Investigation of the Behaviour of the Pedicle Screw - Vertebral Bone Complex, When Subjected to Pure Pull - Out Loads

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ABSTRACT

The analysis of the failure mechanisms of spinal fixation systems and the stress distribution patterns within vertebral bodies constitutes an indispensable demand for the clinical evaluation of these systems. In this paper the influence of various parameters on the failure of fixation systems due to the pull-out phenomenon of the fixation screws is explored. To achieve this goal a Finite Element Model of the human lumbar vertebral bone and of the transpedicular fixation screw is designed simulating the main characteristics of commercial fixation pedicle screws. The parameters studied include the type of the bone-screw interface as well as some geometrical characteristics of the screws and the vertebral bone. The analysis revealed the different behavior of the pedicle screw-vertebral bone system and the different stress diffusion mechanisms activated according to the interface type. It was, also, concluded that the performance of pedicle screws under pull-out loads could be improved by increasing the thread depth.

Introduction

During the last two decades, the pedicle screws became one of the most commonly used spinal instrumentation tools [1]. The transpedicular screw fixation method is particularly indicated for the treatment of spondylolytic and degenerative spondylolisthesis, trauma and tumor due to its ability to achieve rigid spinal fixation. Among the factors which play a crucial role for a successful pedicle screw instrumentation the level of the screw adhesion to the vertebral bone (depending mainly on the quality of the bone and the type of the screw) is perhaps the most important one. Loss of the surgical construction stability as a result of screw loosening is a common complication, particularly in osteoporotic patients. In spite of the constant improvement of both the spinal instrumentation systems and the surgical techniques, there is still no foolproof method for the fixation and stabilization of the spine. The most serious problems encountered are the hurtful results to the spinal segments adjacent to the fixated ones and the failure of the spinal instrumentation either due to fracture of its structural elements or due to loosening of the fit.

In order to overcome the above mentioned problems, deeper knowledge is required concerning the way that each part of the spinal instrumentation system functions when implanted into the human spine. One should have a clear insight of the influence of a spinal instrumentation tool on the behavior of the anatomical region where it is implanted and on the behavior of the spine as a whole. In addition the dependence of this influence on the mechanical and geometrical characteristics of the implant should be clearly understood. In case these conditions are fulfilled it could be much easier to improve existing systems and techniques and, also, to set the proper guidelines and specifications for the development of new systems.

One of the most important factors that should be taken into account for the evaluation of the performance of a pedicle screw is the pull-out strength [2-5]. In this context this paper focuses to the behavior of a transpedicular fixation screw when it is implanted into human lumbar vertebral bone and subjected to “pure pull-out displacement”. Under this term an axial force is denoted applied along the longitudinal axis of the screw and tending to detach the screw from the bone. Obviously such a load is rather simplified compared to the actual loading conditions of the screw when implanted in the vertebra. However and in spite of its simplicity the analysis enlightens some controversial points concerning the way that these two totally different materials (bone and titanium alloy) “cooperate” for the distribution of the stresses developed and the way they react to the separation from each other. The purpose of the paper is the parametric study of the dependence of the behavior of the pedicle screw - lumbar bone system on various factors. These factors include the type of the interface (are the screw and the lumbar bone fully bonded or are they just in simple contact to each other?) and the geometric characteristics of the screw. The
variation of the pull-out force with the geometrical characteristics of the screw was explored in an effort to determine their optimum combination, i.e. the one that corresponds to the most mild stress distribution resulting in turn to the maximization of the pull-out resistance of the system. The study is carried out numerically with the aid of the Finite Element Method (FEM).

