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Finite Element Analysis in Lumbar Vertebrae after Pedicular Subtraction

Marcelo Oppermann[1*], Leandro Xavier Cardoso[2], Lourdes Mattos Brasil[3], Alex Sandro de Araújo Silva[4]

[1]Department of Spine Neurosurgeon, University of Brasília, Spinal Tech Laboratory, Brazil

[2]Department of Medical Physic, University of Brasília, Spinal Tech Laboratory, Brazil

[3]Department of Biomedical Engineering, University of Brasília, Brazil

[4]Department of Mechanical Engineering, Universidade Federal Rural do Semiárido, Spinal Tech Laboratory, Brazil

[*]**Corresponding author:** Marcelo Oppermann, Department of Spine Neurosurgeon, University of Brasília, Spinal Tech Laboratory, Brazil. Tel: +55-61996660675; Email: marcelooppermann@hotmail.com

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Abstract

Lumbar Spinal Stenosis is the most prevalent disease in patients above 65-years-old affecting the lumbar spine. It is a condition leading to a tight vertebral canal. Surgery is the definitive treatment, but has high failure levels. We are studying a new technique for surgical treatment, in which the pedicle structure is lost, in terms of fixation. To regain stability, it is necessary to use Pedicle Screws (PS). However, it is unknown how the PS will have their fixation strength without the pedicle. We studied 5 types of PS inserted into a cylinder with two portions, representing the pedicle and vertebral body, and performed a pullout with 500N. Our end results showed the stress and the strain at the bone-screw interfaces, comparing the intact with subtraction of the pedicle model. In general, the results showed 5 screws have a loss of 47% in fixation, in the terms of displacement. Many PS obtained a lower stress when the pedicle was subtracted. This was further supported by the trabecular bone being more deform-able (lower elastic modulus) and likely to generate lower stress for the same displacement. In the end, this study successfully reported that the removal of the vertebral pedicles brings a large fault capacity, shown by an average increase of almost 50% in the PS displacement when the load of 500N is applied in the form of pullout.

Introduction

Today 11% of the population is above 60 years old and by 2050 this number will rise to 22 percent [1]. Unfortunately, diseases come with age, such as Lumbar Spinal Stenosis (LSS). This condition, described by Verbiest since 1954, occurs in individuals above 60 years old [2]. It is estimated that 8-11% of the American population have LSS and as the "baby boomers" become aged, by the year 2021, 2.4 million people will be affected [3]. Initially, physiotherapy and medicaments are used extensively. However, when neurological deficit appears, surgical treatment is the only option available [4]. The main goal of the surgery is to release the neural components without the compromise of stability.

Although initial results are satisfactory, long term scenarios are not [5]. Accordingly, after some time, surgery is not better than conservative therapy. Pedicle Screws (PS) are important in spinal surgery, especially in the case of instability or when the cause of pain is mechanical. All PS available in the market present the same proposal, immediate rigidity and late osteointegration. The stability is reached by connecting one vertebral structure to another [6].

We are studying a technique to decompress the spinal canal described by Kiapour, et al. [7]. The nerve tissue decompression is released by removing the important structure of the pedicle. It is detached from the rest of the lumbar vertebrae and probably leads to instability. To overcome the loss of vertebral integrity, fixation using implants (as PS) become necessary, however they can be fixed only in the vertebral body structure. Biomechanical studies, testing implants or surgical techniques, can be performed using experimental or analytic methods (i.e., mathematical modeling). Both are considered complimentary approaches and should go hand-in-hand to better understand a mechanical problem [8]. Mathematical models can be repeated as many as necessary to acquire reliability, and today they represent a substantial share of biomechanical studies [9]. The objective of this study was to confirm the need of different implants to perform any technique that removes the structure of the pedicle. For this, we tested 5 PS already used elsewhere [10], the throw Finite Element Models (FEM). We compared the stress and strain interface between the PS and the vertebral body in two scenarios, the intact vertebra (pedicle and vertebral body) against the subtracted model (vertebral body only).

