Basic Science

Biomechanical comparison of pedicle screw augmented with different volumes of polymethylmethacrylate in osteoporotic and severely osteoporotic cadaveric lumbar vertebrae: an experimental study

Da Liu, MD, PhD\textsuperscript{a,1}, Bo Zhang, PhD\textsuperscript{a,1}, Qing-yun Xie, PhD\textsuperscript{a,1}, Xia Kang, PhD\textsuperscript{a}, Jiang-jun Zhou, PhD\textsuperscript{b}, Cai-ru Wang, MD, PhD\textsuperscript{a}, Wei Lei, MD, PhD\textsuperscript{c}, Wei Zheng, MD, PhD\textsuperscript{a,*}

\textsuperscript{a}Department of Orthopaedics, Chengdu Military General Hospital, No. 270, Rongdu Ave, Jinniu District, Chengdu, Sichuan Province 610083, China
\textsuperscript{b}Department of Orthopaedics, 184 Hospital of Nanjing Military Region, No. 4, Hudong St, Yingtai, Jiangxi Province 335000, China
\textsuperscript{c}Department of Orthopaedics, Xijing Hospital, Fourth Military Medical University, No. 15, Changle West Rd, Xi’an, Shaanxi Province 710032, China

Received 24 April 2015; revised 14 February 2016; accepted 21 April 2016

Abstract

BACKGROUND CONTEXT: Polymethylmethacrylate (PMMA) is widely used for pedicle screw augmentation in osteoporosis. Intriguingly, there have been no biomechanical comparisons of the stability of pedicle screws augmented with different volumes of PMMA or studies of the relationship between screw stability and volume of PMMA, especially in different degrees of osteoporosis.

PURPOSE: The purposes of the study reported here were to compare screw stability by different volumes of PMMA augmentation, to analyze the relationship between screw stability and PMMA volume, and to make a preliminary determination of the optimum volume of PMMA augmentation for different degrees of osteoporosis.

STUDY DESIGN: This study is a biomechanical comparison of pedicle screws augmented with various volumes of PMMA in cadaveric lumbar vertebrae.

METHODS: Thirty-six pedicles from 18 osteoporotic lumbar vertebrae were randomly divided into groups A0 through A5, and 36 pedicles from 18 severely osteoporotic lumbar vertebrae were randomly divided into groups B0 through B5. A different volume of PMMA was injected into each one of groups A0 through A5 (0, 0.5, 1.0, 1.5, 2.0, and 2.5 mL, respectively) and into each one of groups B0 through B5 (0, 1.0, 1.5, 2.0, 2.5, and 3.0 mL, respectively), and then pedicle screws were inserted in all vertebrae. After complete solidification of the PMMA, we examined pedicle X-rays, performed axial pullout tests, and determined the maximum axial pullout strength (F_{\text{max}}) for all samples.

FDA device/drug status: Not applicable.

Author disclosures: DL, BZ, Q-YX, XK, J-JZ, C-RW, WI, WZ: Grant: The National Natural Science Foundation of China (81301606) and The Foundation of Chengdu Military General Hospital (2013YG-B015) (A, Paid to the institution), pertaining to submitted manuscript; Consulting Fee or Honorarium: The National Natural Science Foundation of China (81301606) and The Foundation of Chengdu Military General Hospital (2013YG-B015) (A, Paid to the institution), pertaining to the submitted manuscript; Support for Travel to Meetings for the Study or Other Purposes: The National Natural Science Foundation of China (81301606) and The Foundation of Chengdu Military General Hospital (2013YG-B015) (A, Paid to the institution), pertaining to the submitted manuscript; Support for Travel to Meetings for the Study or Other Purposes: The National Natural Science Foundation of China (81301606) and The Foundation of Chengdu Military General Hospital (2013YG-B015) (A, Paid to the institution), pertaining to the submitted manuscript; Support for Travel to Meetings for the Study or Other Purposes: The National Natural Science Foundation of China (81301606) and The Foundation of Chengdu Military General Hospital (2013YG-B015) (A, Paid to the institution), pertaining to the submitted manuscript; Support for Travel to Meetings for the Study or Other Purposes: The National Natural Science Foundation of China (81301606) and The Foundation of Chengdu Military General Hospital (2013YG-B015) (A, Paid to the institution), pertaining to the submitted manuscript; Support for Travel to Meetings for the Study or Other Purposes: The National Natural Science Foundation of China (81301606) and The Foundation of Chengdu Military General Hospital (2013YG-B015) (A, Paid to the institution), pertaining to the submitted manuscript; Support for Travel to Meetings for the Study or Other Purposes: The National Natural Science Foundation of China (81301606) and The Foundation of Chengdu Military General Hospital (2013YG-B015) (A, Paid to the institution), pertaining to the submitted manuscript; Provision of Writing Assistance, Medicines, Equipment, or Administrative Support: The National Natural Science Foundation of China (81301606) and The Foundation of Chengdu Military General Hospital (2013YG-B015) (B, Paid to the institution), pertaining to the submitted manuscript; Other: The National Natural Science Foundation of China (81301606) and The Foundation of Chengdu Military General Hospital (2013YG-B015) (B, Paid to the institution), pertaining to the submitted manuscript.

