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Biomechanics

Biomechanical Performance of Various Cement-Augmented Cannulated Pedicle Screw Designs for Osteoporotic Bones

Tolga Tolunay, MD[a], Kağan Arslan, MD[a], Onur Yaman, MD[b], Sedat Dalbayrak, MD[c], Teyfik Demir, PhD[b,*]

[a]Department of Orthopaedics, Yenimahalle Training and Research Hospital, 2026. Avenue, 06370, Ankara, Turkey
[b]Department of Mechanical Engineering, TOBB University of Economics and Technology, Sogutozu Avenue, 06560, Ankara, Turkey
[c]Department of Neurosurgery, Neurospinal Academy, Istanbul, Turkey

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Abstract

Introduction: Early-stage pullout is a common problem for surgeons during the fixation of osteoporotic bones. Poor bone quality limits the use of pedicle screws for patients with osteoporosis. In this study, the researchers investigated the effects of hole and gap position and type on the pullout strength of cannulated screws.
Methods: Seven different designs were tested, including a control group. All cannula diameters were 2 mm and holes were drilled with a diameter of 1.5 mm. Gaps were milled with a 2-mm-diameter tool with 2-mm displacement proximally. All holes and gaps were drilled or opened unilaterally and bilaterally. Grade 40 and 10 polyurethane foam was used to simulate healthy and osteoporotic bones, respectively. For pullout tests, insertion depth was 30 mm and 2-mm-diameter pilot holes were drilled into blocks before screws were inserted. The cross-head speed was 2 mm/min. For torsion tests, 1 side of the screw was fixed and other was twisted clockwise.
Results: For torsion tests, the maximum torque value exhibited by the control group (non-cannulated) was 14.94 Nm. The highest torsional strength among tested cannulated screws was 13.54 Nm for Single side two holes including design (S2H) ($p < .0001$). The minimum torsional strength was 9.45 Nm with a breaking angle of 39° ($p < .005$). Comparing results for samples pulled out from grade 40 polyurethane foam, single side slot including design (SS) samples exhibited the highest pullout strength with a maximum force of 3,104 N.
Conclusions: The unilateral, sequential, 3-radial hole, drilled, cannulated screw was the optimal alternative when considering pullout and torsional strength as criteria.

Keywords: Pedicle screw design; Cement augmentation; Pullout

Introduction

Spinal fixation is common treatment for certain conditions such as scoliosis, tumor including defects, vertebral fractures, and vertebral bone collapse. For fixation of vertebrae, pedicle screws are widely used [1]. However, most vertebral fractures are caused by osteoporosis, which is silently progressive. The number of the patients who have osteoporosis has increased owing to prolonged lifespan and an increase in the aging population [1]. Osteoporotic bones exhibit a high tendency to fracture because of low bone mineral density. Moreover, early-stage pullout is a common problem for surgeons during the fixation of osteoporotic bones. Poor bone quality limits the use of pedicle screws for patients with osteoporosis [2,3].

To increase the initial pullout strength (before the occurrence of fusion), the researchers studied several parameters. The screw core design was investigated to determine whether the conical core or cylindrical type best fixes vertebra [4-8]. They concluded that conical core is more appropriate for higher pullout loads. In a recent study, radial drilled pedicle screws were investigated on synthetic foam and fresh-frozen calf vertebrae [9]. An optimum design was declared for tendency toward fusion.

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*Corresponding author. Department of Mechanical Engineering, TOBB University of Economics and Technology, 06560 Ankara, Turkey. Tel.: +90-312-2924232; fax: +90-312-2924091.
E-mail address: tdemir@etu.edu.tr (T. Demir).

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Screw thread types were also investigated under design variables of flat overlap area [10], dual or single thread types [6], and tapping or non-tapping [11]. However, all of these design variables significantly affect the performance of screws more on healthy bones than on osteoporotic ones because the design parameters become critical after fusion. On the other hand, the main problem with osteoporotic bones is early-stage failure.

At this stage, expandable screws stand out as a brilliant alternative. There are several studies on expandable pedicle screws (EPS) [12-17]. Expandable screws exhibit 30% and 50% higher pullout strength than pedicle screws (PS) on healthy bone and bone with low mineral density, respectively [12]. Wan et al. [14] reported newly formed bone tissue that grew through the center of EPS. This type of bone ingrowth makes revision operations more complex because of the resulting contra-conical geometry of EPS after expansion.