Methods

In order to obtain the results using the FEM we followed the usual steps, Mesh Modeling, Establishing Mechanical Loads and Constraints, Processing and Post-Processing.

Mesh Modeling

To perform the study, a scenario with the PS and the areas of the vertebra in close contact with the implant, had to be created. The screws were taken from elsewhere [10] and they represented, with some precision, the designs most used by a number of companies. However, in that study, the authors used different lengths and diameters. In this study, all screws were set to having 7.0mm and 45mm respectively. The main characteristic of each screw is described in (Table 1). The references of the variables are according to (Figure 1).

VARIABLES	SCREWS DESIGNED				
	Synthes	A-Spine	MossMiami	Viper	Optimal
PI (mm)	0	0	40	Cylindrical	0
CA (◦)	0.5	0.5	0.5	0	0.5
DHA (◦)	25◦	25◦	25◦	25◦	25◦
DRR (mm)	1.0	1.0	1.0	1.0	1.0
ID (mm)	2.76	4	4.61	4.4	3.8
L (mm)	45.0	45.0	45.0	45.0	45.0
OD (mm)	7.0	7.0	7.0	7.0	7.0
P (mm)	2	2	2.95	2.87	3.3
PHA (◦)	0	0	31.4	29.9	5.0
PRR (mm)	0.2	0.1	3.0	3.0	0.4
TW (mm)	0.1	0.1	0.2	0.33	0.1

Table 1: Designs variables of 5 screws used. BP: Beginning Positions, CA: Conical Angle, DHA: Distal Half Angle, DRR: Distal Root Radios, ID: Inner Diameter, L: Length, OD: Outer Diameter, P: Pitch, PHA: Proximal Half Angle, PRR: Proximal Radio, TW: Tread Width. Modified from Amaritsakul, et al. [10].

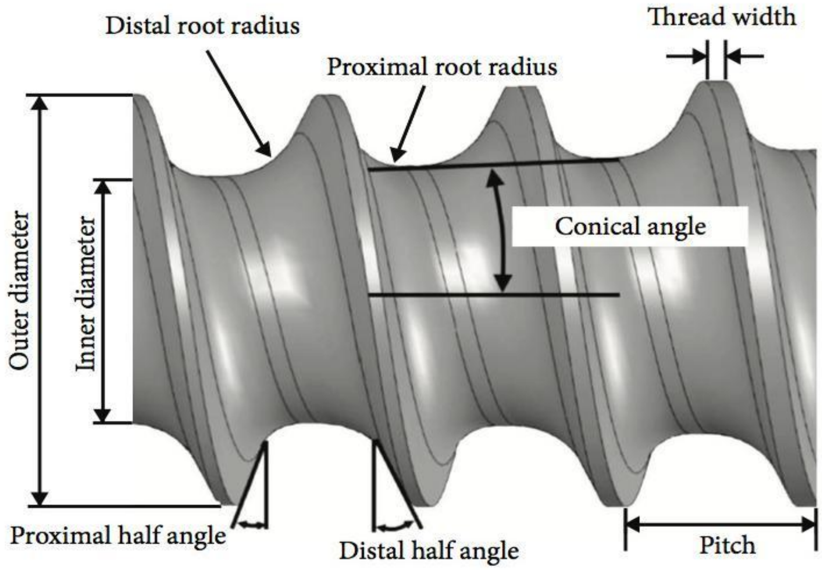

Figure 1: Variables utilized in the mesh of the pedicle screw. Modified from Amaritsakul, et al. [10].

The PS is normally in contact with particular areas of vertebrae, mainly the Pedicles and the Vertebral Body. Both have different physical characteristics [11,12] and microstructure [13], but were here represented differently during the meshing process. Though many studies use the most complex models with a mesh representing the whole vertebrae, the real area around the PS can be drawn by a cylindrical structure. This is a feasible and adequate model and has been used elsewhere [10,14,15]. This study utilized two structures with dimensions shown in (Figure 2).