**Numerical Analysis**

For the purpose of the present analysis a finite element model of the human lumbar vertebral bone and the transpedicular fixation screw was designed. The analysis was performed using the ANSYS 8 software. The model of the screw takes into account the main characteristics of commercially available fixation pedicle screws. The geometry of the screw as well as the direction of the pull-out loads are shown in Figure 1. As it is seen from this figure, the geometrical quantities describing a typical pedicle screw are: The major or external radius, $r_1$, the minor or internal radius, $r_2$, the pitch $p$, the thickness of the thread at its peak, $e$, and finally the inclination of the thread, described by the two angles $a_1$ and $a_2$. The values of these quantities for the original pedicle screw studied were equal to: $r_1=2.75$ mm, $r_2=1.7$ mm, $p=3$ mm, $e=0.2$ mm, $a_1=5^\circ$ and $a_2=25^\circ$. It is mentioned that the tip of the thread was modeled as a sharp notch, formed by two straight lines, in order to avoid introducing “bad” elements in the mesh of the model.

![Figure 1. The geometry and the main characteristics of a typical pedicle screw](image)

Taking into account the relative dimensions of the vertebral bone and the screw it was concluded that it is not necessary at this point to build an accurate 3-D model of the vertebra. Attention should be paid to the area in the immediate vicinity of the screw (Figure 2). Therefore a simplified model was built as it can be seen in Figure 3. The vertebral bone was designed as a cylinder of cancellous bone with two layers of cortical shell at both ends. The radius of the cylinder was $R_3=8$ mm and its depth $C=34.4$ mm. The cortical layer at the side of the pedicle had a thickness of $S_1=3$ mm while at the opposite side the respective thickness was equal to $S_2=0.4$ mm. The threaded hole along the axis of the cylinder, where the screw is driven, was assumed to have identical shape and dimensions with the screw itself, i.e. it was assumed that $R_1=r_1$ and $R_2=r_2$. For simplicity and in a first approximation the fact that in common surgical practice the hole is drilled slightly smaller compared to the screw, was ignored, during the design of most of the models.
All materials were considered to be of isotropic and linear elastic nature. The values of their mechanical properties were obtained from recent literature [6-9]. The screw was assumed to be made from a Titanium alloy with modulus of elasticity $E=193$ GPa and Poisson’s ratio $\nu=0.3$. The respective values for the cancellous bone were $E=100$ MPa and $\nu=0.2$ while for the cortical shell the values adopted were $E=780$ Mpa, and $\nu=0.3$. Finally a friction coefficient equal to 0.2 [2,8] was assigned to the contact between bone and screw.

For simplicity and CPU processing time economy reasons advantage is taken of the symmetry of the system with respect to any plane including the axis of the screw and therefore only one half of the pedicle screw-vertebral bone model was considered. For the meshing the 10 nodded 3-D tetrahedral structural solid element SOLID187 was used. For the optimization of the mesh density, a finer mesh was used in regions with high stress concentration while coarser meshes were introduced in areas of low or constant stress gradient. In order to ensure that the behaviour of the model does not depend on the specific discretization procedure chosen the mesh was created using the “free mesh technique” with element size becoming smaller the closer one gets to the surface of the pedicle screw. A detailed view of the mesh is shown in Figure 4.

Special attention was paid to the optimum simulation of the bone-screw interface, which defines the load transfer mechanism between the bone and the screw. The present study included two different scenarios according to the experience gathered from clinical observations: The first scenario simulates the interface during the first postoperative weeks, when the screw and the bone are just in simple contact (contact model). The second scenario simulates the fully bonded bone - screw interface and is more suitable for the description of the system at about two years after the operation (bonded model)[2].
The interface conditions of the bonded model are easily simulated numerically by merging the elements of the pedicle screw surface with the respective ones of the lumbar bone. In order to simulate the simple contact conditions a surface-to-surface analysis was conducted. This type of analysis begins by identifying the areas in contact, which afterwards are meshed with the aid of suitable contact elements. Two types of contact elements are required for such an analysis, namely the target and the contact ones. Their function is based on the penetration of the target elements into the contact ones. For better performance of the contact elements, the surface of the volume having the higher elasticity modulus is defined as the target area and is meshed entirely with the corresponding target element, while the surface of the volume having the lower elasticity modulus is defined as the contact area and is meshed entirely with contact elements. In the present study the surface of the pedicle screw was defined as the target area, and it was meshed using the TARGE170 element. On the contrary the corresponding surface of the hole into the bone was defined as the contact area and it was meshed using the CONTA174 element. The parameter that governs the function of the contact analysis is the normal penalty stiffness factor (FKN), which controls the “penetration” of the target elements into the contact ones. In order to determine the numerical value of FKN which permits convergence of the results and at the same moment prevents element distortion, series of preliminary tests (‘runs’) were carried out. The results of these tests for the variation of the pull-out force versus FKN are plotted in Figure 4. It is concluded that the dependence of the pull-out force on FKN is eliminated for values of FKN exceeding 10, which was the value finally assigned to the contact elements of the model.

