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The Pullout Performance of Pedicle Screws

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Teyfik Demir
Department of Mechanical Engineering
TOBB University of Economics
and Technology
Ankara
Turkey

Cemile Başgül
Department of Mechanical Engineering
TOBB University of Economics
and Technology
Ankara
Turkey

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Foreword

The advances in health care and technological developments that facilitate human life have increased longevity. As human life span has increased, the incidence of degenerative diseases associated with aging has inevitably increased. The human spinal column has been the most affected part. This has been caused by the disadvantage of humans, unlike animals, of having erect position on two feet, weight gain, sedentary lifestyle, and osteoporosis, all of which have led to a rampage in the incidence of spinal diseases. Likewise, the number and approaches of spinal surgeries have also increased, paving the way for studies that help us better understand the anatomy of the human spine. As a result, interventions to the spinal column and the spinal cord have become safer in light of the information provided by these studies.

Surgical interventions that were used for lumbar disc herniations only in the post twentieth century have become routine procedures for treatment of common degenerative diseases, scoliosis, and complicated vertebral fractures. All of these developments have been facilitated by better understanding of biomechanics of the spinal column. The collaborative studies of orthopedic surgeons and neurosurgeons that frequently operate on the spinal column have made great contributions to the treatment success. Moreover, the joint efforts of biomechanical engineers with medical teams and their extensive knowledge of biomechanics have increased the pace of solutions for diseases and conditions of the spinal column, which earlier, were not possible to treat, and the compatible multidisciplinary studies have yielded success in the treatment of spinal diseases in many clinics throughout the world.

An important issue in the treatment of diseases and conditions of the spinal column is the properties of the pedicle screws, the thorough understanding of which will enable the surgeon to determine the best approach to the treatment. In this respect, this systematic review provides important and valuable information on the pullout strength of pedicle screws in the light of previous studies, paying special attention to the test conditions and the pullout values. Therefore, I believe this review will also help surgeons understand the underlying factors on pullout problems and how to fix them.

Prof. Dr. Hasan Çağlar UĞUR
Ankara University, Faculty of Medicine
Department of Neurosurgery

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—Cemile Başgül

I acknowledge my beloved wife Esra and our great son Ahmed Tarık for their patience while I was working for long times. I also want to acknowledge my mother for being a great life guide to me. My father's vision is also acknowledged as a lighthouse. Thanks to my sister for her lovely support. I want to express my great pleasure to my brother Hasan Hüseyin for his support in my whole life. I also want to thank him for making everything easy for me. Special thanks to Prof. Dr. Hasan Çağlar UĞUR for his great guidance on scientific and social issues. Lastly, I want to express my sincere thanks to our Rector Prof. Dr. Adem ŞAHİN for being a great leader and a great friend.

—Dr. Teyfik Demir

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Contents

Abbreviations

AIC	Amount of Injection Cement
ASTM	American Society for Testing of Materials
BMD	Bone Mineral Density
Coll/CS	Coll/Chondroitin Sulfate
CP	Calcium Phosphate
CPS	Cannulated Pedicle Screws
CS	Calcium Sulfate
CT	Computed Tomography
EPS	Expandable Screw
FEM	Finite Element Modeling
FOA	Flank Overlap Area
HA	Hydroxyapatite
HA-PS	Hydroxyapatite Coated Pedicle Screw
IPD	Interpedicular Distance
JPA	Japanese Orthopedic Association
MAP	Mean Angle of the Pedicle
MPDSD	Medial Pedicle-Dural Sac Distance
NRD	Nerve Root Diameter
ODI	Oswestry Disability Index
PDSD	Pedicle-Dural Sac Distance
PH	Pedicle Height at isthmus
PIRD	Pedicle-Inferior Nerve Root Distance
PMMA	Polymethylmethacrylate
PS	Pedicle Screw
PSRD	Pedicle-Superior Nerve Root Distance
PW	Pedicle Width at isthmus
REA	Root Exit Angle
RoE	Region of Effect

SPS	Standard Pedicle Screw
Sr-HA	Strontium and Hydroxyapatite
Ti-PS	Non-Coated Titanium Pedicle Screws’
VAS	Visual Analog Scale

Abstract

Pedicle screws are used in spinal surgeries to stabilize the spine. The holding strength (pullout strength) of the pedicle screw is an important issue. Loosening of the pedicle screws can cause revision surgeries. Once the pedicle screw is pulled out from vertebra it is harder to stabilize. In this brief the subjects that affect the pullout strength were studied systematically. Screw designs, application techniques, cement augmentation, coating of the screw, test conditions, and finite element analyses were reviewed. The aim of this study is to summarize the information about the pullout strength of different types of pedicle screws which are being used for different purposes and give an overall view about the studies made before. Thereby, this study will lead researchers to further studies of pedicle screws.

Chapter 1
Introduction

The vertebrae and the soft tissues come together and constitute the spine. As the vertebra structure changes according to the region of the spine, the all vertebrae consists an anterior part namely vertebral body, which is durable for compressive and tensile loads and a posterior part (neural arch) consisting and protecting the spinal cord meanwhile allows movement of the spine. Intervertebral discs, which absorb the load applied to the vertebrae and regularize the load distribution as having a viscoelastic structure, are positioned between two adjacent vertebrae. The whole construction of the spine is tied together by ligaments and muscles [7].

The regions of the spine are cervical, thoracic, lumbar and the sacral vertebrae (sacrum) which can be seen on Fig. 1.1. The cervical region is the most movable region of the spine to provide the range of motion for the head. There are seven cervical vertebrae, named C1-C7 from superior to inferior. The thoracic vertebrae (T1-T12) have junctions to the ribs, which protect organs. And the last movable region of the spine is lumbar vertebrae (L1-L5), and also the most strong and durable part. The sacrum (S1-S5) is located in the center of the pelvis and sacral vertebrae fused to each other. And the final part of the spine is called coccyx, which is also known as tail bone [8].

The vertebra is formed by cancellous and cortical bone. Cortical bone is stiffer and forms the exterior surface of the vertebrae. Cancellous bone has lower bone mineral density according to cortical bone and states under the cortical bone layer. The morphology of vertebrae through the spine is changing, however in general the elements of vertebrae (can be seen on Fig. 1.2) are a vertebral body, spinous process, transverse process, pedicle, laminae, inferior and superior facets. For the transpedicular fixation of the different regions of the spine, the pedicle screws are inserted through the pedicle to the center of the vertebral body. This is to advance the 3 dimensional stabilization. Since the pedicle is placed between the two nerve roots and the neighbor of the dural sac, the insertion of pedicle screw in a right position is vital. The position of the pedicle can be seen on Fig. 1.3. As the size and the mass of the vertebra is increasing from the cervical spine to lumbar spine,

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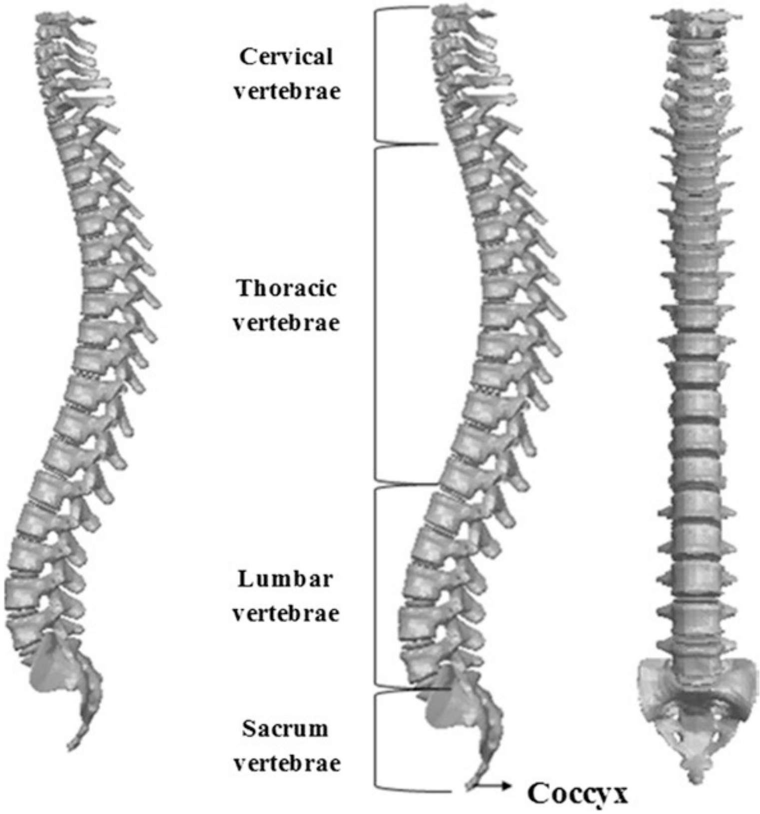


Fig. 1.1 Regions of the spine

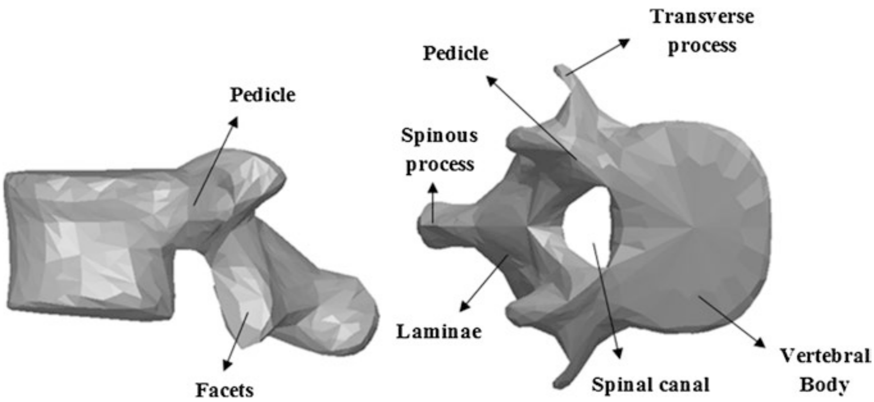
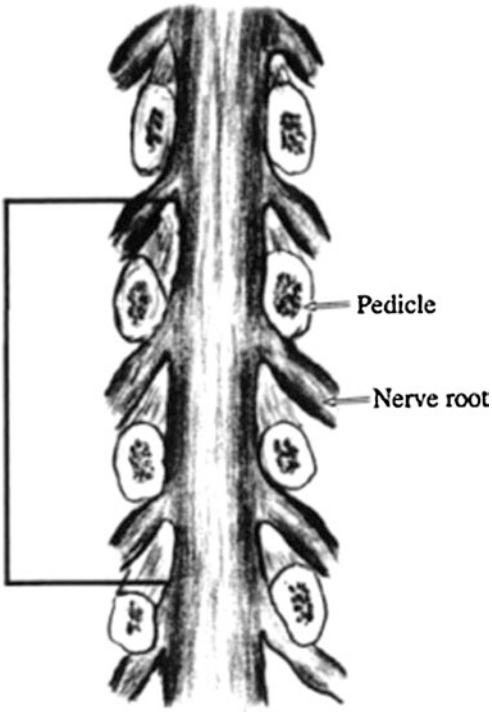


Fig. 1.2 The detailed anatomy of the vertebra

Fig. 1.3 The position of the pedicle (reproduced from Attar et al. 2000)



the pedicle demonstrates different densities and distances to spinal canal and the roots for different segments of the spine.

Uğur et al. [9] investigated important parameters for pedicle screw insertion on upper cervical spine (C3-C7). Since the dural sac is wider at the cervical level, the structure of the vertebrae is quite different from lumbar and thoracic vertebrae. Uğur et al. [9] used human cadavers for 10 different measurements. These were pedicle width (PW) at isthmus (the most narrow pedicle diameter), pedicle height (PH) at isthmus, interpedicular distance (IPD), pedicle-inferior nerve root distance (PIRD), pedicle-superior nerve root distance (PSRD), pedicle-dural sac distance (PDSD), medial pedicle-dural sac distance (MPDSD), mean angle of the pedicle (MAP), root exit angle (REA) and nerve root diameter (NRD) (see Fig. 1.4). They analyzed these values for females and males. This study indicates the importance of pedicle screw placement and the anatomic differences between patients must be taken into account.

Uğur et al. [10] also observed the thoracic vertebrae (T1-T12). In Uğur's study 8 parameters were measured, which are pedicle width (PW) at isthmus, pedicle

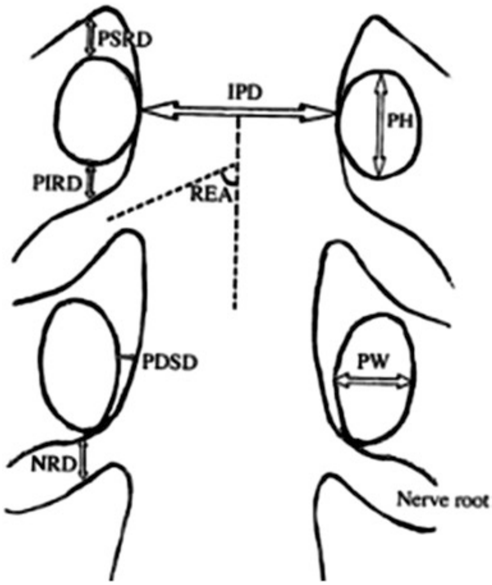


Fig. 1.4 Schematic drawings of the measurements (reproduced from Attar et al. 2000)

height (PH) at isthmus, interpedicular distance (IPD), pedicle-inferior nerve root distance (PIRD), pedicle-superior nerve root distance (PSRD), pedicle-dural sac distance (PDSD), root exit angle (REA) and nerve root diameter (NRD). The results showed that the thoracic pedicles can be different for patients; the CT results of the patient must be carefully analyzed before the transpedicular fixation.

