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Review Article

Toggling effect on pullout performance of pedicle screws: Review

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ABSTRACT

Screw loosening in spine surgery is a clinical complication in patients with poor bone quality. Pedicle screws are subjected to bending moments and axial loads that may cause toggling during daily movements of spine. The purpose of this study was to assess the previous studies related to toggling effect on pullout performance of pedicle screws by surveying the whole literature and to provide some discussion for new studies about pullout performance of pedicle screws after toggling. The search was performed by combining terms of pedicle screw, toggling, screw loosening, fatigue, cyclic loading, and pullout. The retrieved articles dealing with determined terms and also their references were reviewed. Some of these articles were eliminated after review process. Toggling was determined to be crucial for the stabilization performance of pedicle screw because the loosening mechanism of screws was affected directly by cyclic loading. The toggling or cyclic loading affected the holding capacity of pedicle screws negatively, and the possibility of loosening or failure problem for pedicle screws increased with cyclic loading magnitude. Loading conditions, screw properties, test medium, level of spinal region, and cement usage were determined by many researchers as the most important parameters affecting the toggling performance as well as the pullout strength of pedicle screws. The pullout strength of pedicle screws generally decreased with cyclic loading. The parameters of cyclic loading were fairly important for pullout performance of pedicle screws. Screw properties and cement augmentation had critical effects on the stability of screws under cyclic loading, as well.

1. Introduction

Screw loosening is a prevalent complication for the stabilization of the spine after surgery operations. The complication, proved to be challenging especially in the osteoporotic bones, has negative effects on the performance of pedicle screws [1]. Osteoporosis, namely low bone mineral density (BMD), negatively affects the vertebral body and there is not a possibility of sufficient strength provided by pedicle screws at the screw-bone interface, which results in a loosening or failure problem [2]. Fixation stability and holding capacity of pedicle screws in biomechanical applications are determined by pullout tests performed with axial tension loading [3]. The maximum axial load sustained by the screw is accepted as the pullout strength of screw in ASTM Standard (F543-17) [4-5]. In order to improve the pullout strength of pedicle screw constructs and to perform the stabilization of pedicle screws on osteoporotic patients, the pullout performance of pedicle screws and loosening mechanisms were studied by many researchers [6-8]. It was determined that many parameters such as screw properties, augmentation conditions, insertion technique, etc. affected the pullout strength of pedicle screws [2, 9-10]. Demir and Başgül studied the parameters that affected the pullout strength of pedicle screws. They investigated the effect of screw designs, insertion techniques, cement augmentation, screw coating, test conditions, etc. on the pullout strength [11].

Early-stage pullout strength of pedicle screws is crucial for determining the performance of surgery operations [7, 12-13]. On the other hand, there is a necessity of determining long-term pullout strength because it is as important as early-stage performance. In order to determine the long-term pullout performance, the pedicle screws have to be sustained to the cyclic loading which

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simulates the forces that occurred on screws due to movement of the body before pullout testing. When the pedicle screws are subjected to the cyclic loading, the holding capacity is decreased and this decrease enhances the risk of loosening or failure of pedicle screws dramatically [14-17]. In addition to parameters related to the early stage pullout strength, the magnitudes of tensile and compression forces and bending moments are the critical parameters that have to be evaluated for long term pullout performance [1, 16, 18-20].

Reviewing and assessing the articles related to both toggling and pullout is believed to have a valuable contribution to the researchers investigating pedicle screws. Hence, the objective of this article is to review the studies including pullout behaviors of pedicle screws with or without toggling.

2. Methods

A comprehensive search was conducted using the keywords of “pedicle screw” and “pullout” combined with the words of “toggling” or “cyclic loading” or “fatigue” or “loosening”. Furthermore, in order to determine the augmentation effect on pullout strength after cyclic loading, the search was repeated with the terms of “bone cement” and “augmentation”.

The effect of pedicle screw properties, the cyclic loading conditions, test medium (human or animal cadaver, polyurethane foam block or synthetic bone model), level of spinal region, and cement usage on pullout performance of pedicle screws were reviewed comprehensively. The search consisted of articles, conference papers, international standards, thesis, books, technical reports, and case reports published in English and Turkish between 1990 and 2019. Articles not including toggling or cyclic loading and not related to pedicle screws were excluded.

3. Results

During the literature review conducted with the determined keywords, approximately 180 articles were surveyed. The review included the studies describing the long-term pullout performance of pedicle screws inserted to the human or animal cadaver and polyurethane foam or synthetic models. While studies not related to pedicle screws or cyclic loading were excluded, the studies only providing cyclic loading or fatigue behavior or toggling without pullout tests were included in the search. When the articles were divided into groups according to their relation with toggling and pullout, there were 12 studies investigated only the pullout performance of pedicle screws in the first group; 27 studies including toggling, cyclic loading, fatigue, and pullout testing in the second group; 11 studies related with only toggling, cyclic loading, the fatigue of pedicle screws in the third group; and 6 studies describing the subjects apart from others in the fourth group. Thus, a total of 56 articles were identified and included in the systematic review. The included articles are given in tables. Table 1, Table 2, Table 3 and Table 4 depict the studies related with only pullout strength, the studies related with pullout performance after toggling/cyclic loading/fatigue, the studies related with just toggling/cyclic loading/fatigue, and the studies related with pullout test and toggling/cyclic loading/fatigue separately, respectively.

4. Discussion

To the best of our knowledge, this is the first article that systematically reviews the literature related to toggling effect on the pullout strength of pedicle screws. The effects of cyclic loading conditions (load frequency, screw displacement, load direction, and load level, etc.), screw properties (types, geometry, and material, etc.), test mediums (cadaver, polyurethane foams, and synthetic bone models), the spinal region of cadavers (lumbar, thoracic and cervical) and cement usage on pullout performance with and without toggling were reviewed.