The authors have declared that no conflicts of interest exist. Grant support from the National Natural Science Foundation of China (8130160610,000 $) and The Foundation of Chengdu Military General Hospital (2013YG-B015 2,500 $) was received in support of this work. No benefits in any form have been or will be received from a commercial party directly or indirectly to the subject of this article.

* Corresponding author. Department of Orthopaedics, Chengdu Military General Hospital, No. 270, Rongdu Ave, Jinniu District, Chengdu, Sichuan Province 610083, China. Tel.: +86 28 86571113; fax: +86 28 86571113.

E-mail address: zyyzhengwei@126.com (W. Zheng)

\textsuperscript{1} These authors contributed equally to this study.
RESULTS: No PMMA was found around the screws in groups A0 and B0. In groups A1 to A5 and B1 to B5, screws were wrapped by gradually increasing amounts of PMMA. There was no PMMA leakage or screw malpositioning in any samples. The $F_{\text{max}}$ in groups A1 through A5 increased by 32.40%, 64.42%, 116.02%, 174.07%, and 207.42%, respectively, compared with that in group A0. There were no significant differences in $F_{\text{max}}$ between groups A0 and A1, A1 and A2, A2 and A3, A3 and A4, and A4 and A5 (p>0.05), but there were significant differences in $F_{\text{max}}$ between any other two groups (p<0.05). The $F_{\text{max}}$ in groups B1 through B5 increased by 23.48%, 48.40%, 106.60%, 134.73%, and 210.04%, respectively, compared with that in group B0. There were no significant differences in $F_{\text{max}}$ between groups B0 and B1, B0 and B2, B1 and B2, B2 and B3, B3 and B4 (p>0.05), but there were significant differences in $F_{\text{max}}$ between any other two groups (p<0.05). There was a significant positive correlation between $F_{\text{max}}$ and volume of PMMA in both osteoporotic and severely osteoporotic lumbar vertebrae (p<0.05).

CONCLUSIONS: Polymethylmethacrylate can significantly enhance stability of pedicle screws in both osteoporotic and severely osteoporotic lumbar vertebrae. There is a significant positive correlation between screw stability and volume of PMMA. Within a certain range, nevertheless, increasing the volume of PMMA does not significantly improve screw stability. We suggest that 1.5 and 3 mL, respectively, are the volumes of injected PMMA that will optimize pedicle screw stability in osteoporotic and severely osteoporotic lumbar vertebrae.

Keywords: Energy absorbed to failure; Maximum axial pullout strength; Osteoporosis; Pedicle screw; Polymethylmethacrylate; Stiffness

Introduction

Transpedicular screw fixation has been widely used in treating degenerative disorders, unstable fractures, and deformities and tumors of the spine [1–4]. However, osteoporosis severely influences the binding strength of the interface between screws and bone and decreases the holding strength of the screws, which usually results in screw loosening, migration, or back-out [5,6]. Severe osteoporosis increases the need for pedicle screw fixation strength and thus has long been one of the contraindications for spinal internal fixation.

To effectively improve pedicle screw stability in the setting of compromised bone, many researchers have used polymethylmethacrylate (PMMA) to enhance fixation strength [7–21]. There are marked differences for various volumes of injected PMMA and the screw stability that each provides. However, there have been neither any biomechanical comparisons of pedicle screw stability by volume of PMMA nor any studies of the relationship between screw stability and PMMA volume used in different degrees of osteoporosis.

In the study we report here, we injected different volumes of PMMA into both osteoporotic and severely osteoporotic lumbar vertebrae, compared pedicle screw stability by volume of PMMA augmentation, analyzed the relationship between screw stability and volume of PMMA, and conducted a preliminary analysis of the optimal volume of PMMA for both osteoporotic and severely osteoporotic lumbar vertebrae.

Materials and methods

Ethics statement

All procedures involving human cadaveric specimens were conducted according to the ethics guidelines established by our local ethics committee. We obtained approval for our protocol from the ethics committee of the Fourth Military Medical University and Chengdu Military General Hospital.

Specimen preparation

Anteroposterior and lateral radiographs of each cadaveric spine were obtained to exclude specimens with fractures, deformity, and osteolysis resulting from malignancy. Finally, a total of 36 lumbar vertebrae (L1–L5) were obtained from eight fresh-frozen spines from persons (five women and three men) who died at a mean age of 62 years (range, 51–79 years). The vertebrae were cleaned of all soft tissues, disarticulated at the intervertebral disc space, vacuum sealed in plastic bags, and stored at −20°C for further use. Dual-energy X-ray absorptiometry (Lunar Corp., Madison, WI, USA) measurements, using the definitions of the World Health Organization, confirmed that there were 18 osteoporotic lumbar vertebrae (t score −2.5) and 18 severely osteoporotic lumbar vertebrae (t score ≤−3.5). All 72 pedicle screws were identical, with a length of 45.0 mm and an outer diameter of 6.5 mm, and were made of titanium alloy (Medtronic Weigao Orthopaedic Device Co, Ltd, Shandong, China). Polymethylmethacrylate (Cemex, Tecres, Verona, Italy), including cement powder and cement solution, was used for screw augmentation (Fig. 1).