In addition, Attar et al. [6] researched the lumbar pedicle. They investigated the same eight parameters as they did for thoracic vertebrae. They gave each result for all five segments of lumbar region (L1-L5). They concluded emphasizing the importance of the pedicle screw insertion especially medially and inferiorly in lumbar region of the spine.

The pedicle screws used in spinal surgeries can be classified as monoaxial and polyaxial screws. Monoaxial and polyaxial pedicle screws are used in various surgical treatments. Because of the adjustment problem of the monoaxial screws to the rod, polyaxial screws can be alternative as being adjustable to the rod. The pedicle screws also can be separated into two groups for the different head designs as "I" and "tulip" headed screws. Monoaxial and polyaxial "tulip" and "I" headed screws can be seen on Fig. 1.5. In addition to the head designs, for different bone mineral densities different screw designs were developed such as cannulated and expandable pedicle screws. A cannulated pedicle screw allows cement injection through its cannula. Additionally, expandable pedicle screw has an expansion mechanism at the distal part of the screw. These types are classified in Fig. 1.6.

For the clinical use of pedicle screws, all system undergoes a series of standard test protocols. There are several test methods for evaluating the performance

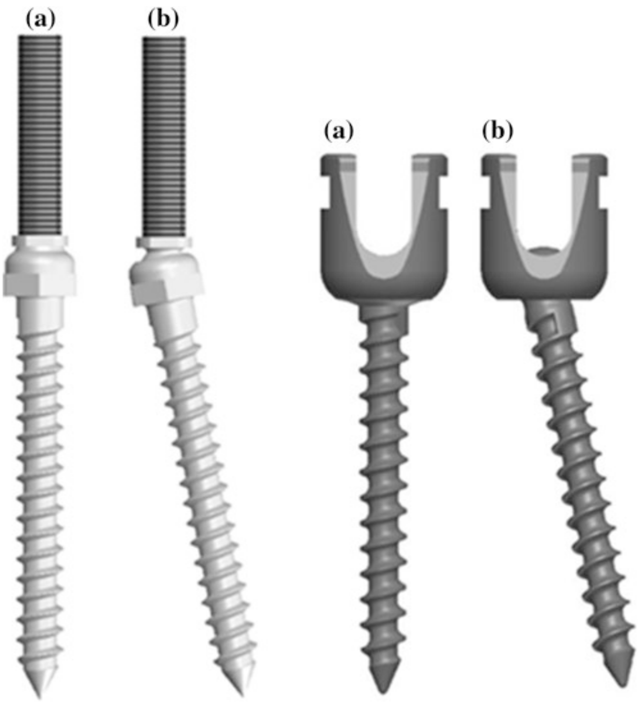


Fig. 1.5 Monoaxial (**a**) and polyaxial (**b**) tulip headed and I pedicle screws

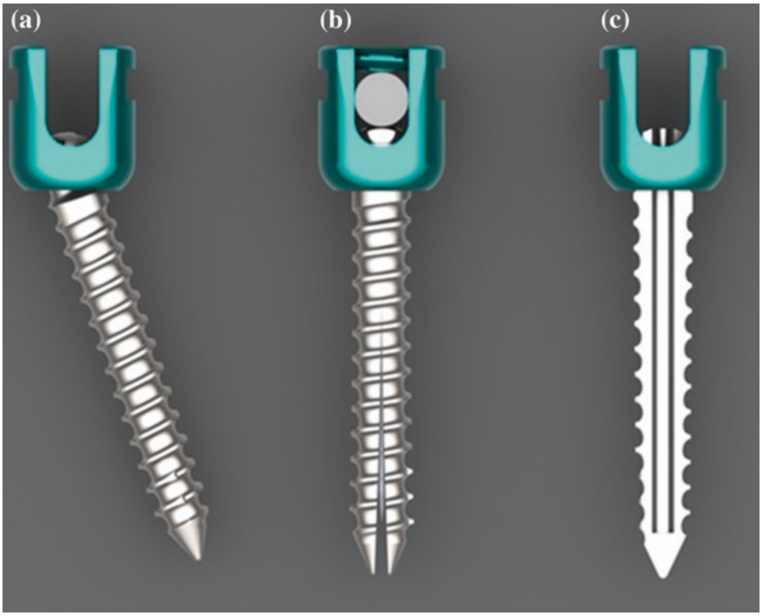


Fig. 1.6 Types of pedicle screws. **a** Standard pedicle screw **b** Expandable pedicle screw **c** Cannulated pedicle screw

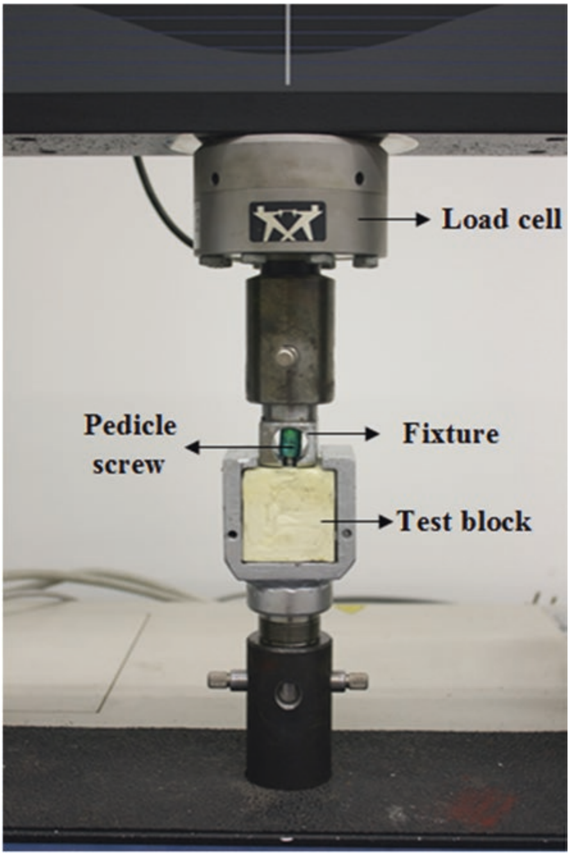


Fig. 1.7 Schematic of test apparatus for pullout test

of pedicle screw. The standards are published by American Society for Testing of Materials (ASTM). The standards related to pedicle screw performances are ASTM F543 [4], ASTM F2193 [5], ASTM F1798 [3], and ASTM F1717 [2]. ASTM F543 [4] regulates the screw's pullout strength, driving torque and torsional strengths of the metallic medical bone screw. ASTM F2193 [5] regulates the mechanical properties of pedicle screw construct components individually. ASTM F1798 [3] regulates the mechanical properties of sub-systems such as axial gripping capacity, torsional gripping capacity and flexion-extension moment capacity of the rod screw connection. In addition to these, ASTM F1717 [2] regulates the mechanical performance of screw rod construct on vertebrectomy model. Fatigue properties of the vertebrectomy models are also investigated in accordance with ASTM F1717 [2].

In this study, we are going to brief the pullout properties of several types of pedicle screws. To make it clearer the pullout test setup that is prepared in accordance with ASTM F543 [4] is given in Fig. 1.7.

1.1 Why Studying the Pullout Performance of Pedicle Screw Is Important?

There are several cases that reports pedicle screw loosening. We believe that there are also several non-reported clinical experiences of pedicle screw pullout failure. Here are some cases stated in the literature about the pedicle screw loosening.

Abul-Kasim and Ohlin [1], studied incidence of pedicle screw loosening on patients who went through segmental pedicle screw fixation. The pedicle screw construct of 81 patients (83 % female) were investigated with low dose CT on 6th week and 2nd year after surgery. They analyzed evidence of screw loosening, evidence of pullout or screw misplacement, coronal Cobb angle (the angle between the inferior most tilted vertebra and the superior most tilted vertebra on anteroposterior radiograph) and rate of screw misplacement. As a result, one or more screws showed loosening indications for 28 % of patients. The percentage of screw loosening evidence was 56 for male where 27 for female. In addition, because of neurological complications of a patient, a revision surgery was conducted. Besides, there was a pullout at maximum 3 mm on 3 of 26 patients, which can be considered as a high rate. Consequently, minor screw loosening was observed on one third of the operated patients after 2 years follow-up.

Another research about pedicle screw loosening was conducted by Wu et al. [11]. They aimed to compare expandable (EPS) and cannulated screws (CPS) used to treat patients who had spinal stenosis in addition to osteoporosis. Patients with spinal stenosis were subjected to lumbosacral fixation either with expandable pedicle screws (n = 80) or cannulated pedicle screws (n = 77). The follow-up time was minimum 2 years. As well as screw loosening, researchers investigated fusion rate, Japanese Orthopedic Association (JPA) score and Oswestry Disability Index (ODI) scoring system and complications. For 7.5 % of the patients with EPS fixation 4.1 % of the screws were loosened and 0.4 % screws were broken. On the other hand, for 19.5 % of the patients with CPS fixation 12.9 % of the screws were loosened and none of them was broken. In other words, pullout problem of EPS was significantly lower than CPS group. In conclusion, EPS can succeed more rigid fixation, however the detailed advantages and disadvantages of expandable pedicle screws will be discussed in next chapters.

In this brief, the studies investigating the pullout strength were systematically classified and reviewed. The articles were divided into the subjects according to effect of screw design, application techniques, cement augmentation, coating and finite element modeling. In addition, testing parameters and embedding medium were also reviewed.

Pedicle screw with radial holes, cylindrical or conical cored pedicle screw, pedicle screws with different thread designs, cannulated and expandable screws all have different pullout responses. This is closely related to their design parameters. Radial holes (holes drilled perpendicular to the normal axis of pedicle screw) significantly affect the pullout strength because of bone in growth through the holes after fusion.

Furthermore, there is a correlation between core geometry and pullout strength. Conical cored, cylindrical cored and dual cored screws all have different core geometries. In addition to the effect of core geometry, thread design is also important for the pullout strength which can increase the interface (flank overlap area) between the screw and bone. The more bone tissues between threads cause the higher pullout strengths. To use the advantage of flank overlap area different designs such as dual lead pedicle screws were studied.

Of course it is not only the screw design that affects the pullout strength. It is difficult to stabilize the vertebrae for the patients with low bone mineral density with normal pedicle screws. Cannulated pedicle screws with cement augmentation and expandable pedicle screw are types of pedicle screws designed for osteoporotic incidents.

In addition to design, it is also important how to apply the pedicle screw through the vertebra. One should avoid decreasing the pullout strength while applying the pedicle screw. In some cases to adjust the rod-screw placement backing out must be done for monoaxial pedicle screws. Than the surgeon has to know how many percentages of strength had been lost. The direction of two pedicle screws applied both pedicles of a vertebral segment is another substantial factor. Pullout strength is also affected by the placement orientation of the screw.

The correlation between insertional torque and pullout strength is another common researched issue that affects the application technique. Most of the researchers found a significant correlation between insertional torque and pullout strength. The temperature during pedicle screw insertion also affects the pullout strength because of micro expansion of the screw. Another application condition was to insert a pedicle screw than pullout the screw first, then insert the pedicle screw again, to demonstrate the revision surgery. The second insertion of pedicle screw was done by either expandable pedicle screws or cannulated screws with cement augmentation.

As mentioned before cement augmentation is commonly used on osteoporotic vertebrae. Different cement materials exhibit different pullout strengths. Cement amount is critical and researched already by numerous researchers. Because more cement amount can provide higher pullout strength. On the other side cement leakage into the spinal canal is still a crucial problem. The cement can be applied both before and after screw insertion and both have different pullout strengths. When cement is injected, it needs time to cure. This curing time is dependable on the cement type and pullout strength does not depend on time if the cement is already cured.

There are also aspects about coating the pedicle screw to increase the pullout strength. The material allows bone in growth on screw surface more than non-coated screws. To coat the pedicle screws there are different mixtures of materials that the most well-known is hydroxyapatite.

To review the pullout strength studies of a pedicle screw 3642 articles were scanned carefully. After a critical elimination under the consideration of a pedicle screw pullout problem, the studies within in the framework of this brief and has an impact in the literature were cited in this study. These 123 studies, which will be separately explained in different subjects, were divided into sub-groups among their research objectives about pedicle screw's pullout strength. As mentioned above, these six main subjects are screw design, application techniques, cement augmentation, coating, test conditions and finite element modeling.

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Chapter 2
Effect of Screw Design

Pullout strength of a pedicle screw is significantly correlated with the screw design. To increase the pullout strength of the screw many researches had already been completed. Pedicle screws with radial holes, different core geometries, thread designs, cannulated screws and expandable screws are different pedicle screw designs with different mechanical properties. Figure 1.6 represents the different pedicle screw types and Fig. 2.1 shows the detailed view of pedicle screw to understand mechanical terms better. These pedicle screw designs were reviewed in this section.

2.1 Effect of Radial Holes

It is important to increase the interface between bone and pedicle screw. The more interface between screw and bone tissues provide more pullout strength. To increase the interface, radial holes could be an option which allows bone in growth through the holes. The number, sequence, angle between the radial holes had already been investigated [32]. A pedicle screw with radial holes could be seen in Fig. 2.2.

For instance, in Demir et al.'s study [15] geometric features of a pedicle screw such as holes drilled normal to screw axis (radial holes), angle and distance between sequential radial holes had been modified and the effects of those modifications were investigated. The screw with the medium core diameter, containing one hole per two pitches, with 90° angle between sequential holes were achieved the optimum results for both pullout and torsional strength. Its pullout performance was also tested on calf vertebra and achieved 84 % of a normal screws' pullout performance. The pullout strength of this screw had been expected to be higher after the fusion.