Biomechanical properties of screw fixations are generally determined by using pullout and toggling tests. Pullout testing standardized in ASTM F543 is commonly used to evaluate fixation stability and holding capacity of pedicle screws [5, 21]. The pullout test apparatus and samples are shown in Figure 1. In order to determine the early stage pullout performance of pedicle screws, the pullout test is performed shortly after the insertion process without cyclic loading. In this way, the short term stability of screws is investigated, because the inadequate holding capacity of pedicle screws is a common problem in surgery operations and it has to be determined before causing more catastrophic problems in the future [9]. The early-stage pullout performance of pedicle screws was studied by researchers in different conditions. The pedicle screws inserted to the vertebra are subjected to the loads in time after the operation, also the long-term pullout performance of pedicle screws is important for surgeons. The toggling situation is simulated by cyclic loading in biomechanical applications. Thus, the long term pullout performance is determined by pullout tests after performing cyclic loading. Defining long term pullout performance is as crucial as defining short term performance. In the toggling test, the tensile or compression and bending moments are applied to the pedicle screws until the failure or loosening and any time for pullout testing to determine the decrease in holding capability of pedicle screws.

It was determined that the cyclic loading generally had a negative effect on the pullout performance of pedicle screws. Applying cyclic loading causes tensile and compression forces sinusoidally and bending moment on the head of pedicle screws. The loading components develop a stress region along with the bone-screws interface and it leads to the loss of the stabilization of fixation in time [15, 20, 22]. The force generated on the screw is transferred through the longitudinal axis of the screw to the bone and the interface is the weakness area in this system [23].

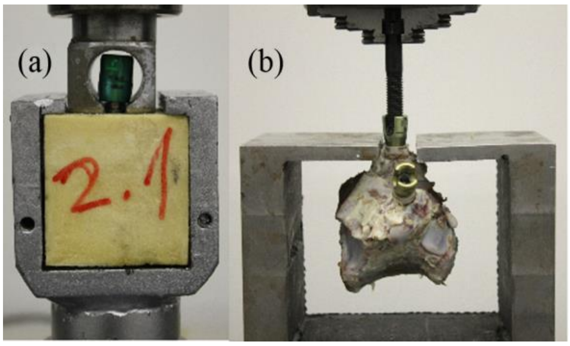

Figure 1. Pullout test apparatus and test samples: (a) PU foam and (b) bovine vertebra [15]

On the other hand, there was another hypothesis that bone tissue which contacted with pedicle screw compressed during the toggling movement, so the compression of bone increased the pullout strength of pedicle screws compared to the initial situation [19]. The bone structure had openings or grooves and these spongy tissues were compressed with compression force in toggling tests. The compressed bone tissue becomes denser and it can withstand the further loads subjected, due to cyclic loading. In some cases, the compression force caused a micro crack in trabeculae bones at higher loading cycles [24]. The magnitude of the force applied to the screw is crucial, and there is a possibility that it may cause damage in the bone adjacent to the screw. The magnitude of forces occurring due to cyclic loading depends on the loading direction and loading conditions, as well. The loads are generally applied to the pedicle screws craniocaudally or mediolaterally or axially in toggling tests [20, 25, 26].

Table 1. The studies related with just pullout strength

No	Authors	Levels	Screw implantation	Cyclic move.	Toggling/ Cyclic parameter	Biomechanics	Results	Comments
[2]	Chao KH, et al.	Human Thoracic Lumbar	Cannulated 6x40 mm	-	-	Pullout tests.	Prefilling and cement injection methods has similar fixation strength.	Prefilling and cement injection
[3]	Hashemi A, et al.	PU blocks	Standard 6.5 mm ø	-	-	Pullout tests.	CP augmentation improved the pullout strength in both failed samples and low density PU blocks.	CP bone augmentation
[6]	Choma T, et al.	Human vertebrae	Solid, PFen, Ffen 6.0x45 mm	-	-	Pullout tests.	The fixation strength increased with all augmentation techniques (Pfen, the greatest fixation).	Prefilling and cement injection
[7]	Tolunay T, et al.	PU foam G20, Bovine vertebra	Solid, DLDC cannulated, 7.5x50 mm	-	-	Pullout tests.	The DLDC with PMMA exhibited the highest pullout values. PS without cement has similar strength.	Prefilling and cement injection
[8]	Yaman O, et al.	PU foam G20, Bovine vertebra	Core and threaded types 5.5x45 mm	-	-	Pullout tests.	Transpedicular with helical angles exhibit higher pullout strength compared to the classical screws	Effect of helical angles
[9]	Tolunay T, et al.	PU foam G10 and G40	Solid and cannulated 6.5x45 mm	-	-	Pullout tests. Torsion tests.	The unilateral, sequential, 3-radial hole, drilled, cannulated screw was the ideal alternative.	Effects of hole, gap type, position
[10]	Varghese V, et al.	PU foam G5, G10 and G15	6.5x45 mm	-	-	Pullout tests.	Increasing density and insertion depth (except insertion angle) increased the pullout strength.	Effects of fixation parameters
[12]	Kim YY, et al.	PU foam G5, G15 and G20	Outer and inner diameter shape, threads	-	-	Pullout tests.	The outer cylindrical and inner conical configuration with a V-shaped thread provide max pullout	Cy/Cy-V B S Cy/Co-V B S Co/Co-V B S
[13]	Mehta H, et al.	Human vertebrae	PS with thick crest, thin crest,	-	-	Pullout tests.	The dual lead osteoporotic-specific PS had significantly larger insertion torques, similar pullout properties.	Effect of differential thickness
[38]	Aycan MF, et al.	PU G10, G40, bovine vertebra	7.5x45 mm, 4.5x45 mm core 7.5x60 mm shell	-	-	Pullout tests.	The novel expandable PS with expandable PEEK shells have higher performance than others.	Screw designs (PEEK shell)
[39]	Demir T.	Grade 10, Grade 40	Solid, cannulated 6.0x45 mm	-	-	Pullout tests.	Cannulated screws without cement for the cases (healthy bone) can be a reliable alternative to solid screws.	Artificial fusion (the first)
[40]	Chen L, et al.	PU foam (0.09 g/cm3)	Conical, cylind. cannulated, 4.8-6.0x60 mm	-	-	Pullout tests.	For the conically and cylindrically solid shaped screw, prefilling offer improved initial fixation strength.	Prefilling and cement injection

