THE INFLUENCE OF PILOT HOLE DIAMETER ON SCREW PULLOUT RESISTANCE

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SUMMARY

Mechanical assays were performed in order to assess the influence of pilot hole diameter versus screw's inner diameter on screw pullout resistance in the vertebral fixation systems applied to the vertebral body. The study was conducted in two stages. In the first, polyurethane test bodies were used for placing 5 and 6 mm screws, and, in the second stage, the screws were inserted into the lateral surface of the lumbar vertebral bodies of pigs. The pilot hole was built with drills with smaller, similar or larger diameter than screws' inner diameter. Mechanical pullout assays were performed using a universal test machine for the assessment of maximum pullout screw resistance. The diameter of the pilot hole versus screw's inner diameter was shown to influence screw pullout resistance.

Keywords: *Spine; Bone screw; Biomechanics*

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INTRODUCTION

Vertebral fixation systems are constituted of different components: anchoring components (screws, hooks, cerclage wires); longitudinal components (nails, plates); transversal connectors and accessories (washers and nuts). Anchoring components of fixation systems can be penetrating (screws) and non-penetrating (hooks and cerclage wires), and act as an anchorage point of fixation systems to vertebrae, over which correction and neutralization forces are applied [1-4]

Screws have been commonly used as anchoring elements of vertebral fixation systems and have been inserted on pedicles, vertebral body and joint mass. Inserting screws on vertebrae requires opening a pilot hole, of which dimension compared to external or internal diameter of the screw is related to insertion torque [5-8]. Thus, making a pilot hole may affect biomechanical properties of screws anchored on vertebrae and influence biomechanical properties of the whole vertebral fixation system, with potential repercussion on treatment end outcome.

The objective of this study was to determine a potential influence of the pilot hole diameter on pullout resistance of implants used for fixing vertebral spine, focusing the anterior fixation of the vertebral body.

MATERIALS AND METHODS

One hundred sixty-eight polyurethane blocks and 60 vertebrae of 150 day-old, 881.20 kg (in average) male Landrace pigs' lumbar spines were used in the study. Vertebrae were dissected, separated and kept in a freezer at a mean temperature of -20ºC until assays could be performed.

The implants used in this study were the stainless steel, 5-6 mm-wide USS (Synthes) screws (Figure 1), which have been inserted into polyurethane bodies of evidence and at the lateral surface of vertebral bodies of swine lumbar vertebrae after preparation of the pilot hole with steel drills. The perforation depth of the pilot hole corresponded to screws insertion depth, which was standardized at 30 mm for all bodies of evidence and screw diameters.

The study was performed in two steps. In the first step, mechanical assays were performed with 5 and 6-mm screws applied to polyurethane bodies of evidence and providing pilot holes of different diameters above and below screw's inner diameter. The analysis of the values obtained from mechanical assays performed on polyurethane bodies of evidence enabled to select a value for pilot hole diameter above and below the screw's inner diameter to be used during the second study stage.

The width of drills employed for preparing pilot holes for 5-mm screws insertion (inner diameter = 3.8mm) into polyurethane bodies of evidence was 2.5mm; 2.7mm; 3.0mm; 3.2mm; 3.5mm; 3.8mm; 4.0mm and 4.5mm. For inserting 6-mm screws (inner diameter - 4.8mm) into polyurethane bodies of evidence, the width of drills were: 3.5mm; 4.0mm; 4.5mm; 4.8mm; 5.0mm and 5.5mm.

In the second stage of the study, 2.5mm; 3.8mm and 4.5mm-wide drills were used for preparing the pilot hole on bodies of evidence made of bovine bones, and 3.5mm; 4.8mm and 5.5mm drills for 6mm screws. Thus, perforations were made with a smaller, equal and bigger pilot hole diameter than the

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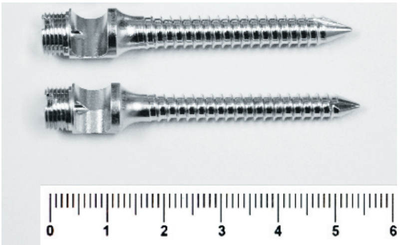

