Osteoporotic Pedicle Screw Augmentation

In recent years, research in biomechanics and orthopedics have focused on issues regarding osteoporosis and surgery methods used in treating patients that can be affected by having osteoporosis. Patients suffering from issues with spinal vertebrae can receive a pedicle subtraction osteotomy (PSO), which is a surgery involving the insertion of screws into the spine to act as anchor points to fasten rods with, in order to grip a spinal segment during a spinal fusion surgery. This procedure has a high rate of failure common in patients suffering from osteoporosis. Research studies are being conducted to evaluate the cause of PSO failure, as well as testing new methods of screw insertion by investigating the mechanical characteristics of pedicle screw insertion in osteoporotic bones.

Osteoporosis is a bone disease that causes bones to become frail as loss of bone mass and density occur. The disease develops when bone mineral density and bone mass decrease, or when the quality of the bone structure changes, such as the porosity of the bone. These changes in the mechanical properties of the bone can lead to a decrease in bone strength, and lead a higher risk of broken bones, most commonly spinal vertebrae, hips, and wrists [1]. As the bones cannot support the same amount of strength as normal healthy bones, complications occur in bone related procedures. Setting a screw in a weaker material may cause failure of the screw earlier, or for the material to splinter and crack. As a result, multiple studies have arisen in recent years targeting the use of pedicle screws in osteoporosis patients.

Pedicle screws are bone screws that are set into the pedicle of a spinal vertebrae (Fig. 1). These screws are used to correct trauma or deformity in the spine by fixing rods or plates to the screws. The screws are used most commonly in the lumbar spine, although they can be inserted in the thoracic and sacral vertebra [2]. During the PSO surgery, a surgeon places pedicle screws above and below the targeted area of the spine, then create wedges in the spine and rectifies the

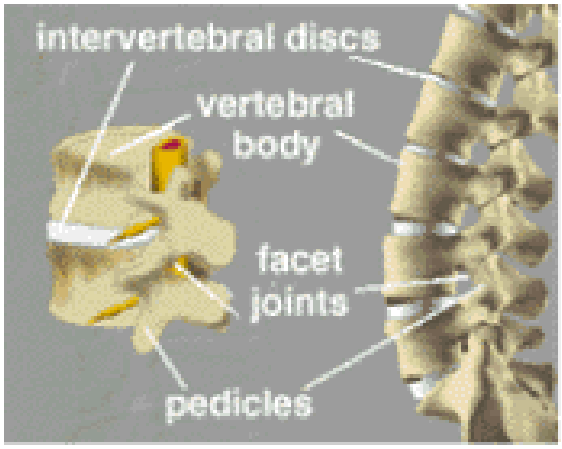

Figure 1: Spine anatomy [2]

spine using a secondary procedure. Rods are attached to the pedicle screws afterwards to keep the spine in place and are left in the body to aid in healing. Although the screws and rods are not needed after the healing process is complete, they are usually left inside the body, and a second surgery to remove the screws is not required.

In the study *Biomechanical analysis of pedicle screw thread differential design in an osteoporotic cadaver model* by Mehta *et al*, pedicle screw designs were tested with osteoporotic cadavers to evaluate the effectiveness of the designs. Standard screws were compared to screws with differential crest thickness dual lead screws. Using six human spines, lead screws of two crest thicknesses and three different insertion techniques were fixed to the spines. The bone mineral density and peak insertion torque values were both measured to determine the mechanical properties of the inserted screw. In this study, the screws designed specifically for osteoporotic patients illustrated significantly greater insertion torque when compared to standard pedicle screws, with the varying sizes of the lead screws providing similar results [3].

In a study conducted by Burval *et al*, pedicle screw pullout tests were conducted in osteoporotic cadavers using augmentation techniques to improve the strength of pedicle screw insertions. The study, *Primary Pedicle Screw Augmentation in Osteoporotic Lumbar Vertebrae: Biomechanical Analysis of Pedicle Fixation Strength,* used both osteoporotic and healthy lumbar vertebrae of the spine to test the insertion of pedicle screws augmented with polymethyl methacrylate. Using kyphoplasty and transpedicular insertion techniques randomly, the pedicle screws were inserted in the vertebra and pullout failure tests were performed before and after 5000 cycles of fatigue conditioning. Using the polymethyl methacrylate proved to increase the fixation strength and fatigue strength of the pedicle screw in osteoporotic vertebrae. The kyphoplasty insertion technique provided a significantly greater pullout strength than the transpedicular augmentation method [4].