Experimental procedures

All lumbar vertebrae were naturally thawed at room temperature. Thirty-six pedicles from 18 osteoporotic vertebrae were randomly divided into six groups, A0 through A5. Thirty-six pedicles from 18 severely osteoporotic vertebrae were randomly divided into six groups, B0 through B5. In all groups, the screw entry point was at the intersection of the midtransverse line and lateral to the zygapophyseal joint line, and
the direction was mildly convergent. The cortex over each lamina was removed with a rongeur. The pilot hole was then made using an awl directed anteriorly and medially along the axis of the pedicle. The hole was then checked with a probe to determine that the pedicle had not been violated. Each hole was then tapped, using a 4.5-mm tap (Medtronic Weigao Orthopaedic Device Co, Ltd), to a depth of 45 mm. The hole was again checked with a probe to verify pedicle integrity. Different volumes of PMMA were injected for groups A0 through A5 (0, 0.5, 1.0, 1.5, 2.0, and 2.5 mL, respectively) and for groups B0 through B5 (0, 1.0, 1.5, 2.0, 2.5, and 3.0 mL, respectively). The bone cement powder was mixed with the cement solution at a ratio of 2:1, according to the manufacturer’s recommendation. Then, we connected the syringe and the injection sheath and injected the PMMA until it appeared at the tip of the sheath. We used visual observation and palpation to ensure that the PMMA had pushed out the air in the sheath cavity and to evaluate the viscosity of the PMMA (Fig. 2). When the PMMA reached a toothpaste-like consistency, we inserted the sheath into the hole (Fig. 3).

Polymethylmethacrylate was injected through the sheath into the hole, and it slowly diffused toward the surrounding tissue under continuous pressure. A screw was inserted into the hole immediately after the injection of PMMA. During this procedure, all specimens were maintained at room temperature and kept moist with resin. After complete solidification of the PMMA, all vertebrae were examined radiographically to determine the position of the pedicle screw and the distribution of PMMA.

**Axial pullout tests**

After radiographic examination, axial pullout tests were performed using the MTS 858 Material Testing System (MTS Systems, Minneapolis, MN, USA). The vertebrae were mounted onto a special jig, which allowed for adjustment to ensure that each screw was pulled strictly along its long axis. Once the specimen was tightly secured, each screw was pulled at a constant speed of 5 mm/min until screw failure. Load and displacement data were obtained in real time and were used to construct a load-displacement curve. On the curve, the maximum pullout strength ($F_{max}$) was defined as the inflection point where the load peaked and then sharply decreased with increasing displacement. Stiffness was calculated from the slope of the linear range of the curve, and energy absorbed to failure was represented by the area under the curve before the onset of failure (Fig. 4).

**Statistic analysis**

Statistical analysis was performed with SPSS Statistics 16.0 (SPSS Inc, Chicago, IL, USA). The data are expressed in this report as mean ± standard deviation. One-way analysis of variance and the Bonferroni correction were used to detect differences in bone mineral density (BMD) and all three biomechanical parameters among the six groups with osteoporosis and among the six groups with severe osteoporosis. The $t$ test

---

Fig. 1. The polymethylmethacrylate (PMMA) cement used in the study reported here included PMMA powder and cement solution.

Fig. 2. Polymethylmethacrylate was injected into the pedicle hole when it had a toothpaste-like viscosity.

Fig. 3. The injection of PMMA into a sample.
was used to compare the difference on all three biomechanical parameters between two groups: vertebrae with osteoporosis, and vertebrae with severe osteoporosis. Relationships between the biomechanical parameters and the volume of injected PMMA were assessed using linear regression analysis. Statistical significance was defined as \( p < 0.05 \).

**Results**

**Bone mineral density of vertebrae**

There was no significant difference in BMD among groups A0 through A5 (\( p = 0.470 \)); all \( t \) values were between \(-3.5\) and \(-2.5\), and all samples in those groups showed osteoporosis. There was also no significant difference in BMD among groups B0 through B5 (\( p = 0.799 \)); all \( t \) values were <\(-3.5\), and all samples in those groups showed severe osteoporosis.

**Radiographic examination**

The distribution of PMMA and position of screws were clearly shown on radiographs (Figs. 5 and 6). No PMMA was found around the screws in groups A0 and B0. In groups A1 through A5 and groups B1 through B5, PMMA was found to be distributed around the screws, which obviously improved the density around the screws. In groups A1 through A5 and groups B1 through B5, we found a gradually broadening distribution range of PMMA around the screws. We found neither leakage of PMMA nor malpositioning of screws in any samples.

