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NUMERICAL SIMULATION OF BONE SCREW INDUCED PRETENSION: THE CASES OF UNDER-TAPPING AND CONICAL PROFILE.

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Abstract:

Even though screw induced pretension impacts the holding strength of bone screws, its implementation into the numerical simulation of the pullout phenomenon remains a problem with no apparent solution. The present study aims at developing a new methodology to simulate screw induced pretension for the cases of: a) cylindrical screws inserted with under-tapping and b) conical screws. For this purpose pullout was studied experimentally using synthetic bone and then simulated numerically. Synthetic bone failure was simulated using a bilinear cohesive zone material model. Pretension generation was simulated by allowing the screw to expand inside a hole with smaller dimensions or different shape than the screw itself. The finite element models developed here were validated against experimental results and then utilized to investigate the impact of under-tapping and conical angle. The results indicated that pretension can indeed increase a screw's pullout force but only up to a certain degree. Under-tapping increased cylindrical screws' pullout force up to 12%, 15% and 17% for synthetic bones of density equal to 0.08 g/cc, 0.16 g/cc and 0.28 g/cc respectively. Inserting a conical screw into a cylindrical hole increased pullout force up to 11%. In any case an optimum level of screw induced pretension exists.

Keywords: Pullout, holding strength, pedicle screw, cohesive material model, synthetic bone, finite element analysis, damage simulation

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1. Introduction

Despite the extensive use of pedicle screws and the significant advances in the field of spinal stabilization the possibility of screw loosening and pullout remains and is even higher in the case of osteoporotic patients [1-3].

There are strong indications in the literature that the pretension developed in the vicinity of bone screws during their insertion can significantly influence their pullout strength. Experimental studies performed on synthetic [4] or cadaveric [5, 6] bone specimens showed that the holding strength of a cylindrical screw can be improved by under-tapping; namely by inserting the screw into a cylindrical threaded hole which is smaller than the screw itself. Screw insertion with under-tapping causes the core diameter of the threaded hole to expand and the screw hosting material in the vicinity of the screw to compact. In this case the screw's hosting material is compacted uniformly along the length of the screw.

In a previous experimental investigation [4] performed by authors of the present study, it was found that using a tap that is one size smaller than the screw, can increase the pullout force by 9%. Further reduction of the threaded hole dimensions did not result in any statistically significant change of the pullout force.

A combined experimental and numerical analysis of the pullout behaviour of cylindrical self tapping screws was performed by Wu et al. [7]. The authors of this study designed an axisymmetric finite element (FE) model of a screw that is inserted into a threaded hole with dimensions and shape identical to the screw itself. The pretension generated during screw insertion was simulated by introducing a

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temperature change. Even though their model appears to be capable of generating an initial pretension inside the screw's hosting material, the way this capability was utilized is not clear. Numerical results are presented only for cases where the radius of the pilot hole is equal to the screw's core radius.

Moreover, screws with conical core were found to have higher pullout strengths than cylindrical screws with similar thread shape and size [8-13]. Screws with conical core are inserted into cylindrical holes with diameters smaller than the maximum core diameter of the screw. In this case, screw insertion results in a non-uniform compaction of the screw's hosting material. Indeed the screw's hosting material that is closer to the screw's entry site is compacted more than that closer to the screw's tip.

In a previous attempt to simulate the effect of bone compaction in the vicinity of a conical screw that is inserted into a cylindrical hole, the elastic modulus of the screw's hosting material was modified based on an estimate of its volume reduction [8, 9]. The main disadvantage of this approach is that the effect of bone compaction is predefined.

Another interesting approach to the numerical simulation of the pretension that is developed in the vicinity of an implant was presented by Janssen et al. [14] for the case of press-fit acetabular implants. The authors of this study simulated the insertion of the implant as a separate load step.

Considering all the above, the present study aims at developing a reliable and accurate technique to integrate the screw induced pretension to the numerical simulation of the

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pullout phenomenon. The accuracy of the numerical analyses performed here was assessed by comparing numerical and experimental results for four different screw insertion scenarios.

One of the key features for the numerical assessment of a screw's pullout strength is the simulation of the screw's hosting material failure [7, 15-17]. For the purpose of the present study the failure of the screw's hosting material was simulated using a bilinear cohesive zone material model [15, 18]. The validity of this technique for the simulation of screw pullout has been previously established for cylindrical screws that are inserted into blocks of synthetic bone without any pretension [15]. Its accuracy has also been validated for different densities of synthetic bone [19].

2. Materials and methods

2.1 Experimental study

Pullout tests were performed with the use of solid rigid polyurethane foam (SRPF) blocks with density equal to 0.16 g/cc and material properties similar to osteoporotic cancellous bone (10 pcf SRPF, Sawbones, Worldwide, Pacific Research Laboratories Inc.) and two commercially available pedicle screws, namely Romeo® polyaxial screws for lumbar fixation (Spineart, International Center Cointrin, Genève, Suisse). The two screws used for the completion of the pullout tests are shown in figure 1. As it can be seen, their thread can be divided into two parts of similar lengths: a cylindrical one and a conical one ($L_{con} = L_{cyl} \approx 20$ mm). The main geometrical features of the aforementioned screws are shown in figure 1 while their values are

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presented in table 1. As one can see the two screws have the same pitch (P), the same outer and core radius at their tips (OR_{min}, CR_{min} respectively) and throughout their length they have the same thread depth (D = OR - CR) and thread inclination angles (a_1/a_2). On the contrary the two screws have significantly different conical angles (a_{con}) and as a result of that they also have different outer and core radius at the transition point from the conical to the cylindrical part of the screw (OR_{max}, CR_{max} respectively). From this point on the pedicle screw with a_{con} = 2.5° and 7.0° will be referred to as Romeo 2.5 and Romeo 7.0, respectively.

The conical part of the aforementioned screws were inserted into the SRPF blocks through cylindrical holes that were previously prepared using a pillar drill. The insertion depth of the screws was equal to 20 mm. The radius of the cylindrical holes was equal to the minimum core radius of the screws, that is equal to 1.3 mm.

The pullout tests were performed following pertinent international experimental standard (ASTM-F543–02) [20] according to which, the SRPF blocks were fixed to the base of the loading frame (MTS Insight 10kN, MTS Systems Corp., Eden Prairie, MN) with the aid of a metallic frame while the screw was suspended from the load cell (MTS 10kN Load Transducer) using a custom-made device (Figure 2). The screw was pulled out of the SRPF block with a constant rate equal to 0.01 mm/s while the respective force was measured with a sampling rate of 10 Hz.