Table 2. The studies related with pullout performed after toggling/cyclic loading/fatigue

No	Authors	Levels	Screw implantation	Cyclic move.	Togglin / Cyclic parameters	Biomechanics	Results	Comments
[1]	Kueny RA, et al.	Human Lumbar	5.5x50 mm, 6.5x50 mm	CC	1 Hz, from 25 N by 25 N every 250 cycles	Pullout tests after toggling,	Injection increased fatigue force, prefilling reduced. Higher diameter increased pullout and fatigue force	Prefilling and screw injection
[15]	Aycan MF, et al.	PU G10, G40, bovine vertebra	7.5x45 mm, 4.5x45 mm 7.5x60 mm	CC	±1 mm, 3 Hz, 5000 cycles	Pullout tests after toggling.	Toggling have negative effect on pullout strength, NPS with PMMA was affected by toggling dramatically	Comparing designs (PEEK shell).
[16]	Paik H, et al.	Human vertebra	5x30 mm	CC	0 to -50 N, 1 Hz, 2000 cycles	Pullout tests after toggling.	Hubbing decreases the pullout strength, It causes a fracture in dorsal lamina, pedicle and superior articular facet	Teeter-totter, windshield wiper
[19]	Patel P, et al.	PU foams 0.32 and 0.16 gcm^{-3}	4.7x30 mm 6.7x30 mm	CC	±1 mm at a rate of 0.1 $mm.s^{-1}$	Pullout tests after toggling.	Screw toggling does not affect screw pullout significantly	Effect of toggling on fixation
[20]	Mehmanparast H, et al.	Porcine Lumbar	5x35 mm	CC, ML	±1 mm, 3 Hz, 5000 cycles	Pullout tests after toggling.	CC toggling significantly affects the pullout force and the screw stiffness.	Loosening in CC and ML
[22]	Mehmanparast H, et al.	PU G10, G20, G30	5x35 mm	CC	±1 mm, 3 Hz, 5000 cycles	Pullout tests after toggling.	Toggling is more likely to affect pedicle screw stiffness than pullout force.	Toggled and non-toggled conditions
[25]	Zhu Q, et al.	Human Lumbar	6x45 mm	CC	30 N to 300 N 1000 cycles at 0.5 Hz	Pullout tests after toggling.	There was no significant difference (toggling and pullout performances) between two cements.	PMMA and Sr-HA cement types
[23]	Lill C, et al.	Calf spines	7x55 mm 6x55 mm	CC	5,000 cycles at ±200 N, 1 Hz.	Pullout tests after cyclic loading.	The pullout strength of pedicle screws reduced after cyclic loading.	Conical and cylindrical screws
[26]	Savage J, et al.	Human cervical	-	Axial	1000 cycles of axial loading	Pullout tests after axial cyclic loading.	C1LM–C2LS has similar stability with a C1LM–C2PS construct after cyclic loading.	Lateral mass translaminar screws.
[29]	Liebsch C, et al.	PU model human vertebra	6.5x45 mm	Cplx. load. tests	5 Hz until 6 mm loosening or 600000 cycles	Cyclic loading.	The loosening characteristics of pedicle screws were similar.	Novel testing model
[33]	Gates TA, et al.	Lumbar vertebral bodies	4.5x25 mm	CC	±200 N at 0.5 Hz for 1000 cycles	Pullout tests after toggling.	A novel anchor for pedicle screws had higher fatigue strength, greater failure force.	PEEK Anchor
[32]	Pishnamaz M, et al.	Human vertebrae	-	CC	3 Hz, 20–200 N, 100,000 cycles	Pullout tests after toggling.	The anchoring stability of high-volume augmented screws is disadvantageous.	The effect of cement volume
[55]	Bostelmann R, et al.	Lumbar (L1-L5)	6.0x45 mm	CC	20–50 N, 0.1 N per cycle and 1 Hz for 5000 cyc.	Pullout tests after toggling.	Augmentation of pedicle screws increased the number of load cycles and failure load.	Load cycles to failure.
[34]	Schmoelz W, et al.	Human Lumbar vertebrae	Cannulated, fenestrated 5.5×35 mm	CC	±50 N by 5 N every 100 cycles until 11,000 cyc.	Pullout tests after toggling.	The novel silicone sustained a higher number of load cycles and load magnitude.	Load cycles to failure
[27]	Mehmanparast H, et al.	Lumbar vertebras, porcine	-	CC	±1 mm, 3 Hz, 5000 cycles	Pullout tests after toggling.	Toggling method is more likely to affect pedicle screw stiffness than pullout force	Comparing stability of pedicle
[30]	Baluch D, et al.	Human lumbar and toracic	4.5x40 mm 6.5x45 mm	CC	±200 N inc. by 25 N every 20 cyc. until 2 mm	Pullout tests after toggling.	Laterally directed cortical pedicle screws have superior resistance to CC toggling.	Laterally, medially directed
[50]	Burval D, et al.	Human lumbar vertebrae	6.25x40 mm	CC	5000 cycles, 3 Hz, ±5 mm	Pullout tests after toggling.	Kyphoplasty technique had significantly greater pullout strength than other techniques.	Transpedicular and kyphoplasty
[46]	Akpolat Y, et al.	Human lumbar vertebrae	6.5x55 mm 4.5x25 mm	CC	±4 Nm bending, 1 Hz, 100 cycles or until 6° loose.	Pullout tests after axial cyclic loading.	Standard pedicle screw had a better fatigue performance than the CBT screw.	Fatigue behavior of CBT screws
[43]	Lai, D.M., et al.	Human thoracic vertebrae	4.35x35 mm, 5.0x35 mm	CC	10 – 100 N at 1 Hz, 5000 cycles and 10000 cycles	Pullout tests after toggling.	Both sizes of screws exhibited comparable pullout strengths post fatigue loading.	Diameter effect on pullout

The craniocaudal or cephalocaudal were the most used directions for cyclic loading in toggling tests. The general view of the toggling test apparatus commonly used is given in Figure 2.

