INFLUENCE OF THE DIAMETER OF THE PERFORATION OF THE PILOT HOLE IN THE MECHANICAL RESISTANCE TO PULLOUT OF SCREW

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Abstract. *The objective of this study was to evaluate the influence of the diameter of the pilot hole in relation to the internal diameter of the screw in the resistance to the pullout of the applied implants. Swine vertebrae were used to fix pedicular screws of 5.0mm and 6.0mm of external diameter. Three types of drill were used for each screw and each size of drill corresponded to one experimental group. For the 5.0mm screw, drills of (1) 2.5mm, (2) 3.8mm and (3) 4.5mm were used. For the 6.0mm screw, (4) 3.5mm, (5) 4.8mm and (6) 5.5mm drills were used. The pullout test were carried through on Universal Testing Machine (EMIC®). These tests evaluated the maximum strenght and the stiffness. For the 5.0mm screw, as much in the maximum load how in the rigidity, significants statistical differences between groups 1 and 3, 2 and 3 were observed, but no showed significants statistical differences between groups 1 and 2. For the 6.0mm screw, as much in maximum load how in rigidity, significants statistical differences between all groups were observed. The results of the two screws showed that the hole diameter was important in the resistance of the pullout.*

Keywords*: Pullout test, vertebrae swine, pedicular screw.*

1. INTRODUCTION

The implants and systems of vertebral fixation are very used in the modern surgery of the spine, with the purpose of provide stability to the vertebral segment or to correct deformities (Haher et al., 1989; Dick, 1987; Weinstein, Spratt and Spengler, 1988).

The use of the screw as element of fixation of the spine is not a recent idea, and its first publication was in 1944, when King used it to fasten facetary articulations in lumbar-sacra column. The most recent progress in the systems of vertebral fixation happened with the use of pedicular screws, that possess the property of supporting loads in all of the directions and with this great advantages biomechanics were observed (King, 1944).

Roy-Camille et al. (1986a) were the first ones to use plates with pedicular screws to increase the stabilization interns of the column the fixation interns of the column revolutionized the surgery and it reduced the time of rehabilitation.

The system of pedicular screw has been used to help the spine, maintaining the stability and solid reach of the bone in patients with fractures, espondilolistesis, arthritides, tumor or scoliosis (Hirano, Hasegawa and Takahashi, 1997).

The pedicular screw has been a lot used in systems of vertebral fixation due to their advantages biomechanics in relation to other implants. Now, it can be considered the implant more used in the surgery of the spine, it has been used in the treatment of traumatic lesions, in those produced by tumors or degenerative lesions of the spine (Browner et al., 1998; Weinstein, Spratt and Spengler, 1988; White and Panjabi, 1990).

The material used in its production is stainless steel or titanium, that present high index of tissue biocompatibilities. The material should be in a systematic way no-poisonous or no-caused carcinogenesis, the parameters of force are equal to tension, compression, torsion forces, stiffness, fatigues and resistance (Schultz, Boger and Dunn, 1985).

The mechanical properties that can be analyzed during the rehearsals with the screws are limited to the maximum strength of pullout and the displacement or prolongation of the proof body.

The main determinant of the resistance of pullout corresponds to the smallest diameter of the screw, thickness of the cortical, depth of penetration of the screw, model and depth of the thread.

The introduction of the interface bone-implant presents two fundamental types: those without the attribute of the pullout resistance and those with this attribute. The first type includes nails, holes and staples that are partly due to its relative inability in resisting a dislocation of pullout. To resistance capacities it is almost null and they usually work as supplements (stabilizers) for implants, and the second type includes screws and the penetration of the implant changes the configuration inside in placement of bone. Those implants present the capacity to resist to pullout (Cook et al., 2000; Leosin et al., 1983; Lieberman et al., 1998).

The properties of the bone inside of which the screw is inserted are decisive factors for the strength of pullout of screws. Certain variabilities, such as, the screw type and the method of preparation of the hole are properties that influenced this pullout strength (Daftari et al., 1994). Also, bone mineral density and its morphologic composition affect this pullout resistance.

Therefore the objective of this study was to study the influence of the size of the hole in the resistance to the pullout of pedicular screws with 5 and 6mm of diameter external using vertebrae of swine.