Ten tests were performed in total (five tests for each screw) to calculate the mean value and the standard deviation of the pullout force, pullout displacement and the corresponding stiffness for each screw. The results for the two screws were compared

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to each other and their statistical significance was evaluated following one way analysis of variance (ANOVA). The level of statistical significance was considered to be equal to 0.05.

2.2 FE modelling and validation

For the purposes of the present study two different FE models were designed using ANSYS12 software: one FE model for the simulation of under-tapping and cylindrical screw pullout and another one for conical screw pullout. The design of both models was based on the same concept and assumptions.

The pullout phenomenon was simulated with 2D axisymmetric FE models of a bone screw and of its hosting material. The hosting material of the screw was simulated as a homogenous, isotropic, linearly elastic - perfectly plastic material. Its Young's modulus, yield stress and Poisson's ratio were defined according to the values provided by the manufacturer [21] for the SRPF's compressive modulus, compressive strength and Poisson's ratio respectively (table 2). A preliminary numerical analysis revealed that using the values of the tensile modulus and strength instead of the compressive ones does not affect the value of the screw's pullout force.

The experimentally observed failure of the synthetic bone was simulated using a technique previously developed for cylindrical screws that are pulled out of SRPF blocks [15]. According to this technique, the FEs which lay in the vicinity of the screw are connected to each other using bonded contact elements (Conta171, Targe169) to form a number of successive areas where failure can occur. The areas of possible failure were cylinders in the case of cylindrical screws (Figure 3) and cones

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in the case of conical screws. Neighbouring elements at opposite sides of the aforementioned surfaces can break apart from one another, should the tangential stress between them exceeds the shear strength of the SRPF.

A bilinear cohesive zone material model was implemented to control mode-II debonding of neighbouring FEs [18]. According to this model, the tangential stress on the interface between a contact pair rises linearly to a critical value (i.e. the shear strength of the SRPF). Beyond this point, any further increase of the relative sliding causes a non-reversible decrease of the tangential stress leading to the complete debonding of the contact pair. From this point on the interface conditions between the initially bonded pair of elements change to simple contact with friction.

As far as the macroscopic behaviour of the model is concerned, debonding of neighbouring elements reduces the total force that resists pullout and causes a clear drop of the force in the force/displacement graph. Indeed the force in the numerically calculated force/displacement graph reaches a maximum value and then drops with increasing displacement. The maximum value of the force is stored as the screw's pullout force. Even though the simulation continues beyond the point where the value of the force starts dropping the solution process becomes slower and finally it stops due to non-convergence. In any case the ultimate force, namely the force calculated for the last sub-step of the solution where convergence was achieved, is always lower than the pullout force.

Taking under consideration the magnitude difference between the Young 's modulus of the screw and of its hosting material, the screw was considered to be rigid [19].

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Moreover the FE model of the bone screw was designed in a way that enabled the modification of its dimensions and shape. The initial geometry of the screw's FE model was modified to fit inside a cylindrical threaded hole, with dimensions similar to the holes drilled for the pullout testing. In the case of cylindrical screws inserted with under-tapping, the initial core diameter of the screw was modified and set equal to the core diameter of the threaded hole (Figure 4). In the case of conical screws the initial value of the big core diameter of the screw (which is the core diameter of the cylindrical part of the screw) was set equal to the threaded hole's core diameter (Figure 4).

The simulation was performed in two steps to incorporate the effect of pretension development into the simulation of the pullout phenomenon. During the first step the radii of the FE model of the screw were extended to reach their actual values, while during the second simulation step the screw was pulled out from its hosting material (Figure 4). More specifically during the second load step a displacement was imposed to the screw in the pullout direction with the help of a pilot-node. The value of the imposed displacement was 0.5 × screw's insertion depth. This relatively high displacement value was used to ensure the failure of the screw's hosting material. Indeed the exact value of the imposed displacement has no effect on the calculation of the pullout force. The solution process stops when it reaches a point of non-convergence.

The accuracy of the numerical analysis was assessed by comparing the numerical results with corresponding experimental ones. For that purpose the FE model of the

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pullout phenomenon was modified to closely match the geometry, size and insertion depth of the screws that were used for the experiments.

In the case of cylindrical screws and under-tapping the accuracy of the numerical analysis for was assessed by comparing the numerical results with corresponding experimental ones from a previous investigation performed by authors of this study [4]. Experimental data for two different conditions of under-tapping were used. In the context of that study a cylindrical pedicle screw with core and outer radius equal to 2.75 mm and 3.75 mm respectively (CD Horizon Legacy MAS(Ti) 7.5×50 mm, Medtronic Sofamor Danek, Memphis,TN), was pulled out from blocks of synthetic bone with material properties similar to osteoporotic bone (10 pcf SRPF, Sawbones, Worldwide, Pacific Research Laboratories Inc.). Screw insertion was performed with under-tapping. Two different under-tapping ratios were tested, namely the ratio of the screw's core radius divided by the respective radius of the threaded hole (CR^{Screw}/CR^{TH}). More specifically the screw was inserted into threaded holes that were smaller than the screw itself by 0.5 mm and 1.0 mm (under-tapping ratios equal to 1.2 and 1.6 respectively). The case where the threaded hole had identical size and shape to the screw was also tested (under-tapping ratio 1.0).

In the case of conical screws, the accuracy of the FE analysis was assessed based on the pullout tests performed in the context of this study for the Romeo 2.5 and Romeo 7.0 screws. The experimental force vs. displacement curves and the experimental pullout forces were compared with the respective numerical ones.

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2.3 Parametric analyses

After its validation the FE model of cylindrical screw's pullout was utilized to investigate the impact of under-tapping on pullout strength. A cylindrical screw with core and outer radius equal to 2.75 mm and 3.75 mm was simulated inside a cylindrical threaded hole of similar size and shape and its pullout force was calculated for different under-tapping ratios (i.e. CR^{Screw}/CR^{TH}). Starting from an under-tapping ratio of 1 (no under-tapping) the threaded hole's core radius was decreased with increments of 0.1 mm. The parametric investigation was terminated when the results indicated that any further increase of the under-tapping ratio will have no effect to the value of the pullout force. This procedure was repeated for three different SRPF densities: 0.08 g/cc, 0.16 g/cc and 0.24 g/cc. The material properties of these SRPFs were defined according to literature [21] and their values are shown in table 2.

