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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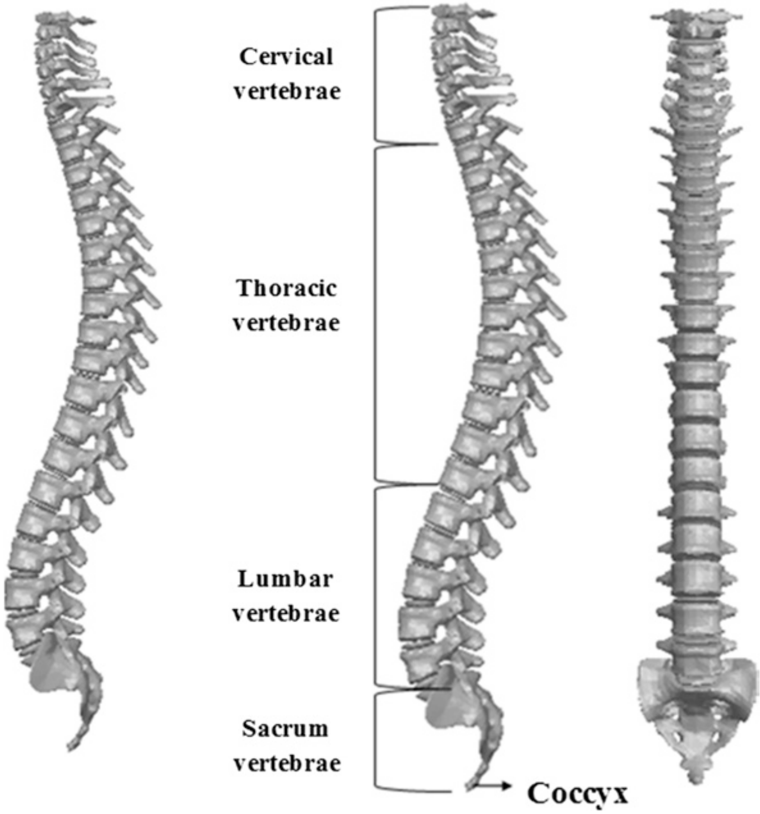


Fig. 1.1 Regions of the spine

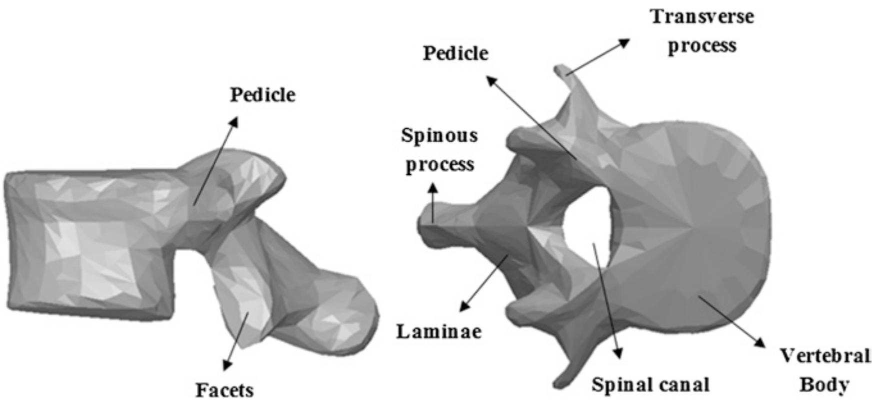
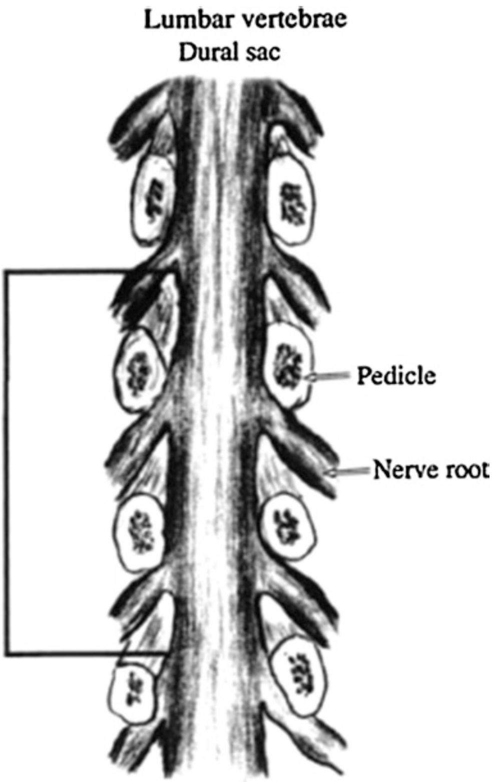


Fig. 1.2 The detailed anatomy of the vertebra

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

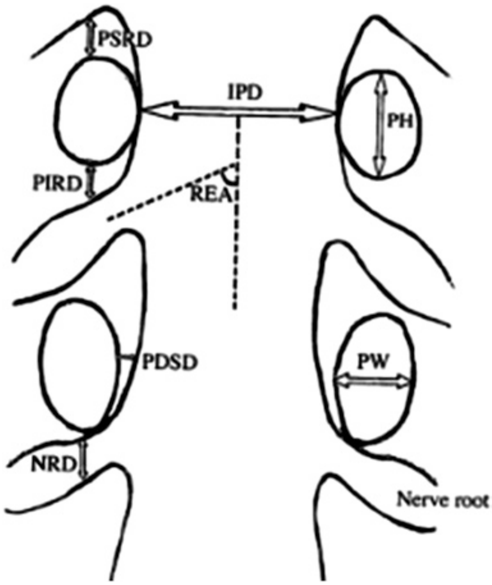


Fig. 1.4 Schematic drawings of the measurements (reproduced from Attar et al. 2000)