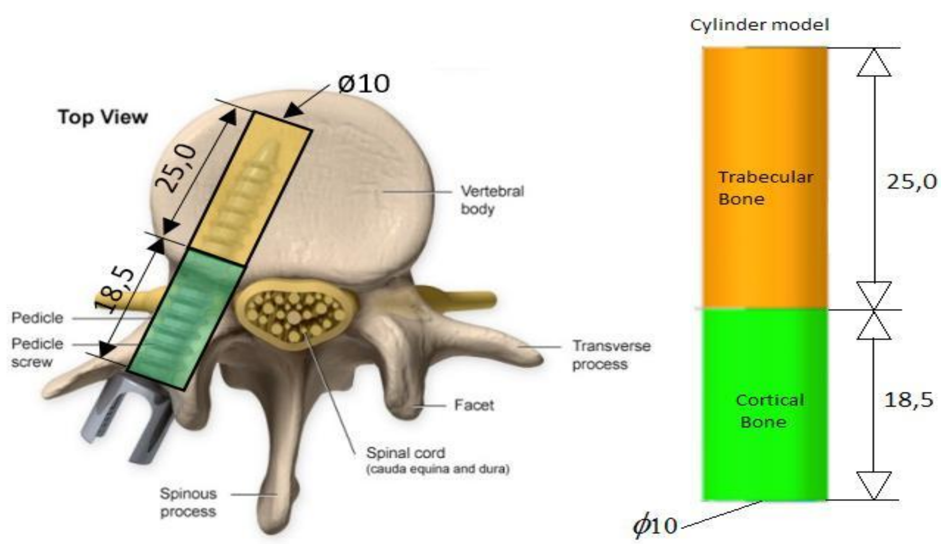

Figure 2: Cylindric representing the two parts. Pedicle in green and the Vertebral Body in Orange (mm).

The bone and screw were initially represented as a parametric 3D CAD model. From this model we could obtain a representative axisymmetric section to simplify the model. Finally, this section could be meshed (Figure 3).

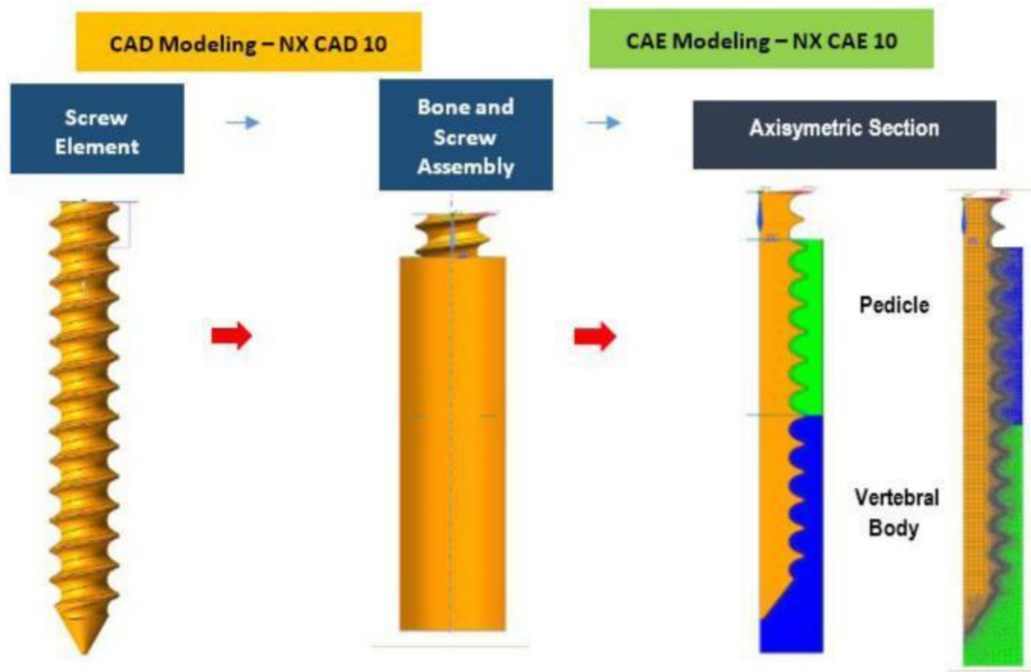

Figure 3: Transformation of a tridimensional model into a asymmetric section. Initially a tridimensional bone and screw are assembled than a transversally cut to great axis is performed and the surface of one half become the model, and finally another transversal section creating an asymmetric model, but with all the important areas represented.