**Axial pullout tests**

We have tested the homogeneity of variances and normal distribution of all the biomechanical parameters in both analysis of variance and linear regression. The \( F_{\text{max}} \) values in groups A0 through A5 were as follows: 528.33 \( \pm \) 109.04 N, 699.50 \( \pm \) 154.89 N, 868.67 \( \pm \) 134.77 N, 1,141.30 \( \pm \) 192.42 N, 1,448.00 \( \pm \) 217.56 N, and 1,624.20 \( \pm \) 225.50 N, respectively. The \( F_{\text{max}} \) values in groups A1 through A5 increased by 32.40%, 64.42%, 116.02%, 174.07%, and 207.42%, respectively, in comparison with the \( F_{\text{max}} \) value in group A0. There were no significant differences in \( F_{\text{max}} \) between groups A0 and A1, A1 and A2, A2 and A3, A3 and A4, and A4 and A5 (\( p > 0.05 \)), but there were significant differences in \( F_{\text{max}} \) between any other two groups (\( p < 0.05 \)). As shown in Fig. 7A1, there was a significant positive correlation between \( F_{\text{max}} \) and volume of PMMA (\( r = 0.919; R^2 = 0.844; p < 0.05, 95\% \) confidence intervals: 0.778–0.906). The \( F_{\text{max}} \) values in groups B0 through B5 were as follows: 358.50 \( \pm \) 86.00 N, 442.67 \( \pm \) 96.02 N, 532.00 \( \pm \) 103.18 N, 740.67 \( \pm \) 120.90 N, 841.50 \( \pm \) 133.42 N, and 1,111.50 \( \pm \) 158.57 N, respectively. The \( F_{\text{max}} \) values in groups B1 through B5 increased by 23.48%, 48.40%, 106.60%, 134.73%, and 210.04%, respectively, in comparison with the \( F_{\text{max}} \) value in group B0. There were no significant differences in \( F_{\text{max}} \) between groups B0 and B1, B0 and B2, B1 and B2, B2 and B3, and B3 and B4 (\( p > 0.05 \)), but there were significant differences in \( F_{\text{max}} \) between any other two groups (\( p < 0.05 \)). As shown in Fig. 7B1, there was a significant positive correlation between \( F_{\text{max}} \) and volume of PMMA (\( r = 0.877; R^2 = 0.769; p < 0.05, 95\% \) confidence intervals: 0.671–0.859).

In augmentation with the same volume of PMMA, the \( F_{\text{max}} \) in groups B0, B1, B2, B3, and B4 was significantly decreased (32.14%, 49.04%, 53.39%, 48.85%, and 48.19%, respectively) compared with the \( F_{\text{max}} \) in groups A0, A2, A3, A4, and A5 (\( p < 0.05 \)). Also in augmentation with the same volume of PMMA, the increased percentages of \( F_{\text{max}} \) compared with those for nonaugmented screws in osteoporotic lumbar vertebrae were higher than those for severely osteoporotic lumbar vertebrae. The \( F_{\text{max}} \) in group A0 was significantly higher than that in group B0 and significantly

![Fig. 4. The load-displacement curve in the axial pullout test.](image)

![Fig. 5. Radiographs of the six groups of osteoporotic lumbar vertebrae: A0, A1, A2, A3, A4, and A5.](image)

![Fig. 6. Radiographs of the six groups of severely osteoporotic lumbar vertebrae: B0, B1, B2, B3, B4, and B5.](image)
lower than those in groups B3, B4, and B5 ($p<.05$). The $F_{\text{max}}$ in group A1 was significantly higher than those in groups B0 and B1 and significantly lower than that in group B5 ($p<.05$). The $F_{\text{max}}$ in group A2 was significantly higher than those in groups B0, B1, B2, B3, and B4 ($p<.05$). The $F_{\text{max}}$ in both groups A4 and A5 were significantly higher than those in groups B0 through B5 ($p<.05$). Except comparison between above-mentioned group A and group B, there were no significant differences in $F_{\text{max}}$ between any other two groups between group A and group B ($p>.05$).