Figure 1– *Screws used in the study*

inner diameter of the screw.
Mechanical assays for implants pullout were performed in an Assay Universal Machine (EMIC®). The bodies of evidence were fixated and the upper portion of the screw was tractioned by means of a steel wire, over which force was applied for promoting screw pullout (Figure 2). The test universal machine was attached to a microcomputer and the 200 kgf load cell, and, by means of a TESC® software, the applied force was recorded until the implant was pulled out. Mechanical assays were performed on 12 polyurethane bodies of evidence and on 10 vertebrae of swine's lumbar spines for each pilot hole diameter studied, in a total of 228 mechanical assays.
The comparison of results of assays performed on polyurethane bodies of evidence was made by means of variance analysis (ANOVA) with the objective of checking the existence of any difference between the averages of drills for each screw alone for each force and stiffness variables. After ANOVA variance analysis, if a difference was confirmed between averages, a multiple comparison test (Tukey) was conducted to check which of the drills were responsible for that difference. A significance level of 5% ($p<0.05\%$) was adopted for comparing values obtained to the different perforation widths of the pilot hole.

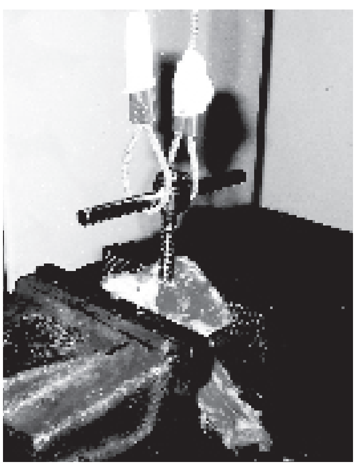

Figure 2– *Screw inserted into swine lumbar vertebra, with device placed on screw head for applying forces during mechanical pullout assay*

The comparison of pullout assays results for screws inserted into swine vertebrae, and the comparison between groups were performed by a mixed effects linear model method (fixed and random effects), establishing a significance level of 5% ($p<0.05$).

RESULTS

The results will be presented according to the nature of the body of evidence used in the assay and to screw diameter.
The results of pullout test for the 5-mm screws inserted into polyurethane bodies of evidence are represented on Table 1 and Figure 3.
The pullout test for the 5-mm screws inserted into polyurethane bodies of evidence showed the occurrence of an enhancement of the maximum implant pullout force with a reduced diameter of the pilot hole as compared to screw's inner diameter. A statistical difference was found between all perforations performed with a diameter smaller than screw's inner diameter. In a decreasing order of perforation diameters, a statistical difference was noted between the 3.5 mm perforation and the perforation corresponding to the screw's inner diameter (3.8mm). The perforation immediately below 3.5-mm perforation was the 3.2-mm perforation, and a statistical difference was found among maximum pullout force values between them. No statistical difference was found between maximum pullout force values with perforations width of 3.2mm and 3.0mm, as well as between widths of 3 mm, 2.7mm and 2.5mm. Thus, from 3.2mm, no statistical difference was noted when comparing immediately decreasing perforation values.

Perforation diameter(mm)	*Maximum pullout force (N)*
2,5 (a)	*41,28 ± 2,73*
2,7 (a)	*41,12 ± 2,43*
3,0 (a) (b)	*38,55 ± 2,36*
3,2 (b)	*36,13 ± 1,92*
3,5 (c)	*33,78 ± 1,70*
3,8 (d)	*28,05 ± 1,79*
4,0 (e)	*20,04 ± 1,19*
4,5 (f)	*4,35 ± 0,81*

Table 1- *Pullout strength values for 5-mm screws inserted on bodies of evidence and with different pilot holes diameters.*

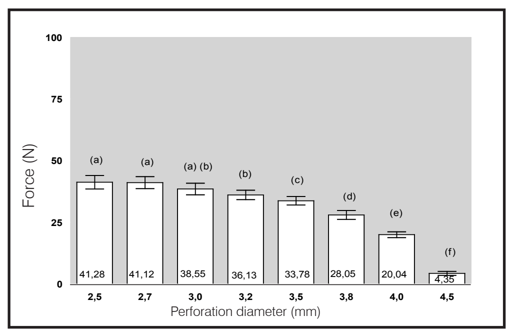

Figure 3 – *Average maximum pullout force of 5-mm screws inserted into polyurethane bodies of evidence and with different pilot hole diameters.*

The results of the pullout assays for 6-mm screws inserted into polyurethane bodies of evidence are represented on Table 2 and Figure 4. An increased implants' maximum pullout force was found with the perforation of a narrower pilot hole than the screw's inner diameter (4.8 mm). A significant statistical difference was found between all perforation values compared to screw's inner diameter (4.8mm) and also between the values compared to each other for smaller perforations than the screw's inner diameter.
A reduction of pullout maximum force values was seen with a wider pilot hole compared to screw's inner diameter. The difference found between perforation values smaller than screw's inner diameter was significant when compared to the screw's inner diameter (3.8 mm) to the perforation values between each other (4.0mm and 4.5 mm).

