의학박사 학위논문

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

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지도교수 이 상 형

이 논문을 의학박사 학위논문으로 제출함
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서울대학교 대학원
의학과 신경외과학전공
윤 상 훈

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2022년 7월

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Abstract

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

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Objective: This study aims to prove what kind of window type fenestration can enhance pull-out strength while maintaining mechanical strength when bone cement augmentation is performed on a pedicle screw fixation.

Materials and Methods: A conventional screw was defined as C1, a screw with a cannulated end-hole was defined as C2, a C2 screw with six side pinholes was defined as C3, and the control group was composed of C1, C2 and C3. All experimental screw groups had one or two fenestrations with a window wider than the pinhole on the side. Among the experimental screws, T1 was designed using symmetrically placed thru-hole type fenestrations with an elliptical shape, while T2 was designed with halfmoon-shaped asymmetrical fenestrations. T3 and T4 were designed with single halfmoon-shaped fenestrations covering three and five pitches, respectively. T5 and T6 were designed with 0.6-mm and 1-mm wider fenestrations than T3. Bone cement augmentation was performed by injecting 3 mL of commercial bone cement in the screw, and mechanical strength and pull-out strengths 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 dynamic fatigue test, at 75% ultimate load, fractures occurred 7,781 and 9,189 times; at 50%, they occurred 36,122 and 82,067 times; and at 25%, no fractures occurred. The mean ultimate load value of C1 was 122.24 ± 73.18(N), and the mean maximum displacement was 6.66 ± 2.19(mm). Comparing the ultimate load values of C2 and C3 (176.13 ± 46.07(N) and 160.22 ± 25.68(N)) with the ultimate load of C1, there was no statistical difference (p=0.158, p=0.277).

In comparison with C1, the ultimate load of all T1, T2, T3, T4, and T6 except for T5 (p=0.143) showed a statistically significant difference ($p < 0.05$). 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. However, 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 but weak 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 positive correlation in the linear correlation analysis ($r = 0.403$, $P = 0.003$).

Conclusion: The window-type fenestrations yielded a superior ultimate load in comparison without bone cement augmentation. Especially in T2 screws with asymmetrical two-way fenestrations showed the maximal increase in ultimate load.

The authors conclude that the screw with asymmetrical two-way side-hole and window-type fenestrations is the optimal screw design for reinforcing the pull-out strength.

Keywords : Window-type, Fenestrated screws, Bone cement augmentation, Ultimate load, Pull-out strength

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Contents

List of Tables

List of Figures

보존용 학위논문 정오표

페이지	정정 전	정정 후
P. 5 : 8	Phoebe et	Matthews et

1. Introduction

Spinal fusion surgery using instrument insertion treats various spinal diseases by stabilizing the spinal column.[1] Pedicle screw fixation surgery is one of the standard spinal fusion methods. It was first reported by Broucher in 1959 as a surgical method in which a screw was inserted into the vertebral body through a pedicle.[2] It was developed into the form currently used by using a spindle rod together.[3] 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.[4]

Osteoporosis is an increasingly prevalent condition characterized by inferior bone quality. It will show up by increased screw pull-out, pseudoarthrosis, and instrument failure. An abundance of reported data has supported the correlation between pedicle screw stability and bone mineral density.[5-7]

The elderly population has a high incidence of osteoporosis and composes a large proportion of those undergoing spinal surgery.[5-8]

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 address the relevant biomechanical characteristics for surgery.[9-23]

The first reported cases of cement augmentation for improved pedicle screw fixation as a salvage technique appeared in the late 1990s.[24-26]

Many experimental studies demonstrated that various cement such as polymethylmethacrylate (PMMA), hydroxyapatite, calcium sulfate, and calcium phosphate was effective in the augmentation of the pedicle screw.[14, 27-34] PMMA is the most available and cost-effective and has been used in many orthopedic applications for many years.[14] Augmentation with PMMA has been used to reinforce the screw-bone interfaces of pedicle screws.[27] Biomechanical testing in cadaveric specimens performed by Zindrick et al.[35] demonstrated that PMMA augmentation could double the pull-out strength. The initial approaches for cement augmentation were performed by cement injection through a tapped pedicle screw tract.[36] With the advent of minimally invasive spine surgery[37] and the introduction of cannulated screws, reports of using fenestrated screws for cement augmentation appeared in the 2000s.[38, 39] Fenestrated screws have the theoretical advantage of cement penetration into the vertebral body directly around the screw, with less opportunity for cement extravasation through pedicle breaches.[36] Numerous studies have focused on different pedicle-screw designs to prevent screw loosening. These designs include screws with an increased outer diameter or length,[40] different thread profiles,[4, 15] cylindrical or conical cores,[41] expanding screws,[19] and cannulated screws with PMMA cement augmentation.[42] Among these screw designs, cannulated screws, in particular, are an efficient alternative and innovative design for preventing osteoporotic incidents when used with cement augmentation.[16, 18, 42, 43]

Various biomechanical studies have suggested that reinforcement using bone cement can increase the mechanical strength of the bone-screw interface.[21, 22, 32, 43-45] Sarzier et al.[32] reported the design and biomechanical research for developing 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.[15, 18, 46] 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 more excellent resistance to rear traction, and we aimed to select a design that exhibits optimal resistance and physical properties. Thus, This study aims to prove what kind of window type fenestration can enhance pull-out strength while maintaining mechanical strength when bone cement augmentation is performed on a pedicle screw fixation.

In order to achieve this study objective, the author established several hypotheses for this study. Bone cement augmentation will induce reinforcement of the pull-out strength of the pedicle screw. Also, window type fenestration will exhibit stronger pull-out strength than the previous pinhole type fenestration. The larger the fenestration area, the stronger the pull-out strength will be. A pedicle screw with two window type fenestration exhibits stronger pull-out strength than a screw with one window.