2. MATERIAL AND METHODS

2.1. Vertebrae bodies

10 spines of swine were used, males of the race Landrasse. The animals presented medium weight of 81.20kg with medium age of 150 days. The columns were dissected, clean and identified one day before the accomplishment of the experiment. The vertebrae were conserved in freezer –20° C. The columns were dissected and separated together of six lumbar vertebrae (L1 L6). All of the vertebrae were sawed the pedicles, transverse and spinal processes, facilitating the handling with the vertebral body and later each vertebral body, it was measured with a paquimeter with resolution of thousandth of millimeter the length, the height and the width (Figure 1).

All of the holes accomplished with the selected drills were standardized in a perpendicular and unilateral axis to the vertebral body for the introduction of the respective pedicular screws (Figure 2).

Figure 1. Swine vertebra without the pedicles, transverse and thorny processes.

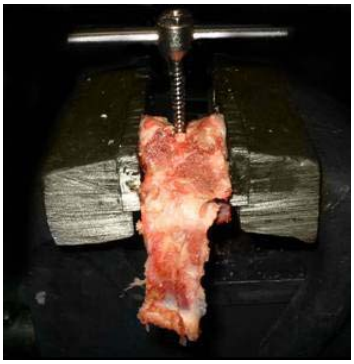

Figure 2. Screw of 6.0mm of external diameter with traverse stem inserted in the vertebral body of the swine vertebra.

2.2. Implants

The implants used in the study were:

a) Screws pediculares (figure 3) of 5.0mm and 6.0 mm of external diameter.

Technical specifications of the screws.

Measures of the screw	5.0mm	6.0mm
Specifications Dimensions (mm)		
External diameter	5.0	6.0
Internal diameter	3.8	4.8
Total length	47	53
Depth of insert vertebrae of swine	30	30

b) Drills of 5.5mm, 4.8mm, 4.5mm, 3.8mm, 3.5mm and 2.5mm,

The Figure 3 presents an example of a 6.0mm of external diameter screw with the respective main parts.

Figure 3. Screw of 6.0mm of external diameter

2.3. Experimental groups

With the vertebrae of swine were made two experimental groups:

Group I: screws of 5.0mm. This group was divided in three subgroups. And each subgroup corresponds it a drill value. The drills used in this group were of (2.5, 3.8, 4.5) mm of external diameter.

Group II: screws of 6.0mm. This group was divided in three subgroups. And each subgroup corresponds it a drill value. The drills used in this group were of (3.5, 4.8, 5.5) mm of external diameter.

2.4. Prepare of the vertebrae of swine

The columns were split up in the height of the 6th lumbar vertebra, later the vertebrae were fleshed with bistoury, without use of any substance, in the sequence was made the identification, those vertebrae were wrapped individually and conserved under freezing of -10º C. In the bodies of the vertebrae of swine all of the screws were standardized starting from the beginning of the screw and unilaterally were implanted in the close vertebral body of the pedicle. For each screw the drills were regarding the internal diameter of each screw. In the lumbar vertebrae the measure of the vertebral body consists of the variable from 4.0 to 3.5 cm in the height 4.2 to 3.6 cm in the width of the vertebral body and 2.6 to 2.0 cm in the diameter.

2.5. Mechanical tests

It was used an Universal Testing Machine EMIC® of the Laboratory of Bioengineering of University of Medicine of Ribeirão Preto of the University of São Paulo for accomplishment of the mechanical rehearsals of pullout screws. This machine is coupled to a microcomputer and a cell of load of 200 Kgf. The software TESC® allows the programming of the parameters stipulated for the test.

2.6. Pullout Test

The screws of 6.0mm and 5.0mm were introduced in each vertebral body in lumbar area.

Each vertebra was arrested in a morse with the screw inserted already and when positioned in the machine, the screw was arrested after steel (Figure 4). Soon afterwards, the computer was programmed for the supply of the graphs and the machine accomplished the pullout test. The tests were accomplished in room temperature with the bones in defrosting process that was maintained controlled in 25º C by system of conditioned air. A preload was activated with time of accommodation of 30 seconds. The speed was standardized in 10,0mm/min.

