

Investigation of pullout strength in different designs of pedicle screws for osteoporotic bone quality using finite element analysis

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Purpose: The purpose of this study was to investigate pullout strength of three types of pedicle screws with and without cement augmentation in osteoporotic bone using finite element analysis. *Methods:* Twelve 3D finite element models were created to investigate the effect of pullout strength when comparing between pedicle screw types and bone cement clouds. The bottom side of bone block model was constrained and U-shape head was applied 1 mm in direction of longitudinal axis of pedicle screw to perform pullout resistance. The material properties of the FEA was set as linear elastic, homogenous, isotropic condition. The element sensitivity of convergence testing has been performed and variation of the sequential analytical results was less than 3%. *Results:* The results showed that the maximum total reaction force (133.8 N) was detected in the model of cannulated pedicle screw combined with a central pin with 4 ml cement augmentation, but, in contrast, the minimum total reaction force (106.8 N) was discovered in the model of cannulated pedicle screw without cement. A strong relationship ($r = 0.9626$) is found in comparison with the biomechanical results between pullout strength of sawbone testing and reaction forces of the FEA. *Conclusions:* The study concludes that the cannulated pedicle screw can not only provide an inner guider for cement flow and increase bending resistance (deflection effect) when a central pin is selected, but also can improve the pullout strength in the osteoporotic bone to add cement augmentation. The design of the cannulated pedicle screw is suggested for poor bone quality to change pullout failure.

Key words: osteoporosis, cement augmentation, pedicle screw, pullout strength, finite element analysis

1. Introduction

Osteoporosis is a disease characterized by low bone mass, compromised bone strength, and structural deterioration of the bone tissue [1]. It leads to increased bone fragility and risk of fracture, particularly for hip, spine, and wrist. These fragility fractures lead to a decreased quality of life and a staggering economic burden [9]. Osteoporosis is also known as “the silent thief” because bone loss occurs without symptoms [11]. The World Health Organization (WHO) criteria for diagnosing osteoporosis and osteopenia are based on a comparison of an individual’s bone mineral density

(BMD) measured by dual-energy X-ray absorptiometry (DEXA) with that of a thirty-year-old adult with sex-matched healthy group. BMD is expressed using a T-score that represents the difference in a number of standard deviations relative to the BMD distribution of that healthy group. The WHO classifies osteoporosis as a T-score lower than -2.5 (or 0.8 g/cm^2) and osteopenia as a T-score between -1 and -2.5 .

Vertebral compression fracture, leading to persistent severe back pain, limited mobility, and significantly impact the quality of life, is the most common complication of osteoporosis [12]. Conservative therapy using external bracing, rehabilitation exercise, bed rest, and analgesic medicine is necessary for pain

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control in patients with osteoporotic vertebral compression fracture [14]. However, some patients can still experience protracted or ongoing pain even with these measures. Patients, who are unresponsive to nonsurgical treatment, may need a major surgery including a big wound, long instrumentation, and bone graft for bony fusion in the past [2], [24]. However, postoperative morbidity, adjacent vertebral compression fracture, loosening or even pullout of the implant, particularly the higher intraoperative risks of anesthesia and major surgery in elderly patients has been often encountered [28].

Spinal instrumentation increases the rigidity of segments at the fusion site, thereby reducing the relative motion between the vertebrae during the biologic healing process [22]. Animal and clinical studies have shown that a successful posterolateral fusion is more likely to be achieved in the presence of spinal instrumentation, and that stiffer constructs result in more stable fusion masses [16]. Posterior spinal implants, which consist of two longitudinal components of plates or rods with segmental pedicle screw attachments to the vertebrae to form a solid construct, typically act as tension band devices [17]. The rigidity of the construct depends on the geometric structure and the material properties of the longitudinal components and pedicle screws, the number of vertebrae spanned by the implant, the method of their attachment to the vertebrae, and the cross links between the longitudinal components.

Roy-Camille and colleagues in 1963 began to use a pedicle screw-plating system for spinal fixation [19]. The advantage of this technique requires the least amount of normal anatomy to be involved in the spinal fusion. However, the pedicle screw needs to be carefully inserted to prevent injury to the neurological structure [20]. The pedicle screw device can be used to provide distraction, compression, and translation. Dick and colleagues developed a pedicle screw-rod system, which was modified from the pedicle screw-plating system, to improve fusion rate and easier handling by surgeons [6]. The pedicle screw-rod system allows for axial and angular as well as rotational adjustments to permit instrumented segments of the spine to be held in distraction, compression, or derotation conditions.

