An Experimental Study on the Biomechanical Effectiveness of Bone Cement-Augmented Pedicle Screw Fixation with Various Types of Fenestrations

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Objective : To analyze the effects of the number and shape of fenestrations on the mechanical strength of pedicle screws and the effects of bone cement augmentation (BCA) on the pull-out strength (POS) of screws used in conventional BCA.

Methods : For the control group, a conventional screw was defined as C1, a screw with cannulated end-holes was defined as C2, a C2 screw with six pinholes was defined as C3, and the control group type was set. Among the experimental screws, T1 was designed using symmetrically placed thru-hole type fenestrations with an elliptical shape, while T2 was designed with half-moon (HM)-shaped asymmetrical fenestrations. T3 and T4 were designed with single HM-shaped fenestrations covering three pitches and five pitches, respectively. T5 and T6 were designed with 0.6-mm and 1-mm wider fenestrations than T3. BCA was performed by injecting 3 mL of commercial bone cement in the screw, and mechanical strength and POS tests were performed according to ASTM F1717 and ASTM F543 standards. Synthetic bone (model #1522-505) made of polyurethane foam was used as a model of osteoporotic bone, and radiographic examinations were performed using computed tomography and fluoroscopy.

Results : In the fatigue test, at 75% ultimate load, fractures occurred 7781 and 9189 times; at 50%, they occurred 36122 and 82067 times; and at 25%, no fractures occurred. The mean ultimate load for each screw type was 219.1±52.39 N for T1, 234.74±15.9 N for T2, 220.70±59.23 N for T3, 216.45±32.4 N for T4, 181.55±54.78 N for T5, and 216.47±29.25 N for T6. In comparison with C1, T1, T2, T3, T4, and T6 showed significantly different ultimate load values ($p<0.05$). However, when the values for C2 and the fenestrated screws were evaluated with an unpaired t test, the ultimate load value of C2 significantly differed only from that of T2 ($p=0.025$). The ultimate load value of C3 differed significantly from those of T1 and T2 (C3 vs. T1 : $p=0.048$; C3 vs. T2 : $p<0.001$). Linear correlation analysis revealed a significant correlation between the fenestration area and the volume of bone cement (Pearson's correlation coefficient r=0.288, $p=0.036$). The bone cement volume and ultimate load significantly correlated with each other in linear correlation analysis (r=0.403, $p=0.003$).

Conclusion : Fenestration yielded a superior ultimate load in comparison with standard BCA using a conventional screw. In T2 screws with asymmetrical two-way fenestrations showed the maximal increase in ultimate load. The fenestrated screws can be expected to show a stable position for the formation of the cement mass.

**Key Words :** Fenestration · Pedicle screw · Bone cement · Ultimate load · Pull-out strength.

INTRODUCTION

Spinal fusion surgery using instrument insertion is used to treat various spinal diseases by stabilizing the spinal column[1]. Although the objective of this surgical method is to achieve bone union, poor bone quality or severe spinal instability at the surgery planning stage are associated with a substantial possibility of arthrodesis failure[7]. Osteoporosis is an increasingly prevalent condition characterized by inferior bone quality. Despite the availability of various medical treatments, osteoporosis remains a critical problem in spine surgery, making the procedure difficult for both patients and clinicians. As a result, various attempts are being made to supplement the design of screws to overcome bone-quality limitations and

thereby address the relevant biomechanical characteristics for use during surgery[3-6,11-14,16,17,23,26,38,40,41].

Numerous studies have focused on different pedicle-screw designs to prevent screw loosening. These designs include screws with an increased outer diameter or length[15], different thread profiles[7,13], cylindrical or conical cores[22], expanding screws[23], and cannulated screws with polymethylmethacrylate (PMMA) cement augmentation[34]. Among these screw designs, cannulated screws, in particular, have been shown to be an efficient alternative and innovative design for preventing osteoporotic incidents when used with cement augmentation[14,17,19,34].

