EFFECT OF THE PILOT HOLE PREPARATION ON THE ANCHORAGE OF PEDICLE SCREWS

Gustavo Silva Abrahão, Rodrigo César Rosa, Rodrigo Okubo, Antônio Carlos Shimano

ABSTRACT

Objective: We evaluated the influence of the diameter and the preparation of the pilot hole on the resistance to the pulling out and the strength when inserting pedicle screws with conical internal diameter. Methods: Mechanical experiments were performed with pedicle conical screws of 4.2 mm and 5.2 mm diameter. They were inserted in the vertebral pedicles of swine. The hole was manufactured with a drill and probes with different diameters. Results: While testing the 4.2 mm screw, the perforation of holes with measure equal or inferior to the lesser internal diameter of the screw increased the torque and the resistance to pull-out strength. Perforations with different instruments have presented similar results. Perforations with probes allowed the holes manufactured with dimensions superior to the lesser internal diameter of the screw to show similar resistance to that of the perforations with dimensions equal to the lesser internal diameter of the implant, made with probes and drills. Conclusions: For 4.2 mm screws, the diameter and the preparation of the hole influence the torque and the resistance. For 5.2 mm screws, there is only influence on the insertion torque. There is no correlation between pulling out strength and insertion torque. ***Level of Evidence II, Therapeutic Studies – Investigating the Results of Treatment.***

Keywords: Spine. Bone screws. Biomechanics. Orthopedic fixation devices. Lumbar vertebrae.

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INTRODUCTION

Implant anchorage failure is a clinical problem frequently found in spine surgery.[1] The mechanical performance of the implants is highly dependent on the integrity of the bone-implant interface and on the biomechanical characteristics of its components.[2-5] Screws have been employed as an anchorage element in the vertebra due to their ability to resist shear, bending and pullout strengths. The loss of stability of the vertebral fixation system can be affected by the loosening or breakage of the anchorage screw of the system.[6-9]

The anchorage of the screw in the vertebra depends on a set of factors related to the bone on which the material is implanted (bone mineral density), implants used (screw design, external diameter, thread size and depth) and pilot hole preparation technique (diameter, tapping, type of perforation).[10-12]

The creation of the pilot hole is of crucial importance for the placement of the screws inside the bone, since it establishes the mechanical relations between the implant and the bone tissue.[13] The preparation of the pilot hole has been achieved using different methods, with special emphasis on the use of drills and probes. Theoretically the use of a drill removes the bone tissue while the use of a probe promotes the compacting of the bone on the wall of the pilot hole. This compacting of the bone on the walls of the pilot hole could improve the quality of the implant fixation. The diameter of the pilot hole in relation to the internal diameter of the screw has not been appreciated in this stage of the procedure, although its influence has been observed in mechanical tests.[14,15] The aim of the study was to evaluate the possible influence of the diameter and of the method of preparation of the pilot hole on the insertion torque and on the pullout resistance of pedicle screws with conical internal diameter, using swine vertebrae.

MATERIAL AND METHODS

The study was carried out on 280 lumbar vertebral pedicles (L1-L6) of pigs of the *Landrace* breed, with age averaging 90 days and approximate mass of 80kg.

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The vertebrae were stored at a temperature of -20ºC. Prior to the performance of the trials, the vertebrae were removed from the freezer and kept for 12 hours at a temperature of 5ºC in the refrigerator, then subsequently for two hours at room temperature in order to reach thermal equilibrium and not alter the physical properties of the bone. The bone mineral density of the vertebrae was evaluated by means of dual-energy x-ray absorptiometry (DEXA®), using the QDR system with version 11 - 2:5 software (*Hologic 4500 W*®, Walthan, MA, USA), observing the mean value of 16.33 ± 1.90 g/cm^3.