2. Materials and methods

2.1. Experimental Design

2.1.1. Design of the pedicle screw

This study used a commercially available cannulated pedicle screw (Cemexious Spinal Fixation System, Huvexel Co., Ltd., S. 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). Based on the results reported by Phoebe et al.[47], 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 already commercialized side-hole type fenestration in a small hole with a 2mm diameter was defined as pinhole type fenestration, and fenestration wider than a 2mm-diameter side hole as the ellipsoidal type or halfmoon type was defined as experimental window type fenestration.(Fig. 1.)

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 an experimental fenestration, and the location and size of the fenestration were varied.

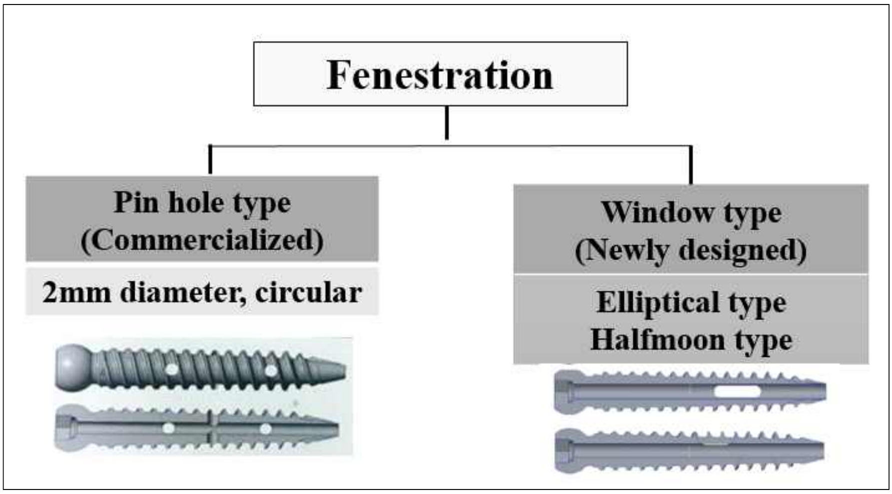


Figure 1. Definition and schematic diagram for each type of fenestration for this experiment. The pinhole type is a circular type with a diameter of 2 mm, which has already been commercialized and used in clinical practice. The window type is newly designed for this experiment and is divided into elliptical and halfmoon types. All types made a fenestration three threads away from the tip of the screws.

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 side holes and a 2-mm diameter was designated Control 3 (C3) (total fenestration area, 18.84 mm^2).(Fig. 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.(Fig. 3.)

The fenestrations were divided into elliptical or half-moon shapes larger than 2 mm holes. Thus, T1 had elliptical shape fenestrations (28.28 mm^2) made through the center of the screw at four thread pitches away from the end of the screw tip. T2 had halfmoon-shaped fenestrations (13.14 mm^2) made on one side at

	C1	C2	C3
Number of side fenestration	**0**	**0**	**6**
Shape of side fenestration	**No**	**No side hole**	**Pinhole (Thru hole type)**
Area of Fenestration (mm^2, total)	**0**	**3.14**	**21.98**

Figure 2. Comparing the characteristics of control group screws with photographs and cross-sections. The screw without fenestration, the prototype of the pedicle screw, was defined as C1, the screw with an end hole at the tip of the screw was defined as C2, and the screw with six thru-hole-shaped side pinholes was defined as C3.

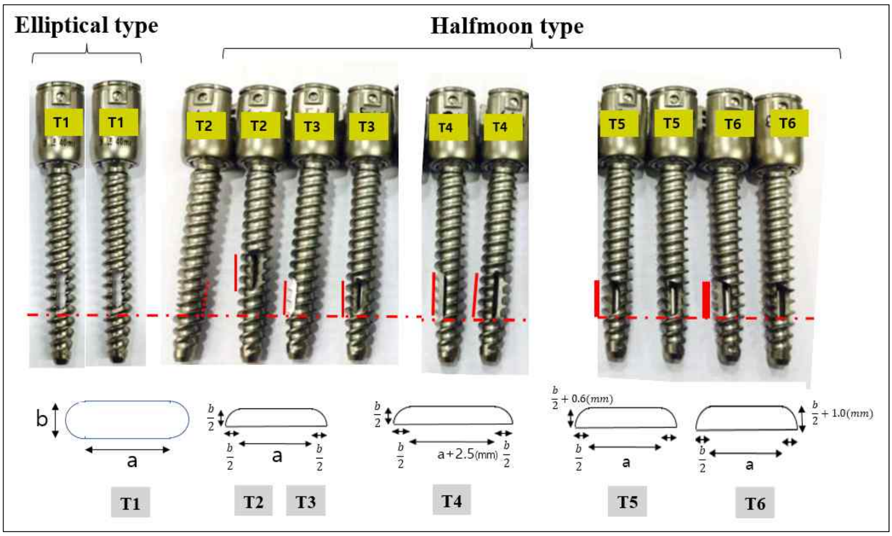
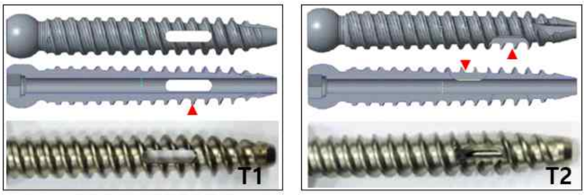


Figure 3. The photographs for the test group and schematic diagram depicted the window types of fenestration. According to the shape of the fenestrations, the authors divided them into an elliptical type and a halfmoon type, and all experimental screws have one or two window-type fenestrations. A distal fenestration was made at a position three-thread away from the tip of the screw, and the fenestration location was designed to avoid the pedicle.