Pedicle screw fixation is indicated for the management of spinal disorders, such as stenosis syndrome, degenerative spondylolisthesis or retrolisthesis, scoliosis, deformity correction, failed back surgery syndrome, or spinal instability due to spinal trauma, tumor, or infection [3]. It offers the advantages of immediate stabilization, higher rates of spinal fusion, easy con-

touring [7]. Pedicle screw fusion has neurologic and orthopedic goals. Neurologic goals include minimization of ongoing injury, decompression of neurologic structure, and good functional recovery. Orthopedic goals include mechanical spinal stability, correction of malalignment and deformity, and remedy or prevention of pseudoarthrosis [13].

Many studies have shown the evidence that the stiffness and strength of pedicle screw fixation can be significantly increased with the pedicle screw augmented with various cements [21]. The cement, such as Polymethylmethacrylate (PMMA), has advantages such as availability, inexpensiveness, short application time, and appropriate fixation strength for clinical application. The proper use of PMMA has been proved to be a safe and reliable material for pedicle screw augmentation. However, conventional pedicle screw augmentation with PMMA has still remained some potential problems in clinical practices, such as elaborate surgical procedures and unable to adjust the position of cemented pedicle screw. Therefore, the purpose of this study is to investigate pullout strength of different pedicle screws in the osteoporotic bone with and without bone cement augmentation by evaluating of finite element analysis (FEA).

2. Materials and methods

Design and specification

The structure of the solid pedicle screw was initially designed according to the ASTM (American Society for Testing and Materials) F543 standard. The solid screw was cylindrical in shape, with a total length of 65 mm, the screw thread of 45.5 mm from the screw tip and the screw head of 14.5 mm as well as the interim screw neck of 5 mm in length. An outer diameter of the screw head was 14.3 mm with a U-shaped slot of 6.3 mm in width for interposition of a connecting rod. A nut of 10 mm in diameter, which has an inner thread to lock outer thread inside the screw head, was used to fix the connecting rod. The outer diameter of the screw is 6.5 mm and the core diameter was 5.2 mm. The thread depth was 0.65 mm and each thread pitch was 2.75 mm. The leading edge radius was 1.2 mm and the trailing edge radius was 0.8 mm. The leading edge angle was 25° and the trailing edge angle was 5°. The FEA models of the cannulated pedicle screw and central pin were presented with dimensions to provide a detail specification in Fig. 1.

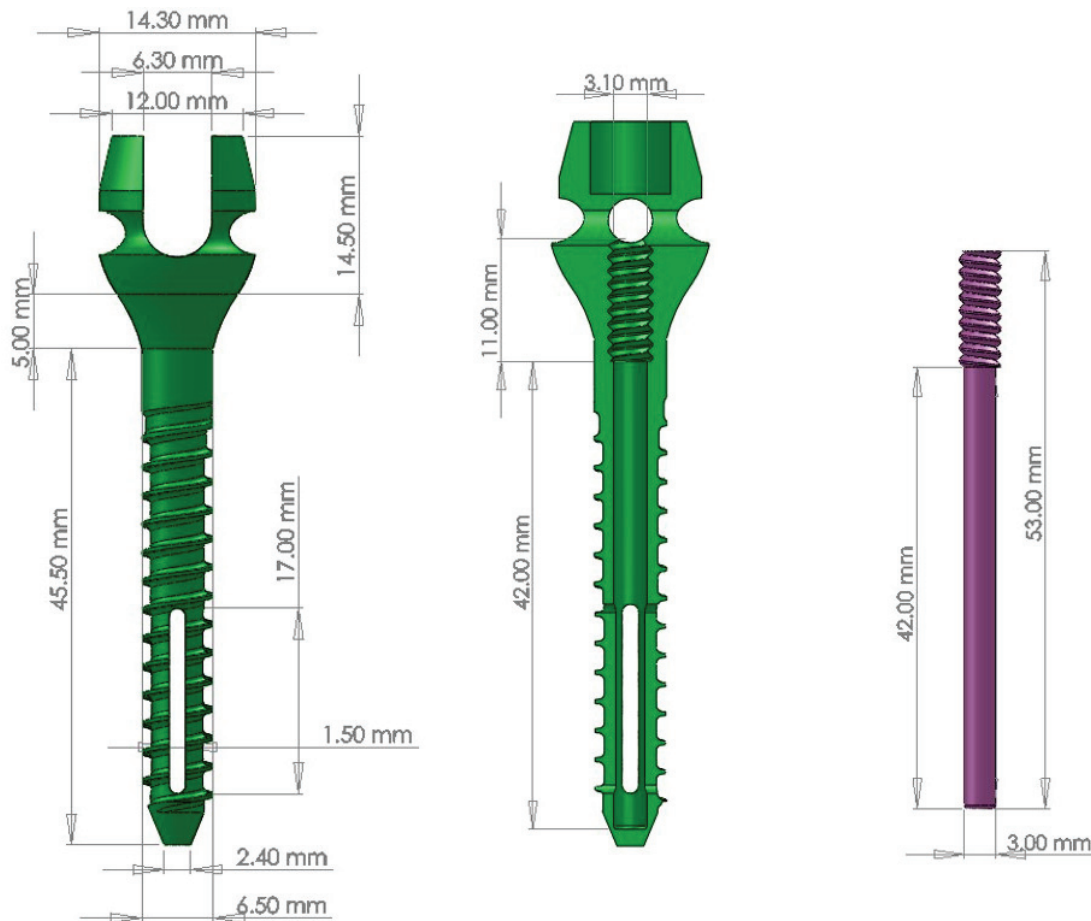
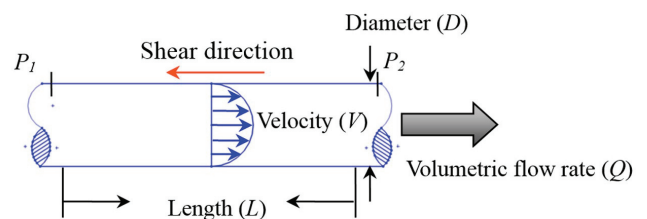