Various biomechanical studies have suggested that reinforcement using bone cement can increase the mechanical
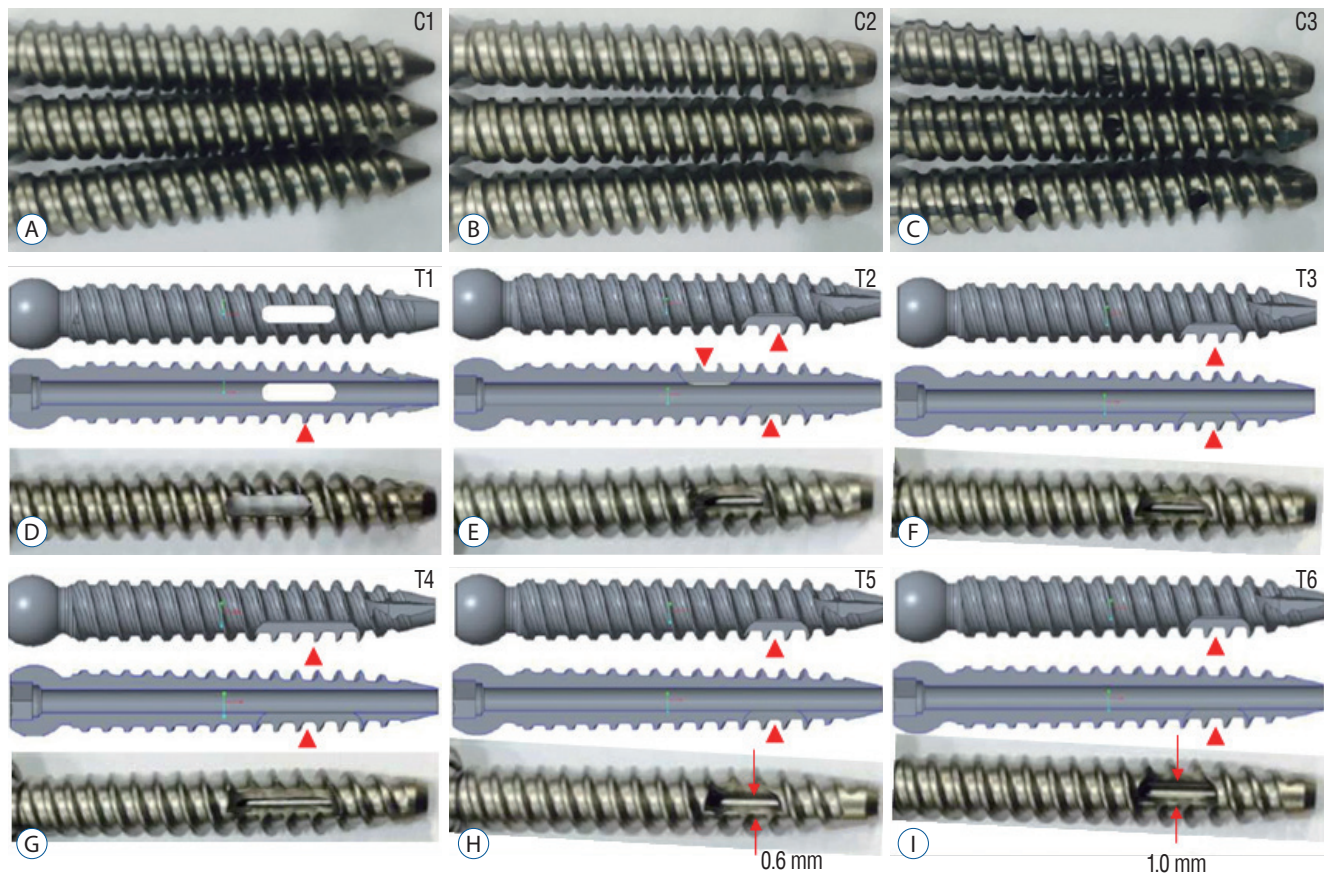
Fig. 1. Cross-sectional and gross photographs showing the characteristics of each type of screw used in the experiment, and external photos showing the characteristics of each screw group. A : A conventional screw (C1 group). B : A screw with a 2-mm-diameter cannulation and an end hole at the tip of the screw (C2 group). C : A screw with six pin holes with a diameter of 2 mm (C3 group). D : T1 with an elliptical-shaped fenestration and a two-way symmetric thru-hole. E : T2 with a two-way asymmetric half-moon (HM)-shaped fenestration. F : T3 with a one-way HM-shaped fenestration located more distally and occupying three pitches. G : T4 with a one-way HM-shaped fenestration occupying five pitches. H : T5 with a one-way HM-shaped fenestration that was 0.6 mm wider than that in T3. I : T6 with a one-way HM-shaped fenestration that 1.0 mm wider than that in T3. Arrowheads indicate the location and shape of the fenestration.

strength of the bone-screw interface[19-21,38,40,45]. Sarzier et al.[45] reported the design and biomechanical research for the development of screws capable of injecting bone cement by up to 160% of pull-out strength with bone cement reinforcement. Other studies have attempted to evaluate the biomechanical significance of the end or side holes of the screw in influencing these characteristics[8,13,17]. An increase in hole size can make bone cement injection easier, yielding differences in the biomechanical characteristics. We used this principle to evaluate a more diverse range of screw designs by placing fenestrations at various screw positions and tried to analyze the biomechanical significance of these modifications. In particular, we hoped that these evaluations would yield an open-ended fenestrated screw that shows greater resistance to rear traction, and we aimed to select a design that exhibits optimal resistance and physical properties. Thus, the aim of this study was to evaluate the influence of fenestrations at various locations and of different dimensions in terms of their ability to enhance the pull-out strength of the screw.

MATERIALS AND METHODS

Experimental design

Design of the pedicle screw

This experiment is not related to IRB or IACUC approval as it is a biomechanical experimental study that did not use humans or animals as subjects. This study used a commercially available cannulated pedicle screw (Cemexious Spinal Fixation System; Huvexel Co., Ltd., Seongnam, Korea). These pedicle screws had the same outer diameter (6.5 mm) and length (45 mm), a pitch of 2.5 mm, and were made of titanium alloy (Ti-6Al-4V, ELI). On the basis of the results reported by Matthews et al.[37], the actual size of the screw was considered as the screw diameter and pedicle position that was not fenestrated, considering the overall diameter and length of the pedicle.