Avoiding the risks of revision surgery of EPS, researchers have focused on cement augmentation techniques [2]. Numerous studies addressed cement augmentation with polymethylmethacrylate (PMMA) [2,15,17-19], calcium phosphate [12,20-22], and cyanoacrylate [23]. Calcium phosphate cement augmentation provides 3 times greater pullout strength on osteoporotic bones compared with bare PS [21]. Evans et al. [2] investigated the viscosity of PMMA and proved that it does not significantly affect pullout strength. The performance of cement types was compared in several studies; all concluded that PMMA is the superior alternative [15,18,24,25]. The main disadvantage of cement augmentation is cement leakage into the spinal canal [4,26,27]. Wu et al. [28] showed that there was no leakage during cement augmentation on human cadavers.

There are also studies combining the EPS with cement augmentation [12,17,28]. Wu et al. [28] reported that EPS with PMMA provides 43% higher pullout strength on osteoporotic vertebrae. Cook et al. [17] reported that EPS with cement augmentation increased pullout strength 2.5 times compared with EPS alone. In addition, some researchers studied pedicle nailing systems as an alternative [29,30]. All of these methods were tested on synthetic foam materials [1,7,20,31,32], living or fresh-frozen animals [2,9,14,29], and human cadavers [4,5,12,17,18,24]. However, only 1 study [33] investigated the type and number and position of holes that are normal to the cannula. This study provides critical information about the position of radial holes. Placing the holes more proximal to the screw tip caused cement leakage to the spinal canal. The position of radial holes is more important than the number of holes for cannulated screws.

This study investigated the effects of hole and gap position and type on the pullout strength of cannulated screws. Seven different designs were tested, including a control group. The researchers tested 2-mm cannulated screws with 2 or 3 holes that were gapped or non-cannulated (control group). In addition, holes and gaps were drilled or opened unilaterally and bilaterally. Synthetic foams were used as a test medium and PMMA was selected as the cement type. None of the designed screws has a self-tap. This work also investigated the torsional properties of designed screws to optimize the design regarding not only pullout but also torsional strength requirements.

Materials and Methods

Synthetic rigid polyurethane (PU) foam was used in this study to mimic trabecular bone. Polyurethane foam is widely used as a standard testing material for pullout studies of orthopedic implants [1,7,20,31,32,34]. The properties of polyurethane foam are stated in ASTM F1839 [34]. According to the related standards and the literature, 2 different grades of PU foam were used: Grades 40 and 10, to simulate healthy and osteoporotic bones, respectively. Foams were produced and characterized in the authors' clinical biomechanics laboratory. The density of the foams was 0.16 and 0.64 g/cm^3 for osteoporotic and healthy bone simulations, respectively. Compressive strength was 2.5 and 35 MPa for Grade 10 and 40, respectively. Use of synthetic bone material eliminated bone quality bias. All test blocks were 5 × 5 × 5 cm in size.

The researchers selected PMMA (BioMechanica, Sao Paulo, Brazil) as the cement type because it is the reference standard [18]. They injected 2 ml cement into all specimens with the same cement injection tool provided by the manufacturer to minimize variance in injections. The literature shows PMMA to be the superior cement type when considering mechanical and histological properties [15,18,24,25]. Cho et al. [27] declared that it is safe to back out screws on revision surgeries when previously augmented with PMMA cement.

None of the designed screws tapped owing to the use of these screws on osteoporotic cases. Chen et al [33], reported that tapping does not affect the insertion torque or pullout strength significantly due the bone quality on osteoporotic incidents.

Design parameters

Seven different screw types were designed and manufactured for the study, including a control group (non-cannulated). All screw types had an outer diameter of 6.5 mm and length of 45 mm. Cannula diameters were 2 mm and holes were drilled with a diameter of 1.5 mm except for the control group. The D2H screws had 2 rows of holes bilaterally. The S2H screws had also 2 rows of holes but they were drilled unilaterally. Furthermore, 3 holes were drilled bilaterally for D3H screws. Similarly, S3H screws were a unilateral form of D3H screws as D2H and S2H screws. In these 4 types of screws, the distance between drilled holes was 3 mm.