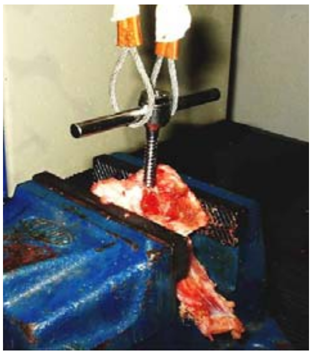

Figure 4. Pullout test

2.7. Mechanical properties

The proof bodies were rehearsed to the pullout. The software of the universal testing machine processed the data obtained starting from the application of load in the models to be tested supplying values that were used to build a graph for each mechanical rehearsal. In the ordinate the strength (N values were registered), in the abscissa, the displacement values (mm). The values contained in the graphs served as base for the calculations of the variables.

The data were registered by Microsoft Excel®, put in tables to verify the average and the standard deviation for the study of the following parameters: maximum load and stiffness (Figure 5).

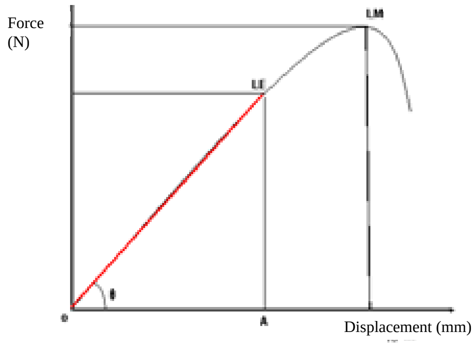

Figure 5. A draw of a graph load x displacement, starting from which are obtained the main mechanical properties.

2.8. Patterns applied in the evaluation of the graph load x displacement

For the analysis of the biomechanical properties of the maximum load the data were used obtained by the rehearsals. Those data were transcribed by Microsoft Excel where the value of smaller displacement was selected to the end and done like this for force corresponding to the smallest displacement. After made all the graphs, the value of maximum load of all of the groups and fact were selected the average and the standard deviation and last the rigidity was calculated using the same program however the graph was used in its lineal area.

For the calculation of the stiffness a segment of longitudinal straight line was drawn in the graph calculating the tangent of the angle formed by a straight line in the graph of the force x displacement. The tangent of that angle was calculated through the division among opposed and the adjacent cathetus. This measured it was done by the computer through Microsoft Excel.

2.9. Statistical analysis

For the analysis of the experiment accomplished with the vertebrae of swine, the lineal model of mixed effects was used (random and fixed effects). They were used in data analysis where the answers were contained and the independence supposition among observations in a same group was not adapted, because a same pig contributed with more than a vertebra to the perforation of the drills. They were considered as fixed effects the drill, the screw and the vertebra and as random effect the pig. For the use of this model it was necessary that their residues present normal distribution with average zero and constant variance. The model described above was used for both screws (5.0mm and 6.0mm).

The adjustment of the model for each one of the answers (force and rigidity) it was accomplished by the SAS software through the procedure PROC MIXED.

3. RESULTS

3.1. Vertebrae of swine with the 5.0mm screw

3.1.1. Maximum strength and stiffness

In pullout rehearsals, the maximum strength of the drills of 2.5mm; 3.8mm and 4.5mm accomplished by the procedure of contrasts, it indicates that there is evidence of statistical difference among the groups rehearsed with P - value 0.002 ($p < 0.05$) (Figure 6). The rigidity made calculations among the drills of 2.5mm; 3.8mm and 4.5mm show that the procedure of contrasts, indicates that there is no evidence of statistical difference with P - value 0.001 considering ($p < 0.05$) (Figure 7).