The results of the pullout assays for 5-mm screws inserted into swine vertebral bodies are represented on Table 3 and Figure 5. An increased implants' maximum pullout force was found with the perforation of a 2.5-mm pilot hole, below screw's inner diameter (3.8 mm), but the difference was not statistically significant. Maximum pullout force values were lower with the pilot hole perforation with the 4.5-mm drill, which was wider than screw's inner diameter, and this difference was statistically significant.
The results of the pullout assays for 6-mm screws inserted into swine vertebral bodies are shown on Table 4 and Figure 6. An increased implants' maximum pullout force was found with the perforation of a 3.5-mm pilot hole (narrower than the screw's inner diameter), and a reduced maximum pullout force with the perforation of a 5.5-mm pilot hole (wider than the pilot hole). The differences between implants' maximum pullout force values were statistically significant for values below and above the screw's inner diameter.

Perforation diameter(mm)	*Maximum pullout force (N)*
3,5 (a)	68,55 ± 5,23
4,0 (b)	62,17 ± 3,70
4,5 (c)	49,45 ± 2,69
4,8 (d)	38,68 ± 2,01
5,0 (e)	27,83 ± 3,29
5,5 (f)	6,03 ± 0,89

Table 2- *Screws' pullout force values for 6-mm screws inserted into polyurethane bodies of evidence and with different pilot hole diameters.*

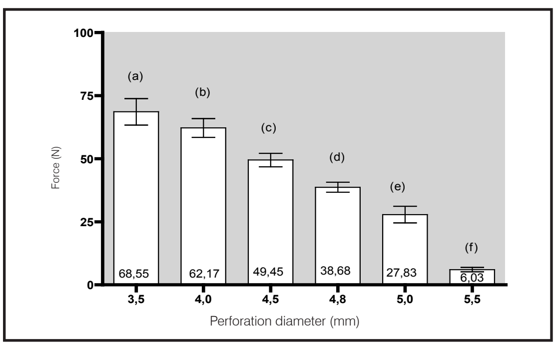

Figure 4 - *Average screws' pullout force values for 6-mm screws inserted into polyurethane bodies of evidence and with different pilot hole diameters.*

Perforation diameter (mm)	*Maximum pullout force (N)*
2,5	1.284,29 ± 249,46
3,8	974,11 ± 144,45
4,5	543,74 ± 102,49

Table 3 - *Pullout strength values for 5-mm screws inserted on swine's lumbar vertebrae bodies and with different pilot holes diameters.*

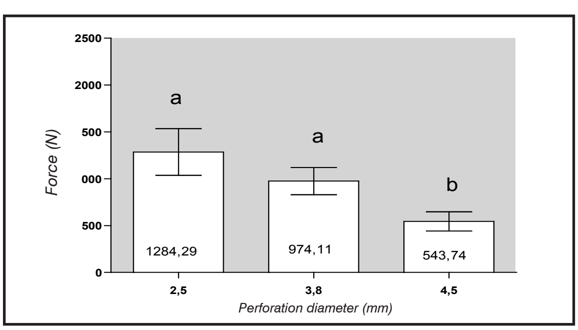

Figure 5- *Average screws' maximum pullout force for 5-mm screws inserted into swine lumbar vertebral bodies and with different pilot hole diameters.*

Perforation diameter (mm)	*Maximum pullout force (N)*
3,5	1806,64 ± 214,50
4,8	1537,42 ± 326,95
5,5	824,81 ± 138,54

Table 4- *Screws' pullout force values for 6-mm screws inserted swine lumbar vertebral bodies and with different pilot hole diameters.*

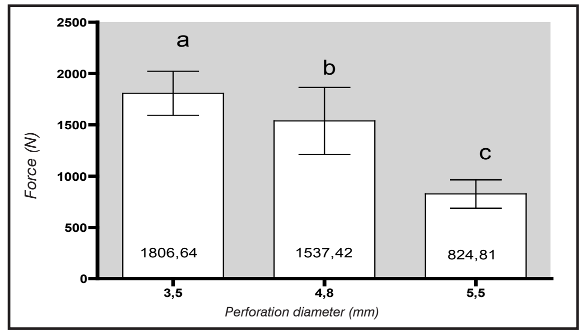

Figure 6- *screws' maximum pullout force for 6-mm screws inserted into swine lumbar vertebral bodies and with different pilot hole diameters.*