As a continuation of this work, Arslan et al. [2] compared the novel pedicle screw (which showed optimum results in Demir et al.'s study [15]) with a classical pedicle screw without radial holes. The pullout strength of this newly designed pedicle screw with radial holes and the classical pedicle screw were obtained for post fusion to understand the effect of radial holes. The newly designed pedicle

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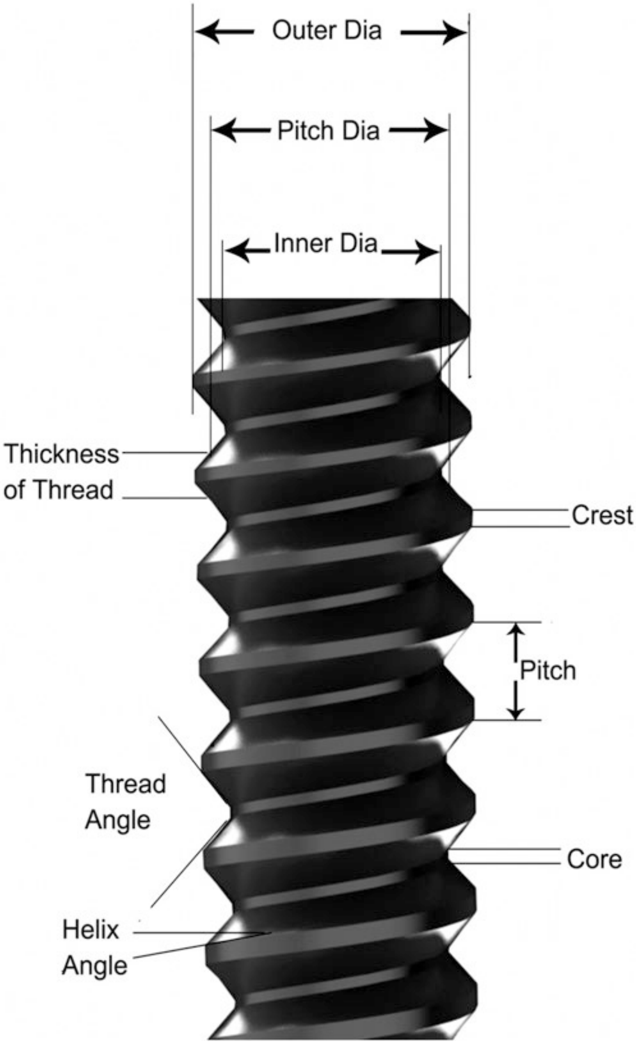

Fig. 2.1 Detailed view of pedicle screw

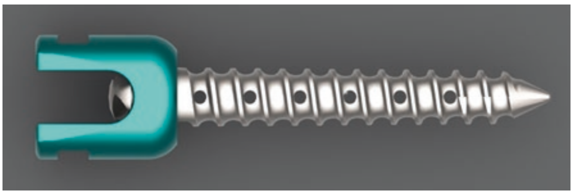

Fig. 2.2 Pedicle screw with radial holes

screw achieved significantly higher pullout values after fusion for osteoporotic bones (70 %), however it did not prove the same success for healthy bones (10 % increment) and severely osteoporotic bones (9 % decrement).

Another useful study about radial holes was made by Mckoy et al. [30] on osteoporotic human vertebrae. They compared the pullout strengths of CPS with radial holes and normal pedicle screw. Both screws were augmented with Polymethylmethacrylate (PMMA). Radial holes increased the amount of the cement exuded from the cannulated screw, so that the cannulated screw showed 2.78 times higher pullout strength than standard pedicle screw.

In addition to Mckoy et al.'s study [30], Chen et al. [9] also investigated the amount of cement exuded from radial holes and also the importance of exudation point. They tested CPS with radial holes cemented with PMMA on polyurethane foams (density = 0.09 g/cm^3) for simulating the severely osteoporotic patient cases. The more radial holes drilled normal to the main axis of the screw, the more amount of cement exuded from the screw which increases the pullout strength. As an expected result, the amount of exuded cement from closer holes to the injection point (proximal side of screw) was much higher than other holes.

In conclusion, radial holes allow osteo-integration for normal pedicle screws, so that the pullout strength increases more than normal PS without radial holes (especially after fusion). However, pullout of a pedicle screw is an early stage problem which occurs before fusion. Therefore, pre-fusion pullout performance of the normal pedicle screw (with radial holes) must be taken into consideration. Besides, radial holes drilled to cannulated screw increase the pullout strength by cement distribution. But, the locations of radial holes are critical for cement leakage risk through the spinal canal.

2.2 Core Geometry

The geometry of the pedicle screw's core can be conical, cylindrical or dual. These three types have all different mechanical strengths. The comparisons of those core types were previously researched [4, 7, 8, 10, 19, 20, 22, 27]. Figure 2.3 shows the pedicle screws with different core geometries.

For instance, Abshire et al. [1] compared the conical cored screws and cylindrical cored pedicle screws with the same thread pitch, flank overlap area, thread contour and core diameter for pullout loads and stiffness. Porcine lumbar vertebrae were used to test those screws. Conical cored screws showed better pullout strength than cylindrical cored screws.

Moreover Kwok et al. [25], compared one conical and four different types of cylindrical cored pedicle screws on human vertebrae. Although conical screws showed higher insertion torque, there was no significant difference between the pullouts of those five different pedicle screws. As another result of this study, insertion torque and pullout strengths were not correlated for all of the pedicle screw types.

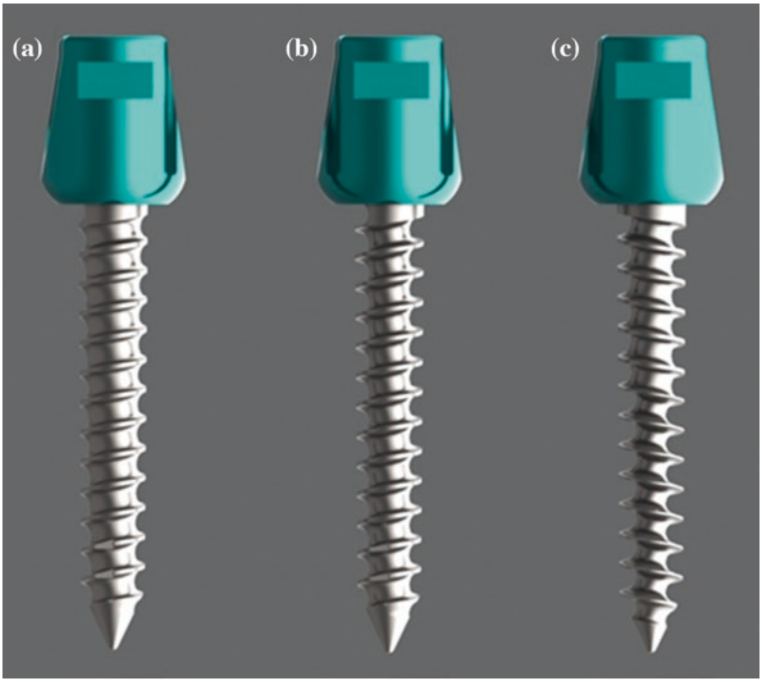

Fig. 2.3 Core types of pedicle screw. **a** Conical cored PS. **b** Cylindrical cored PS. **c** Dual cored PS

On the other hand, Yaman et al. [39] investigated the pullout strength of a dual cored pedicle screw. Three types of screws (conical cored PS, dual lead PS and dual lead dual cored PS) were tested on ovine vertebrae and synthetic foams. The dual lead dual cored PS showed significantly better pullout strength than the other two screws. Dual cored pedicle screw achieved better performance than conical cored pedicle screw.

Another factor which has an impact on core geometry is core diameter. The difference in core diameter influences the flank overlap area and the bone material volume between core and outer diameter [16]. The higher the core diameter was, the less the bone material volume between core and outer diameter and overlap area were. So increasing the core diameter without increasing the outer diameter decreases the pullout strength [2]. For instance, Wittenberg et al.'s study [36] also showed the significant effect of screw diameter on pullout strength.

Finally, it can be concluded that as in most of the studies conical cored pedicle screws showed better pullout performance than cylindrical pedicle screws. However, further studies also came to the solution that the dual cored PS showed higher pullout strength than conical cored pedicle screw. Apart from that, core diameter is an important factor which increases pullout strength if the outer diameter would be kept constant, otherwise it will decrease the pullout strength.

2.3 Thread Design

Thread design of a pedicle screw is another factor that affects the pullout strength [22, 24]. Since, the design of the thread can allow more area between screw threads which called flank overlap area (FOA). As well as FOA, different thread designs such as dual leads can also decrease the operation time which is a vital subject during surgeries. In addition to that, dual lead pedicle screws can provide faster insertion time while maintaining the same pullout strength. More detailed information and researches about these two issues are provided in next two sections.

2.3.1 Effect of Flank Overlap Area (FOA)

As mentioned before the more FOA provides more pullout strength because of higher interface between bone tissue and screw thread.

For instance, Kim et al. [22] investigated different geometric factors (inner diameter, outer diameter and thread shape) of a pedicle screw on three different grades of polyurethane foams. Inner and outer diameter were either conical or cylindrical, thread shape was chosen from V, square and buttress shapes. These different thread geometries are shown in Fig. 2.4. Pedicle screws with V-shaped threads had the highest as pedicle screws with square shaped threads had the lowest pullout strengths. This is an expected result, since V-shaped threads had the highest FOA.

Another study had been made by Krenn et al. [24] to see the effect of FOA with three different pedicle screw designs. Screws were designed indifferent threads, by keeping the length and the outer diameter constant. Those screws were pulled out from polyurethane foam blocks (saw bones) with three different densities. Conical cored, smaller core diameter, larger FOA and moderately small thread pitch provided the best fixation results according to this study.

In conclusion, all those studies showed that FOA is highly correlated with the pullout strength.

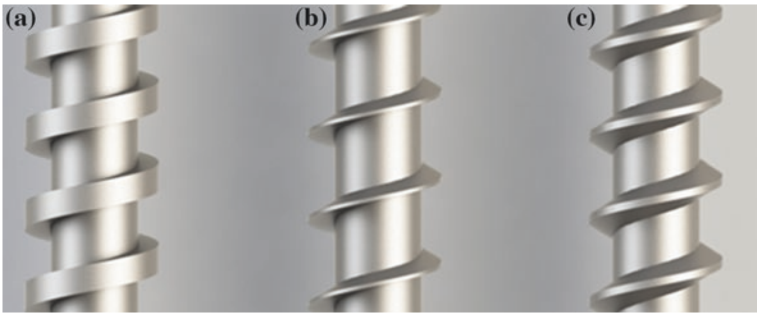

Fig. 2.4 Different thread designs of pedicle screw. **a** Square shape. **b** Buttress shape. **c** V shape

2.3.2 *Effect of Dual Leads*

Dual lead pedicle screws were designed to decrease the insertion time of the pedicle screws [5, 6, 13, 21, 28, 31]. For instance Brasiliense et al. [5] compared dual threaded pedicle screw with the standard pedicle screw. Lumbar vertebrae and polyurethane blocks (demonstrating osteoporotic and normal bone) were used as test medium. Dual threaded PS showed higher pullout strength on high density foams and lower on low density foams than standard PS. This concludes that dual lead is a better option for healthy bone cases.

Another research had been made by Lill et al. [28] for five different pedicle screws that pulled out from calf and human vertebras before and after cyclic loading. Normal pedicle screws were more sensitive to cyclic loading than dual lead screws. As main result of the study dual lead screws had higher pullout strengths than pedicle screws even after screws backed out. Normally, higher pullout performance of the dual lead PS is not an expected result since core of the screw or flank overlap area is not changing because of the dual lead.

Another opinion about dual lead screws is that they show similar pullout strength with normal PS while having faster insertion time. Chang et al. [6] tested two different dual lead PS (thin crest, thick crest) and standard pedicle screw as control group for osteoporotic incidents. Osteogrip thick and thin crests demonstrated similar pullout strengths with standard pedicle screw; however insertion torques of both crests was higher than standard pedicle screw.

Similarly, Mummaneni et al. [31] compared the pullout strength of dual lead and single lead pedicle screws. The pullout tests were conducted on human vertebrae. However, pullout strengths of those two screws were not significantly different from each other.

Furthermore Jacob et al. [21] also tested single and dual lead screws on human cadaveric vertebrae. They found an insignificant difference on pullout strength of single and dual lead pedicle screws as expected.

As the higher pullout performance of the dual lead PS is defended in some cases, it can be concluded that dual lead PS can provide pullout strength as well as normal PS. The best advantage of the dual lead PS is faster insertion time which is vital for the surgeons.

2.4 Cannulated Pedicle Screw

Cannulated pedicle screws are designed for osteoporotic incidents. As bone mineral density diminishes the holding strength of the bone decreases. Cannulated screw with cement augmentation is a viable solution for patients with osteoporosis [3, 11, 14, 33, 40].

For instance, several design parameters on cannulated pedicle screws were investigated in Arslan et al.'s study [3]. CPSs with cement augmentation were tested for pullout strength on polyurethane foams (Grade 10 and 40). For osteoporotic bones CPS with cement augmentation with unilaterally three holes showed the best performance than the other screw designs.

As a future work of this study, Demir et al. [14] investigated the CPSs tested before without augmentation with artificial fusion effect. As a result, cannulated screws without cement augmentation could be a solution for healthy bones according to their promising results. However pullout of a pedicle screw is an early stage problem, so that the results without artificial effect must be considered for this study.

Furthermore, Choma et al. [11] compared non-augmented standard PS, PMMA augmented standard PS, partially cannulated PS augmented with PMMA and fully cannulated PS augmented with PMMA for their pullout strengths and back out torques. Partially cannulated pedicle screw with PMMA demonstrated the highest pullout value between all of those different groups.

On the other hand, Yazu et al. [40] studied the effect of radial holes with cement augmentation in osteoporotic cases. A novel screw with 20 small radial holes was compared with the cannulated pedicle screw by testing the pullout strength. Besides, the novel pedicle screw was augmented with calcium phosphate. The pullout strength of CPS without augmentation was 258 N, while novel pedicle screw with holes was 637 N.