The FE model of conical screw's pullout was utilized to investigate the impact of conical angle and pretension to pullout strength. The minimum core and minimum outer radius of the screw were kept constant while the respective maximum radii were modified to produce conical threads with different conical angles. Eight different values of the screw's conical angle ranging from 0° to 7° were simulated. Two different simulations were performed for each one of these conical angles, to quantify the impact of pretension to a conical screw's holding strength. The pretension generated inside the synthetic bone during screw insertion was taken under consideration during the first simulation but excluded from the second one. During the first simulation, pretension generation was simulated by inserting the conical screw inside a cylindrical threaded hole, with core and outer radius similar to the minimum core and

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outer radius of the screw. On the contrary during the second simulation the conical screws were simulated inside conical threaded holes with size and shape identical to the screw itself. This way no pretension was developed inside the screw's hosting material. The material properties of the screw's hosting material were those of a synthetic bone simulating osteoporotic cancellous bone (10 pcf SRPF, Sawbones, Worldwide, Pacific Research Laboratories Inc.).

3. Results

3.1 Experimental study

All specimens exhibited similar mechanical behaviour and failed under shear. The failure appears on an almost conical surface which connects the edges of the threads of the screw. As it can be seen in figure 5, the failure surface in the case of the Romeo 7.0 screw can be described as a cone with conical angle ≈ 7°, the same as the screw itself. The material between the surface of failure and the surface of the screw is extracted from the block together with the screw. Representative force vs. displacement curves of pullout test are shown in figure 6. The peak value of the force is the screw's pullout force, while the displacement corresponding to this force is the pullout displacement. The tangent of the angle between the linear part of the curve and the X axis corresponds to the stiffness of the screw - screw's hosting material complex. The results of the pullout test are shown in detail in table 3.

One way ANOVA indicated that Romeo 7.0 screw has statistically significant ($P < 0.05$) higher pullout force than the Romeo 2.5 screw, while there are no statistically significant differences in terms of pullout displacement and stiffness ($P > 0.05$).

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299

300 3.2 FE modelling and validation

301 Figures 6 and 7 depict a clear overview of the simulation process. In the case of
302 cylindrical screws with under-tapping (Figure 6) the screw's radii expand during the
303 first load step, generating a strong and relatively uniform stress field in the vicinity of
304 the screw. During the second load step, the screw is pulled out of its hosting material
305 until failure of the synthetic bone. Debonding is observed in the vicinity of the
306 deepest thread (namely the most distant one from the free surface). Debonding of
307 neighbouring elements generates a sudden stress relief in this region and a
308 discontinuity of the stress field. The strong stress concentration at the edges of the
309 SRPF's free surface are caused by the model's supports (figure 3).

310

311 In the case of conical screw's pullout (Figure 7) the shape of the screw is gradually
312 changed from cylindrical to conical to simulate the generation of pretension around
313 the screw. In this case, the stress field developed in the vicinity of the screw is more
314 severe near the free surface of the SRPF block as expected. During the second load
315 step, the screw is pulled out from its hosting material. Most of the pullout load
316 appears to be carried by the thread closest to the free surface.

317

318 In terms of validation. In the case of under-tapping the experimental/ numerical
319 pullout forces for under-tapping ratios equal to 1.0, 1.2 and 1.6 were 438 N ± 5 N/
320 440 N, 480 N ± 7 N/ 506 N and 481 N ± 9 N/ 505 N respectively. As it can be seen
321 the difference between the numerical simulations and the experiments [4] is less that
322 5% for all three cases. Moreover the FE models were able to simulate the
323 macroscopic response of the SRPF block - bone screw complex to loading.

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Representative numerical and experimental results are shown in figure 6A for the case of under-tapping ratio equal to 1.2. As it can be seen the numerically calculated force vs. displacement curve appears to be in good agreement with the experimental one.

The numerically calculated pullout forces for the Romeo 2.5 and Romeo 7.0 screws were equal to 326 N and 381 N respectively. Comparing these values with the respective experimental ones (table 3) gives a difference that is lower than 3%. Moreover, the FE models were able to simulate with satisfactory accuracy the overall response of the SRPF block - bone screw complex (Figure 6B).

3.3 Parametric analyses

The pullout force calculated for different densities of the synthetic bone and different under-tapping ratios can be seen in figure 9. In the case of the synthetic bone with density equal to 0.08 g/cc , pullout force increased significantly with under-tapping ratios ranging from 1 to 1.12. Indeed the pullout force calculated for under-tapping ratio equal to 1 was 126 N, while for under-tapping ratio equal to 1.12 the pullout force was 143 N, equivalent to 12% increase. Increasing the under-tapping ratio to values greater than 1.12, did not affect the value of the pullout force. The pullout force calculated for under-tapping ratio equal to 1.17 was again 143 N.

In the case of SRPFs with density equal to 0.16 g/cc and 0.28 g/cc , pullout force increased significantly with under-tapping ratio for ratios up to 1.17 (Figure 9). The pullout force for these two synthetic bones was 440 N and 894 N for under-taping

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ratio equal to 1, while for under-tapping ratio equal to 1.17 pullout force was 507 N and 1048 N respectively, equivalent to 15% and 17% increase respectively. Increasing the under-tapping ratio to 1.22 had no significant effect to the values of the pullout force (Figure 9). The pullout force calculated for synthetic bones of densities equal to 0.16 g/cc and 0.28 g/cc and under-tapping ratio equal to 1.22 was 506 N and 1050 N respectively.

The pullout force calculated for different values of the conical angle can be seen in figure 10A, for the cases where initial pretension is either included or excluded from the numerical simulation. As it can be noticed, pullout force increases linearly with conical angle when no pretension phenomena are included to the analysis. On the contrary when pretension is included to the numerical simulation the increase is non-linear. The pullout forces calculated in this case are higher than the respective ones calculated without any pretension. Comparing the results for these two series of simulations indicates that pretension has a positive effect on screw pullout strength (Figure 10B). The maximum impact of pretension was calculated for a conical angle equal to 2°. In this case pretension improved the screw's pullout strength by 11.4%. The benefit of pretension on pullout strength becomes weaker for conical angles greater than 2°. Indeed for conical angle equal to 7° pretension causes only a 0.4% increase of the pullout force.

