinserted to their original depth. Then, pullout tests were again performed, and pullout strength was recorded.

Statistical analysis

Data were compiled using the software package SPSS 19.0 (SPSS, Chicago, IL, USA). Descriptive statistics were calculated, including the frequency and the mean±standard deviation (SD). Paired *t* tests were used to compare paired variables in the same vertebra. The statistical significance was defined as p<.05.

Results

No significant difference was observed in the BMD of all vertebrae among the seven groups (p<.05).

Original, augmentation, and revision

In group A1, the augmented screw exhibited the best strength, whereas the strength of the revised screw was weaker than that of the original screw (Fig. 6). The insertional torques and pullout strength of the screw were $0.33\pm$ 0.26 N·m and 482.30 ± 214.29 N in the original pedicle; 0.34 ± 0.26 N·m and 380.67 ± 183.79 N in the revision pedicle; and 0.48 ± 0.25 N·m and 709.01 ± 302.89 N in the augmentation pedicle, respectively (Table 2). Screw augmentation increased the insertional torques by 45% (t=5.621, p=.000) and pullout strength by 47% (t=3.925, p=.003) compared with the screw in the original pedicle. Screw revision obtained the same insertional torques (t=0.183, p=.859) and 79% pullout strength (t=2.728, p=.023) of the screw in the original pedicle. Screw revision only resulted in 71% insertional torques (t=2.597, p=.029)
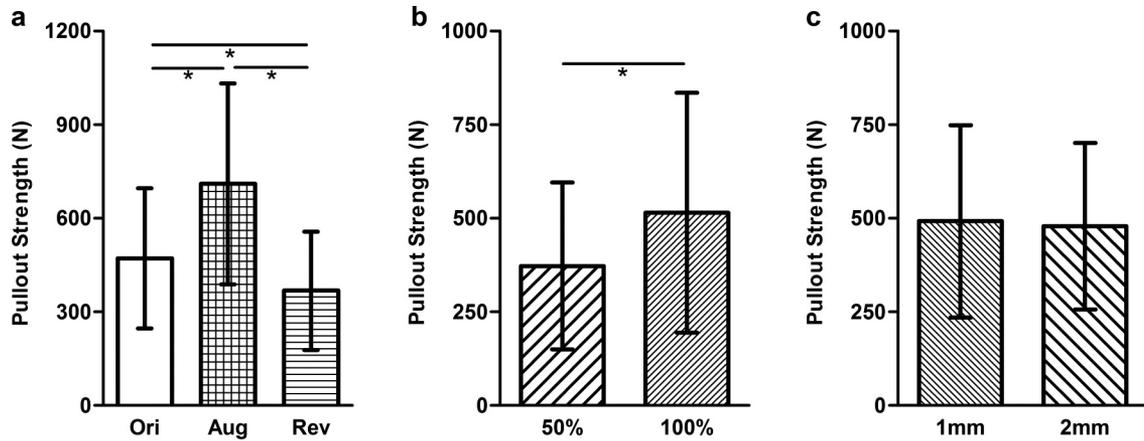
Fig. 6. Graphs showing pullout strength in groups A1 (a), B1 (b), and C1 (c). Error bars represent standard deviation. Statistical significant differences between the two treatments are marked with an asterisk (*). The pullout strength of the screw in augmentation pedicle was 47% higher (p=.003) than the screw in the original pedicle and 86% higher (p=.0002) than the screw in the revision pedicle. Screw revision obtained 79% of the pullout strength of the screw in the original pedicle (p=.023). Full trajectory augmentation increased pullout strength by 39% compared with half trajectory augmentation (p=.021). No significant difference was observed in pullout strength between the screw in 1 and 2mm pedicles (p=.853).

and 54% pullout strength (t=4.460, p=.002) of the screw in the augmentation pedicle.