Although aforementioned studies generally use this cyclic loading, mediolateral, and axial loading methods, which repeated loading in other directions, cause screw loosening, as well [27]. Mehmanparast et al. [20] investigated the craniocaudal and mediolateral direction effects on the toggling behavior of pedicle screws comparing with non-toggling conditions.

Table 3. The studies related with just toggling/cyclic loading/fatigue

No	Authors	Levels	Screw implantation	Cyclic move.	Toggling/ Cyclic parameters	Biomechanics	Results	Comments
[18]	Benson D, et al.	Human Lumbar vertebra	6x45 mm	CC	20-100 at 2,000 cycles for each load, 10,000 cyc.	Cyclic loading (Fatigue tests)	The kyphoplasty technique has similar resistance to vertical toggle movement	Comparing augmentation techniques
[24]	Sterba W, et al.	Human Lumbar vertebra	6 mm	CC	2 Hz, 2000 cycles, peak load of 50 N (R=0.1)	Cyclic loading.	Straight screw insertion has a better fatigue performance.	Screw insertion technique
[29]	Liebsch C, et al.	PU foam model	6.5x45 mm	CC	5 Hz until 6 mm loosening or 600000 cycles	Cyclic loading.	The loosening characteristics of screws were almost similar.	Novel testing model
[36]	Rodriguez-Olaverri J, et al.	Calf Toracic Lumbar	5.5x30 mm	Lat. bend.	3 Hz with the 100 N, at 10-10,000 cycles	Cyclic loading.	The use of angled screw orientations at the ends of anterior constructs have higher stability after cyclic loading.	End screw angulation on construct stability
[52]	Sven H, et al.	Lumbar vertebra	-	CC	50 cyclic loads, 5-50 N, 5-100 N, 5-200 N	Cyclic loading.	Augmentation increases pedicle screw performances for osteoporotic vertebrae.	Augmentation effect under cyclic loading
[57]	McLachlin S, et al.	Sacral vertebra	Sacral screw	Cyclic tens.-comp.	0.5 Nm for the first 1000 cycles 1 Nm every 1000 cycles, 1 Hz	Cyclic loading.	The PMMA augmentation provided increased resistance to cyclic loading compared	Comparing CTBC with PMMA under cyclic loading.
[27]	Mehmanparast H, et al.	Lumbar vertebra, porcine	-	CC	±1 mm, 3 Hz, 5000 cycles	Pullout tests after toggling.	Toggling method is more likely to affect pedicle screw stiffness than pullout force	Comparing stability under cyclic loading.
[28]	Bianco RJ, et al.	Human lumbar vertebra	5.5x45 mm (single lead and dual lead thread)	CC	0 to 400 N, 4 cycles	Cyclic loading.	Lateral loads induce greater bone deformation and risks of failure than cranial loads.	Comparing resulting forces, displ., and rotations
[35]	Lindtner R, et al.	Human lumbar vertebra	6.5x45 mm	CC	±50 N, incr. 5 N every 100 cycles, 10000 cycles or loosening	Cyclic loading.	Nonmetallic CF/PEEK pedicle screws have a similar resistance with standard titanium screws.	Carbon fiber-reinforced PEEK (CF/PEEK)
[41]	Kiner D, et al.	Human lumbar vertebra	6 mm and 8 mm	CC	2000 cycles, 2 Hz, 50 N (peak load), R=0.1	Fatigue tests.	The larger diameter screws were more resilient than the cement augmented standard diameter screws.	Angled and straight insertion technique
[48]	Lim T, et al.	Lumbar vertebra	6.5x55 mm	CC	± 1 mm, 0.5 Hz, 200 N caudal, 100 N cephalad	Cyclic loading.	Positive correlation between the number of loading cycles to induce screw loosening and bone mineral density	The relation between BMD and number of cycles
[45]	Wang, WT, et al.	Sheep lumbar vertebra	4.5x25 mm	CC	± 200 N, increase 25 N every 20 cyc., until 2 mm	Cyclic loading.	In cyclic loading, maximum displacement was lower in DPTCPS compared to SPPS and SPTCPS.	DPPS, SPPS, DPTCPS or SPTCPS

While the toggling significantly reduced the pullout strength and stiffness of pedicle screws in both methods, craniocaudal toggling affected the pullout force and the screw stiffness significantly. On the other hand, Bianco et al. [28] compared the effect of cyclic loading direction on pedicle screw fixation performance and concluded that the lateral loads (mediolateral loading) caused greater bone deformation and failure risks than cranial loads. The pullout performance of pedicle screws after toggling depended on the direction of cyclic loading because the limits of screw plowing occurred in pedicles was affected by magnitude and direction of loading. The sidewalls of the pedicle restrained the plowing movement during the cyclic loading because the distance between the superior endplate and the inferior endplate was larger than the distance between both sidewalls. Liebsch et al. designed a novel test setup for toggling tests [29]. Complex loading components of combined shear forces, tension forces, and bending moments were generated in a novel toggling test setup. This testing model eliminated the limitations of uniaxial loading conditions substantially because it was known that the pedicle screws inserted pedicles of vertebra were subjected to complex loading conditions instead of unidirectional loading during movement of the body.

The loading parameters of toggling affected the loosening behavior and holding capacity of pedicle screws directly. Loading level, loading frequency, number of cycles, and displacement limits were the main parameters of toggling affecting the pullout performance.

The toggling parameters were generally determined in order to simulate the physiological conditions of the spine during walking. It was calculated that the pedicle screws inserted to the lumbar vertebra were subjected to the compressive loads between 270 N and 667 N during normal walking for an average patient [30]. Furthermore, some researchers determined that the displacement of 1 mm were produced by forces generated on screws during walking [19, 31].