We used pedicle screws with conical internal diameter and external diameter of 4.2mm and 5.2mm, belonging to the USSII vertebral fixation system (Universal Spine System-Synthes®). The first with a thread length of 30mm and conical internal diameter, with greater internal diameter of 3.8mm and lesser of 2.2mm, and the second with 35mm of thread length and conical internal diameter, with greater internal diameter of 4.2mm and lesser of 2.5mm. (Figure 1)

The hole for insertion of the implant was prepared using a drill, sharp probe and steel pointed probe, with diameters of 1.6mm, 2.2mm, 2.5mm, 2.8mm, 3.4mm, 3.8mm and 4.2mm, used according to the experimental group. (Figure 2)

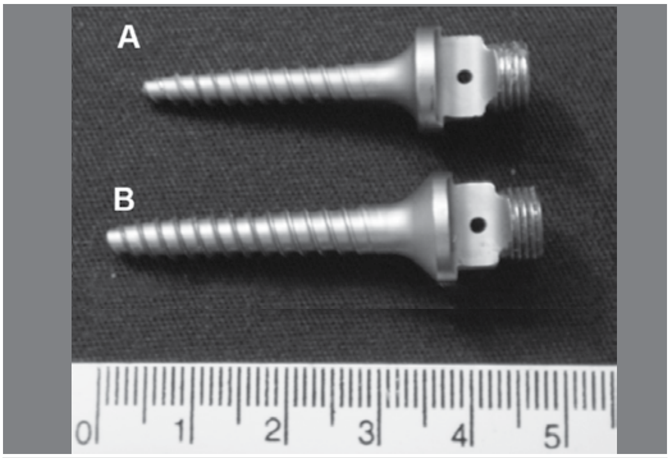

Figure 1. *Screws used in the study. (A) 4.2mm x 30mm screw. (B) 5.2mm x 35mm screw.*

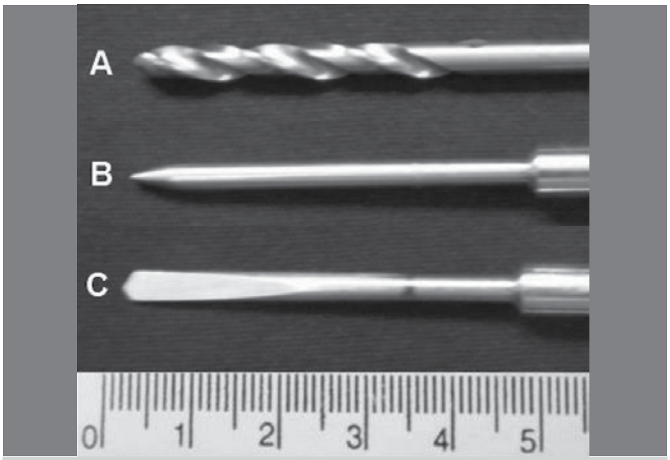

Figure 2. *Instruments used to make the pilot hole. Drill (A); Pointed probe (B) and Sharp probe (C).*

The drilling depth of the pilot hole was defined with a basis on the thread length of the screw. The perforations with the probes were executed manually while the perforations with the drills were executed with a bench drill at a speed of 455 rpm.

The screws were inserted in the vertebral pedicles from the posterior portion of the vertebral arch using anatomical references of the upper articular surface and transverse process. The screw insertion torque was measured with a Mackena® MK-201 digital torquemeter with a capacity of 10 N.m and precision of 0.01 N.m

The mechanical tests were carried out using an EMIC® (model DL 10.000) universal testing machine, Tesc 3.13 software for analysis of results, load cell with capacity of 2000 N and rate of force application of 2mm/min. A 50N preload and a 10 second accommodation time were used in all the mechanical tests. The property assessed in the mechanical tests was the maximum pullout strength. The comparison of the values obtained in the different experimental groups was performed by means of the multifactorial analysis of variance (ANOVA) and when necessary the Bonferroni post hoc method, with significance level $p \leq 0.05$. Pearson's correlation coefficient calculation was used to study the mathematical correlation between the variables.