The methods of each study are similar, as both studies conduct pullout tests of the screws used in order to assess the effectiveness of the screw and insertion method. In the study conducted by Mehta *et al*, three lead screws with varying crest thicknesses were tested against a standard pedicle screw (Fig. 2). The three insertion techniques used were untapped, under-tapped by 1 mm using a single lead tap, and under-tapped by 1 mm using a dual lead tap. A dual energy X-ray absorptiometry (DEXA) scan was conducted to determine the bone density of each specimen. The spinal vertebrae were fastened to a plexiglass board and surgeons inserted the screws, with randomized spinal level, screw type, and insertion method. After insertion, each screw was pulled out using an Instron uniaxial tensile testing machine at a rate of 5 mm/min using [3].

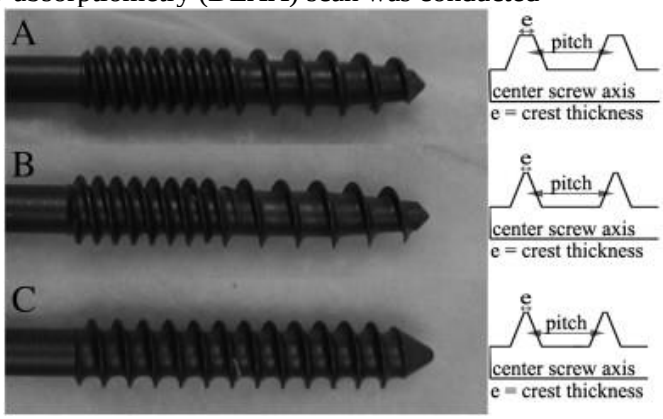

Figure 2: lead pedicle screws tested [3].

In the study by Burval *et al*, the procedure used to conduct the tests are similar. Lumbar vertebrae from cadavers of both healthy and osteoporotic bones were used in testing. Three osteoporotic specimens were used to establish a baseline, and ten specimens were used to test the transpedicular and kyphoplasty augmentation methods. In each augmentation method, the pedicle screw was inserted with a cavity created to inject polymethyl methacrylate cement to the bone and screw (Fig. 3). After the polymethyl methacrylate cured, each specimen was fastened to a testing pot using Cerrobend metal alloy in preparation for biaxial stress testing. The specimen was then fixed to a vise and loaded into a servohydraulic biaxial testing machine. after insertion, the screws used were subjected to cyclical fatigue loading of 5000 cycles at 3 Hz to simulate physiological loads of the lumbar spine. After the fatigue loading, the screws were pulled out at a rate of 1 mm/min [4].