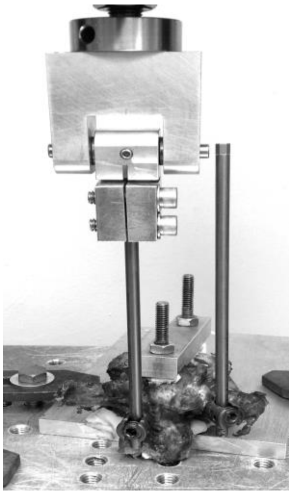

Figure 2. Apparatus for craniocaudal toggle testing [20]

While the number of cycles in toggling tests changed between 200 and 600000 cycles, many researchers used 2000 or 5000 cycles for cyclic loading [15-16, 18, 20]. The preliminary test results showed that the defined number of cycles was sufficient for loosening the pedicle screws before the pullout test. On the other hand, a higher number of cycles might be used in order to determine the loosening amount of pedicle screws under cyclic loading without pullout testing. In this toggling method, the effect of the number of cycles on the loosening behavior of pedicle screws was investigated.

The toggling tests were performed with two protocols: displacement-controlled and load-controlled. In the displacement-controlled tests, the maximum displacement of the pedicle screw head in one axis was controlled in determining limit values which were defined in several studies as ±1 mm, but there was a use of 6 mm displacement value in literature [15, 19, 20, 22, 29]. The applied load to the screw reached the highest level at the beginning of the test and also the peak load was provided at this time. The load level decreased in time until the end of the test or failure of the pedicle screw. The load applied to the screw in response to the displacement had exponential decay during the toggling test.

Table 4. The studies related with pullout test and toggling/cyclic loading/fatigue separately

No	Authors	Levels	Screw implantation	Cyclic move.	Toggling/ Cyclic parameters	Biomechanics	Results	Comments
[14]	Demir T.	PU foam G20 and calf vertebrae	7.5x45 mm expandable, 4.0x40 mm cannulated	-	100 N, 10 Hz, 1000000 cycles	Pullout tests. Flexion/ Extension tests. Axial gripping capacity tests. Torsional gripping tests. Toggling tests.	The pullout and fatigue values for expandable PEEK shell were higher than classical pedicle screw.	Novel PEEK expandable shell and classical pedicle screws
[17]	Brasiliense L, et al.	Lumbar vertebra and PU foam	6.5x40 mm Dual threaded and single thread	CC	2,500 cycles, 2.5 Hz, 75 N (peak load)	Fatigue tests. Pullout tests.	Dual-threaded screws failed at a higher load and endured a higher cycles of loading	Flank overlap area
[42]	Wittenberg R, et al.	Human lumbar,sacra vertebrae	6.25 mm, 5 mm, 6 mm,	CC	± 2 mm, 200 N, 5000 cycles	Pullout tests. Cyclic transverse bending.	PMMA and a biodegradable CBC both increased the axial pullout force and the transverse bending stiffness.	Diameter effect on pullout strength
[31]	Lotz J, et al.	Human lumbar vertebrae	6.5x45 mm	Superior - interior direction	±1 mm, 3 Hz, 5000 cycles	Pullout tests. Cyclic transverse loading.	Augmentation has positive effect on pullout strength, stiffness and absorbed energy under cyclic loading.	Carbonated apatite cancellous bone cement
[37]	Inceoglu S, et al.	Bovine lumbar vertebrae, PUfoam	6.5x40 mm	Axial	0.1, 1, 5 and 50 mm/min rates, during 15 min	Pullout tests. Cyclic loading.	The results showed that the loading rate significantly affected the strength and stiffness of the interface.	Effects of loading rate on the stiffness and strength
[44]	Hirano T, et al.	Human lumbar vertebrae	6.25x40 mm	CC	3 mm/min, 29,4N, 5 cyc 2 mm/min, 19,6N, 5 cyc.	Cyclic loading. Pullout tests.	Approximately 80% of the CC stiffness and 60% of the pullout strength of the pedicle screw depended on the pedicle.	Pedicle and pedicle+ vertebra body
[47]	Wray S, et al.	Human Lumbar	5.5x30 mm 6.5x40 mm	CC	5 kN, 10 mm/min	Pullout tests. Toggling tests.	The shorter cortical screws and traditional pedicle screws has similar pullout and toggling performances.	Pedicle trajectory, cortical trajectory
[49]	Yamagata M, et al.	Lumbar vertebrae	4.5 mm, 5.0 mm, 6.0 mm, 6.5 mm	Four point bending (fatigue)	1000 cycles per min, until 5000000 cyc	Fatigue, compreession, torsion and pullout tests.	Linear positive correlation between the BMD of the vertebral body and the pullout strength of the pedicle screw.	
[51]	Zdeblick T, et al.	Human lumbar vertebrae	6.5x45 mm	CC	0.5 Hz, 300 N	Toggling and pullout tests.	Probing or drilling does not affect the insertional torque and pullout strength.	Probing and drilling effect

Furthermore, the loading values were maintained at defined loading limits in load controlled tests. The peak load with loading ratio (R) in a sinusoidal pattern of compression or peak loads in the sinusoidal pattern of compression and tension forces was used in load controlled tests. For unilateral loading, while the peak load changed from 50 N to 300 N, the loading ratio was defined as 0.1 in most of the studies [24, 25, 32]. Besides, the peak loads between ±50 N and ±200 N were used by many researchers [33-35]. The load controlled protocol was generally used in order to determine the number of cycles at which the bone-screw interface failed or loosening the amount of pedicle screws for a defined number of cycles. For sinusoidal loading, another crucial parameter was loading frequency. Although, different frequency values which showed the interval of loading in one second were defined as a value of between 0.5 Hz and 5 Hz in many studies, 2 Hz or 3 Hz was the most preferable frequency values for cyclic loading [15, 20, 24, 29, 33, 36]. To the best of our knowledge, there are no studies investigated the effect of loading frequency on toggling behavior. However, Inceoglu et al. [37] investigated the effects of loading rate on the pullout behavior of pedicle screws inserted to the polyurethane foams and bovine bone. Thus, the results suggested that the mechanics of the bone–screw interface changed depending on the loading frequency as the loading rate. The bone-screw interfaces in different test mediums and screw designs have a different mechanic and viscoelastic behaviors, as well. Also, it is estimated that the loading frequency affects the toggling behavior, but there is no exact relation between loading frequency and toggling behavior. These speculations have to be verified with further and more detailed analyses for different test mediums and screw designs.