Concerning the boundary conditions the following restrictions were imposed: The external surfaces of the lumbar bone were not allowed to move in any direction, while the two bases of the cylinder were free to move at any direction. In addition it was assumed that all areas of the bone in the inner cross section were restricted along the Y-direction, while all screw areas in the inner cross were restricted along both the X- and Y- directions. Finally a constant displacement was induced on the pedicle screw along its axis. The value of the pull-out displacement was determined by assuming that the equivalent stress developed during pulling the screw out should not exceed the respective yield stress at any point in any material of the system. To achieve this goal several preliminary ‘runs’ were carried out using the contact model since it is expected to produce higher stresses. The critical value of the displacement obtained in this way was equal to $5 \times 10^{-6}$ m.
As a final step of the model-design phase the convergence of the results of the model was checked against the density of the mesh and the value of the normal penalty stiffness factor (FKN). Several convergence ‘runs’ were performed and the respective results concerning the variation of the pull-out strength versus the FKN value and the number of elements of the mesh are plotted in Figures 4A and 4B. It can be seen from this figure that for meshes with less than 100,000 elements the results concerning the pull-out force oscillates from about 25 N to about 26.5 N. For meshes with a number of elements exceeding 100,000 the results converge to a value of the pull-out force equal to about 26 N. Therefore the meshes used for the main part of the present analysis were designed with FKN equal to 10 and number of elements equal to about 105,000.

Figure 3. The FEA model. The different colors denote the different materials: PURPLE stands for the cancelous bone, RED for the cortical shell and BLUE for the titanium alloy.

Figure 4A. Calibration of the contact elements

Figure 4B: Calibration of the density of the mesh
As a final step of the model-design phase the convergence of the results of the model was checked against the density of the mesh. Several convergence ‘runs’ were performed and the respective results concerning the variation of the pull-out strength versus the number of elements of the mesh are plotted in Figure 5. It can be seen from this figure that for meshes with less than 100,000 elements the results concerning the pull-out force oscillates from about 25 N to about 26.5 N. For meshes with a number of elements exceeding 100,000 the results converge to a value of the pull-out force equal to about 26 N. Therefore the meshes used for the main part of the present analysis were designed with FKN equal to 10 and a number of elements equal to about 105,000.

Based on the conclusions of the previously described preliminary analyses thirteen finite element models were constructed: The first two of them were used for the study of the influence of the contact conditions on the pull-out strength (contact and bonded model) nine models were used for the study of the influence of the geometrical characteristics of the screw on the pull-out strength. The remaining model was built with thinner cortical shell layer (Thin model). The contact conditions adopted for the latter ones were identical to those of the contact model.

The geometrical parameters included in the present analysis were the depth of the screw thread (r1-r2) and the angle a1. The numerical values assigned to the depth were equal to 0.5, 1 and 1.5 mm while these assigned to the angle a1 were 0°, 5° and 15°. The values of the remaining geometrical quantities were kept constant equal to $a_2=25^\circ$, p=3 mm and $e=0.2$mm. According to the notation adopted here for the identification of each one of the nine models the depth of the screw thread is denoted by one of the three letters (a,b,c) while the angle a1 is denoted by one of the three numbers (1,2,3). Therefore each model is named by a combination of two characters. For example the model for which the depth of the screw is 1.5 mm and the angle a1 is 5° is identified as “model c2”. The numerical data for all the models used in the analysis are shown in next Table 1.