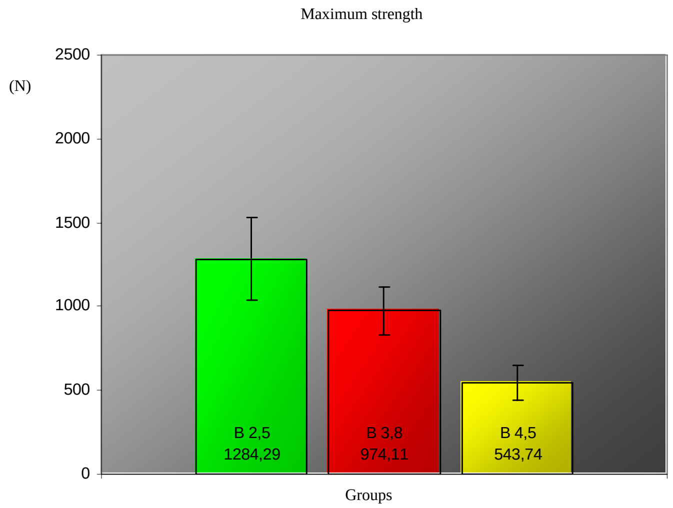

Figure 6. Average and the standard deviation of the maximum strength of pullout (N) of the subgroups of screw 5.0mm fastened in the swine vertebra.

For the 5.0mm screw, as much in the maximum load how in the stiffness, significant statistical differences between groups 1 and 3, 2 and 3 were observed, but no showed significant statistical differences between groups 1 and 2.

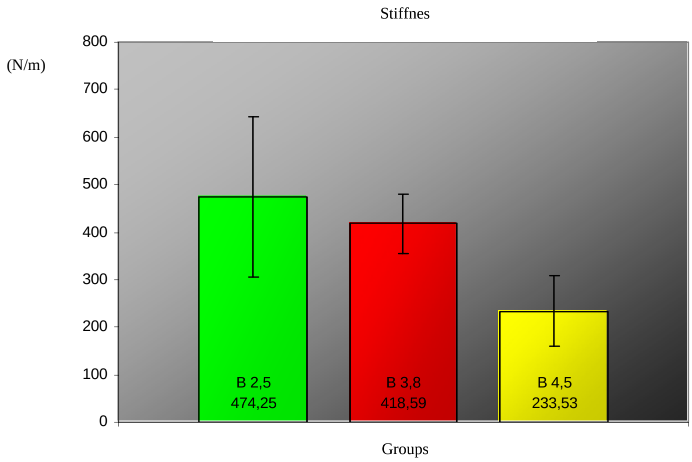

Figure 7: Average and the standard deviation of the pullout stiffness (N/m) of the subgroups of screw 5.0mm fastened in the swine vertebra.

3.2. Vertebrae of swine with the 6.0mm screw

3.2.1. Maximum strength and stiffness

In pullout rehearsals, the comparisons among the drills of 3.5mm; 4.8mm and 5.5mm indicate that there is evidences of statistical difference among the groups rehearsed with P-value <0.0001 considering (p <0.05) (Figure 8). The stiffness made calculations among the drills of 3.5mm; 4.8mm and 5.5mm show that the comparisons among the drills had evidence in the statistical difference among the rehearsed groups and there was no difference statistics for the vertebrae lumbar P value <0.001 considering (p <0.05) (Figure 9).

For the 6.0mm screw, as much in maximum load how much in stiffness, significant statistical differences between all groups were observed.

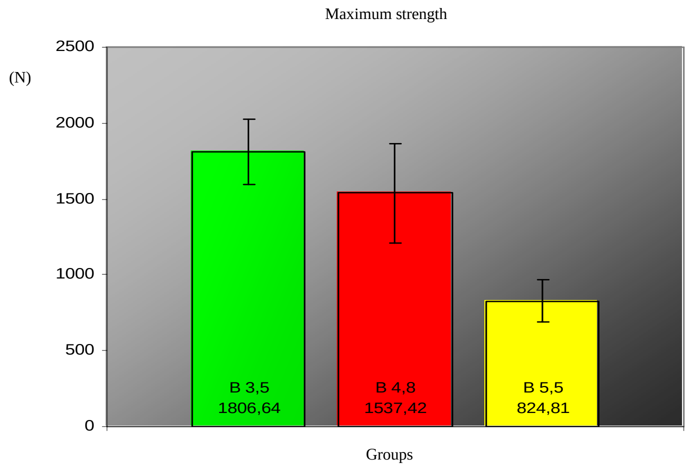

Figure 8. Average and standard deviation of the maximum strength of pullout (N) of the subgroups of screw 6.0mm fastened in the swine vertebra.