The pedicle screw type was the most important parameter affecting the pullout performance with or without toggling [7, 14, 15, 19, 35]. The screw types (conventional, cannulated, expandable, dual lead dual cored, cancellous, cortical, etc.), which had a significant effect on early-stage pullout performance of pedicle screws, were compared by many researchers in different biomechanical test conditions [7, 14, 19, 38, 39]. The long term pullout performances of new designs were compared with the conventional pedicle screw and early-stage pullout strengths of the same designs. The early stage and long-term pullout performances of a novel expandable pedicle screw consisted of a polyether ether ketone (PEEK) shell and a titanium core screw, and cannulated and conventional pedicle screws were compared in several test mediums [15, 38]. The novel expandable pedicle screw had higher early-stage pullout strength than others and had a lower decrease in pullout strength after toggling tests. The samples of pedicle screws are given in Figure 3. The PEEK shell prevented the load transfer from screw to test medium by creating a new interface between the screw and test medium. It absorbed the part of the load generated on screw due to its good damping property, and the loosening values in novel expandable screws were lower than others. Similarly, the pedicle screws with PEEK anchor had higher pullout performance after toggling. Reducing the translation amount during cyclic loading, the anchor resulted in a significant reduction in axial motion at a defined number of cycles [33]. Moreover, the loosening behavior of carbon fiber reinforced PEEK pedicle screw was compared to the conventional titanium pedicle screw by using pullout tests after toggling and it was concluded that the novel PEEK pedicle screws, which had lower elastic modulus, were not successful in withstanding to the loosening [35].

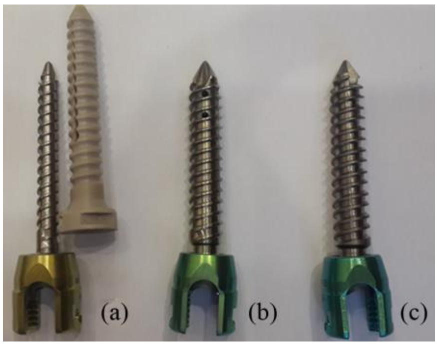

Figure 3. Pedicle screws used by Aycan et al.: a) novel expandable (PEEK shell), b) cannulated, c) standard [15]

The geometry or design parameters of pedicle screws have a notable influence on early-stage and long-term pullout performances. Outer geometry, thread types, cannula or hole orientation, etc. in pedicle screws affected the pullout performance drastically. The pedicle screws which had conical or cylindrical geometries showed different pullout behaviors in different test mediums. While the conical pedicle screws had lower pullout strength than the cylindrical pedicle screws in the case of without cyclic loading, there was no significant difference between the pullout performance of both screw types [23].

The early-stage pullout performance of conical and cylindrical pedicle screws with and without cement augmentation in severe osteoporosis cases were investigated and the results showed that conical and cylindrical screws had almost similar strength values [19], [40]. Using larger diameter provided sufficient improvement for both early-stage pullout strength and fatigue strength [1, 41], it was concluded that the outer geometry of pedicle screws had no significant effect on pullout performance after toggling. Furthermore, Wittenberg et al. [42] compared the axial pullout strength and transverse bending stiffness of pedicle screws which had different diameters, and it was found that the bending stiffness of pedicle screws had not been affected by increasing diameter (1 mm) of the screw. Patel et al. [19]

investigated the pullout behavior of cortical (4.7 mm major diameter) and cancellous (6.7 mm major diameter) pedicle screws after cyclic loading. It was determined that there was no significant difference between the pullout strengths with and without cyclic loading. Although increasing of diameter provided higher pullout strength immediately after fixation, there is no significant effect of outer dimeter size on fixation strength after 5000 and 10000 cycles fatigue loading [43]. On the other hand, even if the results showed that the larger diameter, the higher pullout strength for pedicle screws, the outer diameter of the pedicle screw would be limited by the anatomical structure of the pedicle canal. The vertebra consisted of trabecular and cortical bones from the inside to outside and the load-carrying capacity depended on the bone structures along the cross-section, as well. It was determined that more than 80% of the craniocaudal stiffness and almost 60% of the pullout strength of pedicle screws were provided by the cortical bone in pedicles [17, 44]. Therefore, the smaller diameter screws have a reduced risk of surgical complications in surgery [43]. Dual-threaded pedicle screws were improved instead of single thread screws in order to enhance the pullout performance.

While dual-threaded screws had a trend for better pullout strength than single-threaded ones, there was no significant difference between both screws which had the same geometrical properties. Moreover, screws had similar failure loads and the number of cycles to failure after toggling [17]. The dual-threaded pedicle screws pattern in the cortical zone of pedicle provided greater bone purchase in loading for samples with high BMD and the advantage of dual-threaded pedicle screws were generally lost in high porosity foam or osteoporotic bone samples due to lack of sufficient bone-screw interface, unlike compacting solid foam or healthy bone samples. The biomechanical properties of dual threaded pedicle screws (standard pitch, dual pitch, standard pitch titanium coated, dual pitch titanium coated) were compared for different conditions (at 0 time and postoperative 6 months). The screws were coated with titanium which has good histocompatibility and adhesion properties by a plasma-spray titanium coating method. The dual pitch titanium-coated pedicle screws had significantly higher pullout strength and fatigue performance than standard pedicle screws for early time and post-operative conditions [45]. In addition to this, the long-term pullout performance of cortical bone trajectory pedicle screws and traditional pedicle screws were compared under cyclically sagittal bending conditions [46]. The cortical bone trajectory pedicle screws had better fatigue performance than the traditional pedicle screws since there was no sufficient cortical purchase to withstand the small diameter and length of cortical bone trajectory pedicle screws in maintaining stability under cyclic loading in vertebrae with low BMD. Wray et al. [47] determined that the cortical trajectory provided higher bone density for screw stability by comparing with a traditional trajectory in both high bone density and poor bone density. The cortical trajectory had an advantage in osteoporotic patients due to having inherently greater bone density along its path.