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.(Fig. 4.) T3 had a halfmoon-shaped and three-pitch-wide fenestration with an area of 7.07 mm^2 on one side at three pitches away from the screw tip. T4 had a halfmoon-shaped five-pitch-wide fenestration (12.07 mm^2) at a length of three pitches away from the screw tip. T5 had a halfmoon-shaped fenestration (12.82 mm^2) that was 0.6 mm wider than T3 and three pitches away from the screw tip. T6 had a halfmoon-shaped fenestration (17.28 mm^2) that was 1.0 mm wider than T3 and at the same position away from the screw tip.(Fig. 5.)

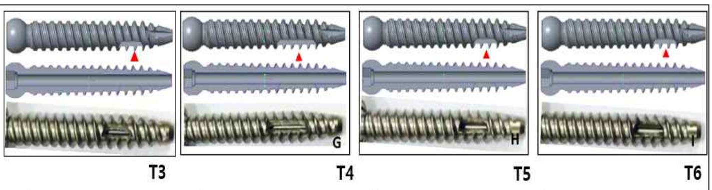
2.1.2. Mechanical strength testing of the fenestrated screws: The worst-case study (T1)

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.[48] This test was conducted at the Advanced Medical Device Support Center (Osong Advanced Medical Industry Promotion Foundation, Osong-si, Chungcheongbuk-do, Republic of Korea). For this test, a universal material testing



	T1	T2
Number of side fenestration	2	2
Shape of side fenestration	Elliptical large hole (Thru hole type)	Halfmoon type hole (Staggered type)
Area of Fenestration (mm², total)	31.42	16.28

Figure 4. The photographs for the window-type screws with two fenestration and schematic diagram. A table comparing the characteristics of T1 and T2 was shown.



	T3	T4	T5	T6
Number of fenestration	1	1	1	1
Shape of side fenestration	Half-moon type (not thru hole)	Half-moon type (not thru hole)	Half-moon type (not thru hole)	Half-moon type (not thru hole)
Area of Fenestration (mm², total)	10.21	15.21	15.96	20.42

Figure 5. The photographs for the window-type screws with fenestration and schematic diagram. A table comparing the characteristics of T3, T4, T5 and T6 was shown.

machine (Bionix, MTS Systems Corp., MN, USA) was used, and 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 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. The fatigue test's load ratio exceeded ten at a frequency of 5 Hz. The temperature for this test was set at 24℃ and the relative humidity was 48%.

2.1.3. 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 cm X 8 cm X 4 cm; the material was an open-cell rigid polyurethane foam with a density of 0.09 g/cm^3 and grade 7.5 pounds per cubic foot (pcf) which simulated cadaveric vertebra with extreme osteoporosis.(Fig. 6.)[49]

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 depths 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, the PMMA cement (Spinofill, Injecta Co Ltd., Gunpo-si, S. Korea) was prepared. In order 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 (liquid-to-powder ratio of 20 mL: 36 g) at room temperature as recommended by the manufacturer. It was introduced into the cannulated screws 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

Figure 6. Synthetic bone (model #1522-505; Pacific Research Laboratory Inc., Vashon Island, WA, USA) made from polyurethane foam was shown. It was supplied as a rectangular feature (test block) with dimensions of 13 cm × 18 cm × 4 cm; the material was an open-cell rigid polyurethane foam with a density of 0.09 g/cm^3 and grade 7.5 pounds per cubic foot (pcf).

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. 3 mL of cement was injected into the cannulated screw for all specimens. For solid screws without fenestration, the solid screw was inserted into the test block through the prepared pilot hole and removed to create a hole with dimensions identical to 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. The mixture was injected using a pressure gauge meter while maintaining as much as possible as ten psi. This pressure was constantly measured. First, the injection amount was constant at 3 cc. 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. 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.

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., MN, USA).(Fig. 7A. and 7B.)

As shown in Fig. 7C., the test jig fastened to the upper head of the inserted pedicle screw was tension at a speed of 5 mm/min until the pedicle screw inserted into the test block was separated. 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.

The pull-out strength was defined as the first peak force measured during axial ramp loading. The Linear stiffness was defined as the slope of the force-displacement curve’s linear

Figure 7. Pull-out strength test using the MTS system (Bionix 858, MTS Systems Corp., MN, USA).(A) The specimen was mounted on the test jig of a universal material testing machine.(B) 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.(C)

region. The ultimate load was defined as the maximum load each screw managed to sustain prior to complete failure or observation of screw pull-out and the yield load as the load value that corresponded to the first deviation from the force-displacement curve's linear region. The authors measured the pull-out distance from the yield load to the ultimate load for maximum displacement. (Fig. 8.)

2.2. Data analysis

During pull-out testing, the ultimate load and ultimate displacement (maximum displacement) were measured, and the measured yield load. and yield displacement was obtained. Statistical software (SPSS 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 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