Fig. 1. Dimension plotting in the cannulated pedicle screw with a central pin

The diameter of the cannulated central hole needs to be determined under function consideration for smooth delivery of bone cement. In 2008, Loeffel et al. [10] introduced a quantitative measure to identify various parameters of bone cement flow and characterize distribution of bone cement in vertebral body. Cement viscosity was calculated by the Hagen–Poiseuille law, which expresses viscosity η as a function of cannula geometry (inner diameter D and length L), volumetric flow rate Q , and injection pressure P (Fig. 2). The equation of Hagen–Poiseuille law could be further expressed into inner diameter D of central hole. Furthermore, the diameter D was calculated for cannulated pedicle screw design to provide a better cannulated central hole to transfer bone cement into vertebrae. For obtaining effectively delivery inner diameter of central hole of the cannulated pedicle screw, design process of numerical evaluation should be performed. In analytical design, assign η as 100 Pa, L as 20 mm, Q as 0.3 mL/sec, 0.4 mL/sec, and P as 42,100 N, according to clinical practice and literature review. According to the equation, when Q is 0.3 mL/sec, the diameter D is calculated to be 2.761 mm, when

Q is 0.4 mL/sec, the diameter D is calculated to be 2.966 mm. Therefore, the cannulated central hole is optimally designed as 3.1 mm in diameter to provide a tract for consistent and smooth delivery of the bone cement.



$$\eta = \frac{\Delta P D}{32 Q} \frac{4 L}{\pi D^3} = \frac{\Delta P \pi D^4}{128 Q L} \rightarrow D = \sqrt[4]{\frac{128 Q L \eta}{P \pi}}$$

Fig. 2. Design and determination of inner hole diameter (D) in cannulated pedicle screw by using Hagen–Poiseuille law

Four side-grooves were slotted perpendicularly because of easily precise manufacture, created on the distal third of the screw with connection to the can-

nulated central hole. The vertical side-groove was 17 mm in length and 1.5 mm in width, located at equal quadrant 6 mm from the screw tip, as illustrated in Fig. 3. A central pin was designed to match the central hole of the cannulated pedicle screw. The length of the central pin was 53 mm and the diameter was 3.0 mm. The pin head had an inner thread to lock an outer thread inside the screw head. Additionally, the central pin can push the residual cement within the pedicle screw out through the quadrantal side-grooves and avoid the bone cement flowing back.

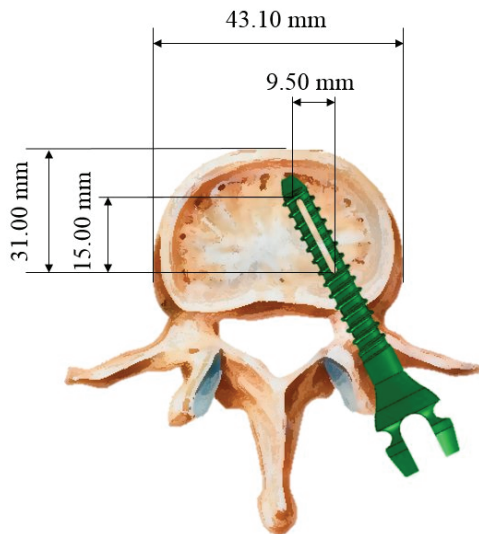


Fig. 3. Consideration of vertical sided-groove 17 mm in length and 1.5 mm in width for inserted vertebral depth of the cannulated pedicle screw