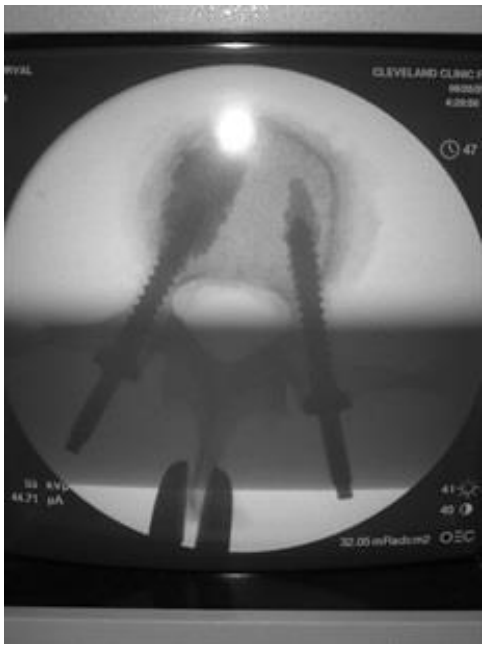

Figure 3: Kyphoplasty and transpedicular augmentation

While both studies test the pullout strength of screws, there are a few core differences in the methods of insertion as well as testing of the screws. In the study by Mehta *et al*, the variable being tested were newly designed pedicle screws with varying crests. The screws were inserted into the bone using various tapping methods. The screws were not subjected to fatigue cycle loading, and were pulled out at 5 mm/min. In the study by Burval *et al*, the variable being tested in screw insertion was the addition of a polymethyl methacrylate cement to help secure the screw to the bone. As a result, kyphoplasty and transpedicular techniques were used to insert the cement into the tapped holes. The screws were then treated to a cyclical fatigue loading before pulling out the screws. Although the methods of preparing samples varied in each study, they both used tensile testing machines to conduct uniaxial stress tests to remove the screw from the bone sample.

In Mehta's study, significantly larger torque values were recorded for the newly designed Osteogrip screws compared to that of the standard pedicle screws. The Osteogrip screws had a higher failure load, and yield strength than that of the standard screws tested. The Osteogrip screws maintained a pullout strength of 424.82 MPa while standard screws had a pullout strength of 351.12 MPa when using the dual tapping method (Fig. 4). The tapping conditions caused variability in the data, but each tapping method provided similar results, along with similar standard deviation and variance in insertion torque and pullout yield strength values [3].

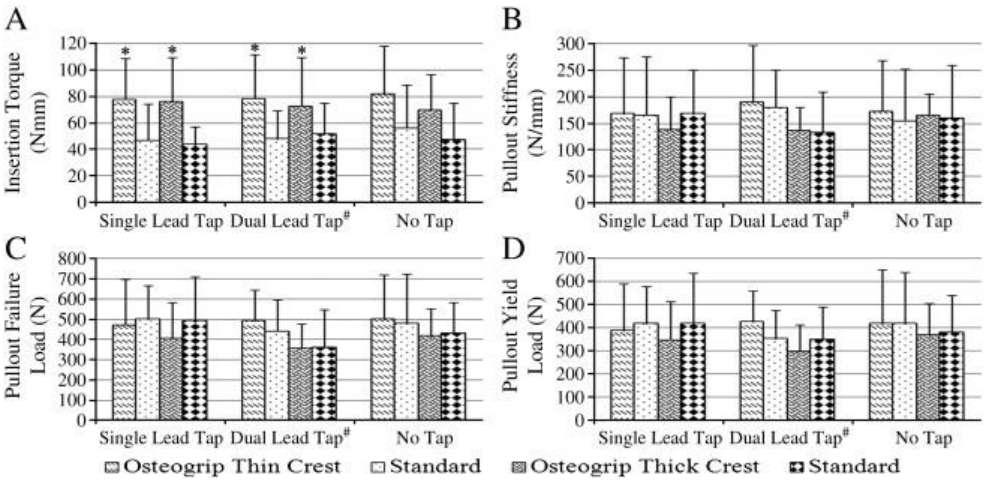

Figure 4: Pullout strength test data

The study by Mehta *et al* examined varying crest sizes in pedicle screws to improve the pullout strength of the screws in spinal vertebrae. In testing, the Osteogrip screws had a significantly higher insertion torque and pullout strength. Using each of the various tapping methods led to similar results. Clinically there is a theory that greater insertion torque leads to better screw and bone interaction and can predict mechanical stability of the system. The data supports this theory, with the insertion torque and pullout strength having a positive correlation. This study is limited in the sample size, as the test samples are osteoporotic human vertebrae. The results also experienced a high degree of variability, as the bone densities of each sample fluctuated greatly with the degree of osteoporosis. The pullout strength testing conducted is also most likely not the orientation in which the pedicle screw will fail in-vivo.