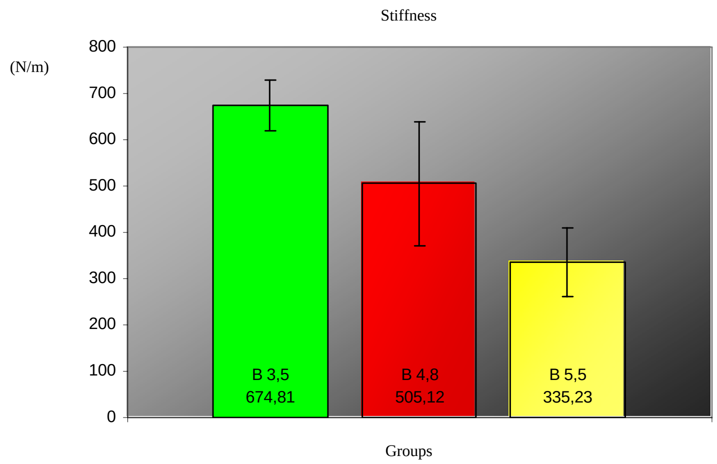

Figure 9.Average and the standard deviation of pullout stiffness (N/m) of the subgroups of screw 6.0mm fastened in the swine vertebra.

4. DISCUSSION

Nowadays, pedicular screws are an important part of a group of resources for column surgery. However, in the extent of the implants used in surgery of spine there are few studies considering variables related to the preparation of the pilot hole. Countless subjects related to the technique of placement of screws used in systems of vertebral fixation stay still without answer.

To begin the work the proof bodies used for rehearsals were measured and a standardization of depth of holes was also made. The section of the pedicle and the mechanical analysis were made unilaterally way to minimize the possible variables could interfere in results.

The reason of choice of swine vertebrae is because they are easy of obtaining and standardization as for race, age and weight, turning as experimental model of the study.

The lumbar column of swine introduces similar characteristic the one of the human in relation to the format of the vertebrae, physiologic lordosis, disposition of the ligaments and of the articulated facets (Callaghas and McGill,1995; Oxland et al., 1991).

Several studies, involving biomechanical tests, they use column of swine, because they present good bone quality, homogeneity and consistence among the specimens that are very important to test the characteristics certain implant (Oxland et al., 1991).

The experiments of the materials were preceded by a pilot study to establish the methodology of rehearsals and the standardization of the accessories used in the fixation of the vertebrae and the parameters of rehearsals.

The screws were always inserted perpendicularly so that there is not another type of effort, being the interest of the work to accomplish the pullout of those materials.

The rehearsals with swine vertebrae were accomplished in vertebral body due to standardization of the established work in a depth of 30mm using the trabecular bone and not reaching the cortical opposed.

Margerl et al. (1984) recommended placement of screw just sloping but not through the previous cortex. Roy-Camille et al. (1979b), in the annoyance, recommended the annulment of previous cortex, although, their reports do not describe now in details the penetration depth used, but illustrative x-rays showed penetration of approximately 50% to 60% of depth.

In the vertebrae L4 and L5 the depth of the screws should be from 20.0 to 30.0mm, but they can vary with depth of insertion of screws along different levels of the column and different sizes of vertebrae (Hirano, Hasegawa and Takahashi, 1997).

As it was shown in this study, the drills of larger diameter than the internal diameter of the screw bring smaller resistance for the pullout probably because the screw is loosened inside of the bone.

Studies morphometrics showed that the diameter of the pedicles usually increases with the decrease of the spinal level and results showed that 1.0mm of decrease in the diameter of screw increase pullout force (Moran et al., 1989).

Some of the results from the literature are inconclusive or contradictory. Krag et al. (1986) told a great fixation force for screws with 80% of penetration when compared with screws with 50% of penetration depth, while Zindrick et al. (1986) said there is no difference statistics in pullout strength in screws with depth of penetration of 50% or 100%. The difference in the results might have been for the different use of techniques. Heller et al. (1996) studied the variations and the dimensions of the screws, as well the insert depth (uni-cortical and bi-cortical), the accommodation quality in bone and vertebral level. They demonstrated that the largest flaw variation in the axial load was close to 100% between the different types of screws and two insert depths. Three larger subgroups were identified. To notable pullout resistance it seemed to be with the insert bi-cortical with diameter of 3.2mm; 3.5mm and 4.5mm in cortical bone, as well as 3.5mm in spongy bone. Seemingly a screw with smaller diameter than 3.2mm, without taking in consideration insert depth did not present pullout resistance of this superior group. In consideration to the largest diameter (4.5mm) in cortical bone, it presented a smaller pullout resistance in uni-cortical insertion. Screws with other diameter among these two values (3.2mm and 3.5mm) seemed to be more effective.