Finally the thin model was build with the two cortical shell layers having the same thickness equal to 0.4mm. The original models had one layer 0.4mm thick and one 3mm thick.

The Results of the Analysis

The results of the analysis concerning the bonded model are shown in Figure 5 in which the distribution of the equivalent stress (according to the von Mises criterion) is plotted for both the bone (A) and the screw (B). The plots are realized on an intersection of the model along the YZ plane. The specific plane was chosen since on this plane the portions of the model of great interest are relatively far away from the constraints imposed at the XZ plane and from those on the surface of the bone-cylinder system. Therefore it can be safely assumed that these constraints do not influence the accuracy of the results of the numerical analysis. As it is observed from this figure, there is a strong stress concentration in the bone at the area around the first thread. In the vicinity of the remaining threads the stress tends to stabilize at significantly lower values. It is therefore extremely important for the orthopedic surgeon to arrange for the first thread to be embedded completely (if it is possible) in the cortical shell. The areas where the stress seems to concentrate is on the major radius ($r_1=R_1$) near the edge of the steeper side of each thread.

In order to explore further the above observation the equivalent stress is plotted along a path that connects the root of a thread with its edge (Path 1, in Figure 5A). The equivalent stress plotted along this path produces the stress profile shown in Figure 6A. It is seen from this figure that the values of the equivalent stress vary between about 1 MPa and 0.9 MPa and the variation is almost monotonous almost all along path 1. However a weak minimum is observed at about the two thirds of the length of the path which should be studied further. It becomes, also, evident from Figure 6A that indeed the maximum stress appears at the edge of the thread. Such a conclusion implies that a complete overview of the dependence of the maximum stress on the order of the thread (in other words on the distance from the head of the screw) could be obtained by plotting the equivalent stress along a path which passes from each thread edge (Path 2 in Figure 5A). The results of this path plot are shown in Figure 7. The maximum equivalent stress into the bone is observed into the cortical shell at the first thread with a value approaching 0.90 MPa. From this point the magnitude of the equivalent stress is reduced dramatically and is kept almost constant for all remaining threads, oscillating around a value equal to about 0.2 MPa. It is therefore indicate the decisive role of the first thread of the screw and its relative position to the cortical shell.
Figure 5. The Von Mises equivalent stress in the bone (A) and screw (B) observed at an intersection towards the Y axis for the bonded model.

Figure 6. The equivalent stresses developed into the bone (A) and the screw (B), plotted along the steepest line of the first thread of the pedicle screw.
Regarding the stress field in the screw the stress distribution on the intersection of the model along the YZ plane (Figure 5B) reveals again a very strong concentration at the first thread. The maximum stress is about 3.5 MPa and appears at the root of the thread, as it can be seen, also, in figure 6B. Around the other threads the stress gradually faints. The concentration of stress around the first thread means that it carries most of the pull-out load. This conclusion is absolutely justified since the first thread is placed completely into cortical shell the Young modulus of which is much higher compared to that of the cortical shell. The pull-out force for this model was estimated to be 42 N.

For the contact model the contour of the equivalent stress for both the bone (A) and the screw (B) are shown in figure 7. The plot is realized for the same intersection as the bonded model. For this model too, high stress concentrations appear for both the bone and the screw in the vicinity of the first thread. It means that in this case, also, most of the pull-out load is carried by this thread. More specifically the maximum stress observed for this model appears at the edge of the first thread and has a value of about 1.15 MPa. In the vicinity of the remaining threads the value of the maximum equivalent stress (at the edges of the threads) ranges from 0.23 MPa to 0.28 MPa. In Figure 8 the equivalent stress into the bone along path 1 is plotted. From this figure it becomes clear that the maximum stress observed at every thread of the contact model is higher than the respective of the bonded model.