The meshing was defined using NXTM Advanced Simulation 10 (Siemens PLM). The pedicle screw and cylinders were meshed with axisymmetric elements CQUADX8 (8 nodes), with the element length ranging from 0.5mm to 0.1mm (Table 2). The axisymmetric elements used a solid ring by sweeping a surface defined on a plane (axisymmetric section) through a circular arc. (Table 2) provides data relative to number and distribution of elements used in each model.

NUMBER OF MESH AND NODES ELEMENTES FOR THE SCREWS						
CHARACTERISITIC		PEDICLE SCREW				
		Synthes	A-Spine	MossMiami	Viper	Optimal
Number of Elements		14334	14529	10281	9836	9186
Number of Nodes		45432	45969	32475	30956	29174
Medium Size of Elements	Normal Mesh	0.5 mm				
	Fine Mesh	0.1 mm				

Table 2: Number of elements and nodes of each PS modeled.

Establishing Mechanical Properties, Loads and Constraints

The material properties from both bone and the screws were considered Isotropic and Linear Elastic with Young Modulus and Poisson coefficient described at (Table 3).

MESH PHYSICAL VALUES		
Material	E (MPa)	v
Pedicle	19900.0	0.3
Vertebral Body	18000.0	0.3
Titanium Alloy (LTi-6Al-4V)	105449,4	0.36

Table 3: Properties of each structure. (E= Young Modulus) (v= Poisson coefficient).

With the model thoroughly created and material properties defined, the load and constraint were applied. The lateral surface of axisymmetric cylinder (specifically the nodes) was fixed, and the screw had pullout with a force of 500N in axial direction according to the (Figure 4).

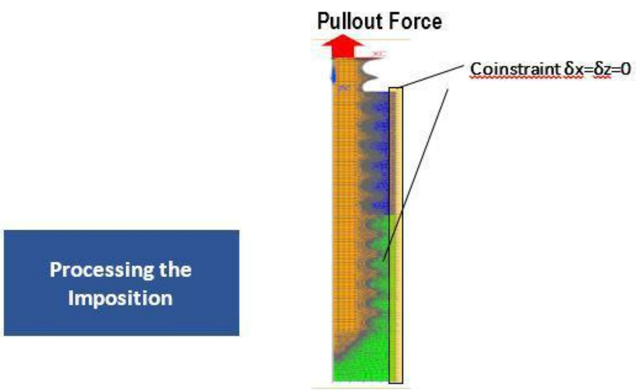

Figure 4: Final stage of the model creation, when the pullout force and the rigid area are created to the screw (yellow) and bone (green and blue) respectively.

In order to promote more precision of stress calculation in contact areas (Figure 5) between the screw and the bone, a fine mesh (0.1mm) was created. Edge-to-edge contact elements were used for the interface between the pedicle screw and cylinder with both a No-Friction and No-Rotation (axial) condition.