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4. Discussion and conclusions

It is well established in literature that the stress developed around a bone screw during insertion can significantly influence its stability [4-6, 8-13, 22]. More specifically, it is indicated that the fixation strength of a bone screw can be improved by under-tapping [4-6] or the use of screws with conical core [8-13]. In the case of under-tapping a cylindrical screw is inserted into a previously opened threaded hole which is smaller than the screw itself. In this case the core of the screw compresses and compacts the bone which lies in its vicinity in the radial direction. The core diameter of the threaded hole is expanded until it becomes equal to the diameter of the screw core. The strong contact pressure that is generated on the interface between the cores of the screw and the threaded hole, also generate frictional forces which resist screw's rotation. If the screw is a self-tapping one then its threads will cut their way through the hosting material of the screw. In this case the pressure field developed on the surface of the threads would be relatively weak.

On the other hand, screws with conical core are inserted into bone using previously opened cylindrical holes. In this case screw insertion causes the core of the hole to change size and shape. The shape of the hole changes from cylindrical to conical causing the screw's hosting material near the screw's insertion site to be compressed more than the material near the screw's tip.

Despite its significance, the pretension that is developed during screw insertion has not yet been fully incorporated into FE simulations of screw pullout. Hsu, Chao et al. [8, 9] were the first who tried to simulate the impact of inserting a conical screw into a

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399 cylindrical hole to the screws pullout strength. Their simulation was based on the idea
400 that the material properties of a screw's hosting material are altered in the vicinity of
401 the screw as a result of material compaction. The main limitations of this approach is
402 the fact that the effect of bone compaction is predefined and that the actual pullout
403 force is not calculated.
404
405 Indeed, assuming that the elastic modulus of the screw's hosting material is a function
406 of volume reduction means that screw fixation strength will continuously increase
407 with compaction. On the other hand there is strong evidence in the literature that
408 fixation strength increases with compaction only up to a certain level [4, 23, 24].
409
410 The impact of the relative dimensions of screw and hole to the screw's pullout
411 strength was investigated experimentally by authors of the present study [4]. A
412 cylindrical pedicle screw was inserted into blocks of synthetic bone using threaded
413 and cylindrical holes of different sizes and the pullout force was measured. The
414 results indicated that there is an optimum ratio of the threaded or cylindrical hole's
415 radius over the respective screw's radius.
416
417 The FE model of Hsu, Chao et al. [8, 9] was capable of calculating the reaction force
418 for a small value of imposed displacement. The value of the reaction force for a
419 constant value of pullout displacement is directly correlated to the stiffness of the
420 screw - hosting material complex rather to the screw's pullout force. According to
421 literature [11, 25-30] and also according to the respective international experimental
422 standard [20] the most appropriate way to quantify the fixation strength of a bone
423 screw is to measure its pullout force.

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In this context the present study's aim was to establish a new method for simulating the pretension that is developed inside the hosting material of a screw during screw insertion and to incorporate it in the numerical simulation of the pullout phenomenon. The screw was simulated inside a cylindrical threaded hole with dimensions similar to the holes drilled for pullout testing. The initial dimensions of the screw's FE model were modified to match the dimensions of the cylindrical threaded hole. The simulation was performed in two steps: 1) Pretension generation, 2) pullout. Pretension generation was simulated by extending the screw's radii to reach their actual values. After the completion of this load step a displacement at the pullout direction was imposed to the screw until the failure of its hosting material.

The experimentally observed failure of the synthetic bone was simulated by implementing a bilinear cohesive material model [18]. This methodology has been proven to give reliable estimations of the pullout force of cylindrical screws that are inserted into blocks of synthetic bone through cylindrical threaded holes of identical size and shape to the screw itself [15]. The main limitation of this approach for the simulation of synthetic bone's failure is that the geometrical domain where failure can occur has to be known in advance [16].

For cylindrical screws that are inserted with under-tapping into blocks of synthetic bone it has been proven previously that failure occurs on a cylindrical surface that includes the screw [4, 15]. Moreover for the case of conical screws it was proven here that failure occurs on a conical surface which includes the screw. These experimental observations indicate that in both cases the screw's hosting material fails under shear

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and that both are eligible for using a cohesive material model to simulate synthetic bone failure.

The accuracy of this FE model was validated by comparing the numerically calculated force vs. displacement curves and also the values of the pullout force with experimental ones for two different cases of under-tapping ratios and for two different conical screws. This comparison indicated that the proposed methodology for introducing pretension in the simulation of conical screw pullout enables the accurate assessment of its pullout strength.

After validation two different parametric analyses were performed. The results of the first parametric study demonstrated that under tapping can significantly increase the pullout force of bone screws. Indeed the impact of under tapping is more pronounced in the case of denser and "stronger" synthetic bones. More specifically under tapping was able to increase pullout force up to 12%, 15% and 17% in the cases of synthetic bones with density equal to 0.08 g/cc, 0.16 g/cc and 0.28 g/cc respectively. Moreover an optimum value of the under tapping ratio exists which appears to be influenced by the mechanical properties of the screw's hosting material. Increasing the under tapping ratio beyond this value has no significant effect on the screw's pullout force.

In the context of the second parametric analysis the minimum core and outer radii of a conical screw were kept constant while the maximum ones were modified to produce different conical angles. According to literature the outer radius of a screw is one of the most important parameters for its fixation strength. Indeed a screw's pullout force increases linearly with its outer radius [15, 31-33]. For the purpose of this study the

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impact of pretension was quantified separately from that of the maximum outer radius.

The results of this parametric analysis indicated that using a bone screw with a conical core generates a pretension inside the screw's hosting material which can improve the screw's fixation strength. The impact of the pretension to the screw's fixation strength appears to be stronger for relatively small conical angles. Indeed for a conical angle equal to 2°, 11.4% of the screw's pullout force is attributed to the pretension generated during screw insertion. On the other hand in the case of a screw with conical angle equal to 7° only a 0.4% of its pullout force is a result of pretension.