In group A2, the augmented screw exhibited the best strength, and the strength of the revised screw was similar to that of the original screw (Figs. 7 and 8). The insertional torques, cycles to failure, and failure loads of the screw were 0.14±0.04 N·m, 6,672±753, and 478.71±37.80 N in the original pedicle; 0.25±0.20 N·m, 6,482±857, and 468.70±40.24 N in the revision pedicle; and 0.36±0.12 N·m, 8,711±1,347, and 580.51±71.36 N in the augmentation pedicle, respectively (Table 3). Screw augmentation increased the insertional torques by 157% (t=4.772, p=.002), cycles to failure by 31% (t=6.278, p=.000), and failure loads by 21% (t=5.808, p=.001) compared with the screw in the original pedicle. Screw revision obtained 180% insertional torques (t=1.502, p=.181), 97% cycles to failure (t=0.985, p=.362), and 98% failure loads (t=0.994, p=.353) of the screw in the original pedicle. Screw revision resulted in 71% insertional torques (t=1.857, p=.119), 74% cycles to failure (t=9.711, p=.000), and 81% failure loads (t=8.796, p=.000) of the screw in the augmentation pedicle.

50% vs. 100%

In group B1, full (100%) trajectory augmentation exhibited the best strength. The insertional torques and pullout strength of the screw were 0.37±0.29 N·m and 502.41± 323.20 N in the 100% pedicle and 0.27±0.22 N·m and 360.66±224.54 N in the 50% pedicle. Full trajectory augmentation increased insertional torques by 37% (t=2.491, p=.042) and pullout strength by 39% (t=2.963, p=.021) compared with half (50%) trajectory augmentation.

In group B2, full trajectory augmentation also showed increased strength. The insertional torques, cycles to failure, and failure loads of the screw were 0.50±0.10 N·m, 7,444±1,597, and 516.33±80.73 N in the 100% pedicle and 0.50±0.09 N·m, 6,333±741, and 461.02±33.79 N in the 50% pedicle, respectively. Full trajectory augmentation resulted in similar insertional torques (t=0.110, p=.916) compared with half trajectory augmentation. However, full trajectory augmentation increased cycles to failure by 18% (t=2.949, p=.021) and failure loads by 12% (t=2.964, p=.021).

Table 2
Measured insertional torques and pullout strength in pullout test (averages±deviation)

Group	Treatments	n	BMD		Axial pullout testing	
			QCT(mg/mL)	DXA(g/cm^2)	Insertional torque(N·m)	Pullout strength(N)
A1	Original	10	65.29±6.12	0.61±0.08	0.33±0.26	482.30±214.29[†]
	Revision				0.34±0.26	380.67±183.79[*]
	Augmentation				0.48±0.25[*],[†]	709.01±302.89[*],[†]
B1	50%	10	71.69±5.35	0.60±0.08	0.27±0.22	360.66±224.54
	100%				0.37±0.29[‡]	502.41±323.20[‡]
C1	1 mm	10	63.61±3.84	0.57±0.06	0.33±0.18	492.17±256.80
	2 mm				0.31±0.17	478.99±222.79

[*] Compared with the original, p<.05.
[†] Compared with the revision, p<.05.
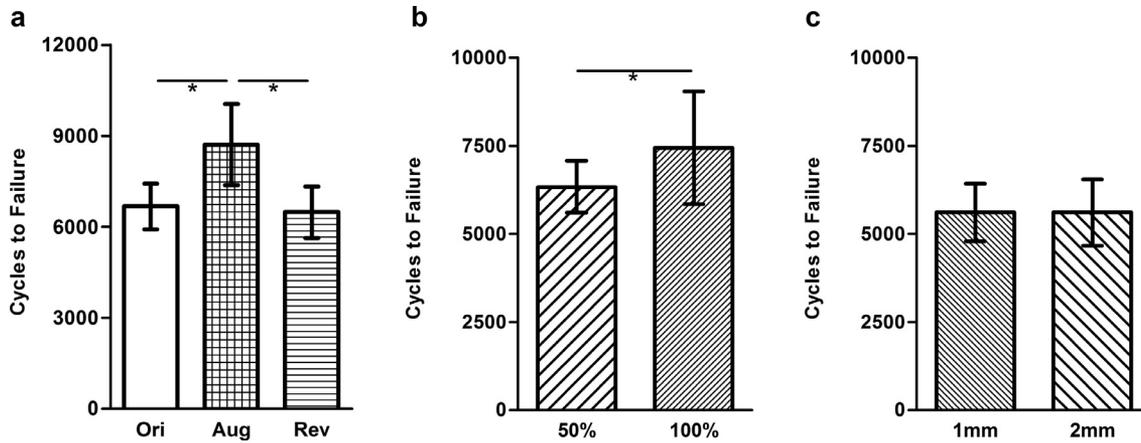[‡] Compared with the 50% p<.05.