The inner diameter of the cannulation was 2 mm. In this type of screw, in addition to the end hole for cannulation, a side hole was created for fenestration, and the location and size of the fenestration were varied. The conventional screw currently used in the medical market was described as control 1 (C1), while an end-hole-type screw (diameter, 2 mm) with a

cannula penetrating the screw shaft was designated as control 2 (C2). A screw with three pairs of thru-holes and a 2-mm diameter was designated as control 3 (C3) (total fenestration area, 18.84 mm^2).

The authors classified the screws with fenestrations into several categories based on the size and location of the fenestrations. Thus, T1 referred to a screw with two fenestrations (T1) that penetrated each other and were symmetrical, while T2 referred to a screw with two asymmetrically placed fenestrations. Among the screws with only one fenestration, T3 and T4 had varying lengths of the long axis based on the number of threads occupied by each fenestration, while T5 and T6 involved wider fenestrations and were obtained by varying the width in the horizontal direction of the fenestration.

The fenestrations were also divided into elliptical (E) or half-moon (HM) shapes that were larger than a 2 mm-hole. Thus, T1 had E-shape fenestrations (28.28 mm^2) made through the center of the screw at a distance of four thread pitches away from the end of the screw tip. T2 had HM-shaped fenestrations (13.14 mm^2) made on one side at a distance of three pitches away from the screw tip, and on the other side of the screw surface without crossing through the screw distal from the previous fenestration. T3 had a HM-shaped and three-pitch-wide fenestration with an area of 7.07 mm^2 on one side at a distance of three pitches away from the screw tip. T4 had a HM-shaped five-pitch-wide fenestration (12.07 mm^2) at a length of three pitches away from the screw tip. T5 had a HM-shaped fenestration (12.82 mm^2) that was 0.6 mm wider than that of T3 and three pitches away from the screw tip. T6 had a HM-shaped fenestration (17.28 mm^2) that was 1.0 mm wider than that of T3 and at the same position away from the screw tip (Fig. 1).

Mechanical strength testing of the fenestrated screws : the worst-case test (T1)

To confirm the stability of each of the newly designed screws, the weak points of the screws were determined in a mechanical strength test based on ASTM F1717[33]. This test was conducted at the Advanced Medical Device Support Center (Osong Advanced Medical Industry Promotion Foundation, Osong, Korea). For this test, a universal material testing machine (Bionix; MTS Systems Corp., Minneapolis, MN, USA) was used, and a total of six representative specimens of the cannulated screws were produced. In these screws, the head and fenestration parts were predicted to be the weakest.

Considering only the fenestration part, the screw with the widest fenestration was most likely to have the lowest structural stability, so it was considered to have the most significant weakness. Accordingly, the T1 screw was selected for the mechanical strength test. The mechanical experiment was conducted by performing compression and tensile tests under 25 KN at a rate of 25 mm/min; the torsional test was performed at 60°/min. For the fatigue test, the load ratio exceeded 10 at a frequency of 5 Hz. The temperature for this test was set at 24°C and the relative humidity was 48%.

Bone cement augmentation and pull-out test

Synthetic bone (model #1522-505; Pacific Research Laboratory Inc., Vashon Island, WA, USA) made from polyurethane foam was used as a substitute for the cadaveric spinal bone because of its consistent and homogeneous structural properties. The synthetic bone was supplied as a rectangular feature (test block) with dimensions of 13×18×4 cm; the material was an open-cell rigid polyurethane foam with a density of 0.09 g/cm^3, which simulated cadaveric vertebra with extreme osteoporosis[27,35,36].

A pilot hole was drilled into the test block using a 3.5-mm drill bit, and a cannulated screw was inserted into the test block via the prepared pilot hole. All screws were inserted at identical depth (45 mm) using a consistent depth gauge, and radiological examinations using fluoroscopy were performed to check the implanted screw depths (Siemens-Arcadis Varic C-arm; Brainlab, AG, Munich, Germany). After cannulated screw insertion, high-viscosity bone cement (Spinofill; Injecta Co Ltd., Gunpo, Korea) was mixed at room temperature as recommended by the manufacturer and introduced into the cannulated screws by using a self-designed cement injector system that exerts pressure on the cement. The cement injector was composed of a cement gun, syringe, adapter, and cannulated screw. One minute after the cement powder and monomer were mixed, the liquid-phase cement was transferred into a 10-mL syringe, which was then inserted into the cement gun. An adapter was used to connect the syringe to the cannulated screw. For all specimens, a total of 3 mL of cement was injected into the cannulated screw. For solid screws without fenestration, the solid screw was inserted into the test block through the prepared pilot hole and then removed to create a hole with dimensions identical to those of the screw contour. A total of 3 mL of cement was then retrogradely injected into the created hole. Next, the biopsy needle was inserted into the prepared pilot hole until the marking point approached the entry edge of the test block. Then, the cement was injected into the pilot hole in conjunction with progressive needle retraction out of the test block until a total volume of 3 mL of bone cement was injected. Using this technique, a uniform cement distribution can be achieved. After pre-filling of the bone cement, the solid screw was fully inserted into the test block. Simultaneously, several tests were conducted to test the fixation force of bone cement.