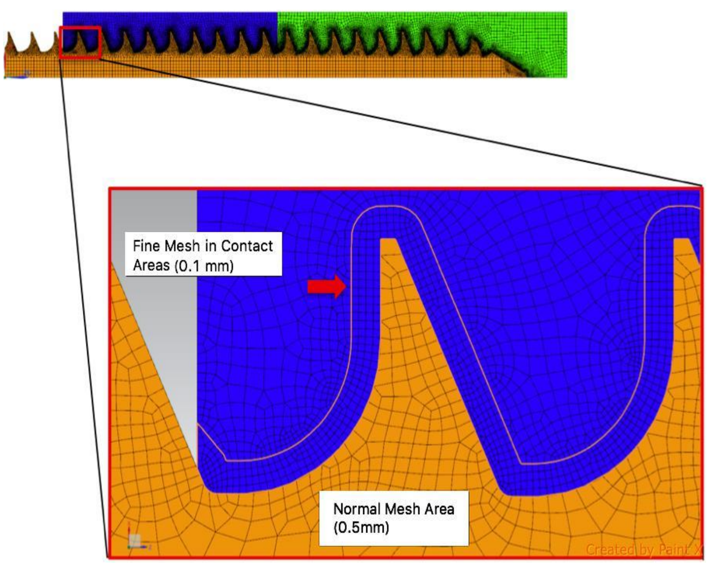

Figure 5: PS (yellow) and bone (blue) interface showing the refining mesh method in contact areas.

Post Processing

The study had two scenarios. One with all screws inserted in an intact model, with the vertebral body and the pedicle present. Then, another without the pedicle area blue area of (Figure 4 and 5). In these two scenarios, the objective was to analyze the variables of the stress and strain after 500N, as pullout force, in all five screws together and separately. The stress was analyzed as maximal stress in the model, and at the first thread. At this point the NX Advanced Simulation/Nastran (Siemens - Germany) was the software utilized for post processing.

Results

There were 10 pullout tests generated. One for each screw in two different scenarios, intact and subtraction of the pedicle region.

Stress

In general, when a pullout load of 500N was applied, the model of the intact vertebra had lower stress values when compared to screws inserted only in the pedicle subtraction scenario. The average stress is presented in (Figure 7) and depicted in (Figure 6).

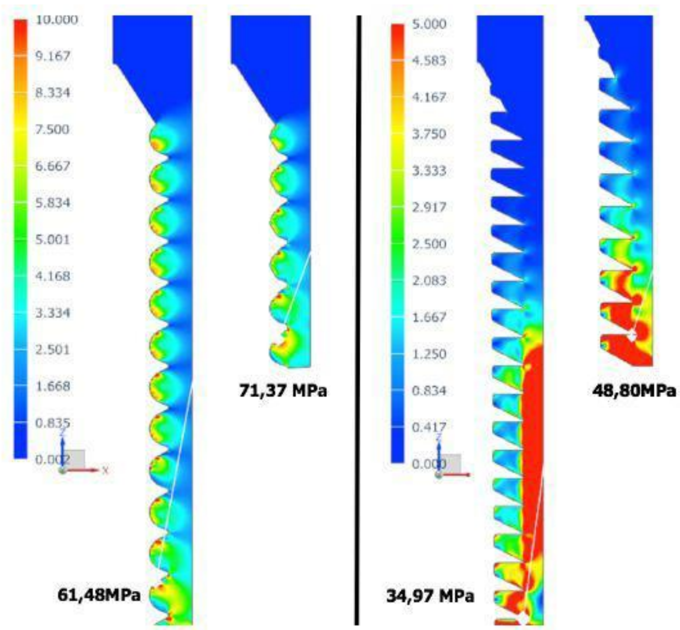

Figure 6: Demonstration of the maximum Strain of two screws (MossMiami - Left, and A-Spine - Right). The screw was removed in order to better demonstrate the tensions. The values according to the color scale, are in MPa (Mega Pascal). Note that the highest stress points (indicated by the white dots) are always the first thread in contact with bone.

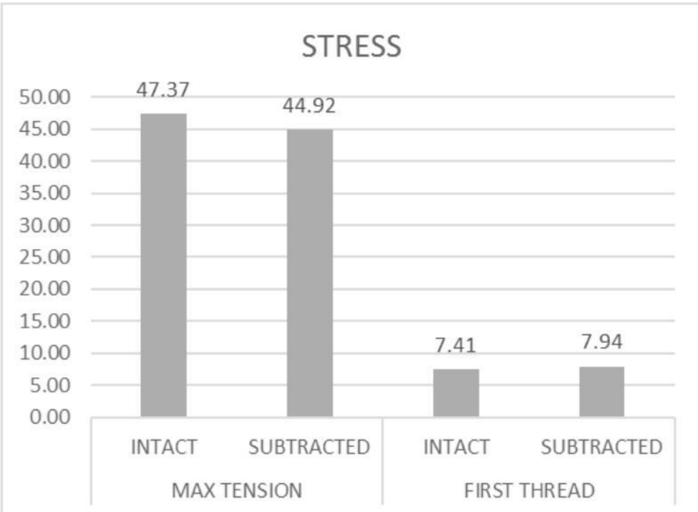

Figure 7: Stress at the first screw and maximal in the intact and subtracted scenarios. Values in MPa.