Finally, to increase the effect of augmentation a new designed cannulated screw was tested by Takigawa et al. [33]. This novel screw with PMMA augmentation was compared with a non-augmented normal pedicle screw. The specimens were subjected to axial pullout and cyclic loading tests. Novel pedicle screw significantly increased the pullout strength against the normal pedicle screw for both pullout and cyclic loading test.

As, cannulated pedicle screws with cement augmentation give higher pullout strength than standard pedicle screws, researchers tried to decrease cement leakage probability with different cannulated screw designs, and proved comparable results.

2.5 Expandable Pedicle Screw

Expandable pedicle screw is an alternative to cannulated screws also designed for osteoporotic incidents [18, 37]. Expansion mechanism of an expandable pedicle screw can be seen in Fig. 2.5.

For instance, Vishnubhotla et al. [34] compared the expandable pedicle screw with the standard pedicle screw for osteoporotic human cadaveric vertebrae. As a result, ultimate load and energy required to failure which shows pullout stability of a pedicle screw were significantly higher for the EPS.

Furthermore, Wan et al. [35] investigated the histological and mechanical properties of an expandable pedicle screw. They tested EPS and standard pedicle screw (SPS) on sheep lumbar spines. Pullout and cyclic bending tests were performed to measure the screws' stability. EPS proved 59.6 % higher pullout strength then PS. Besides researchers histologically indicated that, new bone tissue were formed more at the center of the EPS, which improves the screw stability after fusion.

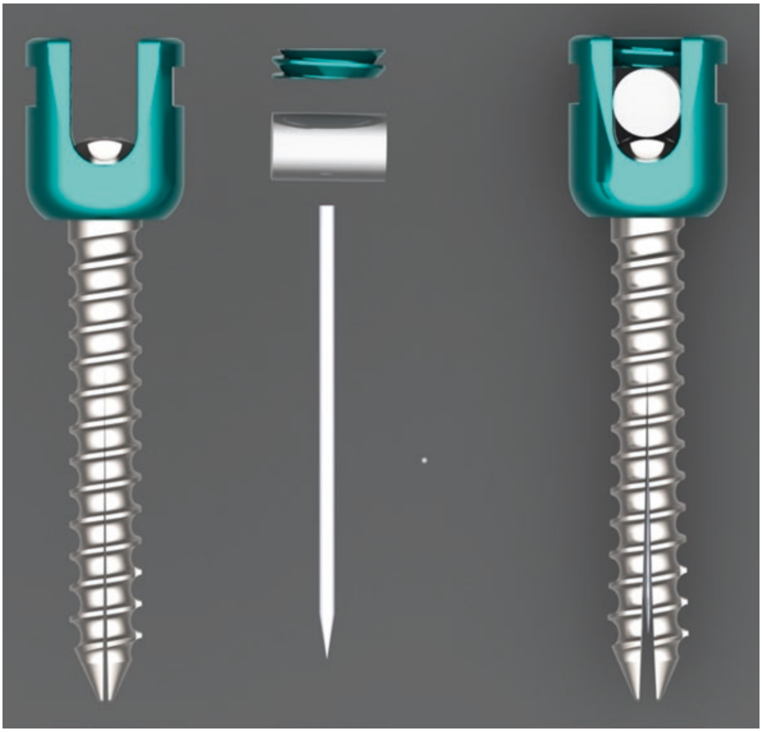

Fig. 2.5 Expansion mechanism of an expandable screw

Moreover, Liu et al. [29] compared the pullout strengths of EPS, SPS and augmented SPS. EPS increased the pullout strength significantly than SPS. Augmented SPS showed higher pullout strength than EPS, however if cement leakage would be taken into account EPS could still be a good option.

In another study, expandable pedicle screws and 3 different conventional pedicle screws' mechanical performances were tested on osteoporotic calf vertebrae both before and after fusion [26]. Expandable PS's pullout strength was higher than both conical and cylindrical cored conventional PS before and after fusion.

Cook et al. [12] also investigated the effect of expandable pedicle screws on human osteoporotic vertebrae. Expandable pedicle screws were compared with standard pedicle screws. Expandable pedicle screws increased the pullout strength 30 % than standard pedicle screws.

On the other hand, Koller et al. [23] investigated a new distal mechanism added to a standard pedicle screw. Mechanical outcomes were compared with standard pedicle screw. The new designed screws' failure load was one-fifth times of the standard screw. So this new screw could be an intermediate alternative to cement augmented screws in osteoporotic bones.

In some cases even expandable pedicle screws cannot ensure the screw stability such as severely osteoporotic patients. That is why researchers investigated the EPS with cement augmentation [17, 38]. For instance Gao et al. [17] tested conventional and expansive pedicle screws with and without cement augmentation on fresh human cadaver spines for normal, osteopenic, osteoporotic and severely osteoporotic cases. The maximum pullout strength, stiffness and energy absorbed to failure were compared for those tested screws. Not only cement augmented but also non-augmented EPS showed better fixation strengths than conventional PS. None of those four different fixation types were useful for the patients with severely osteoporotic bone quality.

Similarly, Wu et al. [38] researched the effectiveness of pedicle screw and expandable pedicle screw with PMMA augmentation. The test groups were divided into four: Conventional pedicle screws, EPS, cemented Conventional PS and cemented EPS. Pullout strength was recorded for those groups. Also an in vivo study was conducted to compare cemented EPS and cemented conventional PS for total 36 cases. As no screw loosening was observed for cemented EPS, 4 screws (4.2 %) were loosened for cemented conventional PS. For both osteoporotic and severely osteoporotic samples cemented EPS showed the highest pullout values.

Cement augmentation can be risky because of leakage through the spinal canal. In such situations expandable pedicle screws can be more preferable than cannulated pedicle screws. On the other hand, revision of expandable pedicle screw is problematic due to bone in growth through expanded fins of screw. It is hard to obtain screw stability on patients with low bone quality. So that expandable pedicle screws can be also used with cement augmentation to increase the pullout strength.

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Chapter 3
Effect of Application Techniques

As well as design, application technique of screw is also important for pullout strength. Surgeons should avoid application techniques which decrease the pull-out strength. Many researches had already investigated tapping, hubbing, fixation techniques and insertional conditions of pedicle screws to increase the holding strength [6, 7, 19].

3.1 Effect of Tapping

Tapping the pedicle screw decrease the pullout strength because of micro cracks caused on the insertion path of pedicle screw [8]. For instance, Chatzistergos et al. [7] compared pullout strengths of tapped, untapped screws and screws used for tapping to understand the effects of tapping on polyurethane blocks demonstrating the osteoporotic bone. Tapped holes were drilled in different sizes, either threaded or cylindrical to understand the effect of pilot hole and tapping. Increasing the outer diameter of threaded hole decreased the pullout strength for tapped screws. Tapping with a tap tool or with a smaller sized screw gave similar mechanical results. Holding strength of the self-tapping screws did not differ significantly from the tapped screws, which is an unexpected result.

In the same manner, Carmouche et al. [6] investigated three different pilot hole preparation (tapping) technique on human lumbar and thoracic vertebrae. No tapping, tapping with same-size screw and one size smaller screw were used for the tested screws. Tapping decreased the pullout strength on human lumbar vertebra, however it did not affect the strength on thoracic vertebrae.

On the other hand, Helgeson et al. [19] investigated the effect of tapping insertional torque on osteoporotic thoracic human vertebrae. Then the pullout results of two groups (1.5 in-lbs or 2.5 in-lbs) were compared. Pullout strength was significantly higher for the second group (2.5 in-lbs insertional torque). They came to the conclusion that tapping insertional torque had correlation with pedicle screws insertional torque and pullout strength.

T. Demir and C. Başgül, *The Pullout Performance of Pedicle Screws*,
SpringerBriefs in Computational Mechanics, DOI 10.1007/978-3-319-16601-8_3

3.2 Effect of Hubbing

Pedicle screw can also be inserted deeper into the vertebra than normal depth of insertion, which called counter sinking method (hubbing). For instance, Paik et al. [32] applied monoaxial screws on osteoporotic and normal human cadaveric vertebrae by hubbed (countersinking method) or standard fixation. As a result of this study, hubbing significantly decreased the pullout strength. In the same time, half of the specimens fractured during hubbing procedure. Additionally, the ones which were not fractured externally, founded to have internal fracture.

3.3 Effect of Backing Out the Pedicle Screw

Monoaxial screws are not adjustable as polyaxial pedicle screws. That is the reason, why monoaxial screws must be backed out for the rod-screw placement. During backing out procedure pullout strength of pedicle screw must be preserved [1, 2, 9, 11, 29].

To observe backing out effect, Abshire et al. [1] divided the test groups of screws into three groups according to their insertion conditions; fully inserted, backed out 180° and backed out 360°. As a result of this study, there were no differences in mechanical properties of either conical or cylindrical cored screws when they were backed out 180° or 360°.

On the other hand, Lill et al. [29] drew attention to a significant difference on pullout strength after backing out of cylindrical and conical pedicle screws. Cylindrical and conical cored pedicle screw were tested when were fully inserted and backed out 180° on calf vertebrae (BMD measured) for the tests. The pullout tests were done either directly or after cyclic loading. When screws were backed out 180° cylindrical cored screws showed significantly higher pullout strength than conical cored screws. That indicated backing out is more dangerous for the conical screws than cylindrical screws.

Moreover, Amaritsakul et al. [2] investigated the effect of backing out on eight different screw designs (seven conventional designs and one novel design). Those screws were inserted on synthetic foams and backed out 360° after insertion, then pulled out. Conical cored screw designs showed higher pullout strength than the other screw designs. However they were less durable to backing out process. On the other hand, dual inner core screw and double dual core screw showed higher stability both before and after backing out.

Backing out for intra operative adjustment is also an important process when screws are needed to be augmented for osteoporotic patients. From this point of view, Cho et al. [20] tested pedicle screws augmented either PMMA or Calcium Phosphate (CP) to understand the backing out a pedicle screw with cement augmentation on human cadaveric vertebrae. As a result, pedicle screw augmented both PMMA or CP could be comfortably removed. However bone growth for CP augmentation must be taken into account in long terms. In the same manner, Chen et al. [9] also tested the screws augmented with PMMA either before perforation or after insertion. The screws were pulled out either after full insertion or after 360° back-out. They also concluded that there was no loss of fixation strength for all cases in this study when pedicle screws were backed out 360°.

3.4 Fixation Techniques

The structure of vertebra had been already researched many times to increase the pullout strength of pedicle screws. A pedicle provides approximately 60 % of the pullout strength [20]. The pedicle and the vertebral body have different bone mineral densities on different areas. Because of this differential density, the varied insertion directions of pedicle screw had been investigated [3, 14, 16, 36].

Firstly, Zindrick et al. [40] investigated different insertional depths by inserting the pedicle screws with various designs into the lumbosacral cadaveric vertebrae. Then pullout and cyclic loading tests were performed for the inserted PS. As a result, pedicle screws which were inserted deeper were more durable to the cyclic testing.

From a different point of view, Crawford et al. [12] investigated different trajectories for pedicle screw by changing the degree of trajectory angle on human cadaveric vertebrae. Angle of trajectory were changed either 10°, 20°, 30° medially or 10°, 20°, 30° laterally. Although 10° medially trajectored screws showed the highest pullout strength, there were no significant differences between pullout values of straight ahead and inward trajectored pedicle screws. Additionally, cortical wall is more prone to get broken for laterally applications than medially applications.

Santoni et al. [34] also showed the sensibility of cortical wall by comparing the traditional medially directed trajectory with cortical bone trajectory on human cadaveric lumbar spines. Pullout, stiffness, failure moment were recorded. New cortical trajectory's pullout strength was 30 % higher than cortical trajectory, however 20 % of new cortical trajectored screws caused wall breach.

Furthermore, Kilinçer et al. [23] conducted a research to investigate the effect of angle between two pedicle screws in a vertebra. 60° screw angle, 60° screw angle with laminectomy and 90° screw angle were prepared as test conditions on calf vertebrae. Then, peak pullout loads were compared. Figure 3.1 depicts the applications of the angle between two pedicle screws on a single vertebra. Mean peak loads of those 3 systems did not differ significantly from each other. Laminectomy had also no effect on pullout strength.

Additionally, Lehman et al. [27] investigated two different insertion techniques by straight forward and anatomic trajectories of pedicle screws. As a result, straight forward trajectory achieved 39 % higher maximum insertional torque and 27 % higher pullout strength than anatomic trajectory.

Moreover, Fürderer et al. [17] compared transpedicular, trans-transverse and supratransverse fixation techniques as different fixation techniques on osteoporotic

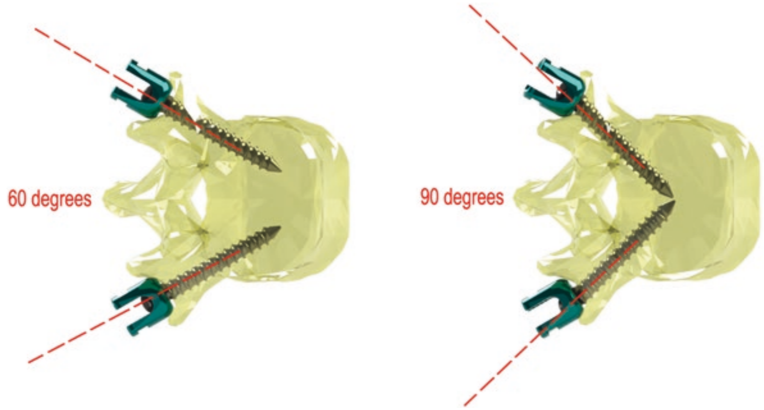

Fig. 3.1 Different angles between two pedicle screws inserted in a vertebra

human cadaveric vertebrae. Pullout strength of pedicle screw for each fixation techniques was recorded. Although transpedicular fixation provided higher pullout strength than trans-transverse and supratransverse techniques, there was no significant difference between these three application types.