RESULTS

Insertion Torque

In the analysis of the insertion torque of the screws with 4.2 mm of external diameter, we observed influence of the method of preparation of the pilot hole in the diameter of 3.4mm, where the drill presented higher values than the pointed probe ($p < 0.05$). No statistical difference was observed in the other comparisons. Influence of the method of preparation of the pilot hole was not observed in the 5.2mm screws. (Figure 3)

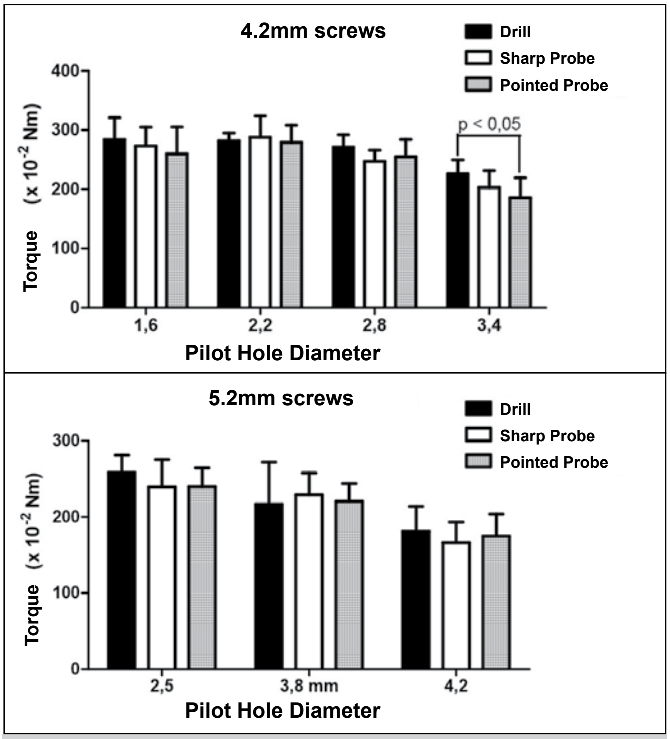

Figure 3. *Results of the insertion torque in the analyses of the method of preparation of the pilot hole with different drilling diameters.*

In the study of the screws with 4.2mm of external diameter, the increase of the drilling diameter promoted reduction of the implant insertion torque in the different pilot hole preparation methods. This reduction did not occur in a similar manner in the different pilot hole preparation methods. In the sharp probe, this reduction occurred gradually, unlike other pilot hole preparation methods where the greatest reduction was observed in the comparisons with the diameter of 3.4mm. (Figure 4)

In the 5.2 mm screws it was verified that the increase in the drilling diameter promoted reduction of the implant insertion torque in the different pilot hole preparation methods. The perforations with 2.5mm drill and probes presented higher values than the perforations with 4.2mm drill and probes. And the perforations with 3.8mm probes were larger than those made with 4.2mm probes. (Figure 4)

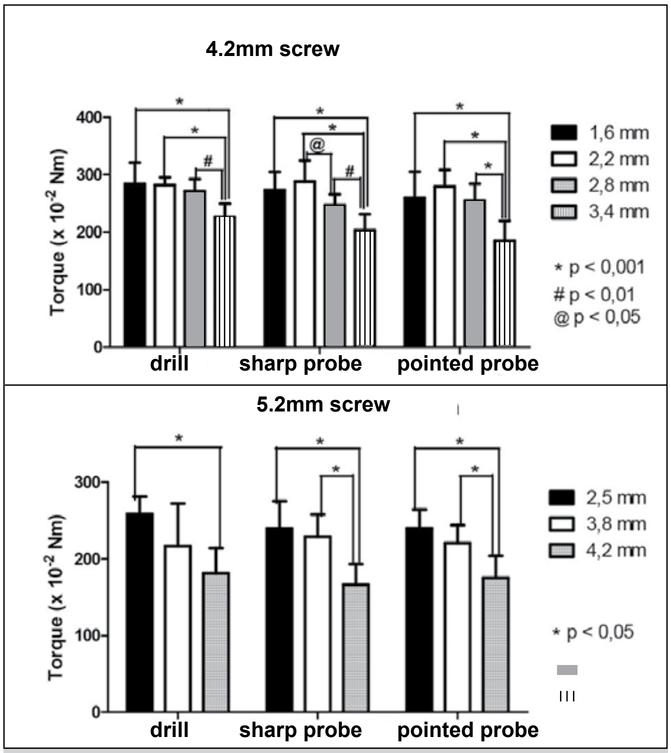

Figure 4. *Results of the insertion torque in the analyses of the diameter, with different drilling instruments.*