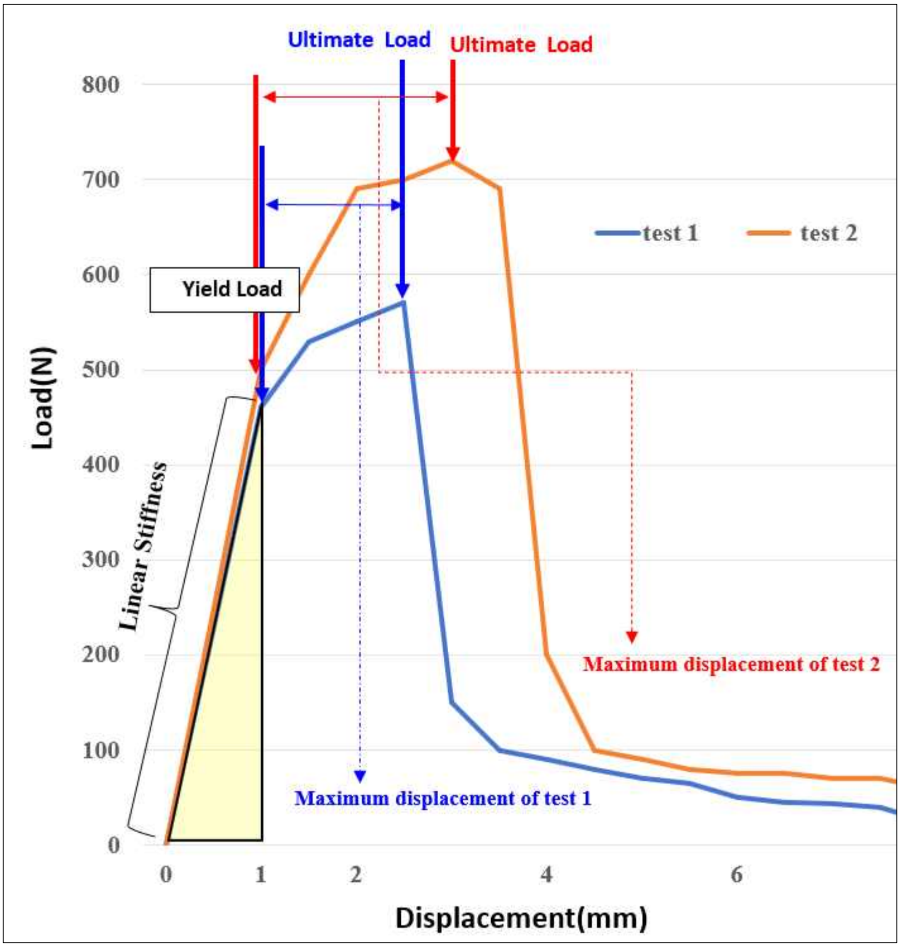


Figure 8. Example of a forced displacement curve for test screws 1 and 2 with bone cement augmentation during pull-out testing. Linear stiffness (N/mm) was defined as the slope of the force-displacement curve's linear region. Yield load was defined as the load value corresponding to the first deviation from the force-displacement curve's linear area. The ultimate load was defined as the maximum load on the curve or observation of screw pull-out.

between continuous variables. The Kruskal-Wallis test was performed for three or more groups. The null hypothesis was rejected at $P < 0.05$.

3. Result

3.1. Mechanical strength test: The Worst-Case Test (T1)

In the assessment of mechanical stability conducted according to the ASTM F1717 method, the worst findings were obtained using the screw with the maximum fenestration area (T1). In the fenestration compression bending test, the average ultimate load value was 475.32 ± 31.58 N, and the maximum displacement value was 25.03 ± 3.60 mm. The yield load was 366.86 ± 11.22 N, and the yield displacement was 14.52 ± 0.61 mm. Stiffness was measured to be 28.19 ± 1.19 N/mm. (Table 1. and Fig. 9A.) 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. (Table 2. and Fig. 9B.) 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·m; ultimate torque, 46.17 ± 0.87 N·m; and stiffness, 1.9 ± 0.14 N/m. (Table 3. and Fig. 9C.) Based on the static compression test, a dynamic fatigue test was performed with 75% (356 N),

Specimens Number	1	2	3	4	5	6	Average	Standard Deviation
Stiffness (N/mm)	27.70	26.34	29.32	29.62	28.32	27.82	28.19	1.19
Yield Displacement (mm)	14.49	14.53	13.86	13.83	15.32	15.08	14.52	0.61
Yield Load (N)	360.99	353.30	360.27	365.99	378.88	381.75	366.86	11.22
Maximum Displacement (mm)	20.28	24.18	21.70	26.72	29.49	27.82	25.03	3.60
Ultimate Load (N)	425.61	468.23	459.94	500.93	514.22	483.02	475.32	31.58

Table 1. The result of the static compression bending test was shown. A total of six specimens were tested in a T1 screw type.

Specimens Number	1	2	3	4	5	6	Average	Standard Deviation
Stiffness (N/mm)	29.16	28.72	27.90	28.91	28.08	27.79	28.43	0.58
Yield Displacement (mm)	19.38	16.41	16.30	16.05	16.09	16.18	16.74	1.30
Yield Load (N)	514.02	435.88	421.35	424.06	420.68	421.91	439.65	36.87
Maximum Displacement (mm)	26.85	22.04	20.29	25.01	20.36	24.22	23.13	2.66
Ultimate Load (N)	586.09	502.37	462.55	503.30	476.61	504.52	505.91	42.87

Table 2. The result of the tensile test was shown. A total of six specimens were tested in a T1 screw type.

Specimens Number	1	2	3	4	5	6	Average	Standard Deviation
Stiffness (N/mm)	1.85	1.83	2.05	1.68	2.03	1.94	1.90	0.14
Offset (º)	1.95	1.95	1.95	1.95	1.95	1.95	1.95	0.00
Yield angle(º)	22.10	23.51	20.11	22.41	20.71	21.32	21.69	1.23
Maximum Torque (N · m)	37.47	39.73	37.48	35.54	38.23	37.95	37.73	1.36
Ultimate Torque (N · m)	46.28	46.63	46.47	44.43	46.81	46.38	46.17	0.87

Table 3. The result of the torsional test was shown. A total of six specimens were tested in a T1 screw type.