![Figure 7. The equivalent stress into the bone, plotted along a line parallel to the Z axis on the YZ plane and at the major radius of the screw.](image)
The profile of the stress distribution at the first thread is represented in figure 6B, where the equivalent stress is plotted along the path 3 (Figure 5B). The pattern of the stress profile is similar to the respective for the bonded model, the only difference being that the concentration at the edge is stronger for the contact model than it is for the bonded. The opposite happens for the rest of the thread, where the concentration is weaker for the contact than it is for the bonded model. These differences into the stress distribution profiles imply that in the case of the contact model the pull-out loads are carried almost exclusively by the areas near the thread edges. This fact leads on one hand to higher stresses, as we already have seen and on the other hand to lower pull-out resistance. The pull-out force for this model was estimated to be 33N, which means 21% lower than the pull-out strength for the bonded.

Figure 8. The Von Mises equivalent stress in the bone (A) and screw (B) observed at an intersection towards the Y axis for the contact model.

Figure 9. The influence of the thread depth to the pull-out force, for different thread angles a1.
For the parametric study of the screw geometry nine models were examined for different thread depths and different thread angles \((a_1)\). The results concerning the pull-out force are shown in Table 2. As it can be noticed above the pull-out strength increases by the increase of both depth and angle \(a_1\), but the influence of the angle seems to be negligible compared to the influence of the thread depth. This influence is can be seen clearly below in Figure 9. The pull-out force seems to increase linearly with thread depth.

At this point it is to be mentioned that the pull-out strength analysis is not enough to provide conclusions concerning the performance of a pedicle screw. Another very important factor is the efficiency of the stress distribution into the bone. The influence of this factor is revealed by examining the pattern of the stress distribution for each one of the models by keeping the angle \(a_1\) constant. These patterns are in Figure 10 for angle \(a_1=5^\circ\) and for different thread depths. The plots are realized along path 3. It is clearly seen from this figure that the maximum stress into the bone appears for all cases at the edge of the first thread, but the absolute values seem to depend strongly on the thread depth. The maximum stress observed decreases for deeper threads. Indeed for the screw with depth 0.5mm the maximum stress is about 1.4 MPa while the maximum stress for depth 1.5mm is about 0.95 MPa. So from this parametric analysis it can be safely concluded that pedicle screws with deeper threads can possibly resist more sufficiently pull-out loads.

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![Figure 10. The influence of the thread depth on the distribution of the equivalent stress](image)

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**Table 1. The parameters and values studied and the estimated pull-out force**

<table>
<thead>
<tr>
<th>(r_1(\text{mm}))</th>
<th>(\text{Depth}= (r_1- r_2)(\text{mm}))</th>
<th>Symbol</th>
<th>(0^\circ)</th>
<th>(5^\circ)</th>
<th>(15^\circ)</th>
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</thead>
<tbody>
<tr>
<td>2.25</td>
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<td>26.7</td>
<td>27.0</td>
<td>26.9</td>
</tr>
<tr>
<td>2.75</td>
<td>1</td>
<td>(b)</td>
<td>32.9</td>
<td>33.4</td>
<td>33.7</td>
</tr>
<tr>
<td>3.25</td>
<td>1.5</td>
<td>(c)</td>
<td>39.4</td>
<td>40.1</td>
<td>40.7</td>
</tr>
</tbody>
</table>
Finally, for the thin model the contour of the equivalent stress for both the bone (A) and the screw (B) are shown in figure 7. The plot is realized for the same intersection as the bonded model. For this model the stress distribution pattern is totally different. The high stress concentrations for the bone appear not in the vicinity of the first thread, but of the last one. It means that in this case most of the pull-out load is carried by the last thread (N=10) thread. More specifically the maximum stress observed for this model appears at the edge of the last thread and has a value of about 1.53MPa. In Figure 12 the equivalent stress into the bone along path 2 is plotted along with the respective for the contact model. From this figure become clear the great differences of the stress distribution mechanism for the two cases.