Besides, White et al. [37] also compared the transpedicular and extrapedicular fixation techniques. Failure load and stiffness values of the screws were recorded. The screw stability for pedicle screws fixed with transpedicular method was significantly higher than extrapedicular fixed screws for both loads.

Contrary to stability increment by pedicle, Yüksel et al. [38] investigated extrapedicular and intrapedicular fixation techniques and the possible usage of extrapedicular fixation technique as revision surgery method. Pedicle screws were inserted either intrapedicular or extrapedicular on human cadaveric vertebrae and then pulled out. The intrapedicular fixed sides were then inserted this time with extrapedicular fixation technique. As a result, extrapedicular fixed screws could be used as a revision technique of failed intrapedicular fixation.

3.4.1 Misplacement

It is difficult to place the pedicle screw into the pedicle always in the right position. Due to the deformity and the position of vertebrae misplacement can occur. Not only it is dangerous when misplacing a pedicle screw, but also the pullout strength decreases. Medial, lateral and normal perforations are shown in Fig. 3.2.

To analyze the loss of pullout strength while misplacement of the pedicle screw, four types of probable misplacement positions were compared in Brasiliense et al.'s study [5]; standard pedicle screw, pedicle screw with medial cortical perforation, pedicle screw with lateral cortical perforation and "airball" screw (a screw which totally misses the body of the vertebrae). Medially misplaced pedicle

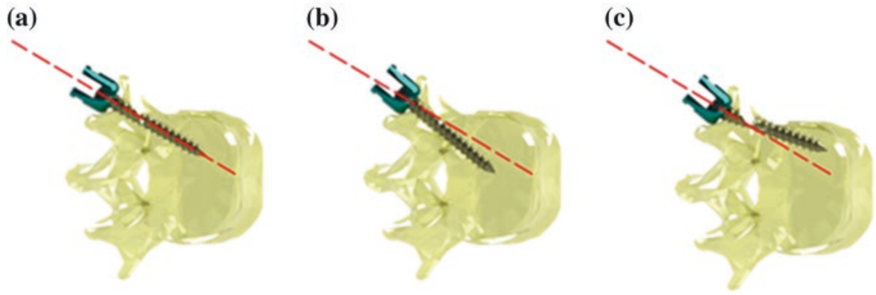

Fig. 3.2 Normal (**a**), Medial (**b**) and Lateral (**c**). Perforation of pedicle screw

screws showed significantly higher and laterally misplaced screws showed significantly lower pullout strength than well-placed pedicle screws. Additionally loss of pullout strength of "airball" screw was observed.

Additionally, to decrease the cortical perforation and root damage (misplacement effects) new designed novel partially non-threaded pedicle screw were tested for pullout strength in Kwan et al.'s study [25]. This novel screw decreased the medial perforation and nerve damage. Also pullout strength of novel screw was not significantly less than normal PS.

3.5 Effect of Insertional Temperature

Insertional temperature is important for the screw stability because of the micro expansion of the pedicle screw after insertion [35]. To understand the effect of different insertional temperatures on pullout strength, pedicle screws were inserted to calf vertebrae on four different temperatures (−100, −35, +4, +24). Then the pedicle screws were pulled out at room temperature. The highest pullout strength on screws that are placed was observed at + 4 °C. In addition to that, the more difference between bone and screw temperature could cause more cracking on bone-screw interface.

3.6 Effect of Insertional Torque

Insertional torque was generally founded to be correlated with the pullout strength and studied by several researchers [1, 21, 26, 29, 35].

For instance, Zdeblick et al. [39] investigated the correlation between pullout and insertional torque in 1993. Insertional torque and pullout strength were tested on human cadaveric vertebrae. As a result, positive correlation was found between insertional torque and pullout strength.

Moreover, Inceoglu et al. [22] tested three types of pedicle screw on calf lumbar spine. Insertional torque, peak torque, pullout and stiffness were recorded.

Contrary to other studies, there was no significant correlation between pullout strength and insertion torque for Xia screws. Because of the Xia screw's design (progressive pitch and thread shape), it showed higher insertional torque and lower pullout strength. In the same viewpoint Mummaneni et al. [31] also showed that there was not a correlation between pullout strength and insertional torque for dual lead PS.

3.7 Effect of Revision

For certain cases such as surgical reasons, implant failures and metal fatigue of stabilization system, revision can be needed [30]. Revision surgeries are challenging for surgeons because the loss of vertebral bone tissues from first insertion. Expandable and cannulated screws with cement augmentation could be solutions for the revision surgeries [10, 15, 18, 28, 33, 38].

For instance, Bostan et al. [4] compared expandable pedicle screws and pedicle screws with PMMA augmentation used for revision surgeries according to their pullout strength. Before and after revision pullout strengths were significantly different for both groups. As a result, both techniques showed higher pullout stability than first insertion as a revision technique.

Moreover, as revision techniques, the pullout strength of pedicle screw either with anatomic trajectored or augmented with Calcium sulfate were compared by Derincek et al. [14]. Anatomic trajectory for revision decreased the maximum insertional torque and pullout strength than straight forward trajectory. On the other hand, cement augmented group increased the pullout strength by comparison to control group. As a result of this study, cement augmentation could be a better solution for revision operations with pedicle screws.

Furthermore, Defino et al. [13] compared dual and cylindrical cored pedicle screws after repeated insertion to understand the stability of these two different screws. The screws were pulled out after first, second and third insertion. The pullout strength difference between after first and third insertion of dual cored screws was 30 %. Similarly, this decrement was 42.3 % for cylindrical cored screws. As a result, dual cored pedicle screw could be a better solution according to its promising pullout result.

Finally, Klein et al. [24] designed partially threaded (no threads in pedicular region) and half-partially threaded pedicle screws to decrease the nerve root damage in revision operations. Those screws and control group (completely threaded) were then subjected to pullout and fatigue tests. Half partially pedicle screws could achieve 80 % of standard screws pullout strength. So that, half partially threaded screw might be a solution without damaging the nerve roots. On the other hand, this new designed screw might be dangerous for the osteoporotic cases due to the less FOA.

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Chapter 4
Effect of Cement Augmentation

It is difficult to stabilize the spine of patients with poor bone quality by normal pedicle screws. To increase the holding strength of screw, different designs and solutions had been found such as expandable and cannulated pedicle screws. Cement augmentation through the cannulated screws increase the pullout strength significantly [17]. In this section, the studies which are concentrated on curing effect of cement, cement types, amount, and application techniques were reviewed.

4.1 Cement Types

Several materials are being used as different cement types [22]. PMMA had been shown as gold standard. On the other hand the bioresorbable materials like calcium phosphate, calcium sulfate also increase the pullout strength significantly when compared to normal pedicle screws without augmentation.

4.1.1 PMMA Augmentation

As mentioned before PMMA had been shown as gold standard of cement material for augmentation. PMMA increases significantly the pullout strength more than any other cement materials [4, 6, 7, 8, 9, 10, 13, 16, 23, 24, 26, 27, 29, 33, 35, 36, 39, 40].

For instance, PMMA was used for cement augmentation in Cook et al.'s [14] study. Non cemented expandable pedicle screw was compared with the cemented EPS on fresh human vertebrae from thoracolumbar spine. Bone mineral densities (BMD) of vertebrae were measured before testing and divided into two groups as osteoporotic and severely osteoporotic. As a result, the mean pullout strength of cemented EPS was two and half times higher than non-cemented EPS for severely osteoporotic bones.

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Moreover, effectiveness of PMMA augmentation in long term was in vivo investigated in Sawakami et al.'s [32] study. Mean follow up period was chosen as 31 months. PMMA augmented screws compared with non-cemented screws. PMMA augmentation increased the incidence of clear zones and fusion rate, as well as decreased the correction loss and back pain of patient.

4.1.2 Calcium Based Cement Augmentation

Although PMMA augmentation has been shown as the gold standard, there are disadvantages like the danger of osteonecrosis because of its exothermic reaction as a synthetic material. Calcium based materials for cement augmentation could be an alternative to PMMA as being osteo-conductive and bioresorbable [12, 15, 19, 37]. Some researches had proved that there was no interface between calcium based cement material and bone tissues after 12 weeks [14]. Calcium phosphate, calcium sulfate and the mixture of them are mostly used as calcium based cement types [3, 12, 29, 30].

For instance, Choma et al. [12] tested CP, calcium sulfate (CS) and mixture of CP and CS augmented pedicle screws' pullout properties and compared with non-augmented group. All types of augmented pedicle screws pullout strengths' were higher than control (non-augmented) group. CP showed the highest pullout strength between all augmented groups. CS followed CP and the mixture of them showed the lowest pullout strength.

In Rohmiller et al.'s [30] study axial pullout tests were performed for non-cemented, cemented with PMMA and cemented with CS pedicle screws on lumbar cadaveric vertebrae. The pullout strength of the pedicle screws cemented with either calcium sulfate paste or PMMA were significantly higher than the non-cemented screws. As calcium sulfate showed similar fixation strength to PMMA, it could be a useful alternative in spinal surgery.

In the same manner, Yi et al. [39] investigated the advantages of calcium sulfate augmentation. Pedicle screws were divided into 3 groups: non augmented, PMMA augmented, CS augmented. Axial pull out and histological tests were done after; 24 h, 6 or 12 weeks. There was no significant difference between 24 h, 6 and 12 weeks on pullout strength for all test groups. Maximum pullout strength was significantly higher for PMMA than CS augmented screws and CS augmented PS than control group. However, CS was completely resorbed after 12 weeks. Resorption of CS also had histologically shown by the thicker bone walls around the screws. As an important result, CS increased the pullout strength over non augmented screws and maintained that effect even after 12 weeks when CS was totally resorbed.

Moreover, Taniwaki et al. [34] investigated the post-operative period of CP augmented and non-augmented groups to show the bioresorbable effect of calcium phosphate augmentation. Post-operative period was specified as 1, 2 and 4 weeks. The vertebrae of living animals that are used in study were osteoporotic. The pedicle screws with augmentation with more period of post operation achieved more pullout strength, which points out the advantages of bioresorbable cement materials.

On the other hand, granular types of calcium based cement augmentation are also used as cement augmentation [20]. The viscosity of the granular cement is higher than normal cement so that the danger of leakage is less than normal cement augmentation. For instance, Hashemi et al. [20] studied granular calcium phosphate as bone augmentation material. Augmented with granular CP pedicle screws and non-augmented pedicle screws were tested for pullout values on polyurethane foams. To demonstrate the osteoporotic and normal incidents, two different densities of blocks were used. The PSs were firstly pulled out and then secondly inserted with cement augmentation to test the effect of cement augmentation for failed screws by pullout. Finally the results showed that the granular CP increases the pullout strength for both failed screws and osteoporotic bones. However for normal bones CP decreased the pullout strength in the short term.

4.1.3 Hydroxyapatite and Cyanoacrylate Augmentation

The effect of hydroxyapatite (HA) augmentation was investigated for patients with osteoporosis in Jang et al.'s [21] study. Radiologic parameters (segmental lordosis, disc height, screw angle, L4 screw angle, and L5 screw angle) were compared between post-operative periods 1 day and 3 months follow up and 1 day and 2 months follow up. To induce the effect of leakage to the spinal canal augmentation to only the distal end of the screw was used for augmentation with a special method. There was no significant changes in radiologic parameters for HA augmented group. On the other hand, there were significant changes in several radiologic parameters for non-augmented group. As the results of this study, HA augmentation could be viable option to decrease the risk of angular displacement of screws and augmentation only at the distal end of the pedicle screw could be a sufficient method without damaging the spinal canal.

In another previous study written by Zhu et al. [41], a novel bioactive bone cement including particles of strontium and hydroxyapatite (Sr-HA) and PMMA were compared for the pullout strength of pedicle screws on osteoporotic human cadaveric vertebrae. Increment of PMMA augmented screws pullout strength was slightly significant. However Sr-HA covered more surface of the pedicle screw than PMMA. So, Sr-HA could be a better option by allowing new bone formation and better osteo-integration in long term.

Finally, Milcan et al. [26] compared the pullout strength of pedicle screws of Butyl-2-cyanoacrylate and PMMA augmentations. Although Butyl-2-cyanoacrylate is a bioresorbable material, there was no statistically difference between non-augmented and cyanoacrylate augmented group. PMMA augmented pedicle screws showed significantly higher pullout strength compared to the native bone or cyanoacrylate augmented group as mentioned before.

4.2 Effect of Cement Amount

As many researches had already proved, cement augmentation increases the pullout strength. The idea first comes to the mind is that increasing the amount of cement will provide higher pullout strength. However, the higher amount of cement, the higher the risk of cement leakage through spinal canal [38].

For instance, to investigate the proper amount of cement, osteoporotic human thoracic and lumbar vertebrae were subjected to pullout force and extraction torque by Paré et al. [27]. The amounts used for thoracic spine were 0.5, 1, 1.5 cc and for lumbar spine were 1.5, 2, 2.5 cc. PMMA augmentation increased pullout force for both thoracic and lumbar spine than standard pedicle screw without augmentation. The highest pullout force achieved for thoracic spine was with 1 cc cement and for lumbar spine with 1.5 cc. Thereby, the idea of higher pullout strength provided by higher cement amount was refuted.

Similar results were obtained by Frankel et al. [18]. They investigated the vertebroplasty augmentation in two different volumes a low-cement group ($\leq$2.8 ml/pedicle) and a high-cement group ($\geq$5.5 ml/pedicle) through a novel fenestrated bone tap which prevents the back flow the cement on human cadaveric specimens. PMMA augmented and non-augmented groups were than subjected to axial pullout tests. However there was no significant difference on pullout strength between those two different volumes.