If there was no leakage to the proximal side after injection of bone cement, it was considered that there was no leakage. Krag et al.[31] and Zindrick et al.[49] reported the length of penetrating the body from the pedicle was suggested to be 45–50 mm. Considering this, it was determined that there was no leakage when bone cement was formed within 50 mm after insertion.

To determine whether the injection of bone cement was easy, the amount of powder and the amount of solvent used to produce bone cement were uniformly mixed. Using a pressure gauge meter, the mixture was injected while maintaining 10

Fig. 2. Pull-out strength test using the MTS system (Bionix 858; MTS systems Corp., Minneapolis, MN, USA). The specimen was mounted on the test jig of a universal material testing machine.

psi as much as possible. This pressure was constantly measured. First, the injection amount was constant at 3 mL. After performing the pull-out test on the amount of injected bone cement, the volume of bone cement attached to the pulled screw was measured directly from a mass cylinder using distilled water. The augmented volume was measured and compared to the injected volume.

As a test method to verify the fixation force between the bone tissue and the pedicle screw, it was based on the ASTM F543-17 test standard that measures the load in the tensile direction of the vertical axis when the pedicle screw is removed from the polyurethane. For this test, the specimen was mounted on a test jig of a universal material testing machine (Bionix 858; MTS Systems Corp.) (Fig. 2).

As shown in Fig. 2, the test jig fastened to the upper head of the inserted pedicle screw was tensioned at a speed of 5 mm/min until the pedicle screw inserted into the test block was separated entirely. The load-displacement data were acquired at a frequency of 30 Hz, and all six specimens per group were tensioned to apply the posterior traction resistance.

Data analysis

During pull-out testing, the ultimate load and ultimate displacement (maximum displacement) were measured, and the measured yield load and yield displacement were obtained. Statistical software (SPSS ver. 21.0; IBM Corp., Armonk, NY, USA) was used for statistical analysis. A Q-Q diagram and Kolmogorov-Smirnov test were performed to verify normality. For evaluation of normality, one-way analysis of variance (ANOVA) was performed. When a significant effect was found, *post-hoc* analysis was performed using Tukey's HSD test (or Student's t-test if the effect had binary levels). Statistical significance was set at $p<0.05$. For non-parametric testing, Pearson's correlation coefficient was used to analyze the correlation between continuous variables. The Kruskal-Wallis test was performed for three or more groups. The null hypothesis was rejected at $p<0.05$.

RESULT

Mechanical strength tests : the worst-case test (T1)

In the assessment of mechanical stability conducted according to the ASTM F1717 method, the worst findings were ob-
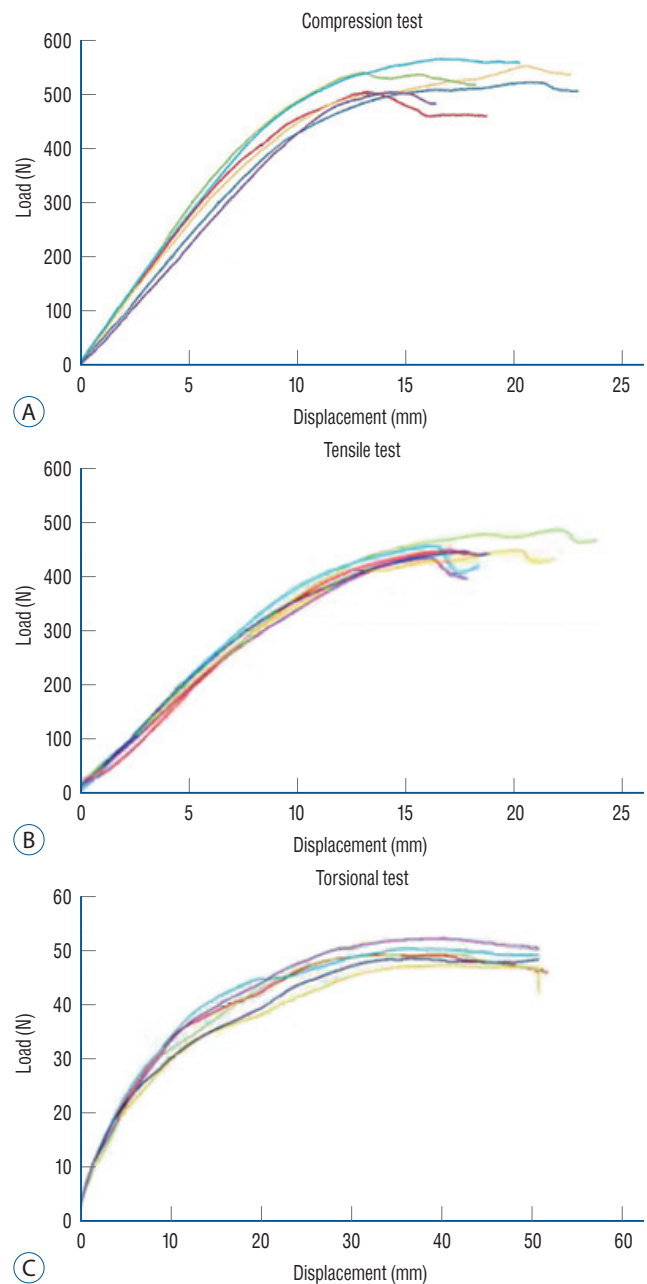