Based on the above it could be deduced that in the case of conical screws with big conical angles the best way to improve their short-term fixation strength would be to insert them into conical holes instead of cylindrical ones. The conical angles of these holes should be a couple of degrees smaller than the screw's itself. A possible way to open a conical hole that is smaller than the screw could be to use another screw of similar shape but smaller in size. In a previous experimental investigation performed by authors of the present study it was concluded that using a self-tapping screw to prepare a threaded hole can be as efficient as if a tap was used [4].

The main limitation of the present study stems from the fact that synthetic bone cannot simulate all aspects of the mechanical behaviour of cancelous bone. Nevertheless synthetic bone can be used to perform comparative analyses and draw useful and clinically relevant conclusions [34]. One of the important aspects of bone tissue that cannot be simulated using synthetic bone is the tissues adaptive response to

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loading. For this reason the results of this study in terms of fixation strength correspond to the first post-operative weeks.

At this point is should be stressed out that the accuracy of the novel technique proposed here for the simulation of pretension has been validated only for the case of a synthetic bone with density equal to 0.16 g/cc. As a result of that interpreting the numerical results for surrogate bones of different densities should be done with caution. Indeed the FE analyses can predict the maximum possible pretension-induced improvement of a screw's pullout strength. The main prerequisite for this prediction to be accurate is that the screw's hosting material fails during pullout under shear and not during screw insertion. Unfortunately under-tapping also carries the risk of a catastrophic failure during screw insertion [35]. Moreover it is possible that in the case of SRPFs that are denser than 0.16 g/cc an 'under-tapping limit' exists beyond which the integrity of the screw's hosting material is jeopardised during screw insertion. The simulation of this type of failure was beyond the scope of the present study.

According to literature under-tapping can lead to pedicle wall breach [35]. Investigating numerically the possibility of pedicle wall breach requires an accurate simulation of the three-dimensional (3D) geometry of the vertebra and of the screw. Investigating the impact of vertebral 3D geometry was beyond the scope of the present study and therefore the geometry of the screw and of its hosting material was simplified.

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On the other hand the main contribution of the present study is the implementation of a novel method for incorporating the impact of different screw insertion techniques and pretension to the FE simulation of the pullout phenomenon.

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Tables:

Table 1: The geometrical quantities that describe the geometry of the threads of Romeo 2.5 and Romeo 7.0 screw.

Screw	P (mm)	D (mm)	OR_{min} (mm)	CR_{min} (mm)	a_{con} (deg)	OR_{max} (mm)	CR_{max} (mm)	a_1/ a_2 (deg)
Romeo 2.5	2.8	0.8	2.1	1.3	2.5	2.9	2.1	5/20
Romeo 7.0					7.0	3.7	4.5	

Table 2: The material properties of three different SRPFs used for the parametric study of under-tapping impact on screw pullout (Sawbones, Worldwide, Pacific Research Laboratories Inc.) [21].

Density (g/cc)	Compressive Strength (MPa)	Compressive Modulus (MPa)	Shear Strength (MPa)	Poisson's ratio
0.08	0.6	16	0.59	0.3
0.16	2.2	58	1.6	
0.24	4.9	123	2.8	

Table 3: The pullout force, pullout displacement and stiffness measured for the Romeo 7.0 and the Romeo 2.5 screw. The respective numerical values are given in brackets for comparison.

	Romeo 7.0			**Romeo 2.5**		
	Force (N)	**Displacement (mm)**	**Stiffness (N/mm)**	**Force (N)**	**Displacement (mm)**	**Stiffness (N/mm)**
a	*385*	*0.83*	*543*	*315*	*0.82*	*433*
b	*393*	*0.86*	*558*	*324*	*0.67*	*580*
c	*379*	*0.85*	*558*	*317*	*0.70*	*536*
d	*391*	*0.88*	*538*	*321*	*0.86*	*443*
e	*376*	*0.89*	*507*	*312*	*0.75*	*476*
Mean	385(*381*)	0.86(*0.80*)	541(*582*)	318(*326*)	0.76(*0.76*)	494(*517*)
STDEV	7	0.02	21	5	0.08	63

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Figure captions:

Fig. 1: The pedicle screws used for the realization of the pullout tests (up) and the basic geometrical features of the conical pedicle screws used (down).

Fig. 2: Schematic representation of the experimental set-up.

Fig. 3: The FE model of a cylindrical screw's hosting material for the case where screw insertion is performed with under-tapping.

Fig. 4: The two load steps realized in the case of under-tapping (up) or conical screws (down) to assess the impact of pretension to pullout strength: Pretension development (left) and pullout (right).

Fig. 5: A central section of an SRPF block after the completion of a pullout test. The test was performed using the Romeo 7.0 screw. The section was pressed against a carbon paper to make the conical hole caused by screw pullout easily distinguishable.

Fig. 6: The experimentally measured and the numerically estimated force vs. displacement curves for cylindrical screw with under-tapping ratio equal to 1.2 (A) and for the conical screws Romeo 2.5 and Romeo 7.0 (B). For each case the experimental curves correspond to the tests which gave the maximum and minimum pullout force.

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Fig. 7: The distribution of the Von Mises equivalent stress (Pa) during different stages of the simulation of pretension generation (left) and pullout (right) for a cylindrical screw that is inserted with under-tapping.

Fig. 8: The distribution of the Von Mises equivalent stress (Pa) during different stages of the simulation of pretension generation (left) and pullout (right) for a conical screw that is inserted into a cylindrical threaded hole.

Fig. 9: The numerically calculated pullout force vs. under-tapping ratio for three different densities of synthetic bone.

Fig. 10: The pullout force calculated for different conical angles for the cases where initial pretension is included or not to the numerical simulation (A) and the % difference between these two cases (B).