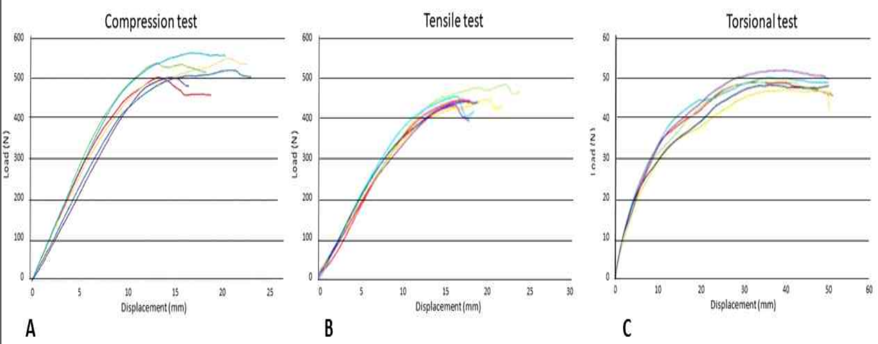


Figure 9. Test results according to ASTM F1717 test standard to analyze the mechanical properties and stability of fenestrated screws (T1). In the fenestration compression bending test, the average ultimate load value was 533.97 ± 25.48 N, and the maximum displacement value was 16.58 ± 3.52 mm. The yield 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・m; ultimate torque, 46.17 ± 0.87 N・m; and stiffness, 1.9 ± 0.14 N/m.(C)

50% (237 N) and 25% (118 N) of the ultimate load (475 N) value (R-ratio = 10). A failure cycle was applied up to a total of 5,000,000 times. At 75% ultimate load, fracture occurred at 7,781 and 9,189 times; at 50%, fracture occurred at 36,122 and 82,067 times; and at 25%, no fractures occurred.

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

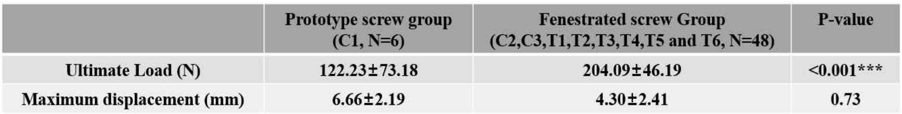
3.2.1. The Effect of Bone cement augmentation

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 cc, and the injection amount did not differ significantly among the groups ($p = 0.703$). The ultimate load in the C1, C2, and C3 groups were 122.24 ± 73.18, 176.13 ± 46.07, and 160.22 ± 25.68 N. Comparing the ultimate load values of C2 and C3 (176.13 ± 46.07(N) and

160.22 ± 25.68(N)) with the ultimate load of C1 did not show any statistical significance (*p*=0.158, *p*=0.277).

All screws used in this study were analyzed by classifying them into the fenestrated screw group for augmentation (C2, C3, T1, T2, T3, T4, T5 and T6) and the prototype screw group (C1 only); the ultimate load of the fenestrated screw group was 204.09±46.19 (N) compared to 122.23±73.18 (N) measured in the prototype, it was confirmed that it increased statistically significantly to the level of $p<0.001$. However, the maximum displacement could not obtain statistical significance.(Table 4.)

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.



	Prototype screw group (C1, N=6)	Fenestrated screw Group (C2,C3,T1,T2,T3,T4,T5 and T6, N=48)	P-value
Ultimate Load (N)	**122.23±73.18**	**204.09±46.19**	**<0.001*****
Maximum displacement (mm)	**6.66±2.19**	**4.30±2.41**	**0.73**

Table 4. Analyzing ultimate load and maximum displacement by classifying into the prototype screw (C1) and the fenestrated screw group. The ultimate load of the fenestrated screw group showed a statistically significant improvement, but the maximum displacement did not decrease to the extent of establishing a statistical difference.

In comparison with C1, the ultimate load of all T1, T2, T3, T4, and T6 except for T5 (*p*=0.143) showed a statistically significant difference ($p < 0.05$). In comparison with C1, the maximum displacement of all augmented screws (C2, C3, T1, T3, T5) did not showed a statistically significant difference ($p > 0.05$) but that of T2 (2.92 ± 0.42 (mm), $p = 0.007$), T4 (2.34 ± 0.41 (mm), $p = 0.008$) and T6 (2.38 ± 0.36 (mm), $p = 0.008$) showed a statistically significant difference.(Fig. 10.)

3.2.2. The Area of fenestrations

When analyzing the correlation between the area of fenestration on forming the bone cement volume, linear correlation analysis revealed a significant but weak 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 significantly correlated in the linear correlation analysis ($r = 0.403$, $P = 0.003$).(Fig. 11.)
However, when the ultimate load and maximum displacement were compared in the area of fenestration, the authors cannot notice the result that the ultimate load increased or the maximum displacement decreased with the statistical significance as the area of fenestration increased.(Fig. 12.)

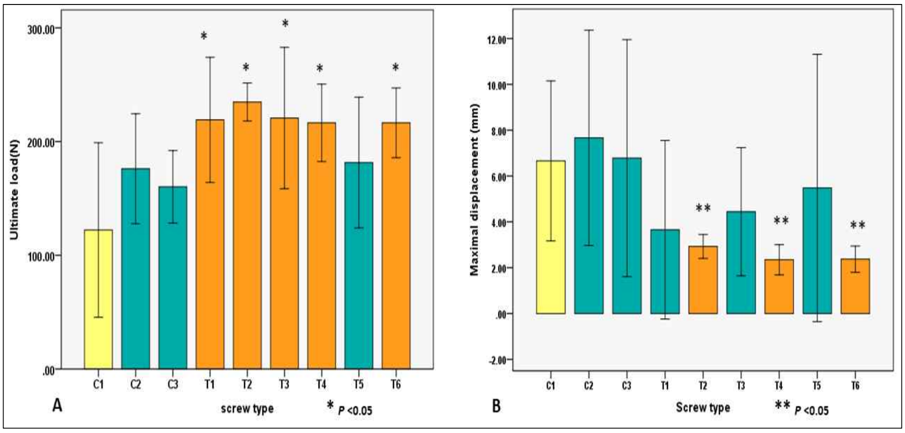


Figure 10. Comparison of the mechanical test values between the non-augmented screw (C1) and all of the augmented screw groups. Comparison of the ultimate load values(A) and the maximum displacement.(B)