Fig. 3. Test results according to ASTM F1717 test standard to analyze the mechanical properties and stability of fenestrated screws (T1). Every test was performed with a T1 screw six times, and the results were displayed on the graph in different colors. In the fenestration compression bending test, the average ultimate load value was 533.97±25.48 N, and the maximum displacement value was 16.58±3.52 mm. At this time, the yield load was 477.75 ±25.05 N, and the yield displacement was 11.00±0.96 mm. Stiffness was measured to be 50.66±4.10 N/mm. A : The tensile test results showed that the yield load was 439.65±36.87 N, and the ultimate load was 505.91±42.87 N. The yield displacement was 16.74±1.3 mm, and the maximum displacement was 23.13±2.66 mm. The stiffness was 28.43±0.58 N/mm. B : The torsional test was performed with an offset of 1.95°. The results of the torsional test were as follows : yield angle, 21.69°±1.23°; yield torque, 37.73±1.36 N·mm; ultimate torque, 46.17±0.87 N·mm; and stiffness, 1.9 ± 0.14 N/mm (C).

tained using the screw with the maximum fenestration area (T1). In the fenestration compression bending test, the average ultimate load value was 533.97±25.48 N, and the maximum displacement value was 16.58±3.52 mm. At this time, the yield load was 477.75±25.05 N, and the yield displacement was 11.00 ±0.96 mm. Stiffness was measured to be 50.66±4.10 N/mm (Fig. 3A). The tensile test results showed that the yield load was 439.65±36.87 N, and the ultimate load was 505.91±42.87 N. The yield displacement was 16.74±1.3 mm, and the maximum displacement was 23.13±2.66 mm. The stiffness was 28.43± 0.58 N/mm (Fig. 3B). The torsional test was performed with an offset of 1.95°. The results of the torsional test were as follows : yield angle, 21.69°±1.23°; yield torque, 37.73±1.36 N·mm; ultimate torque, 46.17±0.87 N·mm; and stiffness, 1.9±0.14 N/mm (Fig. 3C). On the basis of the mechanical stress test, a static compression test was performed with 75% (356 N), 50% (237

N), and 25% (118 N) of the ultimate load (475 N) value (R=10). A failure cycle was applied up to a total of 5000000 times. At 75% ultimate load, fracture occurred at 7781 and 9189 times; at 50%, fracture occurred at 36122 and 82067 times; and at 25%, no fractures occurred.

The effect of the type of fenestration and cement augmentation on the osteoporotic bone model : pull-out strength