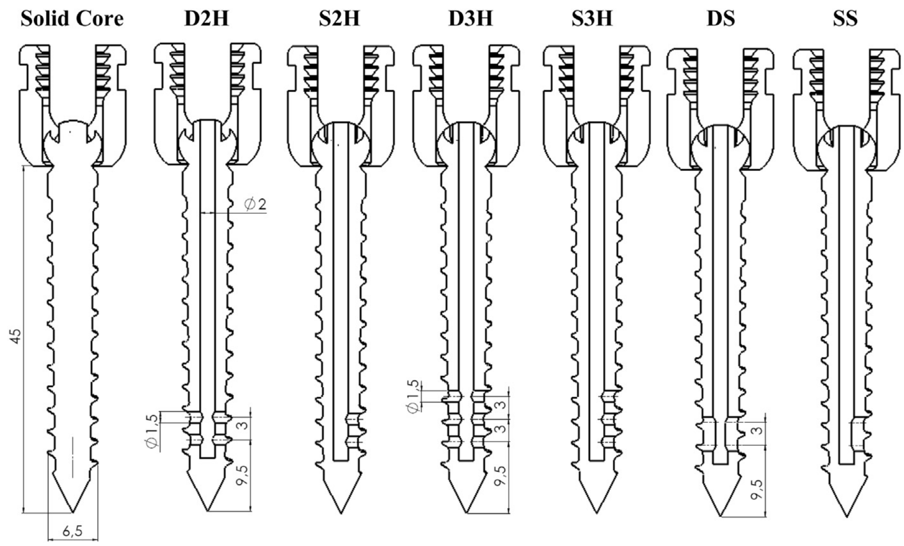

Fig. 1. Design parameters of screws (screw cross-sections). Solid Core, non-cannulated; D2H, 2 holes row bilaterally; S2H, 2 holes row unilaterally; D3H, 3 holes row bilaterally; S3H, 3 holes row unilaterally; DS, screw with gap bilaterally; SS, screw with gap unilaterally.

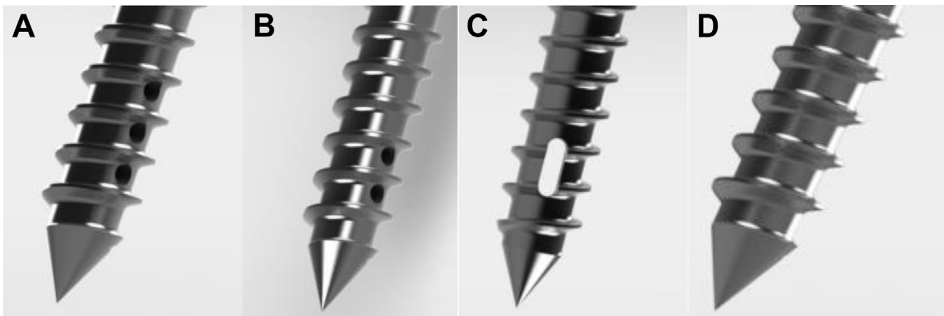

Fig. 2. Screws tips and radial hole/gap position. (A) Screw with 3 holes; (B) screw with 2 holes; (C) screw with gap; (D) non-cannulated screw.