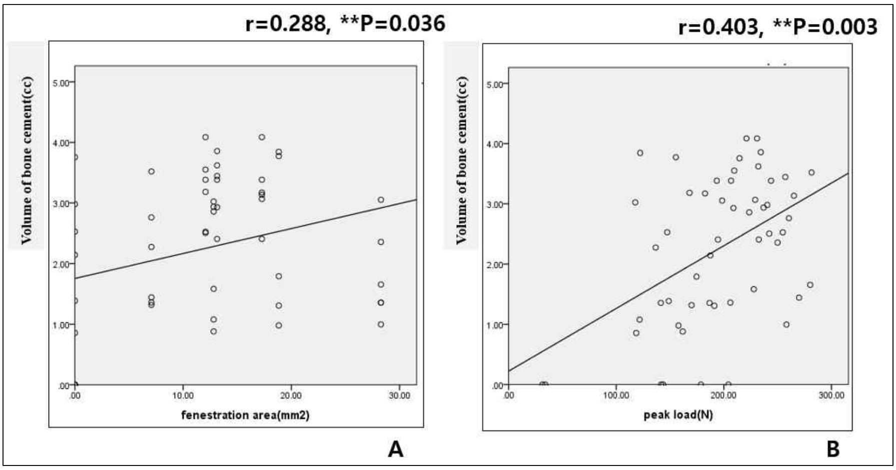


Figure 11. The correlation between the area of fenestration and the volume forming the bone cement augmentation. Linear correlation analysis revealed a significant but weak correlation between the area of fenestration and the volume of bone cement (r = 0.288, P=0.036).(A) The bone cement volume and ultimate load showed a significant positive correlation in the linear correlation analysis (r = 0.403, P = 0.003)(B)

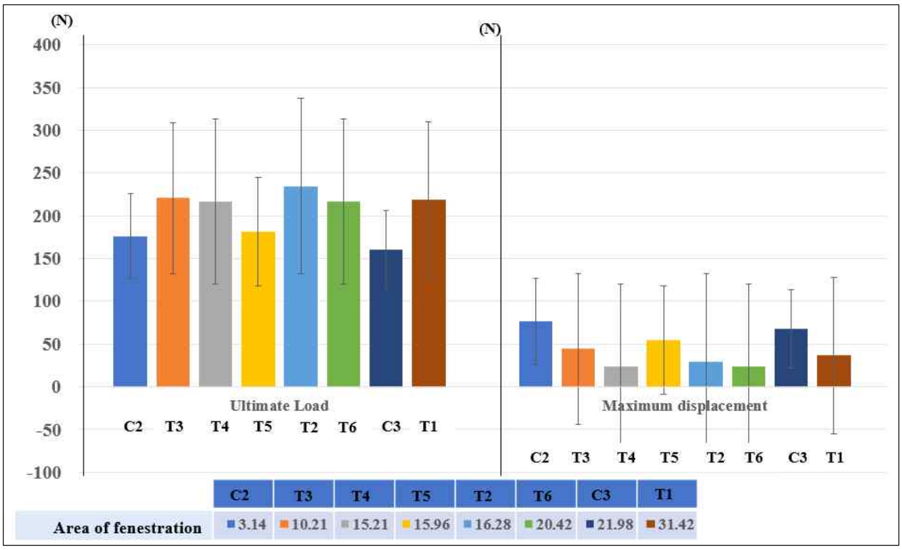


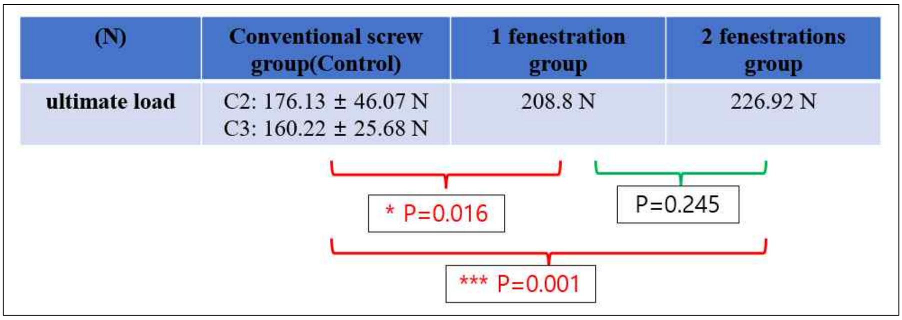
Figure 12. Analysis to verify the effect on bone cement augmentation according to the fenestration area. Although the area of fenestrations compared ultimate load and maximum displacement, there was no statistically significant difference, so it was impossible to confirm that the pull-out strength changed significantly as the fenestration area increased.

In addition, The volume formed by bone cement was 2.25 ± 1.23 cc. T2 showed the largest bone cement volume (3.27 ± 0.52 cc), while T1 showed the smallest volume (1.80 ± 0.77 cc), but the differences among window type fenestration groups were not significant($P > 0.05$).

3.2.3. The number of fenestrations

The authors categorized the screw groups with two window-type fenestrations (T1 and T2) and those with one fenestration (T3, T4, T5, and T6). We 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 both 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 ($p = 0.245$) (Table 5.). By 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 differed significantly from those in the T1 and T2 groups

(C3 vs. T1: $p = 0.048$; C3 vs. T2: $p < 0.001$).



(N)	Conventional screw group(Control)	1 fenestration group	2 fenestrations group
ultimate load	C2: 176.13 ± 46.07 N C3: 160.22 ± 25.68 N	208.8 N	226.92 N

* P=0.016

P=0.245

*** P=0.001

Table 5. The analysis of the ultimate load according to the number of fenestrations. There was no statistical difference in the ultimate load between the groups with one and two window type fenestration. In particular, the case of having two window-type fenestrations showed a more significant increase in pull-out strength than in the conventional screw group.