Pullout Strength

Influence of the pilot hole preparation method in the diameter of 1.6 and 2.8mm was observed in the analysis of the maximum pullout strength of 4.2 mm screws. In the diameter of 1.6mm, the drill presented higher values than the pointed probe ($p < 0.05$). In the diameter of 2.8mm the sharp probe presented values above those observed in the holes created with a drill. No statistical difference was observed in the other comparisons, and no influence of the pilot hole preparation method was observed in the 5.2mm screws. (Figure 5)

Considering the 4.2mm screw the increase in the drilling diameter promoted a reduction of the maximum pullout strength of the implants in the different pilot hole preparation methods. This reduction did not occur in a similar manner in the different pilot hole preparation methods. In the drill, this reduction occurred gradually, where the 2.2mm perforation presented a value above 2.8mm. In the pointed and sharp probes, the diameter of 2.2mm (measurement recommended by the manufacturer) and the diameter of 2.8mm presented similar values, while no influence of the drilling on the different pilot hole preparation methods was observed in the 5.2mm screws. (Figure 6)

Pullout Strength X Insertion Torque

The mathematical calculation of Pearson's correlation coefficient demonstrates that there is no significant correlation in a comparison of the variables of pullout strength and insertion torque in any of the experimental groups evaluated.

Qualitative Analysis

Studying the behavior of the external pedicle surface, after the insertion of the implants in the different experimental groups, it was possible to verify (Figure 7) that the insertion of 5.2mm screws produced fracture line along the medial margin of the pedicles in which they were inserted. A finding that was not observed in the groups in which 4.2mm screws were inserted. Studying the pathway of the screws inside the vertebral pedicles, it was verified (Figure 8), that the space between the implant and the medial wall of the pedicle is smaller when we insert 5.2mm screws than the pedicles with 4.2mm screws.

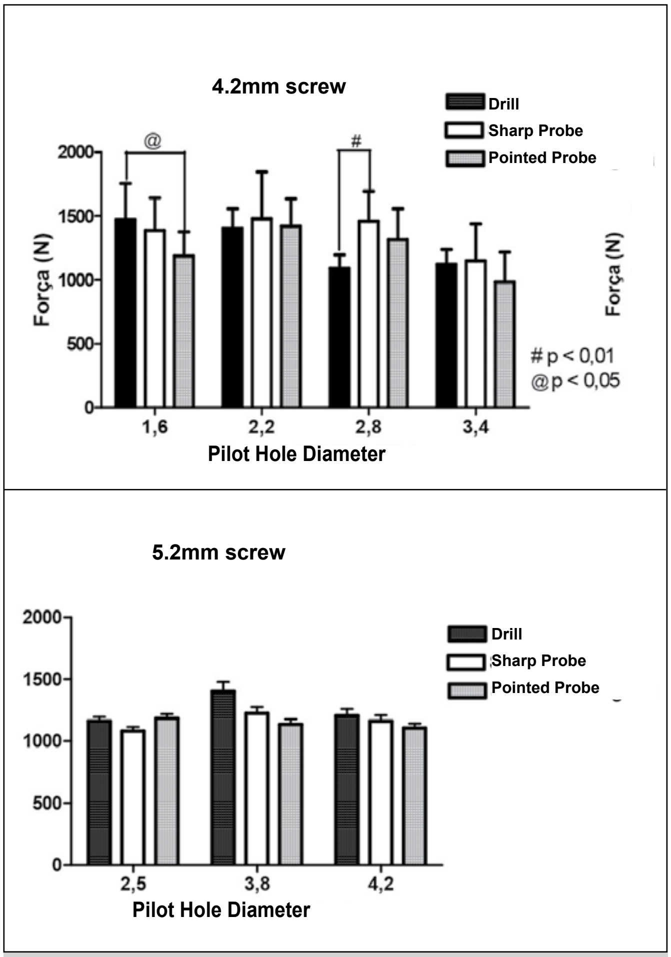

Figure 5. *Results of the maximum pullout strength in the analyses of the method of preparation of the pilot holes, with different drilling diameters.*