Human or animal cadaver, polyurethane foam block, and synthetic bone models were used as a test medium for biomechanical tests. There was a strong correlation between the biomechanical properties of pedicle screws and BMD values of bone [48]. It was concluded that the higher BMD, the higher holding performance for pedicle screws. BMD, which was an indication of the ability to resist shear loading, may be a critical value for loosening of screws inserted to the anterior of vertebral bodies and the number of loading cycles to failure increased by increasing of BMD value of vertebral bodies [48, 49]. While the cyclic loading caused a 20% decrease in pullout strength in healthy bone, it caused a 33% decrease in osteoporotic bone [50]. Pullout performance of pedicle screws was affected by the BMD value of pedicles and there was a significant relationship between pullout performance and BMD regardless of the application type of toggling [20]. Furthermore, the pedicle size of the vertebral body was as effective as BMD on pullout performance. It was concluded that smaller pedicles obtained a greater number of cycles to failure for pedicle screws and the pedicle screws inserted to the smaller pedicles had higher pullout and fatigue strength in case of osteoporosis [51]. The pedicle size depended on the spinal region of the spine as well so that the spinal region of the cadaver affected the pullout performance of pedicle screws with or without cyclic loading [16, 20, 24]. Mehmanparast et al. determined that the pullout strength of the pedicle screws decreased from L1 to L3 of the porcine lumbar region. This decrease was explained in part by changing the pedicle cross-sectional area for each level [20]. Furthermore, the polyurethane foams standardized with related ASTM standards are used in the biomechanical applications for testing pedicle screws. The density of foams determines the severity of the disease: Grade 10 mimics osteoporotic bone and Grade 40 mimics healthy bone. The decrease of density for polyurethane foams caused a decrease in the pullout strength of pedicle screws after toggling, as expected [15, 19, 22]. Aycan et al. [15] determined that the pedicle screws implanted to the Grade 10 had lower pullout strength than those implanted to Grade 40, and pedicle screws in both foams acted almost similarly. While polyurethane foams produced in different densities were used as a test medium, they did not replicate the viscoelastic properties of bone. The differences in densities of polyurethane foams helped the understanding of the pullout mechanism of pedicle screws, but it was suggested that the tests had to be performed in vivo [19].

Cement augmentation is one of the techniques used for increasing holding capacity of pedicle screws in spinal surgery operations. The pullout performance of pedicle screws increased significantly with cement usage. Cement augmentation has a positive effect on both early-stage and long term pullout strength of pedicle screws comparing to non-cemented pedicle screws. While the cement augmentation increased the screw anchorage performance significantly in bones with poor BMD, there was no significant effect on screw stability for healthy bones [52]. Burval et al. [50] investigated the pullout failure of cemented pedicle screws on either primarily or after 5000 cycles tangential fatigue and it was concluded that cement augmentation improved the early stage fixation and fatigue strength of pedicle screws. Aycan et al. [15, 38] compared the early stage and long term pullout strengths of cemented cannulated pedicle screws, cemented conventional pedicle screws, and non-cemented conventional pedicle screws. The results showed that the cemented conventional pedicle screws had the highest pullout strength values for all test conditions with or without toggling. Augmentation of conventional screws was performed with the prefilling method and there was a large and sufficient interface between bone and screw. For instance, according to the study of Aycan et al., the pullout strength of conventional pedicle screws increased to 57% in Grade 10 foam, 51% in Grade 40 foam, and 110% in a bovine vertebra with cement usage. However, the highest pullout decrease after cyclic loading belonged to the cemented conventional pedicle screws. The cement augmentation created a large bone-screw interface and it took an active role in transferring loads from screw to the bone as a mechanical locking mechanism [53, 54]. The brittle behavior of the cement interface significantly increased due to material properties of the cement when compared to the connective tissue after the syndesmosis process in bone structure [15]. Furthermore, this brittle structure did not withstand the sinusoidal loading generated so much and the damage of interface decreased the load transfer capability dramatically. The cement augmentation method is crucial for creating a sufficient interface that enables to successful load transfer. While the conventional pedicle screws cemented with the prefilling method, the injection method is used for cannulated pedicle screws in biomechanical applications. The simulation of cement augmentation methods is shown in Figure 4. The prefilling method created a large cement interface between test material and pedicle screws as mentioned before and it provided that conventional pedicle screws had higher pullout strength than cannulated pedicle screws in all test conditions. On the other hand, the injection method did not succeed in providing enough cement interface, unlike the prefilling method. The penetration of cement from screw to bone (or test medium) was not sufficient to create a large interface due to using hand pressure in the injection of cement and obstruction of the radial hole during the insertion process [7]. On the other hand, Kueny et al. investigated the effect of augmentation method on pullout performance of pedicle screws after toggling and they concluded that the pedicle screw cemented with screw injection had a higher pullout and fatigue strength than the pedicle screw cemented with prefilling method [1]. It was determined that the cement in contact with cortical shell had a significant effect on the fixation strength of bone screws and they hypothesized that in injection method, there was a wider cement distribution which was closer to the pedicle and had a greater contact to the posterior vertebral wall leading to the higher fixation strength. Furthermore, the effect of fenestrated tap, direct injection, and kyphoplasty methods on toggling behavior of cannulated pedicle screws were investigated and it was concluded that the pedicle screw cemented with direct injection method had superior resistance to vertical toggle, and the fenestrated tap method had lower resistance to motion than other methods [18]. Besides, the kyphoplasty method had almost similar resistance to cyclic loading with a decreased risk of cement leakage in comparison with the direct injection method. Moreover, Bostelmann et al. suggested that the pullout performance of pedicle screws increased with augmentation process (cement first, in situ augmented, percutaneously application) compared with non-cemented pedicle screws, but the augmentation methods had no effect on loosening or failure of pedicle screws [55]. The kyphoplasty and traditional transpedicular augmentation methods were compared in osteoporotic vertebrae. Although both methods increased the pullout and fatigue strengths, the kyphoplasty method provided higher pullout strength compared to the traditional transpedicular augmentation method [50]. The kyphoplasty method created a larger contact surface area with trabecular bone tissue than transpedicular augmentation. The reason for providing higher biomechanical properties for the kyphoplasty method was not only the application technique but also the cement amount in the study of Burval et al. [50]. While the amount of 4 cc PMMA was used in the kyphoplasty method due to creating a balloon in bone tissue, the transpedicular augmentation process was performed with 2.5 cc cement. It was hypothesized that the higher amount of cement, the higher cement interface between screw and bone. Unfortunately, Pishnamaz et al. determined that increasing cement amount in augmentation methods had a negative effect on holding the capability of pedicle screws [32].