Figure 11. The Von Mises equivalent stress in the bone (A) and screw (B) observed at an intersection towards the Y axis for the thin model.
Discussion and Conclusions

In the current study, 3-D finite element models of a typical commercially available pedicle screw implanted into a vertebra bone were developed to investigate the failure behavior of the bone during the screw pull-out. The influence of the contact conditions at the pedicle screw - bone interface on the pull-out strength as well as the dependence of the same quantity on some geometric characteristics of the screw were studied.

The simulation of the pedicle screw geometry as well as of the mechanical behaviour of its material was accurate enough, without simplifying assumptions, approaching therefore the behaviour of the real screw in a satisfactory manner. It is to be stressed out that among the main advantages of the models used is the. Important is that the helicoidal structure of the present study is that the helicoidal structure of the screw was taken into consideration. On the contrary for the simulation of the vertebral bone some simplifying assumptions were considered unavoidable. Indeed, it is well known that the stiffness and the strength of the vertebral bone, as a typical cellular solid, are related to the bone density [9]. However, since the present study is focused on the effects of the interface conditions and of screw geometry on the pull-out strength, the material properties of the vertebral bone were simplified and the bone was considered as a homogeneous and linearly isotropic material. For the same reason the geometry of the anatomical area where the pedicle screw is implanted was designed in a simplified manner, since it was assumed that the phenomena of interest for this study appear in the immediate vicinity of the screw. In spite of these simplifications, however, the main characteristics of the anatomical area where the screw is implanted were included into the analysis and special attention was paid to the co-existence of cortical shell and cancelous bone around the implanted screw: For optimization of the simulation at the side of the bone cylinder from which the screw enters the into the bone body, the cortical shell was designed to be much thicker compared to the respective thickness at the opposite side of the cylinder, in order to simulate the existence of much stronger materials in the specific vertebra sections.

As it was expected the results of the analysis showed that the pedicle screw pull-out phenomenon causes failure exclusively of the vertebral bone and little or no damage to the screw. The failure is most likely to start in the cortical shell, which was proved to carry most of the pull-out load due to its increased elasticity modulus (compared to that of the cancelous bone). This observation reveals one of the most important characteristics of pedicle screw, namely the fact that it takes advantage of the existence of strong materials in the area of the pedicle relieving in this way the much weaker cancelous bone. The low equivalent stresses that were estimated to appear into the pedicle screw, agree with the clinical fact that pedicle screw fractures observed are mainly the result of fatigue processes [7].

Figure 12. The equivalent stress into the bone, plotted along a line parallel to the Z axis on the YZ plane and at the major radius of the screw for the thin model (S1=0.4mm) and the original (S1=3mm).
Concerning the influence of the contact conditions it was concluded that the pedicle screw - vertebra bone system is more likely to fail (under pure pull-out loads) during the first post-operative days when the screw and the bone are in simple contact rather than after a long period after the operation when the screw and the bone are firmly attached to other.

On the other hand the parametric analysis of the geometric characteristics of the screw indicated an almost negligible dependence of the pull-out strength on the values of the $a_1$ angle. It is possible that this result is a side-effect of the type of constraints applied to the models. In fact all the FE models of the analysis were constructed in such way that their stiffness along the XX’ and YY’ axis is higher compared to that along the ZZ’ axis, which is the axis of the applied pull-out displacement. Therefore it is necessary to study further the phenomenon using more sophisticated models at least concerning the stiffness of the model along various directions. The dependence of the pull-out strength on the depth of the thread is much more pronounced. It was concluded that an increase of the depth by only 1 mm (from 0.5 mm to 1.5 mm) results to an increase of the pull-out force from about 26 N to about 40 N, in other words to an increase of about 50%.

References