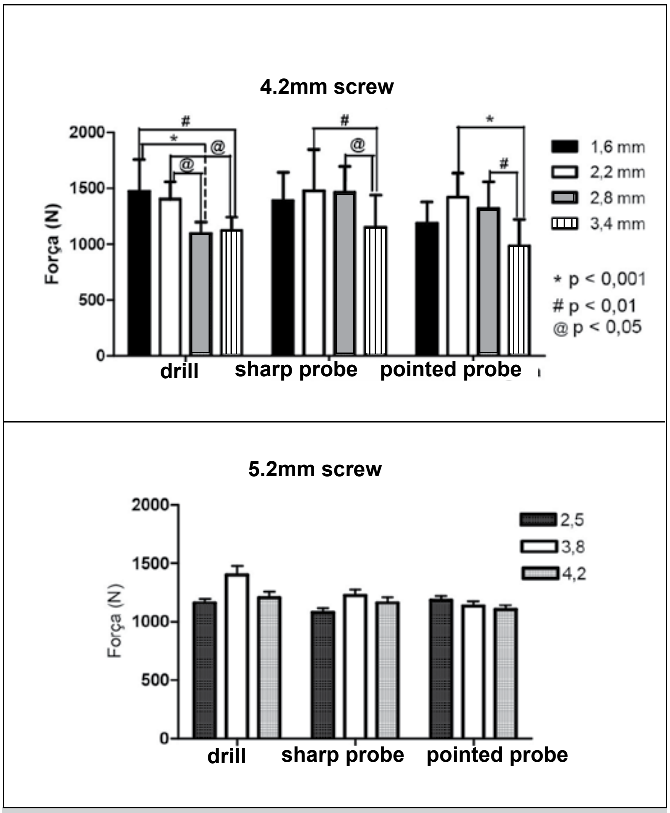

Figure 6. *Results of the maximum pullout strength in the analyses of the diameter different drilling instruments.*

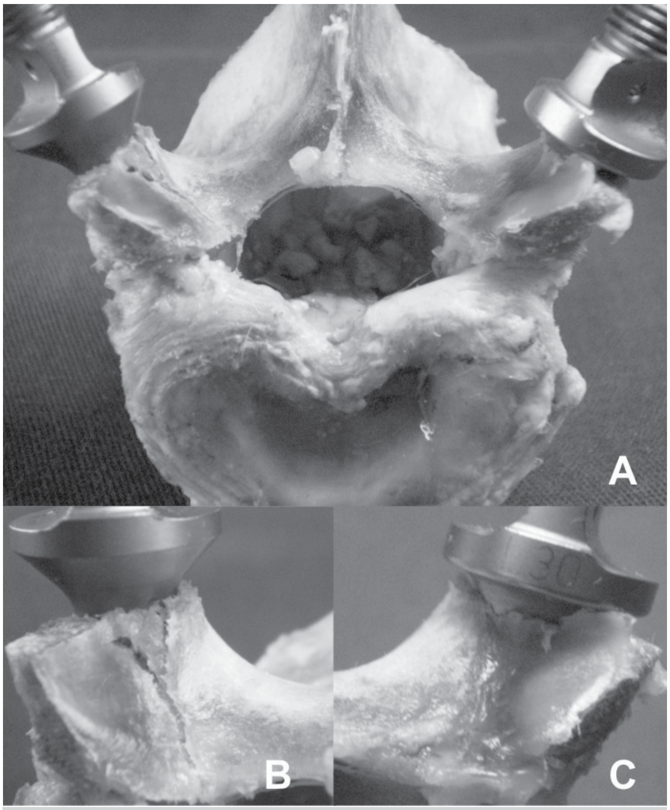

Figure 7. *Swine lumbar spine with screws inserted in the pedicles (A). Detail of the right vertebral pedicle with 5.2mm implant (B). Detail of the left vertebral pedicle with 4.2mm implant (C).*