Model building and simulation

For investigating effects between pedicle screw design and bone cement augmentation, hence, three types of the pedicle screws were built by computer-aided design (CAD) procedure to compare contribution of pullout strength. The pedicle screw had three types of structure designs as mention above, screw types were defined a conventional solid pedicle screw, a cannulated pedicle screw, and a cannulated pedicle screw with a central pin. The bone block with osteoporotic quality and bone cement with different injected volumes, cement cloud size in 2 ml, 3 ml, and 4 ml, were created by uniform ball shape for finite element analysis (FEA). Therefore, the FEA model is consisted of a pedicle screw, a bone block, and with or without cement cloud.

Three basic FEA models of the conventional solid pedicle screw, the cannulated pedicle screw, and the cannulated pedicle screw combined with a central pin were called model A, model B and model C, respectively. Three the same models with different volumes

(2, 3 and 4 ml) of bone cement cloud were divided into model A1, model B1, and model C1 by using 2 ml cement cloud, model A2, model B2, and model C2 by using 3 ml cement cloud, model A3, model B3, and model C3 by using 4 ml cement cloud. Twelve FEA models were computed and compared through computer-aided engineering software (ANSYS 11.0, Canonsburg, PA, USA). The material properties of the FEA models were assumed to be linear elastic, homogeneous, and isotropic, hence, titanium alloy (Ti-6Al-4V) with elastic modulus of 114 GP was selected for the material property of the pedicle screw. Osteoporotic bone with elastic modulus of 100 MPa was selected for the material property of the bone block. Polymethyl methacrylate with elastic modulus of 2,200 MPa was selected for the material property of the bone cement. Poisson ratio of the pedicle screw, bone block, and bone cement was assumed as 0.3. The FEA models were meshed with ten-node tetrahedral elements (SOLID 187) which could reflect a proper mechanical behavior of a biological bone-based FEA model. The total numbers of elements and nodes in the model A, model B, and model C without cement were meshed by regional sizing in the 9729 and 12436, 6476 and 8768, as well as 10826 and 13972, respectively. Moreover, cement clouds by increasing volumes of the 2ml, 3ml, and 4ml could be counted the numbers of elements and nodes were 1014 and 1334, 1568 and 1738, as well as 2026 and 2382, respectively. Hence, the total numbers of the elements and nodes in the each FEA model could be calculated a combination of the pedicle screw with bone block and cement cloud. The above-mentioned have been confirmed by convergence evaluation. The bottom side of the bone block was fixed as boundary constrain, and for pullout loading condition was applied an axial displacement of 1 mm on the head of pedicle screw (Fig. 4). The three main interfaces between the screw and the bone, the screw and the cement, and the cement and the bone in the FEA model were assumed consistently in condition of bonding to reflect previous experimental sawbone model. For obtaining reliably results of the FEA models, the validation must be performed before a series of massive FE simulation. Therefore, the numerical reliability was checked for influence of increasing mesh density, and further convergence sensitivity was confirmed when variation of the sequential analytical results was less than 3%. The twelve FEA models were validated individually through the convergence evaluation of element sensitivity to reflect reliability of the FE results. Hence, the numbers of the elements and nodes used in this study for each FE model with and without cement cloud were according

to convergence test to reflect a suitable element size, a validation of the convergence model was not only to provide a reliable numerical results, but also to decrease consumption of iteration time. Both von Mises stress and total reaction force were analyzed and compared among each group.

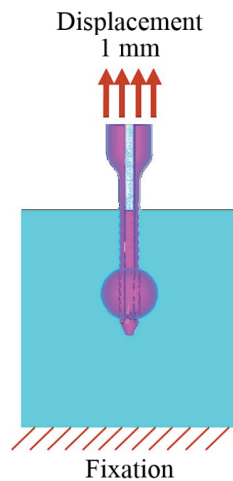


Fig. 4. Displacement of 1 mm of the FEA in the cannulated pedicle screw with cement augmentation