The average stress on the first thread inside the bone was 7,41MPa (2,20 - 12,00MPa, SD 4.06) for the intact model and 7,94MPa (3.16 - 10.97MPa, SD 2.88) for subtracting. The maximum stress achieved was 47,37MPa (62.24 - 30,33MPa, SD 11.08) for the intact model and 44,90MPa (31,54 - 53,30MPa, SD 2.8) for the subtracted. The results show that on average there was a decrease of 5.21% (2,47MPa) to maximum stress, and an increase of 7,15% (0,53MPa) on the first thread when the subtraction was present (Figures 8,9).

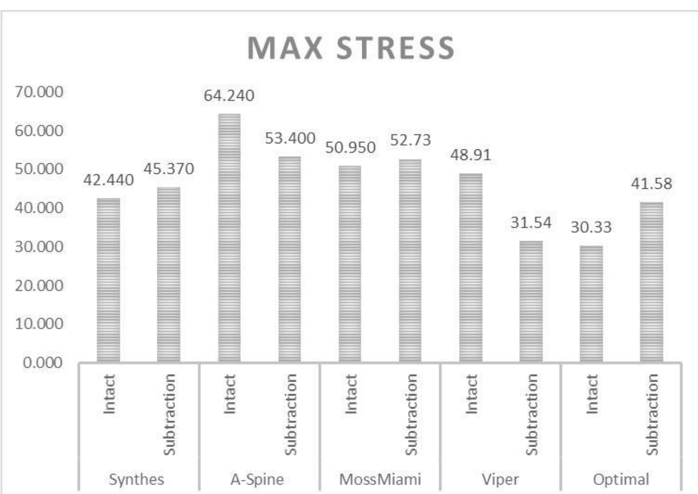

Figure 8: Maximal Stress reached in both scenarios, intact and subtracted. Values in MPa.

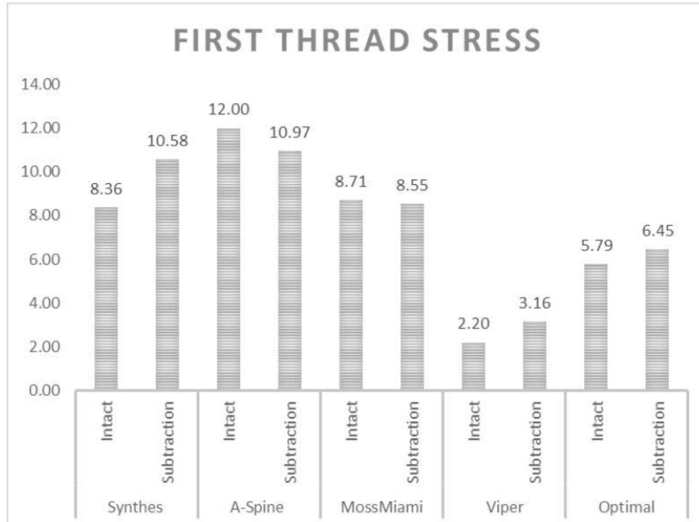

Figure 9: First thread Stress reached in both scenarios, intact and subtracted. Values in MPa.

Displacement

On average, the pedicle subtraction brought a 47% loss of fixation to the screw measured by the displacement, when imposed a pullout force of 500N. The average displacement on the screws with this pedicle was 8,66µm, and without the pedicle was 12,78µm, an increase of 4,12µm mobility (Figure 10).

Figure 10: Average displacement of the all screws in both scenarios (intact and pedicle subtraction). Values in µm.

The results for each screw and their scenarios are described graphically in (Figure 11) and depicted in (Table 4).

