

INFLUENCE OF ORIFICE DEPTH AND PREPARATION ON THE INSERTION TORQUE AND PULLOUT STRENGTH OF PEDICULAR SCREWS

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Abstract. *Pedicular screws are the basis of any vertebral fixation system. Implants are used for the treatment of vertebral diseases. The objective of the present study was to assess the influence of the depth of screw insertion in situations of variation of orifice size, on the insertion torque and pullout strength of pedicular screws inserted into the vertebral bodies. Pig vertebrae and USSI Synthes® screws 5 mm in diameter were used. The holes were drilled with 2.5, 3.8 and 4.5 mm burs and a Mackenna® torque meter was used. The following six experimental groups with 10 test models each, were used: Group 1 – 2.5 mm burr (B) and screw inserted up to the head (Final); Group 2 – 2.5 mm B and only the threaded part of the screw inserted (Thread); Group 3 – 3.8 mm B and Final; Group 4 – 3.8 mm B and Thread; Group 5 – 4.5 mm B and Final; Group 6 – 4.5 mm B and Thread. The pullout tests were performed using an EMIC® Universal Testing Machine. The mean maximum pullout strengths and insertion torques were, respectively: Group 1 – (1014.7 ± 153.3) N and (1.39 ± 0.21) N.m; Group 2 – (909.9 ± 109.9) N and (0.87 ± 0.22) N.m; Group 3 – (996.9 ± 107.4) N and (1.04 ± 0.19) N.m; Group 4 – (947.7 ± 165.4) N and (0.57 ± 0.13) N.m; Group 5 – (862.6 ± 141.2) N and (0.78 ± 0.19) N.m and Group 6 – (669.6 ± 176.9) N and (0.34 ± 0.11) N.m. Data were analyzed by ANOVA and the Tukey-Kramer test, with the level of significance set at 5%. Comparison of pullout strength did not show significant differences between groups 1 and 3 and groups 2 and 4, whereas comparison of Groups 1 and 5, 3 and 5, 2 and 6 and 4 and 6 showed significant differences. All comparisons of insertion torques showed statistically significant differences between the 6 groups.*

Keywords: *Pedicular screw, vertebral fixation, pullout strength, pig vertebrae, insertion torque.*

1. Introduction

Several diseases and injuries can lead to spinal instability such as rachimedullary traumatism, spondylolisthesis, post-laminectomy instability, scoliosis, and tumors, among others. Many techniques and surgical instruments have been developed over the years in order to provide spinal stability.

After removal of the lesion, there is the need for stabilization and arthrodesis of the vertebral segment involved when vertebral stability has been compromised (Defino, 2002). The use of a vertebral pedicle as the site for implant anchorage was first described by Bechtol (1959) and later by Harrington and Tulos (1969) and Roy-Camille and Demeulenaere (1970), with the last authors acting as the disseminators of this technique.

A wide variety of internal fixations have been used for the treatment of spinal disorders. The advantages of the technique of pedicular fixation are the preservation of the normal spinal segments and a good control of all the vertebrae (Aldini et al, 2002). This system has advantages over the ones previously used such as permitting the fixation of only the unstable vertebrae, thus preserving the mobility of other spinal segments, permitting smaller surgical incisions with a consequent more rapid patient recovery associated with a more comfortable (less painful) postoperative period. Also, the degree of rigidity and the quality of arthrodesis in the abnormal segment are superior to those obtained with previous instrumental approaches; during the insertion of the screws there is no need for sublaminar wires with a

reduced possibility of neurological damage during surgery. In cases in which it is necessary to remove the synthesis material, this is done in a much easier manner compared to old instruments. Based on all of these advantages and effective qualities, titanium alloy and/or stainless steel transpedicular screws are being extensively and successfully used for lumbar stabilization.

Vertebral fixation implants started to be used systematically after the development of stainless steel at the end of the 1930 decade. It was then that the first internal fixators were created for the treatment of vertebral fractures. The most recent advance in vertebral fixation systems occurred with the use of pedicular screws, which have the property of withstanding loads in all direction, with consequent great biomechanical advantages (Shimano et al, 1998).

Kuklo and Lehman (2003) reported that pedicular fixation is limited to the lower thoracic region (T10 to T12) due to the relatively large size of the pedicles. Eventually pedicular fixation evolved towards the upper thoracic region where the pedicles are narrower. It is clear that lumbar and thoracic pedicles are morphometrically different, with a significant cortical reduction occurring in the thoracic region.