3. Results

The results of the total reaction forces in pullout strength simulating of the FEA shows in Fig. 5. The result shows that all of reaction forces in the cement models are significantly larger than that in the non-cement models (model A, model B, and model C) when the same pedicle screw design is compared, particularly different in the cement cloud of 4 ml. Moreover, the increase tendency of the reaction force is discovered proportionally to the increase of cement-injected volume. The pedicle screw with cement augmentation can provide a better pullout resistance to prevent interface failure between bone and cement as well as screw and bone, and a larger cement augmentation can also be evidenced to provide a better pullout resistance. In the non-cement models, the pullout force in the model B (cannulated pedicle screw) is less than that in the model A (conventional solid pedicle screw), but all of models in the cement augmentation show that the pullout forces in the cannulated pedicle screw model are significant bigger than that in the conventional solid pedicle screw model. This finding indicates that the function of cement augmentation is efficient for osteoporotic bone quality. The maximum total reaction force (133.8 N) is located in model C3, which is the cannulated pedicle screw with a central

pin using 4 ml cement cloud, and the minimum total reaction force (106.8 N) is located in model B, which is the cannulated pedicle screw without cement cloud. This result indicates that the cannulated pedicle screw is weaker than solid pedicle screw for pullout strength, but cement augmentation combined with the cannulated pedicle screw shows a tendency of a better behavior of pullout resistance for severe osteoporotic bone.

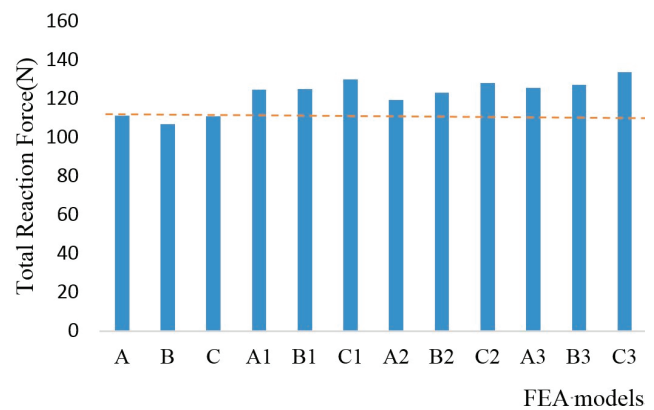


Fig. 5. Comparison of total reaction force in the axial pullout simulating of the FEA without and with cement application

The tendency in the peak von Mises stress of the pedicle screws shows that increasing cement volume seems to enhance stress on the pedicle screw under pullout force in the three groups of the FEA models (Fig. 6). Moreover, the design of the cannulated pedicle screw with a central pin can reduce stress magnitude in the mechanical performance of the screw structure. Regarding the stress distribution of the pedicle screw, the highest stress is concentrated on the proximal portion of the screw body and is gradually decreasing distally over the pedicle screw in each group (Fig. 7). Another stress raiser, which may result

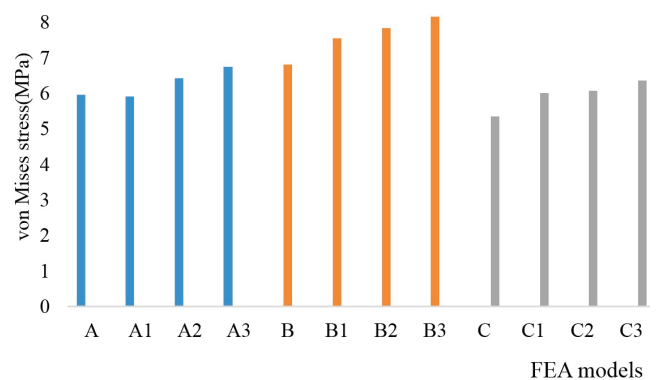


Fig. 6. Comparison of the peak von Mises stresses in the pedicle screws of the FEA models