The stiffness values in groups A0 through A5 were as follows: 131.17±34.59 N/mm, 179.17±54.85 N/mm, 218.50±39.97 N/mm, 299.83±74.67 N/mm, 377.50±63.34 N/mm, and 410.50±52.20 N/mm, respectively. The stiffness values in groups A1 through A5 increased by 36.59%, 66.58%, 128.58%, 187.79%, and 212.95%, respectively, compared with that in group A0. There were no significant differences in stiffness values between groups A0 and A1, A0 and A2, A1 and A2, A3 and A4, and A4 and A5 ($p>.05$), but there were significant differences in stiffness values between any other two groups ($p<.05$). As shown in Fig. 7A2, there was a significant positive correlation between stiffness values and volume of PMMA ($r=0.890$; $R^2=0.793$; $p<.05$, 95% confidence intervals: 0.687–0.872). The stiffness values in groups B0 through B5 were as follows: 93.17±18.50 N/mm, 118.00±33.21 N/mm, 130.17±31.04 N/mm, 183.00±35.77 N/mm, 216.67±42.56 N/mm, and 280.00±52.58 N/mm, respectively. The stiffness values in groups B1 through B5 increased by 26.65%, 39.71%, 96.42%, 132.55%, and 200.53%, respectively, compared with that in group B0. There were no significant differences in stiffness values between groups B0 and B1, B0 and B2, B1 and B2, B1 and B3, B2 and B3, B3 and B4, and B4 and B5 ($p<.05$), but there were significant differences in stiffness values between any other two groups ($p<.05$). As shown in Fig. 7B2, there was a significant positive correlation between stiffness values and volume of PMMA ($r=0.838$; $R^2=0.702$; $p<.05$, 95% confidence intervals: 0.585–0.812).

In augmentation with the same volume of PMMA, stiffness values in groups B0, B1, B2, B3, and B4 was significantly decreased (28.97%, 46.00%, 56.59%, 51.52%, and 47.22%, respectively) compared with those in groups A0, A2, A3, A4, and A5 ($p<.05$). Also in augmentation with the same volume of PMMA, the increased percentages of stiffness values compared with those for nonaugmented screws in osteoporotic lumbar vertebrae were higher than those for severely osteoporotic lumbar vertebrae. The stiffness values in group A0 was significantly higher than that in group B0 and significantly lower than those in groups B3, B4, and B5 ($p<.05$). The stiffness value in group A1 was significantly higher than that in group B0 and significantly lower than that in group B5 ($p<.05$). The stiffness value in group A2 was significantly higher than those in groups B0, B1, and B2 and significantly lower than that in group B5 ($p<.05$). The stiffness values in both groups A4 and A5 were significantly higher than those in groups B0 through B5 ($p<.05$). Except comparison between abovementioned two groups, there were no significant differences in stiffness values between any other two groups ($p>.05$).

The energy values in groups A0 through A5 were as follows: 1.04±0.24 J, 1.44±0.42 J, 1.84±0.40 J, 2.34±0.42 J, 2.93±0.39 J, and 3.38±0.50 J, respectively. The energy values in groups A1 through A5 increased by 38.46%, 76.92%,
125.00%, 181.73%, and 225.00%, respectively, compared with that in group A0. There were no significant differences in energy values between groups A0 and A1, A1 and A2, A2 and A3, A3 and A4, and A4 and A5 (p>0.05), but there were significant differences in energy values between any other two groups (p<0.05). As shown in Fig. 7A3, there was a significant positive correlation between energy values and volume of PMMA (r=0.910; R²=0.827; p<0.05, 95% confidence intervals: 0.753–0.891). The energy values in groups B0 through B5 were as follows: 0.73±0.17 J, 0.93±0.34 J, 1.10±0.25 J, 1.48±0.37 J, 1.70±0.28 J, and 2.25±0.28 J, respectively. The energy in groups B1 through B5 increased by 27.40%, 50.68%, 102.74%, 132.88%, and 208.22%, respectively, compared with that in group B0. There were no significant differences in energy between groups B0 and B1, B0 and B2, B1 and B2, B2 and B3, B3 and B4 (p>0.05), but there were significant differences in energy between any other two groups (p<0.05). As shown in Fig. 7B3, there was a significant positive correlation between energy and volume of PMMA (r=0.851; R²=0.724; p<0.05, 95% confidence intervals: 0.593–0.832).

In augmentation with the same volume of PMMA, energy values in groups B0, B1, B2, B3, and B4 was significantly decreased (29.81%, 49.46%, 52.99%, 49.49%, and 49.70%, respectively) compared with the energy values in groups A0, A2, A3, A4, and A5 (p<0.05). Also in augmentation with the same volume of PMMA, the increased percentages of energy values compared with those for nonaugmented screws in osteoporotic lumbar vertebrae were higher than those for severely osteoporotic lumbar vertebrae. The energy value in group A0 was significantly higher than that in group B0 and significantly lower than those in groups B3, B4, and B5 (p<0.05). The energy value in group A1 was significantly higher than those in groups B0 and B1 and significantly lower than that in group B5 (p<0.05). The energy value in group A2 was significantly higher than those in groups B0, B1, and B2 (p<0.05). The energy values in both groups A4 and A5 were significantly higher than those in groups B0 through B5 (p<0.05). Except comparison between abovementioned two groups, there were no significant differences in energy values between any other two groups (p>0.05).