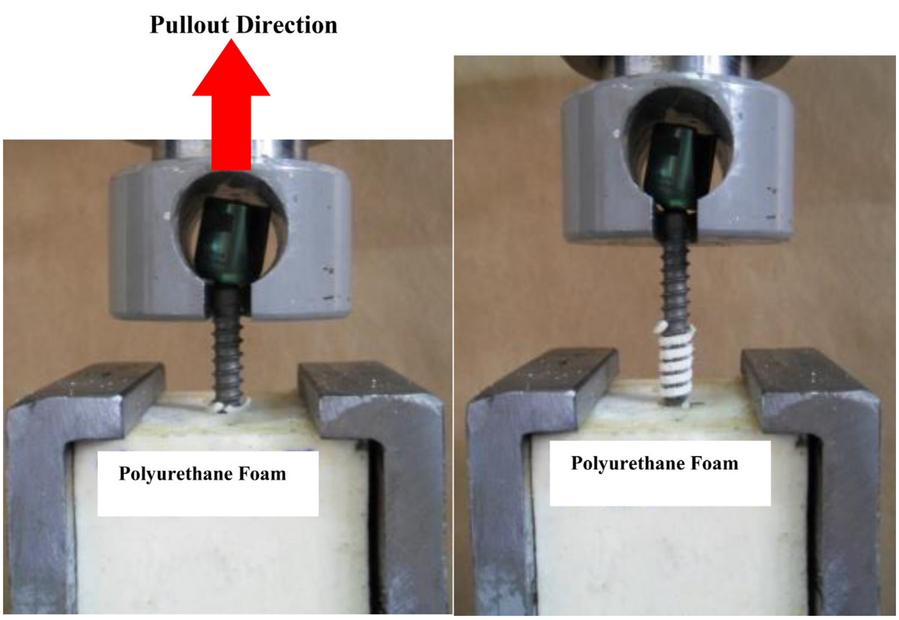

Fig. 3. Pullout test setup: before test (left) and after test (right).

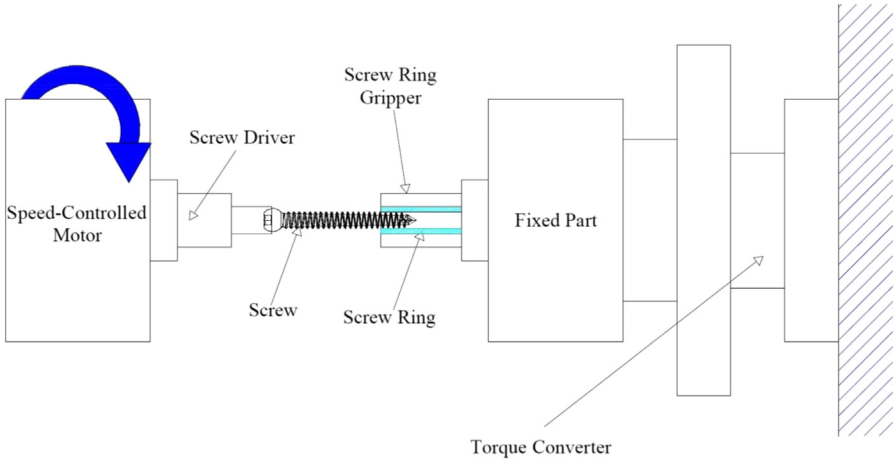

Fig. 4. Torsion test setup.

For the designs of SS and DS bilateral and unilateral slots were machined. Slot opened screws were designed to allow more cement through the vertebral body. Slots were milled with a 2-mm-diameter milling tool with a 3-mm displacement proximally. The slots were opened bilaterally for the DS screws and unilaterally for the SS screws. Figure 1 depicts the design parameters for screws and the denotations. The positions of different hole types and slots are given in Figure 2.

Experimental procedure

Pullout tests

Figure 3 shows the pullout test setup. Screws were placed in to the synthetic foams and 2 ml PMMA cement was injected into the screws. The curing time was 20 minutes. The insertion depth was 30 mm and 2-mm-diameter pilot holes were drilled into blocks before screws were inserted. The Cross-head speed was 2 mm/min. Load versus displacement values were recorded until pullout occurred. Tests were completed in accordance with ASTM F543 [35].

Torsion test

Samples were placed in the torsion test setup (Instron, Norwood, MA, USA). One side of the screw was fixed and other was twisted clockwise. Torque versus angle values were recorded until screw breakage. Figure 4 provides a schematic view of the torsion test setup.

Statistical analysis

The researchers performed *t* tests to determine whether the 2 tested groups of data were statistically different.

Table
Mean values (standard deviations) of torsion and pullout test results.

Sample	Pullout (Grade 40)			
	Maximum torque, Nm	Breaking angle (degrees)	Maximum force, N	Maximum force, N
Solid core	20.3 (0.71)	275.8 (9.1)	671 (60)	236 (17.4)
S2H	13.54 (0.49)	51.91 (4.44)	3,034 (232.9)	432 (46.9)
D2H	11.25 (0.27)	42.21 (4.96)	2,795 (20.5)	498 (22.9)
S3H	12.56 (0.42)	49.07 (7.12)	2,782 (262.4)	511 (52.8)
D3H	10.67 (0.22)	41.94 (5.99)	2,768 (107.8)	492 (19.6)
SS	11.92 (0.30)	46.11 (3.52)	3,104 (98.08)	491 (23.6)
DS	9.45 (0.21)	39.07 (4.09)	2,936 (170.3)	462 (16.0)