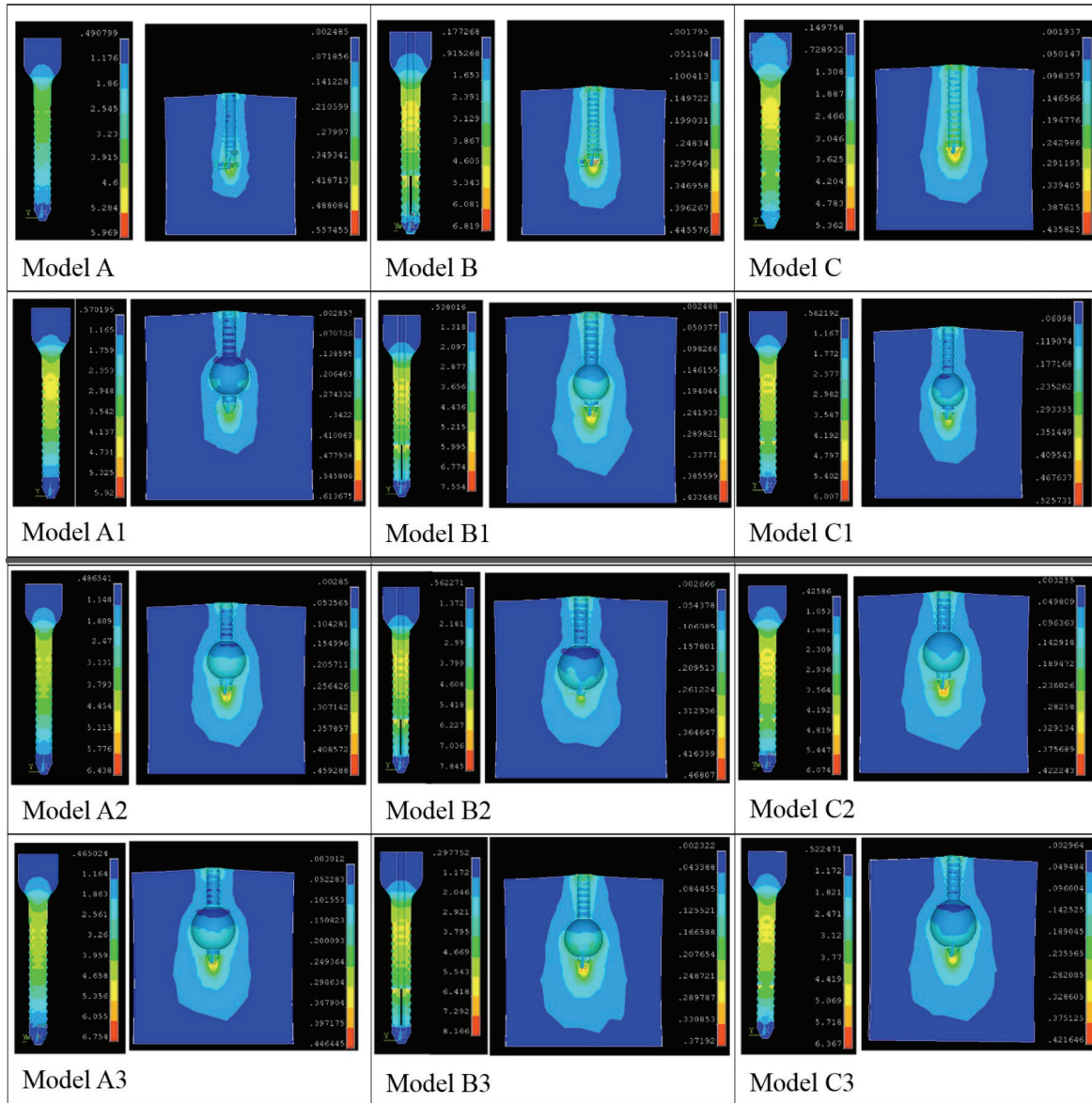


Fig. 7. Distribution of the peak von Mises stress in the twelve FEA models. The peak stresses of the pedicle screw and the bone block were concentrated at the proximal screw body and screw tail, respectively

from the geometric structure discontinuity, is observed at proximal side-grooves of the cannulated pedicle screw with or without a matched central pin insertion. Comparing the peak von Mises stress distribution of the bone block (Fig. 8), the result reveals a decrease trend of the peak equivalent stress in the bone along with increasing cement volumes in the cemented FEA models. The larger cement cloud can provide a larger contact surface between bone and cement to significantly decrease contact stress. The maximum and minimum equivalent stresses of the bone in the FE models are detected with 2 ml and 4 ml cement, respectively. Furthermore, the higher stress is concentrated significantly on the screw tail (Fig. 7). Another

stress raiser is observed at proximal cement cloud in cemented group. The results of the FEA are further coinciding with the results of the biomechanical pullout failure strength testing. The pullout strength of the cemented group is higher than that of the non-cemented group. In situation of the pedicle screw using bone cement augmentation, the larger diameter of the cement cloud expanding, the larger the force needed to pull out the screw/cement composite. Because the magnitude of the mechanical properties of the metallic pedicle screw is much higher than that of the sawbone testing, the destroyed point is located at the screw tail, which also resembles the experimental sawbone result of the previous study [27].