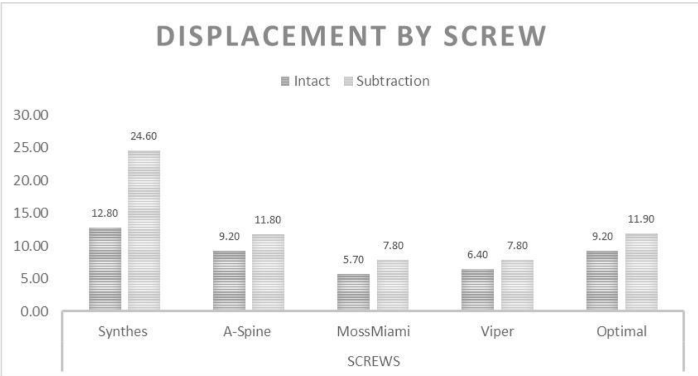

Figure 11: Displacement of each screw in both scenarios (intact and pedicle subtraction). Values in µm.

The difference percentage between the screws with higher and lower displacement in the subtraction model was 68.3% (Synthes vs Viper).

SCREW DISPLACEMENT					
SCENARIO	SCREWS				
	Synthes	A-Spine	MossMiami	Viper	Optimal
Intact (µm)	12,80	9,20	5,70	6,40	9,20
Subtraction (µm)	24,60	11,80	7,80	7,80	11,90
Difference	92,2%	28,3%	36,8%	21,9%	29,3%

Table 4: The displacement of different screws according to the scenario, intact and subtracted.

Discussion

There are many factors associated with a good clinical outcome and mechanical instrumentation of the lumbar spine. Such as cited factors related to bone, like density, geometry of trabecular meshwork and mechanical factors of the bone structure. In addition, the surgical technique used in the screw introduction gives rise to different clinical outcomes and screw designs [16]. Some diseases have registered the use of screws more than others. For example, Lumbar Spinal Stenosis (LSS) where only in certain circumstance implants are necessary. LSS is a condition often found in clinical medicine [17] and affects most of the elderly. It is defined to a narrowing internal spinal channel which maintains all the neural tissue [18]. A technique is being studied which will in principle allow a more durable, and perhaps, permanent process of spinal channel decompression. This procedure, described by Kiapour, et al. [7] has discontinuity and separation of the pedicle from the vertebral body. However, in this case, the instability of the spine is an area not yet studied. Here we created a FEM simulating the pedicle subtraction scenario and comparing it with the intact vertebrae. The FEM is a well-recognized method to study the normal physiological structure of the spine [19-21], test new products [10,14,15] or techniques [22]. There are many forms to represent the structure of the vertebrae, some use only portion [23], others the entire vertebra [24,25], and a third group simplify as a cylindrical structure when used to study PS [10,14,15]. The preference for the cylindrical shape makes the mesh modelling easy as well as the performance of a more simplistic two-dimension asymmetric model requiring less computer resources [26]. The diameter of the cylinder must be sufficient to a point that its surface will not have any influence on stress caused by movement of the screw. Amaritsakul, et al. [10] utilize a cylinder of 30 mm in diameter, Chazistergos, et al. [14] 16mm and our model 10mm, which was considered sufficient enough to keep all the stress inside (Figure 6). Besides, the pedicle diameter will rarely have a diameter greater than 10mm [27].