Results

Table lists the pullout and torsion test results. For the torsion tests, the maximum torque values were exhibited by the control group (non-cannulated) at 20.3 Nm. The highest torsional strength among the tested cannulated screws was 13.54 Nm ($p < .0001$) for S2H. The minimum torsional strength was 9.45 Nm with a breaking angle of 39° ($p < .005$). Opening a gap or drilling screws bilaterally significantly decreased torsional strength. Similarly, opening a gap bilaterally or unilaterally decreased torsional strength to some extent compared with drilling 2 or 3 holes. Breaking angles among all tested samples were close except for the control group.

When the researchers compared pullout test results for samples that were pulled out of Grade 40 polyurethane foams, the SS samples exhibited the highest pullout strength, with a maximum force of 3,104 N. The closest value was 3,034 N (S2H) to the SS. When drilling 3 radial holes to the cannulated screw, drilling the samples bilaterally or unilaterally did not affect the pullout strength significantly. Similarly, opening the gap bilaterally or unilaterally did not drastically affect the pullout strength for Grade 40 PU foams. Unilateral gap-opened screws provided higher purchase on the bone compared with the all of the designed screws in Grade 40 PU foam, at 3,104 N. In Grade 10 PU foam, S3H exhibited the highest pullout strength at 511 N. There was no critical difference in pullout strength among D2H, D3H, and SS samples ($p > .05$).

Discussion

Cannula decreased the torsional strength owing to the reduced moment of inertia on the cylindrical cross-section of the screw. However, this torsional strength drawback was 9% for S2H samples. Opening a gap or radial drilling decreases the moment of inertia and increases the risk of crack initiation because of the machining parameters and tool beach marks. On the other hand, consideration of only the torsional parameters is not enough to assess the highly performing cannulated screw.

Grade 40 PU foam was used to mimic healthy trabecular bone. This means that for a healthy trabecular bone, single slotted, unilateral, gap-opened screws provide higher purchase on the bone compared with all of the designed screws. However, these screws are generally used for patients with osteoporosis. Comparing the pullout performances of designed screws pulled out from Grade 10 PU foam, mimicking the osteoporotic trabecular bone structure, S3H exhibited the highest pullout strength. In the study of Choma et al. [36], cannulated screws with cement augmentation were tested on osteoporotic human vertebrae. The mean pullout strength of cannulated screws was 501 N, which is close to the mean pullout strength value (481 N) of these 6 cannulated screw designs on osteoporotic foams in the current study.

The worst performance was a pullout strength of 236 N in the control group. This proves that it is desirable to use an alternative solution when dealing with a highly osteoporotic bone. The PMMA cement augmented screws were at least 4 times stronger than traditional pedicle screws for purchase in osteoporotic trabecular bone. The distribution of cement inside the PU foam significantly affects the pullout strength. Three radial holes may distribute more homogeneous cement proximally. However, drilling 3 radial holes bilaterally decreased the pullout strength. This was because the inhomogeneous distribution of cement provides a higher pullout strength than homogeneous distribution.

All tested samples satisfied the required torsional strength values stated in ASTM F543.37 Pullout results of all samples that were pulled out from Grade 40 PU foam were also satisfactory according to the related standard. Because pullout is more critical in osteoporotic spines than torsion, it contributes to determining the optimum screw type. Maximum torque values and PU foam grades are compared in here.

Limitations

The main limitation to this study was the lack of living tissue as a test medium. However, this provided a bone quality—independent test platform. In addition, lack of a cortical shell on pullout tests also prevented an exact simulation of pedicle. The optimum design should not be used before the clinical examination. Cyclic toggling parameters were not investigated in this study. Actually toggling is a common loading type on such screws. Moreover, finite element analysis of PMMA distribution inside trabecular bone can be investigated for these designed screws.

In this study, the optimum design of cannulated pedicle screws was manufactured and biomechanically tested considering the pullout and torsional strengths. Seven different designs were investigated in this work. The unilateral 3 sequential radial holes drilled cannulated screw was the optimum alternative when considering pullout and torsional strength as comparison criteria.

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