Fig. 7. Graphs showing cycles to failure in groups A2 (a), B2 (b), and C2 (c). Error bars represent standard deviation. Statistical significant differences between the two treatments are marked with an asterisk (*). Screw augmentation increased cycles to failure by 31% (p=.000) compared with the screw in the original pedicle and increased cycles to failure by 34% (p=.000) compared with the screw in the revision pedicle. Full trajectory augmentation increased cycles to failure by 18% (p=.021) compared with half trajectory augmentation. Between 1 and 2 mm pedicles, no significant difference was observed in cycles to failure (p=.991).
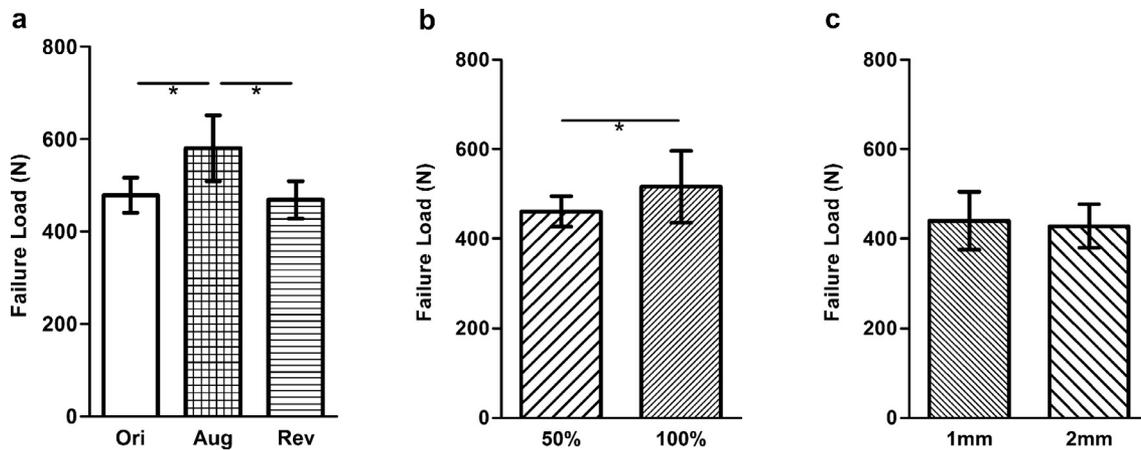

Fig. 8. Graphs showing failure load in groups A2 (a), B2 (b), and C2 (c). Error bars represent standard deviation. Statistical significant differences between the two treatments are marked with an asterisk (*). Augmentation of screw increased failure load by 21% (p=.001) compared with the screw in the original pedicle and increased failure load by 24% (p=.000) compared with the screw in the revision pedicle. Full trajectory augmentation increased failure load by 12% (p=.021) compared with half trajectory augmentation. Between 1 and 2 mm pedicles, no significant difference was observed in the failure load (p=.197).

Table 3
Measured insertional torques, cycles to failure, and failure loads in cyclic fatigue test (averages±deviation)

| Group | Treatments | n | BMD | | Cyclic fatigue loading testing | | |
			QCT(mg/mL)	DXA(g/cm^2)	Insertional torque(N·m)	Cycles to failure	Failure load(N)
A2	Original	10	71.36±5.56	0.71±0.24	0.14±0.04	6,672±753	478.71±37.80
	Revision				0.25±0.20	6,482±857	468.70±40.24
	Augmentation				0.36±0.12*	8,711±1,347*,†	580.51±71.36*,†
B2	50%	10	66.03±5.53	0.62±0.09	0.50±0.09	6,333±741	461.02±33.79
	100%				0.50±0.10	7,444±1,597‡	516.33±80.73‡
C2	1 mm	10	71.31±5.11	0.68±0.11	0.24±0.13	5,609±809	440.03±64.50
	2 mm				0.23±0.14	5,606±948	428.17±48.93

* Compared with the original, p<.05.
† Compared with the revision, p<.05.
‡ Compared with the 50% p<.05.