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709 Figure 1:

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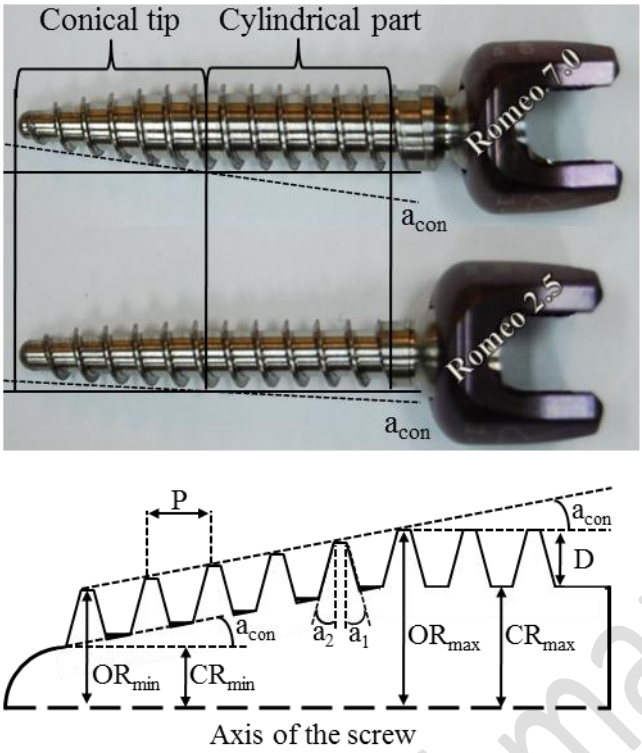

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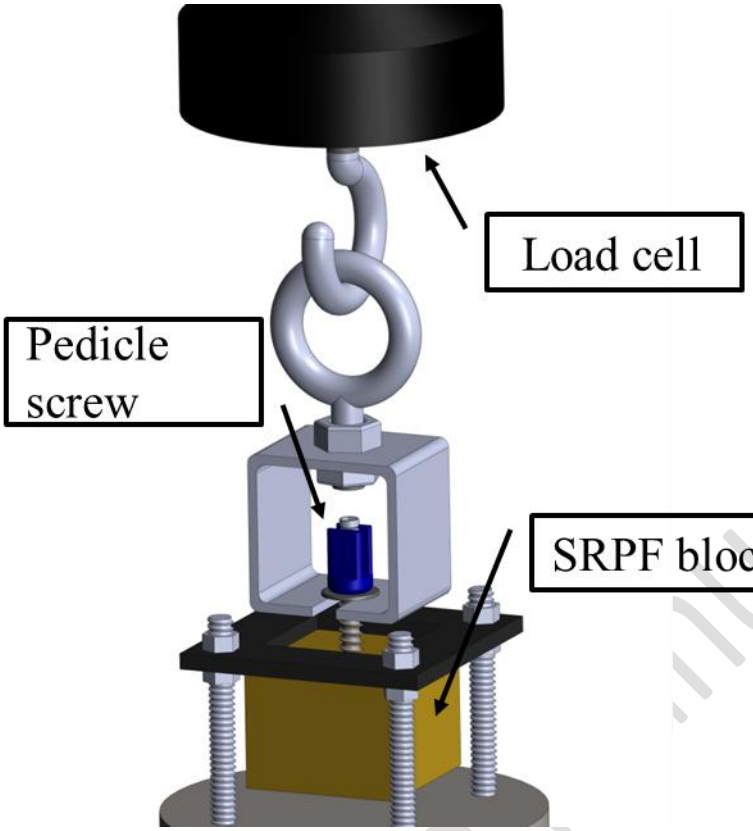
Figure 2:



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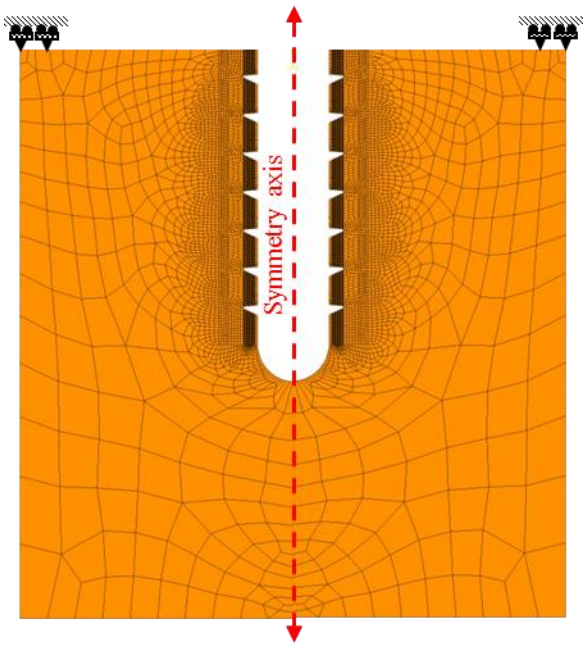

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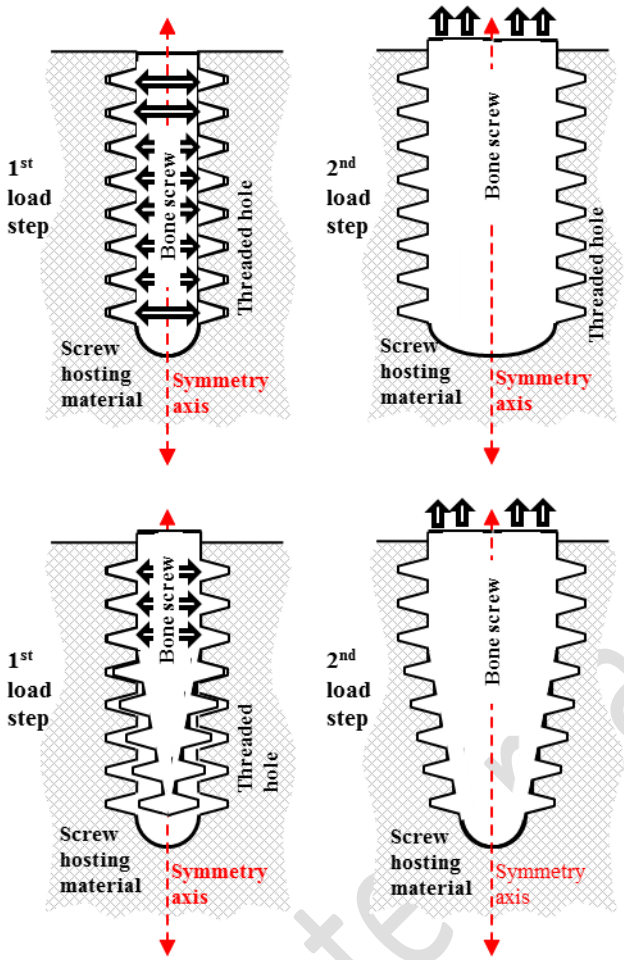