On the other hand, limiting the cement amount with screw design is another option, which was studied [24]. A new designed screw which allows to partial augmentation was compared with full augmentation. Mechanical properties were measured for both groups and control group (non-augmented). Partial and full augmentation with PMMA significantly increased the pullout strength than non-cemented pedicle screws, so partial augmentation could be used to decrease the leakage risk and allow more interface between bone and screw by providing reasonable pullout strength.

4.3 Effect of Curing

Curing of cement is crucial for all types of polymer based mixtures which needs time. Curing time must be known by the surgeons to manage the timelines of surgery.

Cho et al. [11] investigated the effect of curing by inserting the pedicle screws into cadaveric bones after 2, 4 and 6 min from cement (CP) injection. Also primary and secondary pullouts were done to demonstrate the revision surgery. Primary pullout was first done, then for calculating the effect of curing, cement was injected for secondary pullouts. Secondary pullout strength was significantly higher than primary pullout strength which showed the effect of using CP. Pullout strength due to the timing of augmentation increased from 0 to 4 min and decreased after 6 min. However there was no significant difference between fixation strengths of pedicle screws caused by curing time.

Furthermore, Linhardt et al. [23] tested soft cement, cured cement and control groups on human cadaveric specimens to see the effect of curing in kyphoplasty augmentation. Despite the soft cemented group achieved the highest pullout strength, the difference between soft and cured cemented group was not significant. Non cemented group's pullout strength was significantly lower than cemented group. As a result, cured cement was also a sufficient method when kyphoplasty augmentation is chosen.

Masaki et al. [25] also investigated the timing of the cement by augmenting the cement after 2, 5 or 10 min. Cement augmented group and control group (non-augmented) were pulled out from human cadaveric vertebrae. CP cement augmented screws showed 77 % higher than non-augmented group. Although pullout strength was the highest for pedicle screws pulled out after 5 min, the difference between time groups were not significant. Nevertheless, it is important to make adjustments on PS with augmentation before the cement hardens.

Finally, Ying et al. [40] investigated how to change PMMA augmented pedicle screws depths after 24 h of cement augmentation. The groups upon their depths were unchanged, 3 threads in and 3 threads out. Mean pullout for augmented pedicle screws showed significantly higher than non-augmented pedicle screws. Pullout strength of unchanged PS was significantly higher than screws inserted 3 threads out and screws inserted 3 threads in. As a result it could be seen that adjustment of the pedicle screw following 24 h after cement augmentation significantly decreased the pullout strength.

It can be concluded that curing time do not affect pullout strength significantly, but it is important for the surgeons to make adjustments before cement hardens.

4.4 Cement Application Techniques

Cement can be injected before screw insertion to the pedicle for non-cannulated screw applications. Additionally, cement can also be injected through the cannula for cannulated screws after the screw insertion [23].

For instance, Chao et al. [7] tested those different types of cement application techniques to compare the pullout strengths of these applications. Cannulated screws with cement augmentation divided into two groups as cement filled before screw insertion and cement injected after screw insertion. There was also a non-cemented control group. Pullout strengths of pre-filled and injected after screw insertion groups did not differ statistically from each other, although both of them were significantly higher than control group. However, pre-filled cannulated screws showed lower extraction torque and higher pullout strength than screws with cement injected after insertion, which is useful information for revision surgeries.

Along similar lines, Chen et al. [9] compared solid screws with prefilled cement and cannulated screws with PMMA injection during perforation on polyurethane blocks demonstrating the severe osteoporosis. However, to see the effect of cement application techniques in different screws, conical and cylindrical cored screws were used in tests. Cement prefilling increased significantly the initial fixation strength than injection during perforation for both conical and cylindrical cored screws.

Moreover, Chang et al. [6] made an in vivo research on cannulated pedicle screws with PMMA augmentation on human vertebrae. Visual Analog Scale (VAS) pain scale, ODI and screw migration were recorded for the patients operated with cannulated screws and the results were compared with those reported with the needle injection method mentioned with details in another Chang et al.'s [5] study. These two different techniques were also tested on synthetic bones for their pullout strengths, insertional and back out torques. Clinical results of both techniques were sufficient enough and the difference was not significant. Pullout strength and back out torque for needle injection technique was significantly higher. However as an important result, the cannulated pedicle screw augmented with PMMA decreased the operation time and cement leakage probability.

On the other hand, Renner et al. [29] investigated how the cement distribution affects the pullout strength as an application method. The same amount of cement (PMMA or CP) injected either to the distal part or entire length of the pedicle screw. CP and PMMA augmented screws' pullout values were significantly higher than initial pedicle screws'. CP augmented to the entire length of the screw achieved higher pullout value than only distal end augmented screws, this result can be explained by more interface between cement and the screw for the entire length injected screws. However, the risk of cement perforation through spinal canal must be taken into account for entire length injections.

Osteoporotic vertebral fractures become problematic especially if the spine of patient must be fused with pedicle screws. In those situations, kyphoplasty augmentation is generally used which aims regaining the height of vertebral body, correcting the kyphotic distortion, and forming a gap into which bone cement can be injected with the help of specially designed inflatable or expandable cannulas [4, 28].

For instance, Derincek et al. [16] compared kyphoplasty and transpedicular PMMA augmentation for revision of the failed pedicle screws on osteoporotic calf vertebrae. Pullout strength of kyphoplasty augmentation group was significantly higher than the transpedicular augmentation group. Thereby, kyphoplasty could be an effective method for the revision of failed pedicle screws for the patients with osteoporosis.

In a same manner, Burval et al. [4] compared transpedicular and kyphoplasty augmentation (PMMA) techniques on pedicle screws on osteoporotic human vertebrae. Pullout tests were conducted either before or after cyclic loading. Both techniques showed higher pullout strength than non-augmented pedicle screws on osteoporotic vertebrae. Augmentation with kyphoplasty technique showed significantly higher pullout strength than transpedicular technique. Also PS with kyphoplasty augmentation showed higher pullout strength than PS inserted into normal bones without augmentation.

Differently, Benson et al. [2] investigated three different cement augmentation techniques (kyphoplasty, kyphoplasty through a fenestrated tap and direct injection) on human cadaveric vertebrae by using the advantage of kyphoplasty and the novel tap which reduces the cement leakage risk. The vertebrae, inserted with screws were then subjected to cyclic loading and after that total vertical displacement of screw's head was measured. The pedicle screws tapped with novel fenestrated tap for augmentation was less durable to cyclic loading than the screws augmented with other two techniques. However, decreasing the cement leakage risk through nerves is really beneficial. As a result, Kyphoplasty augmentation using the novel tap with more viscous cement could be an option as being safe and efficient.

Vertebroplasty is another augmentation technique used in vertebral compression fractures due to the vanishing bone mineral density and also to stabilize the spine with pedicle screws on those patients [28].

For example, Becker et al. [1] tested cannulated and standard PS augmented with three different cement augmentation techniques. Osteoporotic human vertebrae were inserted with PS and cement material was PMMA. Cannulated PS and standard PS both with vertebroplasty augmentation showed significantly higher pullout strength than control (non-augmented) group. On the other hand, leakage was observed in some cases with CPS insertion. Kyphoplasty augmentation technique was not significantly higher than control group. Additionally, there was no significant difference between these three different augmentation techniques.

Finally, Sarzier et al. [31] tested vertebroplasty augmentation with PMMA on human cadaveric vertebrae. The vertebrae divided into three groups according to Jekei scale. Vertebroplasty augmentation with PMMA significantly increased the pullout strength than non-augmented group.

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Chapter 5
Effect of Coating

Interface conditions affect the pullout strength of the screw. It is important to have a bonded surface rather than a contact surface between pedicle screw and the vertebrae. For this reason, pedicle screw can be coated with bounding materials to ensure this interface and avoid the screw failures [1]. That explains why the screws are coated with bioresorbable materials to increase the holding strength of the pedicle screws.

Hasegawa et al. [2] analyzed the effect of hydroxyapatite coating both mechanically and histologically on osteoporotic canine lumbar spines. Hydroxyapatite coated pedicle screw (HA-PS) and non-coated pedicle screws' (Ti-PS) pullout strength were measured. Pullout strength of HA-PS was 1.6 times higher than Ti-PS. Histological results of HA coated PS also proved better biological bonding.

Furthermore, different mixtures of coating were also investigated by Liu et al. [3] Coll/Chondroitin Sulfate Coated (Coll/CS), Hydroxyapatite coated (HA), Coll/CS/HA coated and non-coated pedicle screws were compared by inserting them into ovine vertebrae. Pullout and histological results were then investigated. Under non-loading conditions Coll/CS/HA coated pedicle screws had the highest pullout values as non-coated pedicle screws had the lowest. Loading and non-loading conditions did not affect the pullout strength. But histologically under non-loading conditions there was newly grown bone tissue mostly in Coll/CS/HA coated screws. It is indicated that, non-loading conditions are better for coated screws by allowing bone formation between screw and bone tissue.

T. Demir and C. Başgül, *The Pullout Performance of Pedicle Screws*,
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Chapter 6
Effect of Test Conditions

Pullout strength of a pedicle screw is also affected by test conditions. Pilot holes drilled before insertion and bone quality of test medium have all effects on holding strength of a pedicle screw. These effects on pullout strength of different pedicle screw types (Standard Pedicle Screw, Cannulated Pedicle Screw, and Expandable Pedicle Screw) are shown in Tables 6.1, 6.2 and 6.3, respectively. Tables are expected to help further researchers for their studies.

6.1 Effect of Pilot Hole

Pilot holes provide easier insertion for pedicle screws, however they decrease the pullout strength of the PS [14, 23, 59]. To see the influence of pilot hole and pilot hole diameter (equal or smaller) on pullout strength, in vivo tests were conducted on ovine vertebrae [68]. Pullout and insertion torques were measured either immediately when the animals sacrificed or after 8 weeks. Insertion torque and pullout strength were significantly higher for smaller pilot holes as expected.

Moreover, Pfeiffer et al. [63] compared 10 different pedicle screws pullout strength to understand how pilot hole tapping affects the screw's stability. Pedicle screws with untapped pilot holes showed higher pullout strengths on low density bones.

Furthermore, Chen et al. [15] tested CPS with and without pilot holes both cemented with PMMA on polyurethane foams for severely osteoporotic patients. As an expected result, pullout strength was less when screws were inserted with a pilot hole.

Wittenberg et al.'s study [75] also involves the influence of pilot hole as well as cement augmentation. They researched the effect of pilot hole preparation tool on the pullout strength. Consequently, same pilot hole created with a probe or a drill did not differ significantly from each other. George et al. [32] found the same results by testing the hole preparation techniques on human cadaveric vertebrae. They also concluded the difference between the holes prepared by a drill or probe was not significant.

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Table 6.1 Pullout strengths of standard pedicle screws

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Arslan et al. [3]	SPS with radial holes	4-mm conical core-shaped, 6.5 mm (outer diameter), 45 mm (threaded length)		Synthetic foam	160.2 kg/m^3	N/A	N/A	516 (before fusion) 572 (after fusion)
					320.4 kg/m^3			2083 (before fusion) 2546 (after fusion)
					640.7 kg/m^3			5214 (before fusion) 5306 (after fusion)
	SPS	5-mm conical core-shaped, 6.5 mm (outer diameter), 45 mm (threaded length)		Synthetic foam	160.2 kg/m^3	N/A	N/A	518 (after fusion)
					320.4 kg/m^3			1485 (after fusion)
					640.7 kg/m^3			5847 (after fusion)
Demir et al. [25]	SPS	4 mm core diameter		Synthetic foam	640.7 kg/m^3	N/A	N/A	863
	SPS with holes							871
	SPS with holes							869
	SPS with holes							868
	SPS with holes							864
	SPS with holes	5 mm core diameter		Synthetic foam	640.7 kg/m^3			853
	SPS with holes							856
	SPS with holes							852
	SPS with holes							861
	SPS with holes	5.5 mm core diameter		Synthetic foam	640.7 kg/m^3			637
	SPS with holes							628
	SPS with holes							645
	SPS with holes							634
	SPS with holes	5 mm core diameter		Animal cadaver	N/A			1346
	SPS with holes	5 mm core diameter						1548
	SPS	4 mm core diameter						1854

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Gao et al. [31]	SPS			Human cadaver	1.05 g/cm^2	N/A	N/A	1546.54
					0.88 g/cm^2	N/A	N/A	1126.15
					0.7 g/cm^2	N/A	N/A	839.12
					0.51 g/cm^2	N/A	N/A	486.66
					1.05 g/cm^2	Calcium based	N/A	1717.66
					0.88 g/cm^2	Calcium based	N/A	1388.78
					0.7 g/cm^2	Calcium based	N/A	994.79
					0.51 g/cm^2	Calcium based	N/A	516.86
Koller et al. [43]	SPS	6 mm		Human cadaver	0.67 g/cm^3	N/A	N/A	773.8
Abshire et al. [1]	SPS	Conical		Animal cadaver	N/A	N/A	N/A	2634.1
		Cylindrical			N/A	N/A	N/A	2256.5
Rohmiller et al. [65]	SPS			Human cadaver	N/A	N/A	N/A	663
					N/A	Calcium Sulfate	N/A	1105
					N/A	PMMA	N/A	1320
Wu et al. [76]	SPS			Human cadaver	0.693 g/cm^2	N/A	N/A	839.12
					0.693 g/cm^2	PMMA	N/A	994.79
					0.597 g/cm^2	N/A	N/A	486.66
					0.597 g/cm^2	PMMA	N/A	616.86
Hashemi et al. [35]	SPS			Synthetic foam	0.32 g/cc	Granular CP	N/A	2132.5
						N/A	N/A	1840.1
				Synthetic foam	0.16 g/cc	Granular CP	N/A	861.6
						N/A	N/A	688.2
Kim et al. [41]	SPS	Cy/Cy-V		Synthetic foam	80.1 kg/m^3	N/A	N/A	185.00