The treatment of any disease of the lumbar spine should include: 1- effective decompression of the spinal canal, 2- treatment of the spine without causing deformities, limitations of movement, instability or pain, 3- early mobilization and simplified nursing care. With the advent of pedicular fixation, spinal surgery was able to achieve the cited objectives (Matuoka and Basile, 2002).

The problem with pedicular fixation is the high rate of complications due to surgery or to the placement of the screw itself in the vertebral pedicle. The complications related to surgery are superficial or deep infection, pulmonary thromboembolism and other complications associated with major surgery. The complications related to the placement of the pedicular screw are placement of the screw outside the pedicle, which may cause root injury, injury to the dura mater, vascular injury, and pedicle fracture. In addition, the implant may break. In a review by several investigators of the complications detected by analyzing various techniques, a 27.4% rate of complications was detected, 9.6% of them intraoperative and 17.8% postoperative. No significant differences in complication rates were observed among the various types of implants analyzed. Regarding frequency, breaking of the screw is the most important one, with a rate ranging from 3 to 25%. This complication may be prevented by improved biomechanical knowledge. Regarding morbidity, radicular injury is the most important one, ranging from 0 to 7%. This complication could be reduced by a refined knowledge of the morphometry of the vertebral pedicle and of its relationship with neural structures (Knoplick, 2003).

Thus, the pedicle is the most resistant site of the vertebra, with advantages such as easy surgical access by the posterior route, early walking after surgery, a reduced period of postoperative rest and the elimination of postoperative external support. Among the disadvantages of the technique are the implantation of the screw in osteoporotic vertebrae, the limited use at certain spinal levels such as the low and lumbar spine, the need for in-depth knowledge of the local anatomy, and the skill needed to implant the screws into the pedicles (An, 2001).

The proposal of the present study was to assess the influence of the depth of insertion of the screw, with varying orifices sizes, on the insertion torque and pullout strength of pedicular screws.

2. Materials and Methods

2.1. Materials

For the experiment we used 60 lumbar and thoracic vertebral bodies from Landrace pigs aged on average 90 days and weighing about 55 Kgf. All material was stored in a freezer at -20° C.

For the pullout strength test we used Synthes® screws, model USS1 5.0 mm in outer diameter, 3.8 mm in inner diameter and 30.0 mm in length.

The burrs used to drill the holes measured 2.5, 3.8 and 4.5 mm in diameter.

2.2. Assembling the experimental models

The following procedure was used assemble each experimental model: 1- Fixation of the vertebral body in the clamp positioned in such a way that the pedicle is turned upwards; 2- The orifice was drilled using a manual drill. The screws were positioned and fixed with a Mackenna® torque meter with the aid of a stable guide fixed on the metal base. Torque was measured at each turn of the torque meter (Fig. 1). Figure 2 shows a vertebra with the screw already fixed in place.



Figure 1: Assembly of the experimental model

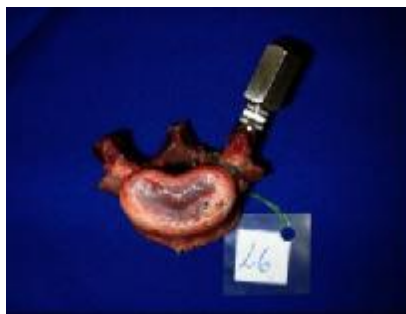


Figure 2: Vertebra with a pedicular screw already inserted

2.3. Experimental groups

The 60 vertebrae used in the present experiment were divided into 6 groups of 10 each according to the diameter of the orifices drilled with burs of three different sizes and according to whether the screw was inserted only to the end of the thread or to the head. The experimental groups were:

- Group 1 – perforation with a 2.5 mm burr and insertion to the head of the screw;
- Group 2 - perforation with a 2.5 mm burr and insertion only to the end of the thread;
- Group 3 - perforation with a 3.8 mm burr and insertion to the head of the screw;
- Group 4 - perforation with a 3.8 mm burr and insertion only to the end of the thread;
- Group 5 - perforation with a 4.5 mm burr and insertion to the head of the screw;
- Group 6 - perforation with a 4.5 mm burr and insertion only to the end of the thread.

2.4. Pullout tests

The pullout tests were performed using the Universal Testing Machine of the Bioengineering Laboratory, Faculty of Medicine of Ribeirão Preto/USP. A load cell with the capacity to measure up to 200 Kgf was used in these assays. A 40 N preload was standardized, with an accommodation time of 30 seconds. The rate of load application was 10 mm/min.