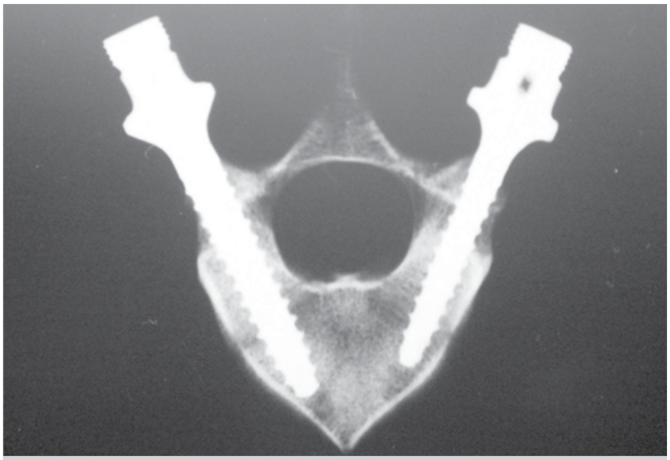

Figure 8. *Radiograph of swine lumbar spine with screws inserted in the pedicles. 5.2mm screw (A). 4.2mm screw (B).*

DISCUSSION

The pullout resistances of screws are complex and multifactorial phenomena that are related to intrinsic properties of the fixation system and anchorage in the vertebrae.[16] This primarily influenced by bone mineral density, by the insertion technique and by the implant geometry.[17-19]

The preparation of the pilot hole facilitates and guides the penetration of the implants inside the vertebra and, theoretically, the creation of holes of lesser diameter than the internal diameter of the screw increases the quantity of compacted bone around it, enhancing the pullout resistance of the implants.[14,17,20]

The development of implants with conical internal diameter allowed better accommodation in the vertebra and anchorage in the spongy bone tissue, which predominates inside the pedicle.[11] The first models presented conical internal and external diameter, which favored good clinical results, but reduced the resistance of the fixation system.[18] The current models, like those used in the experiment, are composed of a cylindrical external and conical internal diameter, which increases from the towards the head. The progressive increase of the internal part promotes the compression of bone material around the implant, boosting the mechanical resistance of the system.[21,22]

In this study we observed that the diameter and the pilot hole preparation method exert influence on the maximum pullout strength and the insertion torque.

The results found demonstrate that, using a screw with 4.2mm of external diameter, the reduction of the pilot hole in relation to the internal diameter of the screw tends to increase the pullout resistance of the implants and the increase of the pilot hole diameter reduces the pullout resistance. However, when making a pilot hole inferior to the lesser internal diameter of the screw, the resistance was no higher than that presented with the hole equal to the lesser internal diameter. Similar findings were presented by Hee *et al*.[23] and Zamarioli *et al.,*[24] concluding that for conical screws, the highest pullout resistance is observed when these are inserted in holes made with measurement equal to that of the lesser internal diameter of the screw. To fix a screw in a structure or in bone, the first step is to make a pilot whole whose size is between the external and internal diameters of the screw.[14] Therefore, the resistant area depends on the external and internal diameter of the screw besides other variables such as pitch, geometry, height of the thread and thread angle. When a screw is inserted, torque is applied to overcome the friction of the threads with the threaded material.[16] In the insertion, the screw also functions as a thread opening "male", cutting the bone in the geometry of the screw thread. Thus, a smaller hole allows greater deposition of material between the threads.

However, a hole inferior to the lesser internal diameter of the screw increases the insertion torque, but there is no proportionality to the pullout strength, as appropriate alignment is not obtained, and the greater tension generated may injure the bone structures.[14]

This result shows the direct relation between the reduction of maximum pullout strength and the increase in the pilot hole diameter in relation to the internal diameter of the screws. As a greater quantity of bone is removed during drilling, a smaller quantity of bone is compacted around the screw threads, weakening the interface between implant and adjacent bone, and consequently leading to the reduction of the implant pullout resistance.[16]

When considering the instrument used to produce the pilot hole made to accommodate the screws with an external diameter of 4.2mm, we observed that drills, sharp probes and pointed probes exhibit similar pullout resistance in most of the groups. However, when using probes, whether pointed or sharp, the resistance behavior in the hole made with a 2.8mm instrument (dimension superior to the lesser internal diameter of the screw) was similar to that of the 2.2mm probes and drills (smaller than the internal diameter of the implant), which was not verified in the group made with a drill. This suggests that when the probe is used to produce the hole, it is possible to use a slightly larger instrument and to obtain the same performance as a drill or probe of the size of the lesser diameter of the implant. Similar results were found in the studies of Carmouche et al.[20] where the drillings performed with probes provided higher pullout resistance values than those performed with drills in osteopenic models.