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
		Cy/Cy-V			240.3 kg/m^3			520.29
		Cy/Cy-V			320.4 kg/m^3			1788.56
		Cy/Cy-B			80.1 kg/m^3			163.18
		Cy/Cy-B			240.3 kg/m^3			441.66
		Cy/Cy-B			320.4 kg/m^3			1162.16
		Cy/Cy-S			80.1 kg/m^3			159.12
		Cy/Cy-S			240.3 kg/m^3			464.33
		Cy/Cy-S			320.4 kg/m^3			1388.46
		Cy/Co-V			80.1 kg/m^3			254.70
		Cy/Co-V			240.3 kg/m^3			849.42
		Cy/Co-V			320.4 kg/m^3			2284.08
		Cy/Co-B			80.1 kg/m^3			204.91
		Cy/Co-B			240.3 kg/m^3			745.73
		Cy/Co-B			320.4 kg/m^3			1970.39
		Cy/Co-S			80.1 kg/m^3			195.80
		Cy/Co-S			240.3 kg/m^3			601.22
		Cy/Co-S			320.4 kg/m^3			1976.59
		Co/Co-V			80.1 kg/m^3			210.98
		Co/Co-V			240.3 kg/m^3			744.90
		Co/Co-V			320.4 kg/m^3			1968.09
		Co/Co-B			80.1 kg/m^3			185.77
		Co/Co-B			240.3 kg/m^3			681.99
		Co/Co-B			320.4 kg/m^3			1805.57
		Co/Co-S			80.1 kg/m^3			171.04
		Co/Co-S			240.3 kg/m^3			471.86
		Co/Co-S			320.4 kg/m^3			1702.61

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Hasegawa et al. [34]	SPS			Animal cadaver	0.549 g/cm^3		Hydroxapatite	165.6
							Titanium	103.1
Esenkaya et al. [27]	SPS	Alıcı 6.5		Animal cadaver	N/A			2910.9
		Alıcı 7						1890.8
		Alıcı 6.5						2900.2
		Alıcı 6.5						3040.9
		Alıcı 7						2117.2
		Alıcı 6.5						3115.8
Krenn et al. [44]	SPS	Thread type 1		Synthetic foam	0.12 g/cm^3			355
		Thread type 2			0.12 g/cm^3			296
		Thread type 3			0.12 g/cm^3			248
		Thread type 1			0.16 g/cm^3			727
		Thread type 2			0.16 g/cm^3			307
		Thread type 3			0.16 g/cm^3			406
		Thread type 1			0.32 g/cm^3			2176
		Thread type 2			0.32 g/cm^3			1526
		Thread type 3			0.32 g/cm^3			1420
Lei and Wu [48]	USS			Animal cadaver	2.219 g/cm^2			1929.9
	Tenor				2.009 g/cm^2			1849.8
	CDH				1.979 g/cm^2			1980.9
Paik et al. [61]	SPS		Hubbed	Human cadaver	0.98 g/cm^2	N/A	N/A	418
			Hubbed		0.468			243
			Nonhubbed		0.980			772
			Nonhubbed		0.468			414

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Chen et al. [15]	SPS	Conical		Synthetic foam	0.09 g/cm^3	PMMA		396
						N/A		35
		Cylindrical				PMMA		421
						N/A		42
Derincek et al. [26]	SPS			Human cadaver	1.686 g/cm^2	PMMA		3443
			Kyphoplasty augmentation		1.432 g/cm^2			2088
					1.686 g/cm^2			3702
			Kyphoplasty augmentation		1.432 g/cm^2			3664
Zhu et al. [81]	SPS			Human cadaver		PMMA		1400
						Sr-HA		928
Liu et al. [52]	SPS			Animal cadaver	1.170	PMMA		598.5
			Partial augmentation		1.14			877.3
			Full augmentation		1.15			744.5
Cho et al. [17]	SPS			Human cadaver	0.89	PMMA		723.1
					0.86	CP		671.2
Choma et al. [18]	SPS		Static loading	Synthetic foam	0.09 g/cm^2	N/A		20.95
						CP		61.16
						CS		45.58
						Mixture of CP and CS		40.34
			Dynamic loading			N/A		20.25
						CP		57.6
						CS		44
						Mixture of CP and CS		41.25

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Fürderer et al. [30]	SPS		Transpedicular	Human cadaver	52.14 mg/cm^3			400
			Supratranverse					368.3
			Trans-transverse					368.3
Brasiliense et al. [7]	SPS		Standard	Human cadaver	0.674 g/cm^2			839.6
			Airball					554.9
			Medial perforation					904.1
			Lateral perforation					660.4
Chatzistergos et al. [14]	SPS	5.50	Tapped	Synthetic foam	0.16 g/cm^3			481
		6.5						480
		7.5						438
			Untapped					443
		4	Screw tapping					473
		5						418
Bostan et al. [6]	SPS	6	Before revision	Animal cadaver	N/A	PMMA	N/A	2162.9
	SPS	6	After revision					2794.3
Crawford et al. [22]	SPS	Control side	30º medial	Human cadaver	0.36–1.88 g/cm^2			1017
			20º medial					1183
			10º medial					1471
			0º					834
			10º lateral					1250
			20º lateral					1256
			30º lateral					1157

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
		Study side	30º medial					1144
			20º medial					1192
			10º medial					1487
			0º					797
			10º lateral					956
			20º lateral					1143
			30º lateral					986
Santoni et al. [66]	SPS		New cortical trajectory	Human cadaver	0.786 g/cm^2			367.54
			Traditional					287.59
Tosun et al. [72]	SPS	Xia	−100 °C	Animal cadaver	742 mg/cm^2			2350
			−35 °C					3230
			4 °C					4440
			24 °C					3730
Chao et al. [12]	SPS	Type I-1		Synthetic foam	0.32 g/cm^3			1926
		Type I-2						1937
		Type I-3						1908
		Type I-4						1809
		Type I-5						1830
		Type II-1						1471
		Type II-2						1497
		Type II-3						1505
		Type II-4						1498
		Type II-5						1494
		Type I-1			0.16 g/cm^3			794
		Type I-2						803

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
		Type I-3						818
		Type I-4						793
		Type I-5						818
		Type II-1						627
		Type II-2						632
		Type II-3						645
		Type II-4						652
		Type II-5						653
Kilinçer et al. [40]	SPS		60° angle	Human cadaver	N/A	N/A	N/A	2070.9
			90° angle					1753
			60° angle with laminectomy					2185.5
Yüksel et al. [80]	SPS		Intrapedicular	Human cadaver	0.585 g/cm^2	N/A	N/A	932
			Extrapedicular					715
			Repair Screw (extrapedicular)					572
Lill et al. [50]	SPS	Type 1		Animal cadaver	0.5 g/cm^3	N/A	N/A	3430
			Backing out					2460
			Cyclic loading					2350
			Backing out and cyclic loading					1750
								3280
				Human cadaver	0.2 g/cm^3			1830
			Backing out					890
			Cyclic loading					970

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
			Backing out and cyclic loading					790
		Type 2		Animal cadaver	0.5 g/cm^3			3980
			Backing out					2590
			Cyclic loading					3000
			Backing out and cyclic loading					2080
								4060
				Human cadaver	0.2 g/cm^3			1830
			Backing out					1100
			Cyclic loading					1060
			Backing out and cyclic loading					850
		Type 3		Animal cadaver	0.5 g/cm^3			3670
			Backing out					2560
			Cyclic loading					2870
			Backing out and Cyclic loading					1840
								4480
				Human cadaver	0.2 g/cm^3			1730
			Backing out					930
			Cyclic loading					1380
			Backing out and cyclic loading					710

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
		Type 4		Animal cadaver	0.5 g/cm^3			3340
			Backing out					2490
			Cyclic loading					3390
			Backing out and Cyclic loading					2200
								3740
				Human cadaver	0.2 g/cm^3			2380
			Backing out					960
			Cyclic loading					1540
			Backing out and cyclic loading					890
		Type 5		Animal cadaver	0.5 g/cm^3			3090
			Backing out					1950
			Cyclic loading					2290
			Backing out and cyclic loading					1920
								3480
				Human cadaver	0.2 g/cm^3			1610
			Backing out					890
			Cyclic loading					940
			Backing out and cyclic loading					630

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Linhardt et al. [51]	SPS			Human cadaver	56.4 mg HA/mL			232
			Soft cement					452
			Cured cement					367
White et al. [74]	SPS		Extrapedicular	Human cadaver	N/A	N/A	N/A	584
			Transpedicular					826
Milcan et al. [57]	SPS			Animal cadaver	N/A		N/A	1550
						BCA		1620
						PMMA		2550
Renner et al. [64]	SPS		Intact	Human cadaver	0.58	CP (only distal end)	N/A	1032
					0.58	CP		839
					0.61	PMMA		910
			Revision		0.58	CP (only distal end)		895
					0.58	CP		1571
					0.61	PMMA		2496
			Augmentation		0.58	CP (only distal end)		1617
					0.58	CP		1852
					0.61	PMMA		2797
Lehman Jr et al. [47]	SPS		Straight forward trajectory	Human cadaver	632 mg/cm^2	N/A	N/A	611
			Anatomic trajectory					481

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Inceoglu et al. [38]	SPS	Xia		Animal cadaver	N/A	N/A	N/A	1783
		7.5 Ost						1943
		6.5 Ost						1641
Klein et al. [42]	SPS	6.50		Human cadaver	0.8344			657
Yi et al. [79]	SPS		24 h	Living animal	N/A		N/A	1030
						CS		1920
						PMMA		3630
			6 weeks					1260
						CS		1850
						PMMA		3750
			12 weeks					1320
						CS		2040
						PMMA		3720
Takigawa et al. [70]	SPS			Human cadaver	0.39 g/cm^2	PMMA	N/A	346
Derincek et al. [26]	SPS		Anatomic trajectory	Human cadaver	0.948 g/cm^2		N/A	297
			Straight forward trajectory					469
		Revision				CS		680
			Straight forward trajectory					477

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Masaki et al. [55]	SPS	5.5	2 (insertion time(min)	Human cadaver	0.713 g/cm^2	CP	N/A	819
			5					850
			10					785
		6.25	2					898
			5					1021
			10					867
		5.5				N/A		549
		6.5						744
		5.5	Revision			CP		1055
		6.5						1202
Kwok et al. [46]	SPS	TSRH		Human cadaver	N/A	N/A	N/A	816.4
		Steffee VSP						723.7
		Diapason						833.6
		AO Shanz						985.2
		Synthes USS						696.1

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Taniwaki et al. [71]	SPS	Osteporotic	1 week (after surgery)	Living animal	N/A	CP	N/A	415.4
			2 weeks					512
			4 weeks					573.5
			1 week (after surgery)			N/A		324.4
			2 weeks					346
			4 weeks					366.8
		Non-osteoporotic	1 week (after surgery)			CP		531.7
			2 weeks					720.3
			4 weeks					732.2
			1 week (after surgery)			N/A		285.2
			2 weeks					381.2
			4 weeks					478.2
Chang et al. [11]	SPS		Needle injection method	Synthetic foam	0.12 g/cm^3	PMMA		234.1
Burval et al. [9]	SPS		Kyphoplasty augmentation		0.71 g/cm^2	PMMA		1414
			Transpedicular					756
			Cycled		0.76 g/cm^2			398
								591
			Cycled		1.08 g/cm^2			811
								1002

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Choma et al. [19]	SPS	Partially fenestrated		Human cadaver	0.581 g/cm^2	PMMA		159
		Fully fenestrated						525
Liu et al. [53]	SPS			Living animal	202 mg/cc	N/A	Coll/CS/HA	994.17
Silva et al. [68]	SPS	Pilot hole 2 mm		Living animal	0.62 g/cm^3	N/A	N/A	2196.9
		2.8 mm						1926.8
Helgeson et al. [36]	SPS		Tapping IT 1,5 in-lbs	Human cadaver	0.6 g/cm^2	N/A	N/A	712.3
			Tapping IT 2,5 in-lbs					877.9
Brasiliense et al. [8]	SPS	Single threaded		Human cadaver	0.794 g/cm^2			1002
				Synthetic foam	0.16 g/cm^3			661
					0.32 g/cm^3			2307
		Dual threaded		Human cadaver	0.794 g/cm^2			1080
				Synthetic foam	0.16 g/cm^3			536
					0.32 g/cm^3			2452
Defino et al. [24]	SPS	Cylindrical cored	After first insertion	Human cadaver	0.156 g/cm^3	N/A	N/A	541.2
			After second insertion					484.4
			After third insertion					312.1
		Dual cored	After first insertion					595.8
			After second insertion					541.8
			After third insertion					421.9

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Jacob et al. [39]	SPS	Single threaded		Human cadaver	0.684 g/cm^2			524.9
		Dual threaded						533.89
Becker et al. [5]	SPS			Human cadaver	830 mg HA/cm^3	N/A		513
			Vertebroplaasty					920
			Balloon kyphoplasty					781
Mckoy and An [56]	SPS		Embalmed specimen	Human cadaver	N/A	PMMA		572.2
			Fresh frozen specimen		0.692 g/cm^2			781.3
Evans et al. [28]	SPS	N/A	N/A	Animal cadaver	N/A	N/A	N/A	1203
						Palacos LV		1970
						Cortoss		2021
Lill et al. [49]	SPS	Cylindrical cored		Animal cadaver	N/A	N/A	N/A	4000
		Conical cored						2700
		Cylindrical cored	180° back out					4300
		Conical cored						1800
		Cylindrical cored	After cyclic loading					7300
		Conical cored	After cyclic loading					5600
		Cylindrical cored	After cyclic loading 180° back out					4000
		Conical cored						2600