Discussion

Effectively improving pedicle screw stability in osteoporosis has always been a tough problem for spine surgeons. Cook et al. [7] injected 2–3 mL of PMMA through expandable screws to enhance fixation and found a 250% increase in mean pullout strength compared with noncemented expandable screws, and an increase in pullout strength of more than twofold in the most severely osteoporotic bone. In their study, cemented conventional screws had pullout strength similar to that of noncemented expandable screws, showing that PMMA fixation produced excellent pedicle screw fixa-

tion in the setting of weak bone. After that study, the augmentation of screw fixation with PMMA increased because of its excellent mechanical strength.

In early studies, many researchers directly injected PMMA into the pilot hole to improve screw stability. Over time, more researchers injected PMMA through injectable screws with various designs to enhance fixation. However, there was a significant variation in the volumes of PMMA injected and in screw stability across studies. As shown in the Table, the volume of PMMA injected ranged from 0.8 to 8.0 mL, and incremental screw stability varied markedly from 28.7% to 1,031%.

Frankel et al. [9] injected PMMA (mean volume, 3.7 mL; range, 2–8.0 mL) through a novel fenestrated bone tap into the vertebral body between T5 and L5 to enhance pedicle screw stability in osteoporotic human cadaveric specimens. After PMMA augmentation, the Fmax of the pedicle screw increased in primary and salvage procedures by 119% and 162%, respectively, but pullout strength did not significantly change with increased cement usage between the low-cement group (≤2.8 mL/pedicle) and the high-cement group (≥5.5 mL/pedicle).

Paré et al. [17] injected different volumes of PMMA into vertebrae through fenestrated pedicle screws (0.5, 1.0, and 1.5 mL in thoracic vertebrae, and 1.5, 2.0, and 2.5 mL in lumbar vertebrae). Except for the screw receiving 0.5 mL of PMMA in thoracic vertebrae, the Fmax of the augmented fenestrated screws was significantly increased compared with non-PMMA–augmented pedicle screws for the screws receiving 1.0 mL (186%) and 1.5 mL (158%) of PMMA in the thoracic vertebrae. Statistically significant increases were observed for the screws receiving 1.5 mL (264%), 2.0 mL (221%), and 2.5 mL (198%) of injected cement in the lumbar vertebrae. There was no significant difference, however, at higher volumes of cement. Paré et al. suggested that increasing cement volume did not lead to significantly higher pullout strength, and that use of excessive amounts should be avoided to reduce the risk of cement toxicity, thermal injury, and extravasation. They found that screw stability did not increase with incremental increases in PMMA volume. However, they did not analyze the relationship between screw stability and volume of PMMA in their study.

Föltsch et al. [18] augmented fenestrated screws with PMMA in synthetic osteoporotic bone and used a range of cement volumes, from 0.5 to 4.5 mL. They found a high (r=0.88), significant (p<0.01) correlation between cement volume and pullout strength, which increased by more than fivefold with a volume of 3 mL. The correlation appeared linear at least up to a cement volume of 4 mL, and failure always occurred at the cement-bone interface. Compared with control samples, a cement volume of 2.0 to 3.0 mL increased pullout strength significantly and is relevant for clinical purposes, whereas a volume of 0.5 mL did not. A cement volume of >3.0 mL should further increase pullout strength because the correlation was linear at least up to 4.0 mL, but the possibility of in vivo cement leakage with increasing
volume has to be considered. Chen et al. [19] found that injection of 1, 2, or 3 mL of PMMA significantly improved the screw stability by 259%, 508%, and 715%, respectively, in severely osteoporotic blocks compared with non-PMMA–augmented pedicle screws, and there were significant differences between any two groups. With every 1-mL increment of PMMA, there was a significant improvement in fixation strength.

All of those studies show that there are significant differences in the screw stability provided by various volumes of PMMA. Nevertheless, most comparative studies of different volumes of PMMA mainly focused on injection through fenestrated screws; few studies have focused on the traditional injection method. In studies that did focus on the traditional method, there was no comparison of screw stability for varying volumes of PMMA and no correlative analysis of screw fixation strength and PMMA volume, especially in different degrees of osteoporosis. Thus, our study was designed to fill that research void.

We found that PMMA (appearing as high-density areas in Figs. 5 and 6) was wrapped around screws in both osteoporotic and severely osteoporotic lumbar vertebrae, improving the local density around the screws, adhering the screws tightly to synthetic bone, and enhancing the strength of the hold between the screws and the bone. Radiographs showed that the amount of PMMA around screws grew with the volume of injected PMMA, increasing from groups A1 to A5 and from groups B1 to B5. Biomechanical tests proved that augmentation with different volumes of PMMA could all increase pedicle screw fixation strength compared with nonaugmented screws in both osteoporotic and severely osteoporotic lumbar vertebrae. Screw stability increased synchronously with the increase in volume of injected PMMA. There was a significant positive correlation between screw stability and volume of PMMA in both osteoporotic and severely osteoporotic lumbar vertebrae, just as was found in the study by Fölsch et al. [18]. The $F_{\text{max}}$ for PMMA-augmented screws in osteoporotic lumbar vertebrae was significantly higher than that in severely osteoporotic lumbar vertebrae augmented with the same volume of PMMA. In augmentation with the same volume of PMMA, the increased percentages of $F_{\text{max}}$ compared with those for nonaugmented screws in osteoporotic