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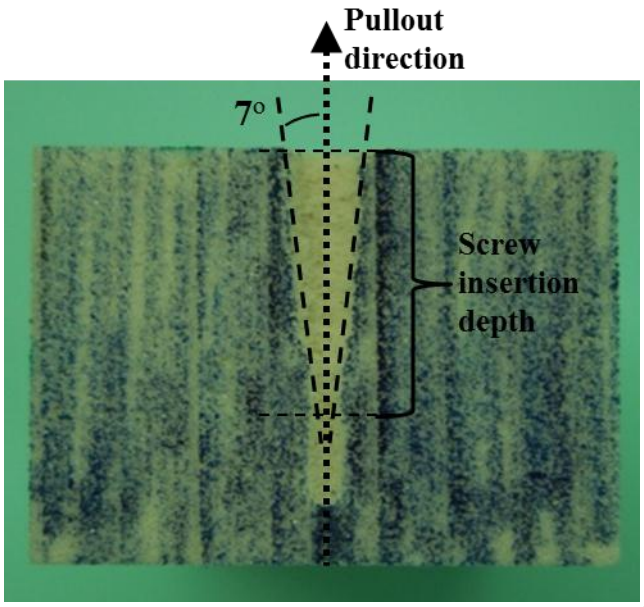

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789 Figure 6:

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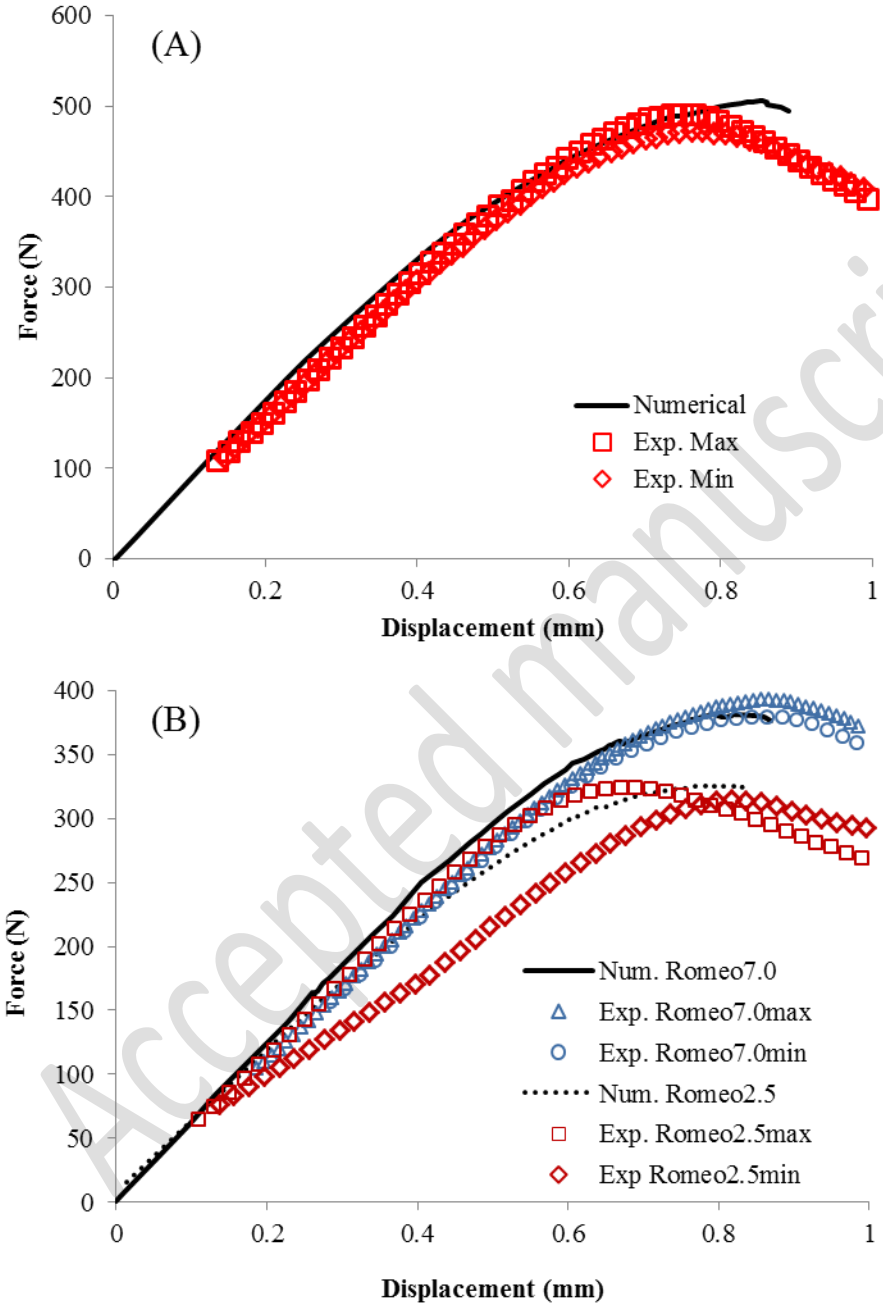

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796 Figure 7:

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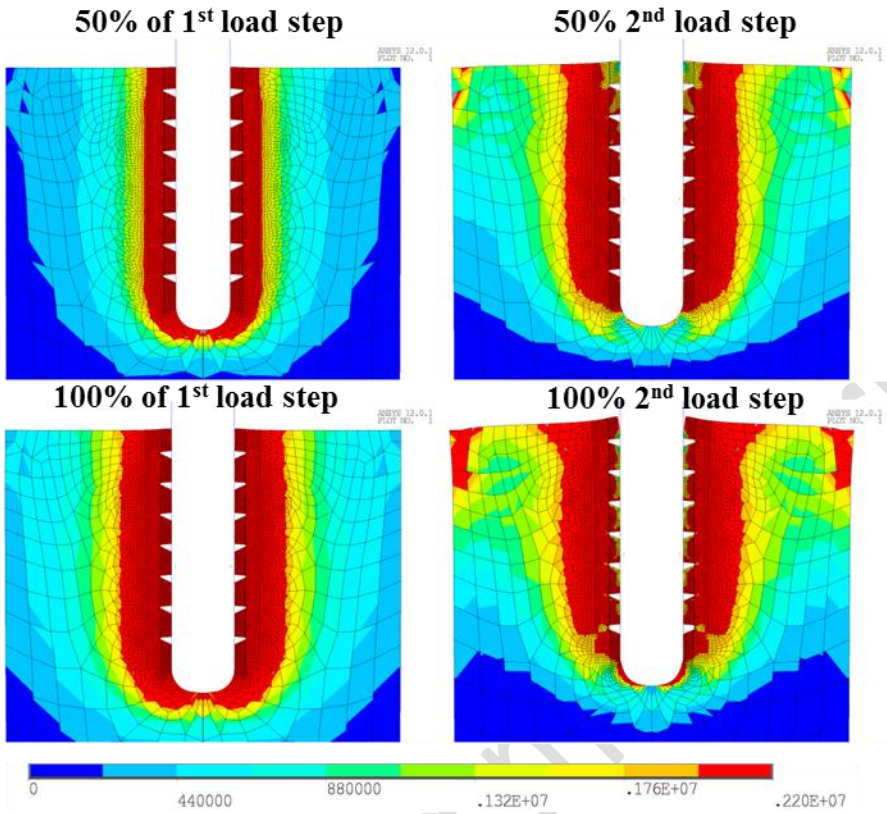