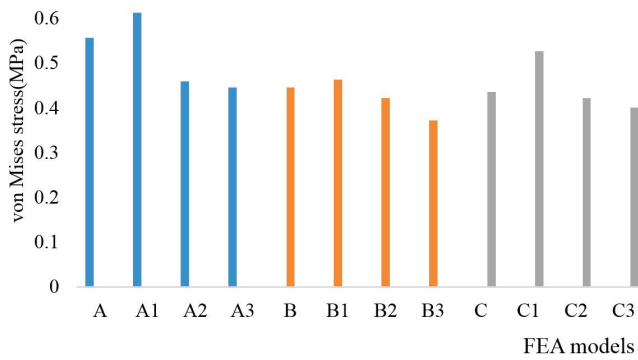


Fig. 8. Comparison of the peak von Mises stresses in the bone blocks of the FEA models

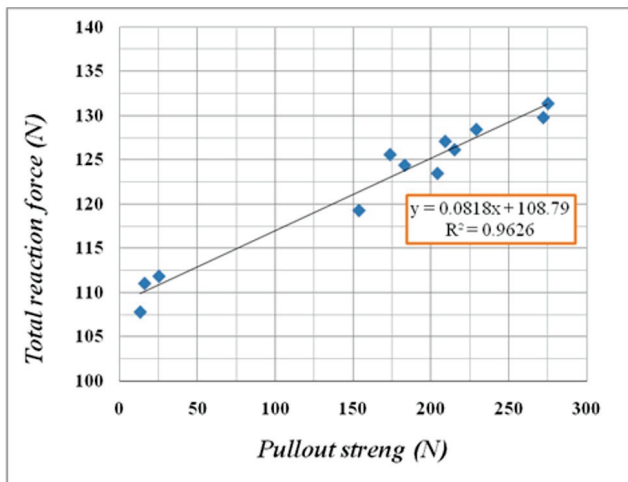


Fig. 9. The total reaction forces among twelve models are closely related to the pullout failure strength measured in the experimental sawbone testing. Linear regression indicates that a high correlation (correlation coefficient $r = 0.9626$) is obtained between total reaction force and pullout strength by comparing the FEA and sawbone experiment

4. Discussion

The concepts and underlying principles of bone cement anchored pedicle screw design are based on smooth bone cement delivery and associated with optimal pedicle screw structural strength. It is hypothesized that high-viscosity bone cement stabilizes the forces underlying cement flow, thus increasing the uniform distribution for the filling pattern. A cannula of the pedicle screw can be optimally designed regarding internal diameter for the delivery of thick bone cement. Several studies showed that pedicle screw pullout causes failure of the connection due to bone shearing with little or no damage to the screw [25]. A matched central pin is also designed to enhance

the structure strength of the cannulated pedicle screw and push the residual bone cement through four quadrantal side-grooves outside the screw. Therefore, this novel pedicle screw is developed under the following principal criteria:

- (1) the conventional solid pedicle screw based on the ASTM standard and modified under clinical and functional consideration is proposed to provide adequate structural strength,
- (2) a cannulated central hole in the pedicle screw is proposed to provide a tract for consistent and smooth delivery of the bone cement,
- (3) four quadrantal side-grooves located at distal third of the cannulated pedicle screw are proposed to facilitate the bone cement flow to outside the screw,
- (4) a matched central pin is proposed both to augment the structural strength of the cannulated screw and push the residual bone cement inside the screw to outside for interdigitating the bone cement with the surrounding osteoporotic bone more uniformly.

The exploitation of the pedicle as a site for segmental fixation is a major advance in modern spinal surgery. The intrinsic factors that influence screw holding power are material property, outer thread diameter, thread length, and thread configuration. Extrinsic factors are bone quality, screw insertion orientation, screw position, and driving torque [15]. Augmentation of pedicle screws with PMMA bone cement has been shown to improve the initial fixation and fatigue strength of instrumentation in osteoporotic vertebrae. Different techniques have been described for bone cement augmentation of pedicle screws. Recently, the most popular method is conventional open vertebroplasty, in which a spinal biopsy needle is used for bone cement injection after the pedicle tract created [8].

Pullout strength of pedicle screw is an important factor to affect holding power of screw-locked system between the pedicle screw and osteoporotic bone. The literature of 2D FEA for evaluating the pullout strength of the pedicle screw is rare in recently. The Varghese et al. [23] investigated the pullout strength of the pedicle screw with axial pullout force through plane stress method of 2D evaluation. The results showed that outer diameter had highest effect on the pullout strength of the pedicle screw. Moreover, coarser thread of the pedicle screw could provide better holding power for osteoporotic bone. For the pullout strength of the pedicle screw in 3D FEA, Chao et al. [4] utilized ten thread shapes of the pedicle screw combined with a cylinder bone block to investigate the effect of the pullout strength. The FEA result indicated that the

design shape of conical screw increased effectively the pullout strength in the bone. Furthermore, this study was also evidenced the method of the FEA could reliably predict the results of *in vitro* experimental sawbone test. In 2014, shape effects of bone cement augmentation were evaluated using 3D FE model to compare normal and osteoporotic lumbar vertebrae from Wang et al. [26]. The results revealed that the pullout forces in cylinder cement were greater than those in spherical cement, and the pullout force was increased significantly proportionally to the amount of injected cement volumes. Moreover, the detected effects of the shape and volume of bone cement were more obvious in osteoporotic bone than in normal bone.