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Yaman et al. [77]	SPS	Type A	25 mm synt. Foam	Synthetic foam	Grade-20	N/A	N/A	874
			50 mm synt. Foam					910
				Animal cadaver	2.26 (t-score)			431
		Type B	25 mm synt. Foam	Synthetic foam	Grade-20			820
			50 mm synt. Foam					967
				Animal cadaver	2.26 (t-score)			614
		Type C	25 mm synt. Foam	Synthetic foam	Grade-20			926
			50 mm synt. Foam					1050
				Animal cadaver	2.26 (t-score)			752
Halvorson et al. [33]	SPS			Human cadaver	0.985 mg/cm^2	N/A	N/A	841.2
					1.17 mg/cm^2			1540
					0.818 mg/cm^2			206
Oktenoğlu et al. [59]	SPS		With pilot hole	Synthetic foam				895.5
			Without pilot hole		N/A			995.3
Frankel et al. [29]	SPS		2.9 ml/pedicle (cement amount)	Human cadaver	0.70 g/cm^2	PMMA	N/A	596
								1086
			5.5 ml/pedicle					621
								1872
						N/A		797
			5.2 ml/pedicle (revision)			PMMA		2091

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Soshi et al. [69]	SPS	7 mm		Human cadaver	Normal	N/A	N/A	1056.4
		6.25 mm						1045.7
		5.5 mm						495
		4.5 m						237.2
		7 mm			Initial stage			953.5
		6.25 mm						732.1
		5.5 mm						382.2
		4.5 mm						335.2
		7 mm			Grade I			495.6
		6.25 mm						384.2
		5.5 mm						246.1
		4.5 mm						276.4
		7 mm			Grade II			269.5
		6.25 mm						195
		5.5 mm						185.2
		4.5 mm						78.4
		7 mm			Grade III			274.4
		6.25 mm						174.4
		5.5 mm						–
		4.5 mm						71.5
Cook et al. [20]	SPS		Self-tapping	Human cadaver	0.62 g/cm^2	N/A	N/A	70.76
					0.28 g/cm^2			57.75
					0.95 g/cm^2			82.77

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Mummaneni et al. [58]	SPS		Double threaded	Human cadaver	N/A	N/A	N/A	567
			Single threaded					614.67
Wittenberg et al. [75]	SPS	6 mm	Shanz	Human cadaver	82 mg/cm^3	N/A	N/A	994
		5 mm						459
		6 mm	Kluger screw					1930
		5 mm		Animal cadaver	146 mg/cm^3			1660
		shanz	3.5 mm probe					1990
			3.5 mm drill					1890
		Steffee	3.5 mm probe					2280
			3.5 mm drill					2140
						PMMA		709
								1860
						PFF		633
								1270
Carmouche et al. [10]	SPS		Tapped	Human cadaver	0.833 g/cm^3	N/A	N/A	306.9
			Undertapped					366.88
			Not tapped					325.2
George et al. [32]	SPS		Drilled	Human cadaver	N/A	N/A	N/A	907.4
			Probed					919.8
Sarzier et al. [67]	SPS			Human cadaver	Grade I (Jekei scale)	PMMA	N/A	764.7
								1363
					Grade II			412
								856
					Grade III			289
								576

(continued)

Table 6.1 (continued)

Research	Screw type	Screw properties	Application technique	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Amaritsakul et al. [2]	SPS	CYSID	Full insertion	Synthetic foam	0.32 g/cm^3	N/A	N/A	2115.44
		CYLID						1360.56
		COISID						2401.85
		COILID						1674.71
		CO2LID						1755.04
		DIC						2189.99
		DOC						1509.05
		DDC						2226.93
		CYSID	Backed out 360°					2065.8
		CYLID						1312.61
		COISID						2169.82
		COILID						1545.35
		CO2LID						1460.39
		DIC						2014.28
		DOC						1369.34
		DDC						1941.29
Kwan et al. [45]	SPS	5 mm		Human cadaver	N/A	N/A	N/A	1419.3
			Partially threaded					1336.6
		6 mm						2126.0
			Partially threaded					2036.5
Liu et al. [54]	SPS			Synthetic foam	0.12 g/cm^3	PMMA		217.40
						N/A		48.50
Paré et al. [62]				Human cadaver	t score-6.0			310

Table 6.2 Pullout strengths of cannulated pedicle screws

Research	Screw type	Screw properties	Application techniques	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Chao et al. [13]	CPS			Human cadaver	0.42 g/cm^3	N/A	N/A	144.3
			Cement prefilled		0.39 g/cm^3	PMMA		810.6
			Cement injected		0.43 g/cm^3	PMMA		579.3
Chen et al. [16]	CPS	Conical		Synthetic foam	0.09 g/cm^3	PMMA		321
		Cylindrical						298
Paré et al. [62]	CPS	Fenestrated				PMMA		573
Takigawa et al. [70]	Novel PS			Human cadaver	0.39 g/cm^2	PMMA		346
Taniwaki et al. [71]	CPS			Synthetic foam	0.12 g/cm^3	PMMA		187.8
Choma et al. [19]	CPS	Partially fenestrated		Human cadaver	0.581 g/cm^2	PMMA	N/A	690
		Fully fenestrated				High viscous		612
						Less viscous		501
Yazu et al. [78]	CPS	Twinflex (ordinary screw)		Human cadaver	0.866 g/cm^2		N/A	257.75
		Novel screw with radial holes				CP		637.49
Becker et al. [5]	CPS		Vertebroplasty	Human cadaver	830 mg HA/cm^3	N/A	N/A	917
Mckoy and An [56]	CPS		Embalmed specimen	Human cadaver	N/A	PMMA	N/A	1011.1
			Fresh frozen specimen		0.692 g/cm^2			2956.3

(continued)

Table 6.2 (continued)

Research	Screw type	Screw properties	Application techniques	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Arslan et al. [4]	CPS	S2H		Synthetic foam	Grade 40	N/A	N/A	3034
		S2H			Grade 15			432
		D2H			Grade 40			2795
		D2H			Grade 15			498
		S3H			Grade 40			2782
		S3H			Grade 15			511
		D3H			Grade 40			2768
		D3H			Grade 15			492
		SS			Grade 40			3104
		SS			Grade 15			491
		DS			Grade 40			2936
		DS			Grade 15			462

Table 6.3 Pullout strengths of expandable pedicle screws

Research	Screw type	Screw properties	Application techniques	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Gao et al. [31]	EPS			Human cadaver	1.05 g/cm^2	N/A	N/A	1827.40
					0.88 g/cm^2	N/A		1537.16
					0.7 g/cm^2	N/A		1066.96
					0.51 g/cm^2	N/A		737.44
					1.05 g/cm^2	Calcium based		1916.25
					0.88 g/cm^2	Calcium based		1771.61
					0.7 g/cm^2	Calcium based		1200.71
					0.51 g/cm^2	Calcium based		776.38
Koller et al. [43]	EPS	6 mm		Human cadaver	0.67 g/cm^3	N/A	N/A	910.3
Cook et al. [21]	EPS			Human cadaver	0.51 g/cm^3	N/A	N/A	106.34
					0.51 g/cm^3	PMMA		262.64
					0,72 g/cm^3	N/A		111.56
					0.72 g/cm^3	PMMA		330.83
					0.45 g/cm^3	N/A		102.27
					0.45 g/cm^3	PMMA		209.59
Wu et al. [76]	EPS			Human cadaver	0.693 g/cm^2	N/A	N/A	1066.96
				Human cadaver	0.693 g/cm^2	PMMA		1200.71
				Human cadaver	0.597 g/cm^2	N/A		637.44
				Human cadaver	0.597 g/cm^2	PMMA		776.38
Esenkaya et al. [27]	EPS	Type 1		Animal cadaver	N/A	N/A	N/A	1850.6
		Type 2						2136.2

(continued)

Table 6.3 (continued)

Research	Screw type	Screw properties	Application techniques	Test medium	bmd or d	Cement material	Coating material	Pullout value (N)
Lei and Wu [48]	EPS			Animal cadaver	2.219 g/cm^2	N/A	N/A	2872.7
					2.009 g/cm^2			2604.6
					1.979 g/cm^2			2480
Bostan et al. [6]	EPS	7	Before revision	Animal cadaver	N/A			2605
	EPS	7	After revision					3327.1
Cook et al. [20]	EPS		Self tapping	Human cadaver	0.62	N/A	N/A	91.78
					0.28			85.17
					0.95			98.38
Liu et al. [54]	SPS			Synthetic foam	0.12 g/cm^3	N/A	N/A	84.5

6.2 Bone Mineral Density

BMD of the patient affects the fixation of pedicle screws as indicated before by many researches [26, 33, 60, 69, 73].

For instance, Halvorson et al. [33] investigated the effect of bone mineral density on pullout strength on human cadaveric spine. They concluded that there was a positive correlation between bone mineral density and pullout strength. Likewise, Soshi et al. [69] tested the pedicle screws on five different grades of human vertebrae and find a strong correlation between pullout strength of pedicle screw and BMD.

Moreover, a previous study done by Okuyama et al. [60] aimed to show the relationship between screw loosening, screw failures and BMD. BMD's were measured in patients with or without screw loosening. There was a significant difference between the mean BMDs of patients with and without screw loosening. The BMD's of patients were lower for the screw loosening group than non-loosening group.

Finally, Hirano et al. [37] measured the pedicle cross sectional bone mineral density of vertebra for normal and osteoporotic bones to understand the effect of the pedicle on screw's stability. BMD was significantly lower for the osteoporotic human lumbar vertebrae than normal ones. Also to indicate the importance of the pedicle on screw's pullout, the vertebral body was cut and only the pedicle of the vertebra was tested for pullout strength. As the most important result, 60 % of the pullout strength of the screw depends on the pedicle.

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Chapter 7
Finite Element Modelling Studies

Computer aided mechanical analysis is a common application for engineering problems. Conducting such analysis to newly developed systems can reduce the number of design variations without testing. Finite element modeling (FEM) gives the advantage of disabling the over usage of cadavers, synthetic materials, test equipment and so on.

Following the FEM studies, results are also compared with biomechanical tests to validate the model. There are several studies that FEM were used as a design tool.

For instance, Wagnac et al. [5] investigated the pullout strength of pedicle screw through a detailed FEM to demonstrate pullout mechanism and analyze bone-screw mechanical interaction. New model's pullout strength was compared with experimental data and the predicted pullout strength found within the range of the experimental data. In other words, this research can lead the researchers for the further FEM studies on pullout strength of pedicle screw.

Furthermore, a finite element model was designed in Zhang et al.'s [7] study to determine the effects of bone materials on the screw's pullout. The FE model's pullout strength results in different foam materials were then compared with the experimental results. As a result, bone mineral density was significantly correlated with the stability of pedicle screw.

Chatzistergos et al. [3] also designed a finite element model to predict pullout strength of cylindrical pedicle screws. To obtain experimental results three types of pedicle screws were pulled out from polyurethane foams. Then both results were compared. It was obvious that the new model could be a good predictor of cylindrical pedicle screws' pullout behavior. Recorded parameters which were projected to change pullout strength of a pedicle screw were outer diameter, core radius, pitch, thickness and inclination of the thread. The most recognizable change in parameter was apparently outer diameter. 36 % increment on outer diameter provided 34 % increment on screw's pullout strength, as expected.

Moreover, experimental and finite element analyses were done by Hsu et al. [4] to compare mechanical performances of conical pedicle screws and cylindrical pedicle screws. Experimental studies were performed on polyurethane foams

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with two different densities. Three different screws and three different sizes of each screw type were used for the test. The experimental results were as follows; for the foams with high density, pullout strength and insertion torque was higher than low density foams. Conical screws showed higher pullout and insertion torque than cylindrical screws. Pullout strength and insertion torque was correlated. FEM showed similar results with the experimental results. FEM showed that increasing the outer diameter caused increment on pullout strength approving the Chatzistergos et al.'s [3] study.

Another study was done to compare the conical and conventional cylindrical pedicle screw by Chao et al. [2]. Ten types of pedicle screw with different core tapering and core diameter were tested on polyurethane foams. In addition to those experimental results, finite element models were used and the results were compared with the tests. Conical screws showed higher pullout strength than cylindrical screws as expected. This study showed that there was a good correlation between finite element analysis and the actual test results.

On the other hand Bianco et al. [1] investigated effect of the screw placement on the pullout by FE analysis. Two types of trajectories (straight ahead and straight forward), two different screws (single leaded and dual leaded) and major diameter and length of the screw were parameters that researched in this previous study. The core diameter, length, type of the screw and insertion trajectory were founded to be the main factors that significantly affect the peak pullout force. Screw diameter played a major role on the pullout force and initial stiffness. On the other hand, entry point enlargement 46 % decreased the peak pullout strength of pedicle screw. This was FEM only study.

On another research made by Yan et al. [6], three different finite element models (2 screw-foam models and 1 screw-bone model) were designed to evaluate the proper cement amount injected through the pedicle screw. Region of effect (RoE) and proper amount of injection cement (AIC) were investigated by using these models. The outcomes were compared with the previous experimental data from the literature, and models showed promising results. This FE study could be a lodestar for the future studies and spinal instrumentation with cement augmentation.

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Chapter 8
Conclusion

This systematic review stated the current status of research on the pullout strength of pedicle screws. All types of pedicle screws were reviewed with a focus on pullout properties. Numerous researchers had been studied to increase the pullout strength of screws especially for osteoporotic incidents. Authors of this study paid special attention to the test conditions and the pullout values of previous studies. This study will make easier to understand the underlying factors on pullout problems and how to fix them. The provided tables will give quick and brief information about the pullout properties of all pedicle screw systems that were previously studied.

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