3.3. 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. (2) No bone cement flowed out from the position of the pedicle. Bone cement formation was confirmed within a range of 50 mm, known as the distance from the start of the pedicle to the anterior end of the vertebral body, and beyond this range, no results to worry about leakage were observed.(Fig. 13.)

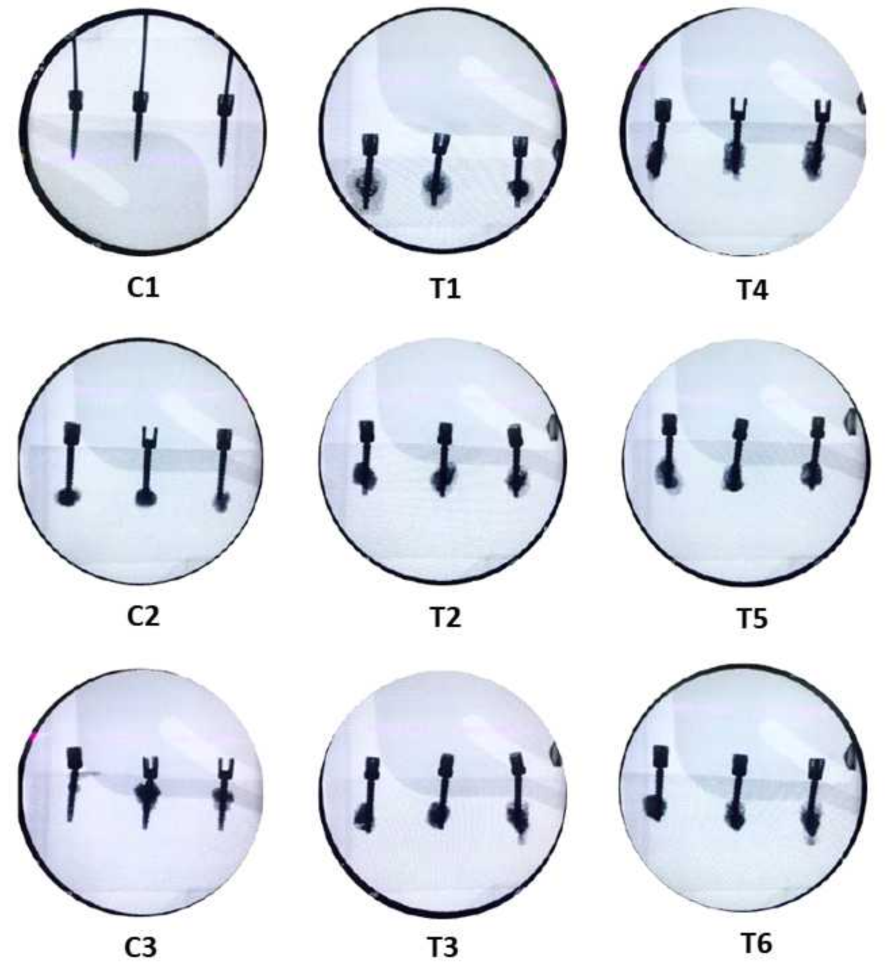


Figure 13. Characteristics of the fenestrated screws in radiographic images obtained using fluoroscopy.

4. Discussion

The pedicle screw is a standard surgical instrument 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,[50] hydroxyapatite-coated screws,[51, 52] bicortical screw purchase,[35] larger-diameter screws,[50, 53, 54] and PMMA augmentation.[26, 55] The PMMA augmentation procedure can be improved using fenestrated pedicle screws designed specifically for cement injection.[9] 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.[9]

Various morphological parameters of screws have been analyzed for possible correlations with implant loosening. An increase in screw size with pedicle diameter is known to increase screw anchorage in the pedicle.[56, 57] Many studies have suggested that the shape of the screw using PMMA can influence the pull-out strength. Considering these details, various designs of fenestration have been devised.[4, 42, 57] 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 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 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 bone cement augmentation volume and 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 (FDA) and the Korean Food and Drug Administration (KFDA), so its safety was considered to be 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.[48,58] 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 determining the axial pull-out force until the pedicle screw is entirely displaced. The reference value for conventional screws without reinforcement in normal bone is 812-1546 N.[17, 22, 58] 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.[12, 18, 22, 46, 59] 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 based on 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, 60] and as a predictor of the fixation strength of pedicle screws. It has been accepted as a standard measure of tensile strength in comparing pedicle screws of different shapes.[48] Thus, after excluding other forces, the straight axial pull-out strength alone was considered an adequate parameter to compare and analyze tensile strength after bone cement augmentation of screws.[61]

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.[62, 63] The Sawbones model provides physical strength properties that are more similar to those of the 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 the mechanical comparison of various designs of orthopedic devices.[64, 65] 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 confirmed that the ultimate load was higher for all fenestrated screws compared to the conventional screws with currently available hole patterns. In particular, the 2-way type fenestration showed a significantly greater ultimate load. In the 1-way type fenestration, the ultimate load did not increase significantly even when the fenestration size increased. On the other hand, in the 2-way type fenestration, the maximum load increased significantly with the asymmetric-type fenestration compared 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 appropriately distributed and located in the body.

In this study, the authors observed some unexpected features: the cement volume formed by bone cement augmentation was not formed consistently as the area of fenestration. In addition, the ultimate load of the group subjected to conventional augmentation did not show a significant increase in pull-out strength compared to the group without augmentation. It is because it is not a study using a model with the pedicle and a vertebral body, but rather a foam cell type model with homogeneous and uniform distribution was used. It is estimated that further study will be meaningful if an experiment using a vertebral body-shaped osteoporosis model is carried out.