For the pullout tests, the models were fixed with a clamp on the base of the Testing Machine and the pullout force was applied through a steel cable coupled to the screw and to the upper mobile base of the machine (coupled to the lower part of the load cell). Some important precautions were always taken regarding the alignment and parallelism in the positioning of the models for the execution of the tests. Figure 3 illustrates the model positioned for the execution of the pullout test.



Figure 3. Experimental model prepared for the screw pullout test

2.5. Statistical Analysis

Maximum insertion torque and maximum pullout strength were measured in each test. The maximum mean values were calculated for each experimental group.

The mean maximum insertion torque and pullout strength values for the screws of the experimental groups were analyzed by ANOVA to test the normality of the data and later by the Kolmogorov-Smirnov test. The level of significance was set at 5%.

3. Results

The mean maximum insertion torques for the 6 groups analyzed were: Group 1 (1.39 ± 0.21) N.m; Group 2 (0.87 ± 0.22) N.m; Group 3 (1.04 ± 0.19) N.m; Group 4 (0.57 ± 0.13) N.m; Group 5 (0.78 ± 0.19) N.m, and Group 6 (0.34 ± 0.11) N.m (Fig. 4).

In all the comparisons of the insertion torques between the 3 experimental groups in which the screw was inserted only up to the end of the thread and between the 3 groups in which the screw was inserted up to the head of the screw, we observed that the size of the orifice influenced the insertion torques of the screws, with a significant difference ($p < 0.05$). For the insertion torques of the screws inserted into holes drilled with burrs 2.5 mm in diameter, we observed that, on average, group 1, in which the screws were inserted up to the head, was 37.5% superior to group 2, in which the screws were inserted only to the end of the thread. In groups 3 and 4, in which the holes were drilled with burrs 3.8 mm in diameter, we observed that, on average, group 3 was 45.5% superior to group 4. And for groups 5 and 6, in which holes were drilled with burrs 4.5 mm in diameter, we observed that, on average, group 5 was 59.0% superior to group 6. All groups of models prepared with screws inserted up to the head (final insertion) showed a significant difference when compared to the groups in which the screws were inserted into the models only up to the end of the thread (thread insertion) ($p < 0.05$).

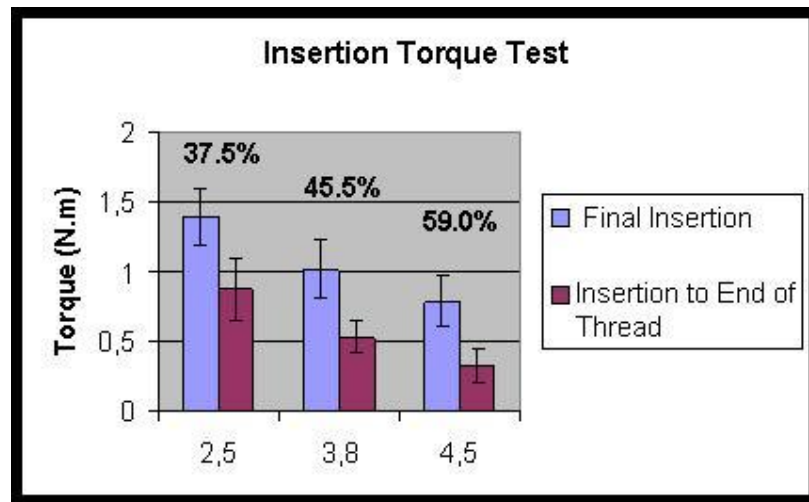


Figure 4: Comparison of mean (\pm SD) maximum insertion torques

The mean maximum pullout strengths were (1014.7 ± 153.3) N for Group 1, (909.9 ± 109.9) N for Group 2, (996.9 ± 107.4) N for Group 3, (947.7 ± 165.4) N for Group 4, (862.6 ± 141.2) N for Group 5, and (669.6 ± 176.9) N for Group 6 (Figure 5).

Comparison of pullout strength did not show statistically significant differences between groups 1 and 3 or between groups 2 and 4, whereas significant differences were detected in the comparisons between groups 1 and 5, 3 and 5, 2 and 6 and 4 and 6 ($p < 0.05$). For the pullout strength of screws in test bodies in which holes were drilled with burrs 2.5 mm in diameter, the mean for group 1 was 10.3% higher than the mean for group 2. In groups 3 and 4, in which the holes were drilled with burrs 3.8 mm in diameter, the mean for group 3 was 5.0% higher than for group 4 and this was the smallest difference found when we compared test models with screws inserted to the head and with insertion of only the threaded part. Regarding groups 5 and 6, in which the holes were drilled with burrs 4.5 mm in diameter, the mean for group 5 was 22.4% higher than for group 6.