<table>
<thead>
<tr>
<th>References</th>
<th>Reported time</th>
<th>Type of study</th>
<th>Volume of injected PMMA (mL)</th>
<th>Increment of pedicle screw stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fransen et al. [8]</td>
<td>2007</td>
<td>Clinical study in patients with osteoporosis and severe osteoporosis (T12–L1, L3–L5)</td>
<td>1.5</td>
<td></td>
</tr>
<tr>
<td>Frankel et al. [9]</td>
<td>2007</td>
<td>In vitro study in osteoporotic thoracic and lumbar vertebrae (T5–L5)</td>
<td>2.0–8.0</td>
<td>First surgery, 119%; revision surgery, 162%</td>
</tr>
<tr>
<td>Becker et al. [10]</td>
<td>2008</td>
<td>In vitro study in osteoporotic lumbar vertebrae (L1–L4)</td>
<td>2.0</td>
<td></td>
</tr>
<tr>
<td>Chang et al. [11]</td>
<td>2008</td>
<td>Clinical study in patients with osteopenia, osteoporosis, and severe osteoporosis (T2–S1)</td>
<td>Lumbar vertebrae, 3.0; thoracic vertebrae and S1, 2–2.5</td>
<td></td>
</tr>
<tr>
<td>Moon et al. [12]</td>
<td>2009</td>
<td>Clinical study in patients with osteoporosis and severe osteoporosis (T2–S1)</td>
<td>1.7–2.0</td>
<td></td>
</tr>
<tr>
<td>Waits et al. [13]</td>
<td>2009</td>
<td>In vitro study in osteopenia lumbar vertebrae</td>
<td>2.5</td>
<td></td>
</tr>
<tr>
<td>Blattert et al. [14]</td>
<td>2009</td>
<td>In vitro study in osteoporotic thoracic and lumbar vertebrae (T9–L4)</td>
<td>1.5</td>
<td></td>
</tr>
<tr>
<td>Chen et al. [15]</td>
<td>2009</td>
<td>In vitro study in severe osteoporotic synthetic bone block</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Bullmann et al. [16]</td>
<td>2010</td>
<td>In vitro study in osteoporotic thoracic and lumbar vertebrae (T7–L3)</td>
<td>0.8–2.0</td>
<td>28.7%</td>
</tr>
<tr>
<td>Paré et al. [17]</td>
<td>2011</td>
<td>In vitro study in osteoporotic thoracic and lumbar vertebrae (T7–L5)</td>
<td>Thoracic vertebrae (0.5, 1.0, 1.5), and lumbar vertebrae (1.5, 2.0, 2.5)</td>
<td>Thoracic vertebrae: 186% (1.0 mL) and 158% (1.5 mL); lumbar vertebrae: 264% (1.5 mL), 221% (2.0 mL), and 198% (2.5 mL)</td>
</tr>
<tr>
<td>Fölsch et al. [18]</td>
<td>2012</td>
<td>In vitro study in osteoporotic synthetic bone block</td>
<td>0.5–4.5</td>
<td>&gt;50%</td>
</tr>
<tr>
<td>Chen et al. [19]</td>
<td>2011</td>
<td>In vitro study in severely osteoporotic synthetic bone block</td>
<td>3</td>
<td>1031%, 817.1%, 902.4%, 609.5%</td>
</tr>
<tr>
<td>Liu et al. [20]</td>
<td>2013</td>
<td>In vitro study in osteoporotic synthetic bone block</td>
<td>2.5</td>
<td>448%</td>
</tr>
<tr>
<td>Chen et al. [21]</td>
<td>2014</td>
<td>In vitro study in severely osteoporotic synthetic bone block</td>
<td>1, 2, and 3</td>
<td>259%, 1.0 mL; 508%, 2.0 mL; 715%, 3.0 mL</td>
</tr>
</tbody>
</table>

PMMA, polymethylmethacrylate.
lumbar vertebrae were higher than those in severely osteoporotic lumbar vertebrae.