The given mechanical properties (Table 3) of the two parts of the vertebral bone were based in two principles. First, the vertebral body is a typical trabecular [23,28,29] formed by cells and trabecular pillars. Also, the pedicle has a pronounced amount of cortical structure [11,29] with more dense bone tissue. Moreover, these areas were related according its constituents. Although there are a great variety of mechanical indicators like Elastic Modulus and Poisson Coefficient [9], some authors are hypothesizing that the trabecular and cortical have minor mechanical differences. Bayraktar, et al. [30] conducted a study and found only 10% less rigidity of the trabecular bone, and others have confirmed [31,32]. The pullout force in a mechanical test utilizing physical structures is highly dependent at the rate in which the force is applied. The ASTM standard F543-00 for testing metallic medical bone screws advocate a 5mm/min pullout force [33]. Chen, et al. [34] utilizing human vertebrae found at this rate a failure pullout less than 500N. Furthermore, the preference for the pullout force can be discussed. Numerous tests can be applied to assess the binding capacity of a pedicle screw to the vertebral bone. The pullout test is the most commonly used to assess the binding capacity of the pedicle screw [35]. However, other tests, such as the torsion test, alternating test or load cycling are used, but with less frequency [36-40]. When a pedicle screw is pulled out of the bone, the structures arranged between threads are usually fractured. Thus, the quantity and quality of the bone screw between the structures are very important. In general, the more and better bone existing in this space, the greater the pullout strength. The more one particular screw can purchase bone tissue among its thread, the better pullout force. So, even the pullout test is not recognized as representative of the biomechanical movement, it has a good correlation with immediate fixation [35].

Our results gave us some important information. First, the stress imposed to the bone was smaller in the subtracted model. At first glance we suspected the opposite. However, after closely looking at why this happens, we understand that a bone tissue with less stiffness (lower Elastic Modulus) will be less stressed with a certain force, and is much higher with the Young's Modulus where more stress will be imposed to it. Furthermore, even in the screw with the highest stress (A-Spine in intact model), (Figure 8) did not reach the yield stress point for the trabecular bone. Bayraktar, et al. [30] using femoral bones of cadavers, found that the deformation limit value before the failure was 87,52MPa (yield stress). In other words, since the stress does not reach 87MPa, the bone structure can resist breakage. The second finding this study can provide was predictable, the superior displacement in the subtracted scenario.

The average displacement was 12,78 μm, 47.5% greater than the intact scenario. The screw design was important to make this difference smaller or larger. For example, the Synthes screw had 92,2% of increment and the Viper only 21,9%. These results are in agreement with Hirano, et al. [11] and Weinstein, et al. [12]. In both papers the authors refer to the pedicle as holding 60% of the PS strength. Unfortunately, because there are so many variables on the screw designs, we cannot infer what causes the difference between these two implants. This was not our objective, but in a model using ordinary mesh construct, it is difficult to build a scenario with typical trabecular features. So, the differences in the screw characteristics become less evident. Recently, some authors are using FE models based directly off the Computerized Tomography (CT) by means of Standard Triangle Language (STL) format to create the elements [41]. STL is a CAD format that is primarily used to send CAD to rapid automated prototyping machines.

However, the trabecular definition used in conventional CT are not appropriated or accurate to be transported to a FEM Software, this can only be performed with micro-CT [42].

This study also poses some limitations. We utilized a linear and isotropic model to the FEM. The cortical can be related as anisotropic, even having a more dense, solid resemblance [43], and this is also true for the trabecular bone [13]. In fact, the trabecular bone can be considered transversally orthotropic [44]. Moreover, it has to be validated in a porcine or human vertebra. For our understanding, it will be very enlightening if a study can test each screw design variable separately and not a particular commercial screw. In the future new forms of spinal fixation will be available. One example, is the use of nanoparticles of cements that connect the tip of one screw to another, increasing exponentially the strength of the implant. Instead of being pushed inside the vertebral body, they will occupy the space of the trabecular bone without braking, leading to high states of fixation. This type of cement is being studied, and their preliminary results favor to better state of osteointegration with no extravasation outside the vertebral structure (unpublished data).

Conclusion

In this paper, we confirmed the necessity of new implants or techniques when the removal of the pedicle structure. We tested 5 Pedicle Screws already used elsewhere using Axisymmetric FEM and compared the stress and strain interface between the PS and the vertebral body in two scenarios, the intact vertebra (pedicle and vertebral body) against the subtracted model (vertebral body only). The results showed considerable increase of screw displacement with and without pedicle structures. In order to confirm that in the case of pedicle subtraction, the market screws are not appropriate, it will be necessary to test these results in an intact spinal unit with all the ligaments and perform the mechanical scenario.

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