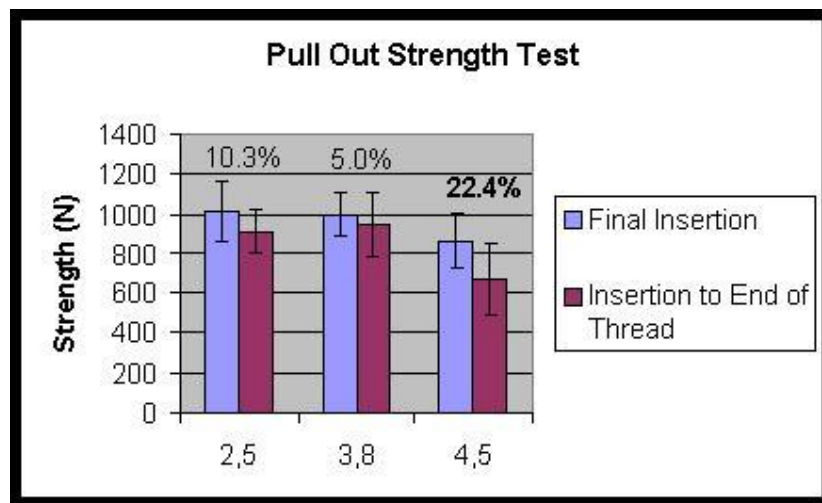


Figure 5: Comparison of the maximum pullout strengths

4. Discussion

The present study was carried out to evaluate the advantages of pedicular insertion and also the correlation of insertion torque with the pullout strength of pedicular screws. An (2001) also described some advantages of transpedicular fixation such as the fact that the pedicle is the most resistant site of the vertebra, the easy surgical access by the posterior route, the early walking and the elimination of external support during the postoperative period. As disadvantages of the technique, he cited the implantation of the screw in osteoporotic vertebrae, the limited use at

certain spinal levels such as the low thoracic and lumbar spine, the need for in-depth knowledge of local anatomy, and the skill needed to implant the screw into the pedicles.

Pihlajamäki *et al.* (1997) also reported that lumbar pedicular fixation is being increasingly used for the treatment of diseases of the lumbar vertebral spine that generate instability, requiring arthrodesis. The objective of instrumentation is to reduce the incidence of pseudoarthrosis after posterior or posterolateral arthrodesis. Thus, an advantage of transpedicular fixation over other methods for fixation of thoracolumbar fractures is the better stabilization they provide, in addition to involving only a small extension of the spine and permitting early patient mobilization without external support.

The mechanical performance of pedicular screws depends on the physical properties of the screw and on the biomechanical properties of the bone-screw junction. The quality can be determined by bone type, screw size, diameter of the threaded part of the orifice and bone mineral density. Also, the insertion torque is the result of resistance in the friction between the tightening of the screw and the bone, as well as of trabecular compression (Inceoglu *et al.*, 2004). In the present study, three different orifice sizes were used to simulate fixation using a hole smaller than the inner diameter and a hole larger than the inner diameter of the screw. When we compared the groups of models with screws inserted up to the head to the groups of models with screws inserted only up to the end of the threaded part, we observed a significant difference only between groups 5 and 6. The remaining comparisons, i.e., between groups 1 and 2 and between groups 3 and 4 did not show statistically significant differences ($p > 0.05$). This result probably indicates that the effect of inserting the screw only up to its threaded part or up to the head is important only when the initial orifice drilled with the burr is wider than the inner diameter of the screw.

5. Conclusion

The results show that the size of the orifice affects the insertion torque but not so much the pullout strength of the screw. Fixation of the screw with insertion only of the thread or up to the head was important for the insertion torque but did not affect directly the pullout strength. On the basis of the results obtained, we suggest that, if pedicular screws are used clinically for spine fixation, burrs of a diameter equal to the internal diameter of the screws should be used and it not necessary to tighten them up to the head. This may increase the insertion torque but, due to the probable ruptures caused in the pedicle by the wider diameter close to the head of the screw, there may be a reduced resistance in the fixation of these screws into the vertebra.

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