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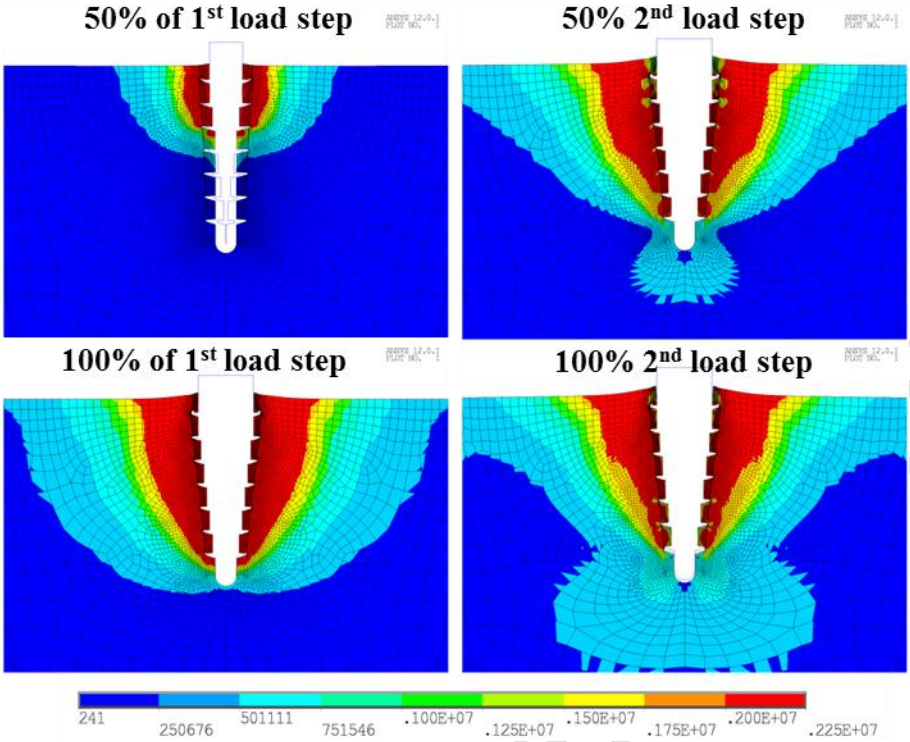
Figure 8:



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827 Figure 9:

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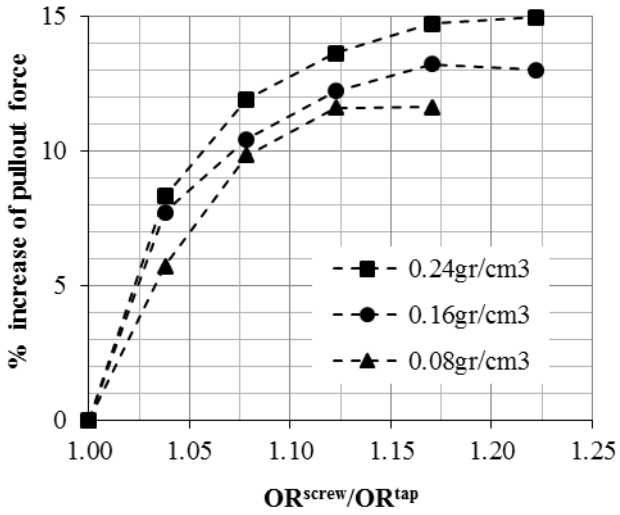

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847 Figure 10:

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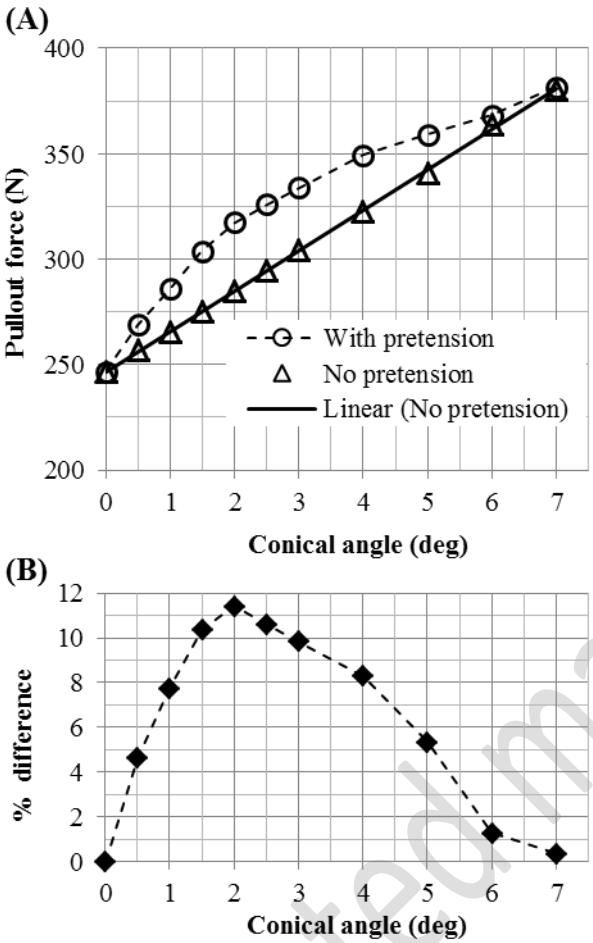

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