5. Conclusion

The authors confirmed that fenestration yielded a superior ultimate load compared to standard bone cement augmentation using a conventional screw. In particular, we confirmed that the asymmetric two-way-fenestration screws (T2) showed the maximum increase in ultimate load. The authors conclude that the screw with asymmetrical two-way side-hole and window-shaped fenestrations is the optimal screw design for reinforcing the pull-out strength.

Informed Consent

This study is a biomechanical experimental study that has not been tested on humans or animals. Therefore, it is not necessary to obtain informed consent of the subject for the study.

Conflict of interest

The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article. No financial support has been received in association with this submission.

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국문초록

다양한 유형의 창(窓)을 가진 골시멘트 보강용 척추경 나사못이 척추 고정술에서 보이는 생체역학적 효과에 관한 실험적 연구

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척추경 나사못의 인발 강도를 높이기 위해 나사못에 만든 천공은 나사못에 만들어진 천공의 수와 모양에 따라 나사못의 기계적 강도와 인발 강도에 영향을 미칠 것으로 예상된다. 기존의 작은 구멍형 천공보다 커다란 창문형 천공을 새로 디자인하여 다양한 창문형 천공을 가진 나사못을 이용하여 골시멘트 보강을 시행할 때 미치는 영향을 연구하고자 하였다. 대조군의 경우 일반적인 척추경 나사못을 C1, 캐뉼러 끝 구멍이 있는 나사못을 C2, 나사못의 측면에 핀홀이 6개가 추가되어 있는 C2 나사못을 C3으로 정의하고 대조군은 새로운 저자가 제작한 천공 유형을 가진 시험용 나사못으로 정의했

다. 시험용 나사못인 T1은 대칭적으로 배치된 타원형의 천공이 서로 개통하여 마주보는 형태로 설계되었으며 T2는 반달 모양의 타원형 창이 천공되나, 천공의 위치가 비대칭으로 서로 개통되지 않도록 설계되었습니다. T3와 T4는 나사못의 원위부 끝에서 각각 3개의 피치와 5개의 피치를 두고 떨어진 위치에 단일 반달 모양의 창으로 천공되도록 설계되었습니다. T5 및 T6은 T3보다 나사못의 진행방향 축과 직각으로 0.6mm 및 1mm 더 넓게 창으로 설계되었습니다. 나사못에 골시멘트 보강을 하기 위해 사용한 골시멘트는 3mL씩 정량으로 나사못에 주입되도록 균일하게 골시멘트를 주입하였으며 기계적 강도 및 인발강도는 ASTM F1717 및 ASTM F543 기준에 따라 시험하고 결과를 측정하였다. 골다공증을 모방하는 골의 모형은 폴리우레탄폼으로 만든 합성골(model #1522-505)을 사용하였으며, 이는 대표적으로 아주 심한 골다공증과 같은 효과를 내는 모델임이 검증된 합성골모델로 형광투시를 이용한 방사선 검사를 시행하여 골시멘트 보강이 나사못의 개창을 통해 어떤 모양으로 이루어지는지 확인하였다.

동적 피로 강도시험에서 나사못의 극한하중의 75% 범위에서 7,781회 및 9,189회 파단이 발생하였다. 50%에서는 36,122회 및 82,067회 발생하였다. 25% 범위에서는 골절이 발생하지 않았다. 각 나사 유형에 대한 평균 극한 하중은 T1의 경우 219.1 ± 52.39 N, T2의 경우 234.74 ± 15.9 N, T3의 경우 220.70 ± 59.23 N, T4의 경우 216.45 ± 32.4 N, T5의 경우 181.55 ± 54.78 N, T6의 경우 216.45 ± 32.4 N으로 측정되었다. C1과 비교하여 실험군 중 T1, T2, T3, T4, T6의 경우 극한하중 값이 통계적으로 C1의 극한하중 값과 유

의미하게 다른 것으로 나타났다($p < 0.05$). 그러나 C2와 시험군 (T1~T6) 나사못의 극한 하중 값을 독립적 paired t-test로 평가했을 때 C2의 극한 하중 값은 T2의 극한 하중 값과 유의한 차이를 보이고($p = 0.025$), 다른 시험군 나사못과는 차이를 보이지 않았다. C3의 극한 하중 값은 T1 및 T2의 그것과 통계적으로 유의한 정도로 차이를 보였다 (C3 vs. T1: $p = 0.048$, C3 vs T2: $p < 0.001$). 선형상관분석을 시행한 결과 천공면적은 골시멘트가 형성한 부피와 유의한 약한 양의 상관관계가 있는 것으로 나타났다 (Pearson 상관계수 $r = 0.288$, $P = 0.036$). 또한 골시멘트 부피와 극한하중은 선형상관분석에서 유의한 양의 상관관계를 보였다($r = 0.403$, $P = 0.003$).

결론적으로 나사못에 창문형 창을 천공하여 골시멘트 보강을 시행하면 기존의 골시멘트 보강이 없이 사용하는 나사못의 인발강도나 기존의 시판중인 작은 구멍형 천공 모델을 사용하여 골시멘트 보강을 한 나사못의 인발 강도에 비해 통계적으로 의미있는 극한하중 값이 상승을 확인할 수 있었다. 특히, 양방향의 비대칭형 반달 모양의 천공이 있는 T2 나사못에서 극한 하중이 최대로 증가됨을 확인하였다. 이와 같은 결과에 따라, 창문형의 엇갈린 위치의 측면 천공을 가진 나사못이 인발강도 보강을 위한 최적의 나사못 천공 모델로 결론지을 수 있다.

주요어 : 창문형, 창형 나사못, 골시멘트 보강, 극한 하중, 인발 강도
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