1 mm vs. 2 mm

In group C1, the screw augmented with 1 mm ABP resulted in higher values of insertional torques and pullout strength compared with screw augmented with 2 mm ABP. The insertional torques and pullout strength of the screw were 0.33±0.18 N·m and 492.17±256.80 N in 1 mm pedicle and 0.31±0.17 N·m and 478.99±222.79 N in 2 mm pedicle, respectively. However, no significant differences were observed in insertional torques (t=0.996, p=.352) and pullout strength (t=0.193, p=.853) between the two treatments.

In group C2, the screw augmented with 1 mm ABP obtained higher values in insertional torques, cycles to failure, and failure loads compared with the screw augmented with 2 mm ABP. The insertional torques, cycles to failure, and failure loads of the screw were 0.24±0.13 N·m, 5,609±809, and 440.03±64.50 N in 1 mm pedicle and 0.23±0.14 N·m, 5,606±948, and 428.17±48.93 N in 2 mm pedicle, respectively. However, no significant differences were observed in insertional torques (t=0.532, p=.612), cycles to failure (t=0.012, p=.991), and failure loads (t=1.424, p=.197) between the two treatments.

Repeat pullout testing

The average pullout strength of the initial test was 483.75±258.23 N, and the average pullout strength of the repeat test was 163.87±92.14 N. The reinserted screw without any revision technique only obtained 33% pullout strength of the original screw (t=6.342, p=.000).

Discussion

The incidence of OP is continually increasing. In addition, pedicle screw placement in the osteoporotic vertebral body is becoming a challenge to spine surgeons. The augmentation of pedicle screw fixation with various bone cements has been studied to provide potential solutions to inadequate fixation. The bone cement most commonly used to date is PMMA. However, it has exothermic properties and has a high risk of neural injury in the event of extravasation [31−35]. In consideration of these factors, allograft bone may be an alternative to PMMA as trajectory reinforcement material.

For many years, researchers have suggested of using bone graft in trajectory to increase the strength of the pedicle screw. However, evidence showing that bone graft in trajectory can significantly improve the strength of the pedicle screw is limited. Pfeifer used milled femoral head allograft bone and matchstick-shaped bone in trajectory revision and found that bone graft in trajectory cannot improve the strength of the screw in failed trajectory [6]. Chrea used allograft bone plugs in trajectory augmentation and found that the pullout loads of the augmented screw are significantly lower than those of the unaugmented screw [12]. To improve the bone grafting technique, we selected allograft cancellous bone particles with diameters of 1 and 2 mm as the bone graft. We used a delivery tube in the bone graft instead of forceps. Autogenous bones provided by patients with OP used in bone graft are of poor quality and limited. Considering that most patients with OP are elderly people, autogenous bone-harvesting techniques may be traumatic for them. Thus, we selected allograft bone as the source of the bone graft. Concerning that the specimens in the present study were osteoporotic vertebrae, using cortical bone in trajectory bone graft may damage the trajectory because of the high mechanical strength of the cortical bone. Thus, we used allograft cancellous bone. The use of the delivery tube allows the bone graft particles to be fully and evenly distributed in the trajectory. Small-diameter bone particles were also used for good distribution of the bone in the screw−bone interface. The inner diameter of the delivery tube mentioned previously was 3 mm. Thus, we decided to use bone particles with a diameter of 1 or 2 mm. The CT scan after trajectory augmentation showed that the bone graft technique we used was effective.

The experimental design used in this study was bilateral biomechanical testing. Bilateral testing was performed to allow pairwise comparisons of different bone graft augmentation methods and eliminate the effect of BMD, screw trajectory, and screws [13]. The lower thoracic vertebrae and lumbar vertebrae were selected in this study because these parts are common sites of spinal diseases, such as trauma, tumor, and degenerative diseases.

Different from previous research results, we found that augmentation of the trajectory bone graft before screw insertion could significantly increase the pullout strength, cycles to failure, and failure loads of the augmented screw compared with the original screw. This finding may be caused by the following: the small-diameter cancellous bone particles can be fully embedded in the screw−bone interface, thereby enhancing the interface strength. Thus, bone graft particles improve the biomechanical properties of the screw. Concerning excessive compaction of the bone graft that may lead to the screw trajectory shift during screw insertion, we did not compact the bone particles in the trajectory bone graft. We found that the screw augmented by ABP could attain 147% pullout strength of the original screw. In other studies of augmentation techniques, expansive pedicle screw could attain 130% to 150% pullout strength of the traditional pedicle screw, whereas carbonated apatite cement augmentation, CBT screw, and PMMA augmentation attained 168%, 130%, and 202% of the original screw, respectively [34,36−38]. Although the strength provided by ABP augmentation is not as powerful as PMMA augmentation, ABP augmentation is still advantageous compared with other augmentation techniques. ABPs are absorbable and osteoconductive biomaterials. In this study, pedicle damage and penetration of ABP into the spinal canal were not observed. Thus, ABP augmentation is a safe technique and will not cause great difficulty to surgeons during secondary operation.