DISCUSSION

Screws belong to penetrating pullout-resistant implants category, and it has been one of the most used implants in vertebral fixation surgeries[4]. Screws have different parts: head, outer diameter, inner diameter, threads and thread steps. The outer diameter is the widest diameter between both outer edges of screws' threads, and the inner diameter is the width of the screw body over which threads are fixed [2,4]. In general, screws are classified as cortical-type or spongy screws, according to their threads and inner diameter. Cortical-type screws have a narrower thread, shorter distance between thread steps and a narrower diameter. Spongy-type screws have wider threads, longer distance between thread steps and narrower inner diameter [2,4].
Screws have different parts with different mechanical functions: head, body and tip. The outer portion of the screw body is constituted of the thread and the solid inner portion, which is called screw core [2,4].
The inner portion of a screw provides resistance to torsion and flexion moments, and is proportional to the third power of the inner diameter ($R=\pi D3/32$). The threaded portion of the screw is more closely related to screws pullout resistance [1,4,5].
Screws pullout resistance is a complex phenomenon, and is also related to other additional factors to the screw thread, such as quality and density of the bone tissue and pilot hole [1,7-9].
The pilot hole is made for guiding and facilitating the introduction of screws into the vertebra. Screws inserted into the vertebral body make contact to the spongy bone, except

those crossing the opposite cortical. During screw insertion into vertebral body, the adjacent spongy bone is compacted, producing a stronger interface between the implant and the adjacent bone, which results in an increased resistance to implants pullout [4,10].

Theoretically, performing pilot holes with a diameter smaller than screw's inner diameter increases the amount of compacted bone around the screw, thus increasing implants' pullout resistance.

In previous assays, we found this correlation between pilot hole diameter and screw's inner diameter regarding pullout force. In this assay, we changed the pullout force applied, the screw insertion site, and the kind of body of evidence, and the results were consistent to previous findings. A reduced pilot hole diameter compared to screw's inner diameter increases implants' pullout resistance, while an increased pilot hole's diameter reduces implants' pullout resistance.

The finding about the behavior of the maximum force required for pulling out implants as the pilot hole diameter reduced, showed an increased implant's pullout resistance. However, from certain values on, this difference was not statistically significant, suggesting that perhaps from a given limit pilot hole diameter value, the impaction ability of the spongy bone around a vertebral implant does not depend on the pilot hole diameter anymore. The impaction of the spongy bone occurring around implants has not been studied, and, so far, long-term biological and biomechanical consequences of these microfractures produced by implants insertion are unknown.

A pilot hole increase caused a reduction to implants' pullout resistance, and a statistical difference was found in all values below pilot hole diameter and also a statistical difference between different pilot hole diameter values. This result shows a direct correlation between reduced implants' pullout resistance and an increased pilot hole diameter compared to screws' inner diameter. As a greater amount of bone is removed during perforation, a small amount of bone is impacted around the screw, thus weakening the interface between implant and the surrounding bone, consequently reducing implants' pullout resistance.

Implants' pullout resistance is a complex phenomenon, and depends on several factors [4,5,6,10,11]. In the experimental model used here, we sought to simulate the insertion of implants into homogenous-matrix bodies of evidence, justifying the use of wooden and polyurethane bodies of evidence, which have been used in experiments related to this topic. The use of swine vertebrae is related to the difficulty of obtaining non-osteoporous human vertebrae having similar characteristics regarding bone density. We cannot leave unmentioned the current medical-legal difficulties in obtaining cadaver vertebrae for this kind of study, which has been directed to using animal vertebrae. Nevertheless, the nature of the bodies of evidence has not interfered on the study's objectives, because we were interested only in the study of one of the parameters involved in screws' pullout resistance, and we've been able to establish and repeat the relationship between studied parameters in different bodies of evidence.

Screws' pullout resistance is dependent on many factors, but we have been able to establish the correlation between pilot hole diameter and screw's inner diameter on implants' pullout resistance. This fact has a wide clinical application and should be noticed when inserting screws into vertebral bodies intending to achieve the highest possible implant performance by being aware of its biomechanical properties and characteristics.

CONCLUSION

In the mechanical assays performed, the relationship between pilot hole diameter and screw's inner diameter influenced screw's pullout resistance. Perforating a narrower pilot hole than screw's inner diameter causes an increased pullout resistance, while perforating a wider pilot hole than screw's inner diameter causes a reduced pullout resistance.

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