We also found that the $F_{\text{max}}$ of pedicle screws augmented with 0.5 mL of PMMA in osteoporotic vertebrae was significantly higher than that for screws augmented with 0 mL or 1.0 mL of PMMA in severely osteoporotic vertebrae, was significantly lower than that for screws augmented with 3.0 mL of PMMA, and was not significantly different from that for screws augmented with 1.5, 2.0, or 2.5 mL of PMMA. The $F_{\text{max}}$ of pedicle screws augmented with 1.0 mL of PMMA in osteoporotic vertebrae was significantly higher than that for screws augmented with 0, 1.0, or 1.5 mL of PMMA in severely osteoporotic vertebrae, was significantly lower than that for screws augmented with 3.0 mL of PMMA, and was not significantly different from that for screws augmented with either 2.0 or 2.5 mL of PMMA. The $F_{\text{max}}$ for pedicle screws augmented with 1.5 mL of PMMA in osteoporotic vertebrae was significantly higher than for screws augmented with 0, 1.0, 1.5, 2.0, or 2.5 mL of PMMA in severely osteoporotic vertebrae, but there was no significant difference compared with the $F_{\text{max}}$ for screws augmented with 3.0 mL of PMMA. The $F_{\text{max}}$ for pedicle screws augmented with either 2.0 or 2.5 mL of PMMA in osteoporotic vertebrae was significantly higher than for screws augmented with 0, 1.0, 1.5, 2.0, 2.5, or 3.0 mL of PMMA in severely osteoporotic vertebrae.

Comparison of different volumes of PMMA for the same bone condition revealed that screw stability was positively correlated with volume of PMMA in both osteoporotic and severely osteoporotic lumbar vertebrae. Although there were 32.40%, 24.18%, 31.38%, 26.87%, and 12.17% increments, respectively, in $F_{\text{max}}$ of pedicle screw in osteoporotic lumbar vertebrae with increasing volumes of injected PMMA from 0 to 0.5 mL, from 0.5 to 1.0 mL, from 1.0 to 1.5 mL, from 1.5 to 2.0 mL, and from 2.0 to 2.5 mL, none of these increments were statistically significant ($p > 0.05$). Similar to Paré et al. [17] and Fölsch et al. [18], we found no significant differences in fixation strength between 0 and 0.5 mL of injected PMMA. These findings indicate that a larger volume of PMMA should be injected to significantly enhance screw fixation strength.

Although there were 23.48%, 20.18%, 39.22%, 13.61%, and 32.09% increments, respectively, in $F_{\text{max}}$ of pedicle screw in severely osteoporotic lumbar vertebrae with an increasing volume of injected PMMA from 0 to 1.0 mL, from 0 to 1.5 mL, from 1.0 to 1.5 mL, from 1.5 to 2.0 mL, and from 2.0 to 2.5 mL, none of those increments were statistically significant ($p > 0.05$). Chen et al. [21] found that injection of 1, 2, or 3 mL of PMMA could significantly improve screw stability in severely osteoporotic blocks, and there were significant differences between any two groups. With every 1-mL increment of PMMA, there was a significant improvement in fixation strength, which was different from our findings. In our study, injection of $>1.5$ mL of PMMA into the hole led to significant improvement in screw stability in severely osteoporotic vertebrae. This discrepancy may be related to the different distribution of PMMA around screws and the differences in structure between synthetic bone blocks and lumbar vertebrae. Because we found no significant difference in screw stability in PMMA augmentation with 1.5 to 2.0 mL and with 2.0 to 2.5 mL in osteoporotic lumbar vertebrae, we prefer to inject 1.5 mL of PMMA in osteoporotic lumbar vertebrae to enhance screw fixation and reduce PMMA leakage. There was also no significant difference in screw stability in PMMA augmentation with 2.0 to 2.5 mL in severely osteoporotic lumbar vertebrae; however, screw stability was highest in augmentation with 3.0 mL. Moreover, we found no PMMA leakage, so we prefer to inject 3.0 mL of PMMA in severely osteoporotic lumbar vertebrae.

Our study had several limitations. As we know, there are rare body donations due to cultural background, especially for bodies of aged people. It has been reported that screw loosening generally results from “teeter-tottering” of screws owing to the multidirectional load placed on pedicle screws in the body, where the outer cortex acts as a fulcrum and the trabecular bone around the anterior part of the screw is swept away by it [22]. Therefore, the screw stability is determined mainly by axial and vertical fixation strength [23]. Clinically, the high incidence of screw failure due to loosening has been associated with cyclic loading [24]. Because it was difficult to obtain many cadaveric samples to perform multifaceted biomechanical tests, we only used the axial pullout test to evaluate screw stability. It is more scientific to evaluate screw stability through multifaceted biomechanical tests based on more specimens. So we would harvest enough specimens as possible as we could.

**Conclusion**

Our findings show that PMMA can significantly enhance the stability of pedicle screws in both osteoporotic and severely osteoporotic lumbar vertebrae. There was a significant positive correlation between screw stability and volume of PMMA, and screw stability increased with increasing increments in the volume of PMMA. Within a certain range, nevertheless, increasing the volume of PMMA does not significantly improve screw stability. Our study showed that in the use of pedicle screws in lumbar vertebrae, injection of 1.5 mL and 3 mL of PMMA is optimal in osteoporosis and severe osteoporosis, respectively.

**Supplementary material**

Supplementary material related to this article can be found at [http://dx.doi.org/10.1016/j.spinee.2016.04.015](http://dx.doi.org/10.1016/j.spinee.2016.04.015).

**References**