Diameter of screw, model, and insert technique and place can also affect the fixation force. The use of the screws now includes screws of small and big diameter and with little thread depth. The internal cortical diameter in axis of pedicle to the isthmus is an important factor that it influences the selection of the screw.

This experiment showed the importance of the cortex in the fixation of screw. The force of fixation of screws is dependent on combination of forces of the spongy bone and the cortex.

Öktenoglu et al. (2001) observed the effect of the micro-fracture, being more attributed to pattern no homogeneous where the trabeculs are fractured with the introduction of the drill.

Many studies have been executed to examine the property of force of screws in bone. Important factors increased pullout resistance and they showed to be related with geometry and diameter of screw, decrease of the thread number for a smaller degree and the largest relationship and the smallest diameter of the screw.

The variables that seem to influence the force of pullout of the screw are the diameter, profile of the thread and penetration depth. Although these variables have been studied thoroughly, there is no consensus of opinions concerning that these are responsible for pullout force (Sell et al., 1988; Zucherman et al., 1988).

Variations in thread number, configuration and depth of insert of the screws were investigated (Zindrick et al., 1986), Krag et al. (1986) demonstrated that the thread number and configuration does not modify the decrease of the load. The smaller diameter of the screws has a variable influence in decrease of load, but, the increased force of the screw did not probably justify the increase of depth of thread. They concluded that these discoveries were solid with the relative theories to flaws of screws. In agreement with this theory, the pullout of screws is caused by an excess of flaw of the cylindrical bone that it surrounds the external diameter of the thread immediately, not being probable that differentiate in the thread configuration are a flaw factor for screws.

The density of mineral bone affects the biomechanics of fixation of screws. Hirano, Hasegawa and Takahashi (1997) showed that the pedicle was composed by a number of areas with different mineral bone density.

In biomechanics researches, the researchers frequently prefer synthetic models or animal to eliminate the incompatible effects of the mineral bone density and to compare different treatments (McKinley et al., 1997; Pfeiffer et al., 1996).

Carlson et al. (1992) supposed that the mineral bone density is an important parameter influencing the stability of screws. It has also been demonstrated that the loosening of pedicular screws was caused by a movement cyclical in the interface bone-screw when a compression load in axis was transmitted through the plate or stem for the screw. The smallest diameter of screw is particularly interesting when screw is subject to accomplish the pullout. The largest diameter of screw reduces the resistance, but, in the effect of pullout force it was not tested seemingly, although the recommendation for the depth of the thread has been made (Perren et al., 1979).

Notice that the smallest diameter of the screw is not so important because it does not change the area of the bone that will be perforated, not affecting the pullout resistance, but it produces a larger volume of bone interfering among the thread, but that is not still an important parameter.

Kwok et al. (1996), in their study, tried to put all of the screws in a same depth to eliminate the penetration depth as a variable. The concern was to isolate the effects of model of screws and they associated the relationship of the diameter of pedicle to the screw, they showed there not to be a specific effect of the diameter of the screw in pullout force.

The complications associated with the use of pedicular screws suffered revision in many studies and the precision of the insertion of the screw was discussed in many goods. Most of series involved a single diagnosis or procedure, usually a fracture of spine or an arthrodesis of the lumbar-sacral area. Even so, there are few complications associated with the insertion of screws as long as the surgeon is experienced and it adheres to beginnings and details of the operative technique. The revision revealed a low tax of postoperative complications related to pedicular screws. The problem lately has been pain in beginning that can be related to the implants; however it is difficult to identify the exact etiology accurately (Lonstein et al., 1999).

This experiment shows the importance of the cortex in the fixation of the screw. The force of fixation of the screw is dependent of the combination of the force of spongy bone and cortical bone.

5. CONCLUSION

The results of the two screws showed that the hole diameter was important in pullout strength.

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7. RESPONSABILITY NOTICE

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