If the trajectory fails, trajectory bone graft cannot provide the pullout strength, cycles to failure, and failure loads of the revised screw to the level of the original screw. This finding is consistent with the study conducted by Pfeifer et al. [6]. In our repeat pullout testing, the reinserted screw without any revision technique only obtained 33% pullout strength of the original screw. In Moore et al.'s study, after pedicle screws were pulled out, they were reinserted to their original trajectory without any revision technique. The authors found that the strength of the reinserted screws only achieved 27.1% of the original screw [13]. In the present study, the screw revised with ABP achieved 79% pullout strength of the original screw. Compared with other revision techniques (extrapedicular screws (65%), increasing the diameter of the revision screw by 1 mm (73%), CPC revision (102%), and PMMA revision (147%)), the trajectory revision by ABP is one of the most considerable revision techniques [13,39,40].

Fan et al. studied the effect of different volumes of bone cement used in pedicle augmentation on the biomechanical properties of pedicle screw fixation [41]. With reference to the experimental design of other studies, we evaluated the effects of different amounts of bone graft on the biomechanical properties of screws. To eliminate the influence of the shape of bone particles, we used bone particles with uniform specification, which made the present experiment more advanced than previous studies. In the pre-experiment, we measured the amount of bone particles, which could fill the trajectory to the maximum. We found that 0.3 g of ABP could cover 5.5 mm×40 mm trajectory, and 0.5 g of ABP was sufficient for 6.5 mm×45 mm trajectory. This finding was confirmed by CT scan results. We hope that this finding could provide a reference for clinical application. Furthermore, we found that filling the trajectory with bone particles to the maximum could attain much greater pullout strength, cycles to failure, and failure loads compared with filling the trajectory by only half. This finding may be caused by the following: the area of the augmented screw−bone interface in the fully augmented trajectory is larger than that in the half augmented trajectory.

When evaluating the effects of the grain diameter of bone particles on the biomechanical properties of the screws, we did not find significant difference between the 1 and 2 mm bone particles. This can be explained by two reasons. On one hand, this phenomenon may be caused by the small sample size in this study. On the other hand, some 2 mm bone particles may be damaged and transformed to 1 mm particles during trajectory bone graft and screw insertion because the bone particles used in this study were all cancellous bone, which is vulnerable. However, the insertional torque, pullout strength, cycles to failure, and failure loads of the screw augmented by 1 mm ABP were all greater than those by 2 mm ABP. This finding may be caused by the following: 1 mm bone particles could be better embedded than the 2 mm particles in the screw−bone interface. In a previous

study [6], no statistically significant difference was observed between the milled bone group and matchstick-shaped bone group. This finding was consistent with the results of our study. We hypothesized that the size of the bone graft may not affect the biomechanical properties of the pedicle screw.

Inevitably, this study has some limitations. The first limitation is the relatively small sample size, which was caused by limited specimen availability. This condition may be the reason for the large SD of data in each group. Furthermore, a biomechanical cadaver model is not able to simulate in vivo conditions. Thus, live experiments must be conducted before clinical promotion. As mentioned above, ABPs are absorbable and osteoconductive biomaterials. In the process of bone tissue transformation and structural remodeling, the effects of ABP on the mechanical properties of screws may change. Thus, this area needs to be explored through animal experiments. Finally, a more comprehensive and physical fatigue test program is needed.

Conclusions

Trajectory augmentation with ABP can significantly increase the strength of augmented screws. Full trajectory augmentation can provide greater strength compared with half trajectory augmentation. In patients with OP, we recommend using 1 mm ABP in full trajectory augmentation (0.3 g ABP for 5.5 mm×40 mm and 0.5 g ABP for 6.5 mm×45 mm) before trajectory fails.

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