To compare the experimental findings obtained under the same conditions and to check whether the experiment was conducted stably, the injection amount of bone cement for each group and the injection pressure applied when injected were compared. The mean injection amount of bone cement was 3.31 mL, and the injection amount did not differ significantly among the groups (p=0.703). The ultimate load in the
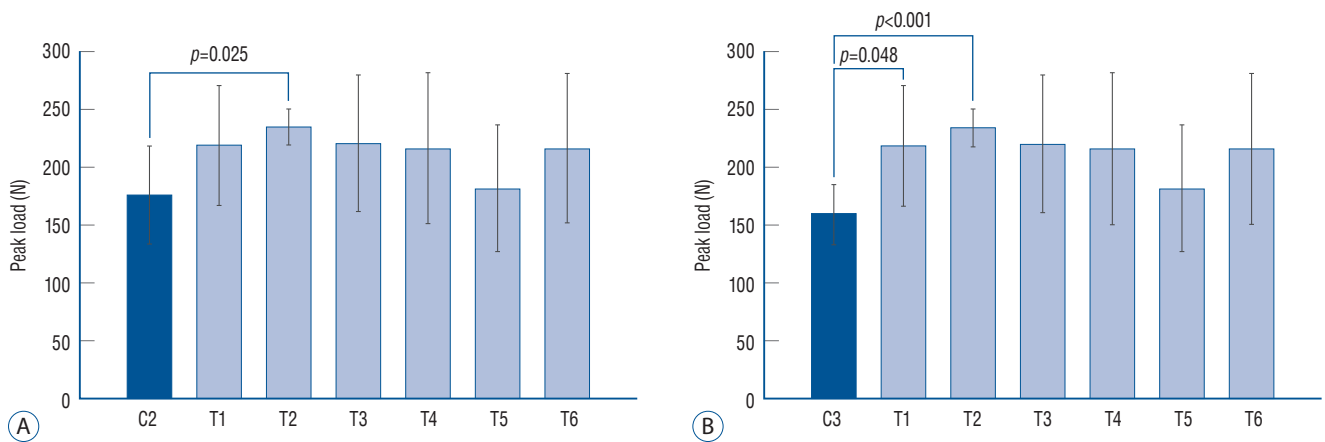
Fig. 4. Comparison of ultimate load values between the conventional augmented screw group and the fenestrated screw group. A : Comparison of independent paired t-test results between the C2 (cannulated type) and fenestrated screw groups. B : Comparison of C3 pinhole type screws with fenestrated screw groups.
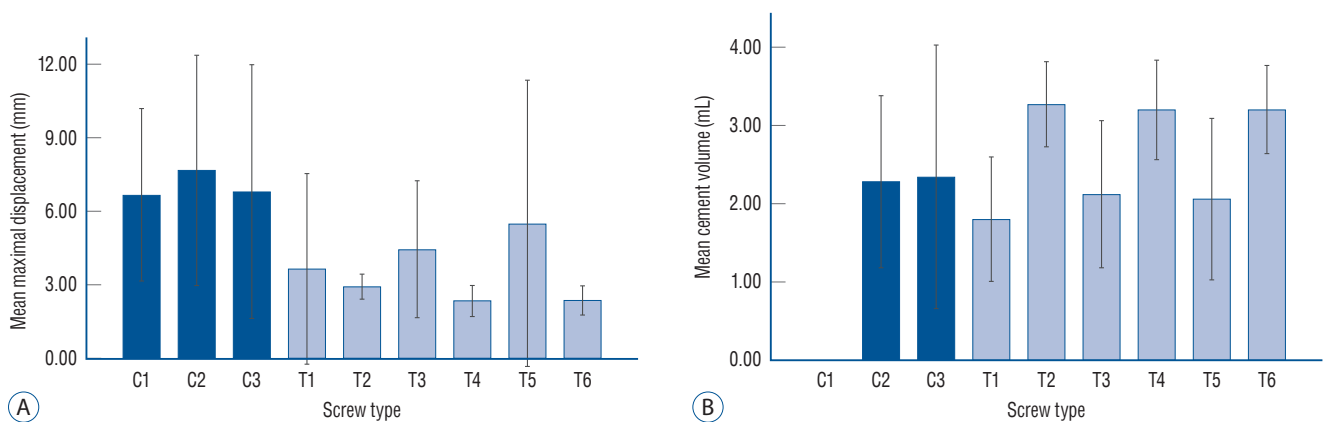
Fig. 5. Maximum displacement (mm) (A), and the bone cement volume injected into each screw (B).

C1, C2, and C3 groups was 122.24±73.18, 176.13±46.07, and 160.22±25.68 N, and it did not differ significantly among these groups (p=0.401).

The mean ultimate load for the experimental screw types was 219.1±52.39, 234.74±15.9, 220.70±59.23, 216.45±32.4, 181.55±54.78, and 216.47±29.25 N for the T1, T2, T3, T4, T5, and T6 groups, respectively. No statistically significant differences were observed among the values for the experimental screws (p=0.497). Analysis using one-way ANOVA and post-hoc analysis showed no statistically significant differences in ultimate load among the T1–T6 groups. In comparison with C1, the ultimate load values in T1, T2, T3, T4, and T6 showed statistically significant differences (p<0.05). However, in comparisons between C2 and the fenestrated screw groups by using the independent paired t-test, the ultimate load value in the C2 group differed significantly only from that in the T2 group (p=0.025). The ultimate load value in the C3 group dif-

fered significantly from those in the T1 and T2 groups (C3 vs. T1 : p=0.048; C3 vs. T2 : p<0.001) (Fig. 4).

We also categorized the screw groups with two fenestrations (T1 and T2) and those with one fenestration (T3, T4, T5, and T6) and compared their ultimate loads with the conventional augmentation screw groups (C2 and C3). The findings showed a statistically significant increase in the ultimate load in groups with one and two fenestrations (p=0.016 with the single-fenestration group and p=0.001 with the two-fenestration group). The ultimate load in the group with two fenestrations was 226.92 N, which was higher than that in the single-fenestration group (208.8 N), but the difference was not statistically significant (p=0.245).