The results of the screw insertion torque presented a behavior similar to those found by Inceoglu *et al*.[21] and Hsu *et al.*[10] The reduction of the diameter of the pilot hole in relation to the internal diameter of the screw, tends to increase the insertion torque of the implants and the increase of the pilot hole diameter tends to reduce the torque. Yet the conical screw does not provide such a reliable correlation as that found in cylindrical screws.[22]

When we consider the instrument used to make the pilot hole, the behaviors of the groups that used drill, sharp probe and pointed probe are similar, with insertion torque reduction only verified in the group that used pointed probes with a dimension of 3.4mm. This value similar to the greater dimension of the implant suggests that the pointed probe of greater diameter can cause more severe damage to the pedicular structure.[23]

The results found demonstrate that when using a screw with external diameter of 5.2mm, the reduction of the pilot hole in relation to the internal diameter of the screw did not produce an increase in the maximum pullout strength of the implants, and that neither did the increase in the dimensions of the pilot hole reduce the pullout resistance, irrespective of the instrument used. These findings contradict those of Hsu *et al.*[10], Lill *et al.*[11], Zamarioli *et al.*[24], and the results found in the first stage of this study, when swine vertebrae with the same characteristics, whose holes were prepared following the same methodology, were submitted to the insertion of a screw of the same model, yet with smaller diameter. However, this behavior can be understood considering that the mechanical performance of a pedicle screw depends on the physical properties of the implant and biomechanical properties of the bone-screw union.[12] The maximum pullout strength, besides being directly related to the bone type, thread geometry and bone mineral density, is dependent on the size of the screw.[1]

Some studies described that the anchorage depends more on the pedicle than on the spongy bone of the vertebral body. Thus, the rupture of the pedicle reduces the resistance of the fixation system.[22,23] The mechanical behavior of the vertebral pedicle is directly related to the diameter of the implant, and when the dimensions of the latter are close to those of the pedicle, there can be damage to the pedicular structure.[23] The pedicles with 5.2mm screws inserted had the space between the implant and the medial cortical wall reduced, which compromised structural integrity generating fracture line along the medial margin.

The results of the insertion torque of the screw with external diameter of 5.2mm and the mechanical behavior produced by the different instruments exhibit a behavior similar to those found by Hsu *et al.*[10], Lill *et al.*[11] and Hee *et al.*[23], and to the results found in the first stage of this study. The reduction of the pilot hole diameter in relation to the internal diameter of the screw tends to increase the insertion torque of the implants and the increase of the pilot hole diameter tends to reduce the torque. These results indicate that the structural changes undergone by the pedicle were capable of influencing the maximum pullout strength, but did not exert any effect on the insertion torque. According to Hee *et al*.[23], the pedicular wall breach does not alter the insertion torque when conical screws are used.

The result of the calculation of Pearson's correlation coefficient demonstrates that there is no mathematical correlation between the variables of pullout strength and insertion torque in any of the experimental groups, indicating that in the conical screw the insertion torque is not fully reliable to estimate the resistance of the implant.[1,21]

CONCLUSION

Using the 4.2mm screw, the diameter and the method of preparation of the pilot hole exerted an influence on the pullout resistance and on the insertion torque of the screw. The drilling in which the dimension was equal or inferior to the lesser diameter of the screw, increased the pullout resistance and the insertion torque of the implant.

The drillings with the different instruments presented similar behavior. However, the drillings with pointed and sharp probes allowed a hole made with a dimension superior to the lesser internal diameter of the screw to present resistance similar to that of the drillings of the same size as the lesser internal diameter of the implant performed with probes and drill.

Using the 5mm screw, the pilot hole diameter exerted influence only on the insertion torque of the screw, indicating that the mechanical resistance of the pedicle was compromised, since the implant dimensions exceeded the pedicular capacity.

There is no correlation between the insertion torque and pullout strength measurements regardless of the screw dimensions, drilling instrument or size of the hole made.

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