The finite element method is initially used to analyze and compare the pullout strength and bending strength among three different pedicle screw designs of the conventional solid pedicle screw, the cannulated pedicle screw, and the cannulated pedicle screw with a matched central pin. In pullout strength analysis, the higher stress is almost equally distributed on the pitches of the whole conventional pedicle screw. The higher stress is then shifted to concentrate on the pitches of the side-grooves of the cannulated pedicle screw and the cannulated pedicle screw with a matched central pin. The results of finite element analysis imply that the structural strength of the cannulated pedicle screw is weaker than the conventional pedicle screw. It is noted that von Mises stress occurs mainly at the side-grooves, which can be the destroying point if the cannulated pedicle screw is unable to resist a force higher than 391.80 MPa. However, the pullout strength are closely to the structural strength of the conventional solid pedicle screw if a matched central pin is inserted for augmentation. The structural strength of the bone cement anchored pedicle screw prototype is as strong as that of the conventional solid pedicle screw. In clinical practice, the magnitude of the mechanical properties of the human cortical or cancellous bone is much lower than that of the metallic pedicle screw, especially in patients with osteoporosis. Therefore, the pullout failure of pedicle screw instrumentation in osteoporotic spine usually results from bone shearing, with little or no damage to the pedicle screw structure.

For comparison of FEA and sawbone experiment in the cement augmentation, the relationship was further investigated between total reaction force of the FEA and pullout strength of the experimental sawbone testing to present a confidence and connection of the results by two different biomechanical methods. A strong relationship was found in com-

parison with the results of the experimental sawbone testing and the FEA. The total reaction forces among twelve FE models were closely related to the pullout strength measured in the previous experimental sawbone testing [20] ($r^2 = 0.9626$, Fig. 9). This comparison strongly evidenced that the high correlation in the pullout strength between the FEA and the experimental sawbone testing. Moreover, a strong positive correlation of the pullout index revealed that the results could be considered to reflect a reliable consequence in the pullout testing of the pedicle screw.

Additionally, the numerical reliability of the FEA can be checked by decreasing the element size and increasing mesh density [5]. For purpose of decreasing consumption of numerical iterations and increasing reliable of the FEA results, hence, the element size of less than 1 mm was selected for meshing of the FE models when criteria of convergence testing in the analytical results was less than 3%. Moreover, the FEA is a powerful tool to investigate biomechanical effects in the surgical reconstruction and/or stress concentration in relationship between medical device and bone [18]. In other words, the result of the FEA can be further compared with that of experimental study, thus, more detail information about biomechanical influence can be provided and identified. The limitation of this study is that vertebral shape effect, particularly in size and shape of the pedicle structure region, is not considered for evaluating influence of the pullout strength. This assumption of bone block usage could not reflect bone-shaped limitation in the pullout strength of the pedicle screws. Moreover, as investigation of severe osteoporotic bone quality in the bone block model was shown, there is lack of cortical layer in the FEA, so the effect of cortical thickness must be clarified in the future work. Moreover, bone block model without cortical layer is that the reason wants to compare with previous experimental sawbone test result. In addition, the shape of the bone cement model is different from that of the clinical reality. The shape and size of the bone cement are important factors to influence the pullout strength of the pedicle screw out of the bone block. The loading condition was applied only an axial displacement of the pedicle screw, that means the bending effect is not considered for evaluating the pullout strength between pedicle screw design and bone cement volume. In the future work, more complete parameters and more rigorous models will be considered so that the most reliable results can be explored for treatment reference of pedicle screw fixation system.

5. Conclusions

It was confirmed that the pedicle screw fixation with cement augmentation gives better mechanical effect in pullout strength than that in only pedicle without cement usage. Moreover, regarding the cement cloud size, it was also discovered that a larger cement cloud in pullout strength (such as reaction force) is more effective than a smaller cement cloud. Although a pullout resistance of a large cement cloud is confirmed, the prevention of cement leakage problem is still considered priority in patients. The design of the cannulated pedicle screw with side-grooves can not only provide a channel for cement circulation and solidification but also can combine with a central pin to increase the pullout strength. Furthermore, a cannulated pedicle screw with a central pin combined with cement augmentation has the best pullout strength performance for all comparisons in the FEA, thus, the usage of the bone cement may reduce for surgery. Finally, the cannulated pedicle screw with a central pin combined with small cement augmentation is recommended to provide the best effective in the spinal reconstruction.

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