The mean maximum displacement was 4.57±2.48 mm. In the C1, C2, and C3 groups, the mean maximum displacement was greater than those for all of the fenestrated screw groups, but the differences were not statistically significant (p>0.05).
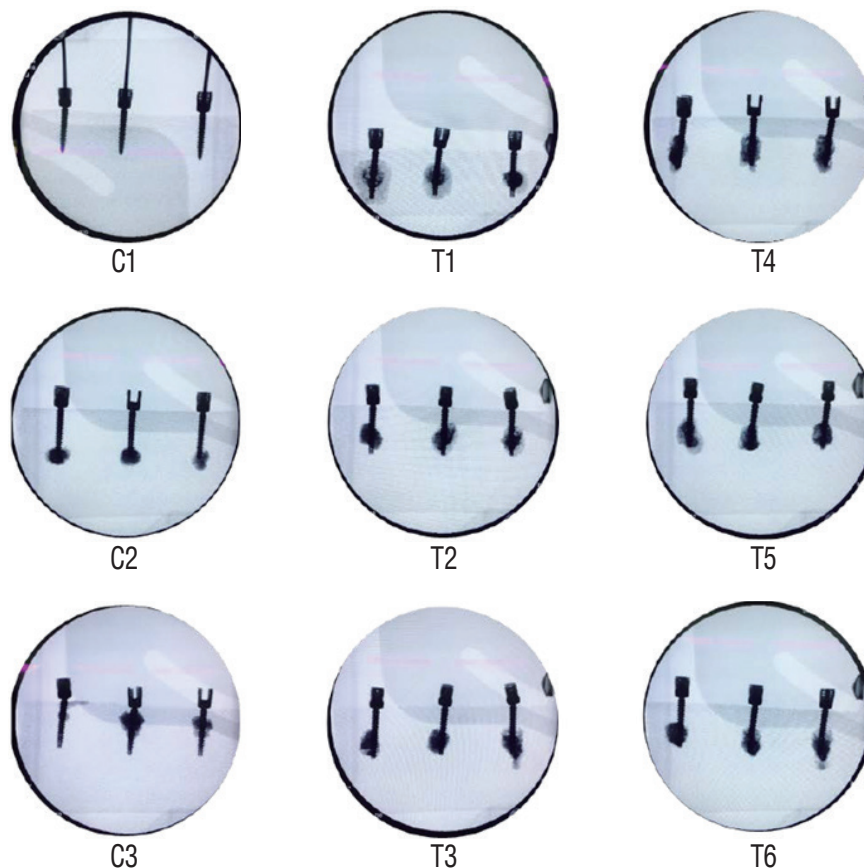
Fig. 6. Characteristics of the fenestrated screws in radiographic images obtained using fluoroscopy. C1 : A conventional screw without bone cement augmentation. C2 : Bone cement distribution at the tip of screws around the end hole. C3 : Bone cement distribution at the shaft of the screws near the pedicle level. T1-T6 : No flowed-out feature of bone cement at the position of the pedicle.

The volume formed by bone cement was 2.25±1.23 mL. T2 showed the largest bone cement volume (3.27±0.52 mL), while T1 showed the smallest volume (1.80±0.77 mL), but the differences among groups were not significant (*p*>0.05) (Fig. 5).

The linear correlation analysis showed a significant correlation between the total area of fenestration for each screw and the ultimate load (Pearson's correlation coefficient r=0.317, *p*=0.021). In addition, linear correlation analysis also revealed a significant correlation between the area of fenestration and the volume of bone cement (r=0.288, *p*=0.036). The bone cement volume and ultimate load showed a significant correlation in the linear correlation analysis (r=0.403, *p*=0.003).

Radiographic characteristics

The commonly observed characteristics of the fenestrated screws in radiographic images obtained using computed tomography and fluoroscopy were as follows : 1) all fenestrated screws showed bone cement flowing along the fenestration instead of flowing along the end hole of the cannula. And 2) no bone cement flowed out from the position of the pedicle (Fig. 6).

DISCUSSION

The pedicle screw is a standard surgical instrument used for stabilizing the anterior or posterior lumbar spine. However, since screw insertion is performed to secure stability, many clinicians and patients are concerned about the possible mechanical failure associated with this surgical method. Mechanical failures due to screw loosening are a significant cause of morbidity in the elderly because of their poor bone quality. Many solutions have been proposed to reduce this risk, including the use of expandable screws[18], hydroxyapatite-coated screws[2,28], bicortical screw purchase[49], larger-diameter screws[18,25,42], and PMMA augmentation[9,44,47]. The PMMA augmentation procedure can be improved by using fenestrated pedicle screws designed specifically for cement injection[3]. When PMMA is extruded through the screw hole, it polymerizes and hardens to form a continuous bone cement mass between the screw core and the screw in the cancellous bone of the vertebral body[3].

Various morphological parameters of screws have been analyzed for possible correlations with implant loosening. An increase in screw size in relation to pedicle diameter is known to increase screw anchorage in the pedicle[31,46]. Many studies have suggested that the shape of the screw with the use of PMMA can influence the pull-out strength[44]. Considering these details, various designs of fenestration have been devised[7,34,46]. Theoretically, the pull-out force required to remove the composite structure (bone with cement infiltration) from the adjacent trabecular bone is proportional to the composite/bone contact area, so a larger composite/bone interface would be conducive to improving the fixation strength of the screw. The authors thought that if cement was pre-inserted into the screwed hole in advance, or if the cement flowed out from a small hole, there was a high possibility that the cement injection would flow backward or the injection would not work well. To address these concerns, we envisioned that fenestrations of different sizes would be helpful and decided to test them. In our study, the groups without bone cement augmentation, thru-hole type screws, and cannulated-type screws were considered as controls, respectively, and compared with all fenestration groups.