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

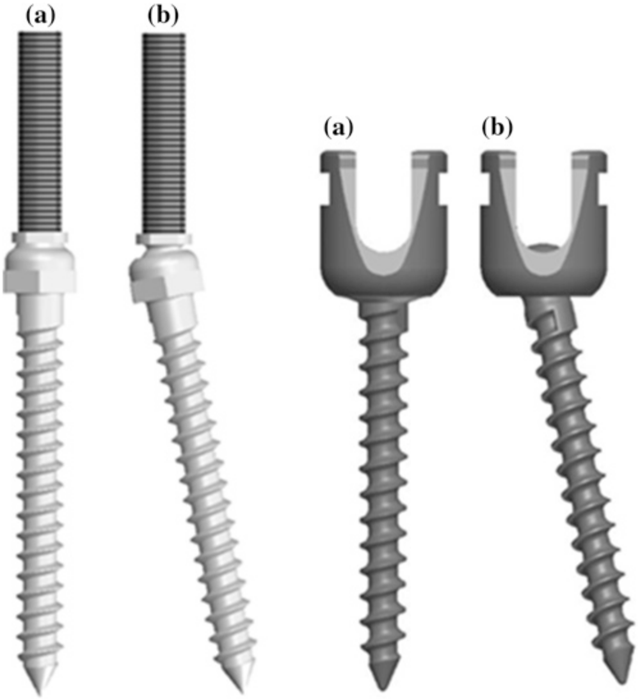


Fig. 1.5 Monoaxial (**a**) and polyaxial (**b**) tulip headed and I pedicle screws

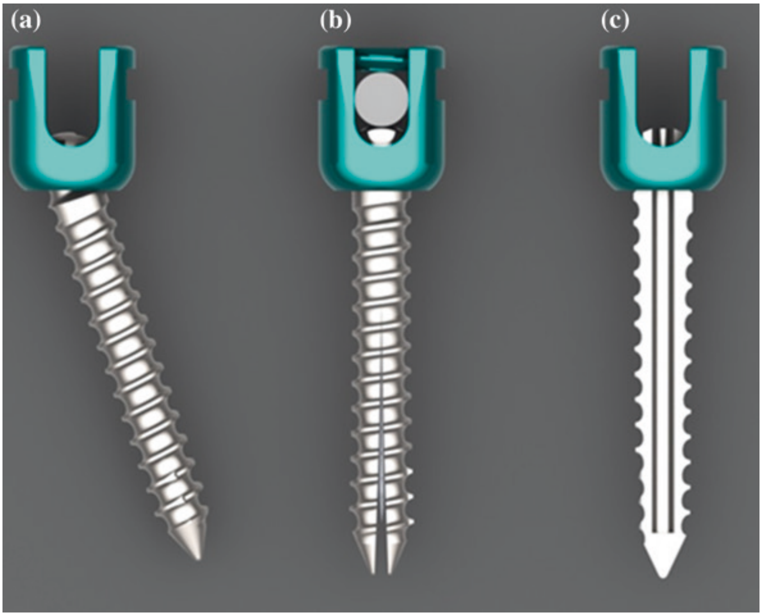


Fig. 1.6 Types of pedicle screws. **a** Standard pedicle screw **b** Expandable pedicle screw **c** Cannulated pedicle screw

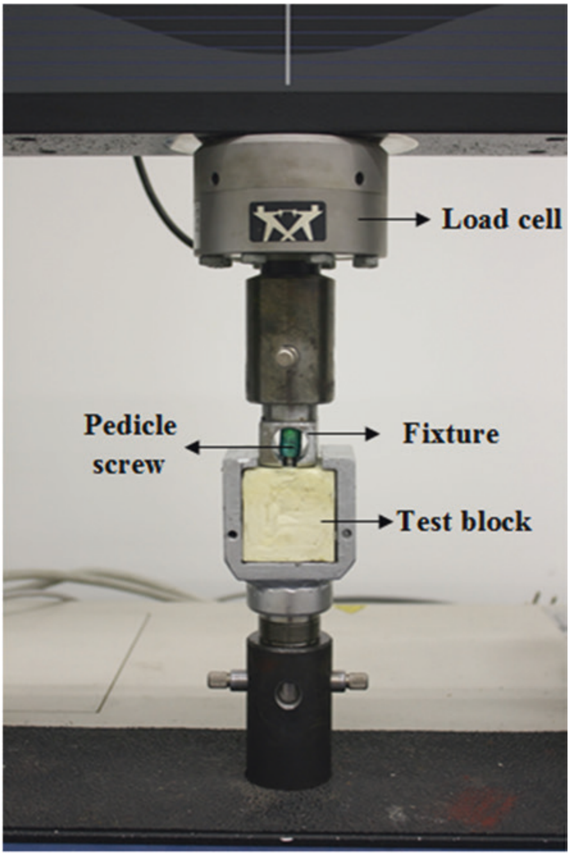


Fig. 1.7 Schematic of test apparatus for pullout test

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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