The forces generated due to the cyclic loading on the head of the screw sometimes caused the rotation of the screw with a fulcrum in the pedicle, and a large amount of cement limited the rotation movement of the screw in the fulcrum of the pedicle. The limitation of the rotation led to an increase in higher forces on pedicle during the cyclic loading and finally these forces caused the loss of the stability of fixation and cut out of the screw through the superior endplate as a result of cyclic loading [32, 55]. Schmoelz et al. compared the pullout performance after cycling loading of pedicle screws which augmented with medical silicone using the kyphoplasty method and in situ augmented with PMMA [34]. A balloon cavity was created and filled with 3 ml of self-curing elastomer before the insertion of the screw in the novel augmentation method. After the implantation of cannulated pedicle screws, they were augmented in situ with 2 ml PMMA. The novel augmentation method had higher pedicle screw anchorage under cyclic loading in comparison with conventional PMMA augmentation. Although the cement type and amount of cement were different in comparison to kyphoplasty and in situ augmentation methods, the results showed that self-curing elastomeric silicone might be a good alternative to the PMMA. The material properties of cements were determinant on the anchorage performance of pedicle screws. The PMMA, which had higher stiffness than bone, interdigitated with trabecular bone tissue and provided reinforcement and interlocking mechanism with trabecular bone [56]. On the other hand, the stiffness of elastomer silicone was almost similar with the bulk stiffness value of trabecular bone instead of the stiffness of single trabecula, and this resemblance between silicone and trabecular bone enabled silicone to have higher anchorage performance due to creating a cavity and filling it with silicone [34]. Both the novel bioactive bone cement (Sr-HA) and PMMA were filled to the pedicle holes by the prefilling method within about 3 minutes before the insertion of the screw. While the PMMA cemented pedicle screws had higher pullout and toggling performance than Sr-Ha cemented ones, it was hypothesized that Sr-HA and PMMA cements provided an almost similar fixation performance for pedicle screws.

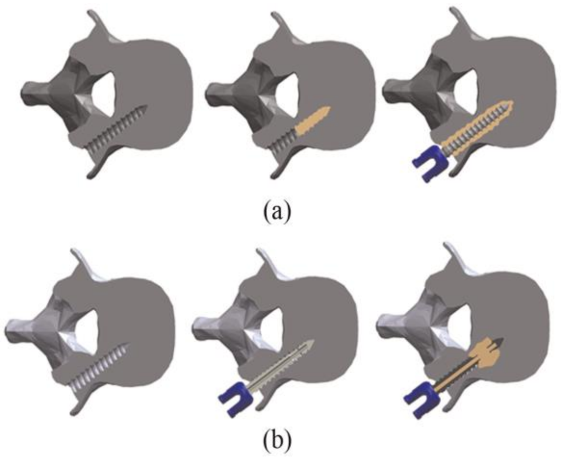

Figure 4. Cement application techniques; (a) prefilling, (b) injection [7]

Despite having lower mechanical strength, Sr-HA cement provided a larger bone-screw interface and it also covered most of the length of the screw after insertion due to having longer handling time than PMMA [25]. Moreover, the modulus of elasticity of PMMA was drastically higher than bone, which was almost similar to calcium triglyceride bone cement (CTBC). While this similarity provided some advantages to the CTBC compared to PMMA for in vivo usage, more cycles and bending moments applied higher were required in order to reach the same screw loosening for PMMA due to lower mechanical properties of CTBC [57].

5. Conclusions

The toggling test, which simulates the movement of the body in time, is performed in order to determine the long-term pullout performance of pedicle screws. It was concluded that the pullout strength of pedicle screws generally decreased with toggling. The parameters of cyclic loading determined by observing the movement of the spine were fairly crucial for the pullout performance of pedicle screws because they had an important impact on the stability of screws. The cement augmentation, design parameters of screws, and properties of test medium had important roles in determining the holding capacity of pedicle screws under cyclic loading, as well. Although the cement augmentation increases the pullout strength without cyclic loading indisputably, there are various studies providing different results about the effect of cement augmentation on pullout performance after toggling. In these studies, the types or design parameters of pedicle screws affected the pullout performance directly as expected. The screw types as normal, cannulated or expandable screws, conical or cylindrical, cortical or trabecular, and the design parameters as outer diameter, core diameter, length, lead, and core geometries were compared in different studies. Furthermore, the pullout performance of screws changes with insertion techniques, test medium, and spinal level; however, there is not a certain discussion whether these parameters have a significant effect on long term pullout behavior or not.

Declaration

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article. The author(s) also declared that this article is original, was prepared in accordance with international publication and research ethics, and ethical committee permission or any special permission is not required.

Nomenclature

BMD : Bone mineral density
ASTM : American Society for Testing and Materials
CC : Craniocaudal
PEEK : Polyether ether ketone

PMMA : Poly (methyl methacrylate)
Sr-HA : Strontium-containing Hydroxyapatite
CTBC : Calcium triglyceride bone cement

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