Among the screw types we devised, T2, which contained asymmetrically placed fenestrations, formed an enormous cement volume and showed better pull-out strength than all controls, so this type of fenestration was considered to yield adequate pull-out strength, thereby confirming the expected reinforcement with this approach. Bone cement augmentation with two fenestrations appeared to be better than that with only one fenestration, while increasing the fenestration size was expected to increase the volume of bone cement augmentation and increase the pull-out strength. However, these effects had limits. In particular, when both sides were fenestrated in the thru-hole type, the reinforcement of the pull-out strength did not significantly increase in comparison with the control group despite the large fenestration area. The T2 group showed the highest increase in pull-out strength because the leakage area was widely distributed, so the pull-out strength may be improved if the leakage occurs more widely along the shaft of the screw.

According to the results of our experiments conducted under ASTM F1717, the screw we devised was formed within the range of values suggested as reference values by the U.S. Food and Drug Administration and the Korea Food and Drug Administration (KFDA), so its safety was confirmed. For reference, according to the test standards of the KFDA, the yield load should be at least 300 N for a compression test and at

least 400 N for the tensile test. Moreover, the torsion should be greater than 7 N·m, and the failure rate in the fatigue test should be within 25%. In the present study, all experimental screws met the test criteria.

Pull-out strength is usually evaluated by the determining the axial pull-out force until the pedicle screw is fully displaced. The reference value for conventional screws without reinforcement in normal bone is 812–1546 N[16,24,40]. According to one study that tested the pull-out strength in a model of osteoporosis, the average axial pull-out forces of pedicle screws inserted without augmentation ranged from 159 to 663 N[6,8,17,40,43]. Considering these ranges, the compression test results for our designed screws can be considered valid regardless of the design.

The authors assessed the experimental method and selected the steps on the basis of the following considerations : the straight axial pull-out strength served as a representative measure for the attachment between the screw pedicle and bone under different experimental conditions[1,39], and as a predictor of the fixation strength of pedicle screws. It has been accepted as a standard measure of tensile strength in comparisons of pedicle screws of different shapes[33]. Thus, after excluding other forces, the straight axial pull-out strength alone was considered to be an adequate parameter to compare and analyze tensile strength after bone cement augmentation of screws[48].

Synthetic bone materials such as Sawbones and polyurethane foam are widely used because of their homogeneity and reproducibility in comparison with cadaveric samples and are well-established bone surrogates for biomechanical testing[10,29]. The Sawbones model provides physical strength properties that are more similar to those of the actual spine than polyurethane foam, especially in studies in which anatomical simulation factors are essential. Numerous *in vitro* experiments have been conducted to improve screw fixation strength using polyurethane test blocks, and their findings have suggested that these synthetic bone materials provide a valuable platform for mechanical comparison of various designs of orthopedic devices[30,32]. However, the test blocks are rectangular, in contrast to the actual bone morphology, and this factor may influence the reliability of the results obtained in these studies.

Our findings confirmed that the fenestrated screws we devised yielded adequate bone cement augmentation and a more robust pull-out strength than that achieved with conventional screws inserted without augmentation. In addition, we con-

firmed that the ultimate load was higher for all fenestrated screws in comparison with the conventional screws with currently available hole patterns. In particular, the two-way type fenestration showed a significantly greater ultimate load. In the one-way type fenestration, even when the fenestration size increased, the ultimate load did not increase significantly. On the other hand, in the two-way type fenestration, the maximum load increased significantly with the asymmetric-type fenestration in comparison with the thru-hole type. Thus, the T2 type showed the best results.

As fenestration was performed, the expected weak point was not significant. The mechanical strength test confirmed that stability could be expected even with such a design. During radiographic examination and bone cement augmentation, unexpected phenomena associated with bone cement leakage to the pedicle location were not observed. Thus, the findings confirmed that bone cement was appropriate distributed and located in the body.

CONCLUSION

Among the screw types we devised, T2, which contained asymmetrically HM-shaped fenestrations, formed an enormous cement volume and showed better pull-out strength than all controls, so this type of fenestration was considered to yield adequate pull-out strength. It showed the highest increase in pull-out strength because the leakage area was widely distributed, so the pull-out strength may be improved if the leakage occurs more widely along the shaft of the screw.

AUTHORS' DECLARATION

Conflicts of interest

No potential conflict of interest relevant to this article was reported.

Informed consent

This type of study does not require informed consent.

Author contributions

Conceptualization : SHY, TAJ; Data curation : SHY; Formal analysis : SHY; Funding acquisition : SHY; Methodology :

SHY, TAJ; Project administration : SHY, SHL, TAJ; Visualization : SHY, SHL; Writing - original draft : SHY; Writing - review & editing : SHY, SHL

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