In Burval's study, similar results were found. The pedicle screws inserted in osteoporotic vertebrae had larger pullout loads when reinforced by kyphoplasty rather than transpedicular augmentation, where kyphoplasty screws had a pullout load of 1414 N, 80% larger than that of transpedicular augmentation (Fig. 5). When tested with fatigue cycle loading, the kyphoplasty still provided a higher pullout resistance even against the control tests with healthy vertebrae. Vertebrae tested with transpedicular augmentation did not maintain pullout loads higher than that of healthy bone. The average bone density of the osteoporotic vertebrae used in testing was 0.72 ± 0.07 g/cm^2 [4].

Table 2. Average Pullout Loads per Group

	Group	Pullout Load (N)	No.	BMD (g/cm^2)	Age/Gender
1*	Osteoporotic kyphoplasty type augmentation	1414 ± 338	10	0.71 ± 0.08	54 ± 22/(4 M/4 F)
2*	Osteoporotic transpedicular augmentation	756 ± 300	10		
3†	Osteoporotic control	398 ± 97	3	0.76 ± 0.02	58 ± 4/(1 M/2 F)
4†	Osteoporotic control	591 ± 160	3		
5‡	Normal control	811 ± 361	9	1.08 ± 0.10	60 ± 5/(4 M/1 F)
6‡	Normal control	1002 ± 396	9		

*, †, ‡ indicate indices designating paired groups.
F indicates female; M, male.

Figure 5: Average pullout loads per group

The study by Burval *et al* tested the augmentation of pedicle screws in order to improve the pullout strength of the screws in lumbar vertebrae using polymethyl methacrylate. The results illustrate that using either transpedicular or kyphoplasty techniques increase the pullout failure load up to 300% in

osteoporotic vertebrae. When compared to healthy vertebrae, the kyphoplasty technique still performed significantly higher. The cyclical loading fatigue had a negative effect on the test samples. The fatigue caused a 20% decrease in pullout loads in healthy vertebrae, and a 33% decrease in pullout load in osteoporotic vertebrae. Although the data collected supports the analysis, this study is limited in the bones used, as the varying bone densities, architecture, and pedicle morphology of osteoporotic vertebrae caused variance in the data. As with the study by Mehta *et al*, the testing is limited by sample size of the human osteoporotic vertebrae.

In both studies, the augmented pedicle screws tested provided the largest pullout strength. Both studies were similar, using osteoporotic spinal vertebrae for test specimen. The study by Burval *et al* used healthy human spinal vertebrae as a control group, and only used spinal vertebrae from the lumbar. As Mehta's study was heavily limited in the number of specimens, the tests were conducted using every region of the spine and only using osteoporotic vertebrae, extrapolating the data for healthy human vertebrae. Both studies experienced high variability in the data due to the variance in bone density of the osteoporotic bone samples, due to the varying levels of osteoporosis in each sample.

Although the main objective of each study was to improve the pullout strength of pedicle screws when inserted in bone, the methods of insertion, augmentation, and testing vary between the studies. The study by Mehta *et al* focused on the redesign of the pedicle screw used. Rather than redesigning the pedicle screws, Burval's study tested the ability to use adjunct spine surgeries to strengthen the bone before inserting the pedicle screw. While both studies illustrate more effective methods of pedicle screw insertion, Burval's study provides inaccuracy in its testing. The amount of polymethyl methacrylate cement used in kyphoplasty and transpedicular augmentation varied, being 4 cc and 2.5 cc respectively. The superiority of kyphoplasty in having a larger pullout strength could be attributed to the increased polymethyl methacrylate used, or the augmentation technique itself. Despite the variation in testing, both augmentation methods are more effective than standard pedicle screw insertion.

The study by Burval *et al* provides a large margin of uncertainty in the data, but Mehta's study lacks a range of tests. Burval's study conducts fatigue preloading of some samples to provide a more accurate model of a failing pedicle screw. Mehta's study ignores the necessity of fatigue testing, and only conducts standard pullout tests. Since sample size was a large limitation in Mehta's study, only one form of stress test could be performed. Despite the small sample size, conclusive results were able to be determined from the data. Although these studies tested the pullout strength of pedicle screws, it is highly unlikely that the screws will fail in this orientation. Ductile screws in a brittle material tend to fail due to shear stresses. Further testing is required to fully define the mechanical properties of each screw augmentation method.

Bibliography

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