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Functionally Graded Coating Material of Cementless Knee Prosthesis

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Authors' contributions

This work was carried out in collaboration between all authors. Authors SAA and NF wrote the first draft of the manuscript, managed the analyses of the study and literature searches. Authors SAA and HSH designed the study, performed the analysis and wrote the protocol. All authors read and approved the final manuscript.

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ABSTRACT

Surfaces are the primary place of contact a biomaterial and its host organism. Surface treatment or coating provides a means to overcome the problem which appeared after knee replacement surgery. There are two main problems; the stress shielding and subsequent bone remodeling causes bone resorption around the implant especially at the proximal part of the knee under the tibia tray. The other problem is stem tip pain. Therefore, the aim of this investigation is to find a new design of coating material of a cementless total knee replacement using functionally graded material (FGM). The objective of this research is to find the optimal material compositions, as well as the optimal gradation direction. It is found that using both vertical and horizontal FGM coating increased the von Mises stress at the proximal part of the tibial cancellous bone. Von Mises stress in cancellous epiphyseal bone is increased by 77% using vertical and horizontal FGM coating

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compared to hidroxyapatite HAP coating. It is found that this new coating design will improve the performance of a cementless tibia tray and will increase the life of the knee prosthesis.

Keywords: Cementless knee replacement; coating material; functionally graded material; von Mises stresses, stress shielding; finite element analysis.

1. INTRODUCTION

After knee replacement surgery the stiffer implant carries the majority of the load, which was actually carried by the bone itself before implantation. The resulting implant induced stress-shielding and subsequent bone remodeling causes bone resorption around the implant especially at the proximal part of the knee under the tibia tray [1]. Stem tip pain following revision total knee arthroplasty is a significant cause of patient dissatisfaction, which in the presence of an aseptic well-fixed component has no widely accepted surgical solution. A definitive cause of stem tip pain remains elusive, however it has been suggested that high stress concentrations within the region of the stem tip may play a role [2,3].

Many researchers have studied the effect of using HAP coating for different biological applications. Tibial component fixation with a peri-apatite coating was analyzed by Allen et al. [4]. Radiostereometric analysis was used to document implant migration in 48 dogs that underwent TKA with cementless peri-apatite coated and cemented tibial components. Migration at 12 weeks was similar in the 2 groups. At 12 months, there was greater migration in the periapatite coated group. In a prospective randomized study using radiostereometric analysis (RSA), Therbo et al [5] examined migrations of the tibial implant, in an uncemented TKA with and without bioactive coating. Two different groups were examined one group with bioactive (hydroxyapatite or periapatite) coating (+HAP), the other without bioactive coating (-HAP). At 12 months follow-up they found no significant differences in migrations between the two groups. However, in general the -HAP group migrated more than the +HAP group, and they found a significant larger variation in migration pattern in the -HAP group. In the +HAP group the tibia component stabilized after 6 months, whereas the -HAP group showed continuous migration. The most recent review article was carried out by Love et al. [6] about coating materials. They concluded that Diamond like Carbon (DLC) coatings exhibit properties that could make them viable for implants. Overall DLCs seem to be an effective coating for implants but with the variance in results, further testing is required for clarification of use. Structure and composition of silicon nitride and silicon carbon nitride coatings for joint replacements were investigated by Pettersson et al. [7]. Findings in this paper support further development of these coatings for surfaces in joint replacements. Cossetto et al. [8] designed a new uncemented tibial fixation for knee arthroplasty consisting of a central polished stem and 4 peripheral pegs. The undersurface of the tray and pegs has a porous surface that is overcoated with hydroxyapatite. They found that this design provides a predictably stable fixation, with excellent midterm clinical and radiological outcomes. A comparison between cemented, press-fit, and HAP-coated interfaces in Kinemax total knee replacement was carried out by Walker et al. [9]. The indications are that uncemented tibial components need to be designed with a combination of posts or screws, which would reduce the interface micromotion to an insignificant level, together with accurate bone-cutting tools. For such a design, the addition of HAP- coating would be expected to provide an advantage to long-term fixation and may even present an advantage to cement. HAP has the ability to bond directly to the bone, to achieve earlier and greater fixation strength and to reduce healing time and levels of pain [10]. Bone growth was shown to be quicker on the surface of a HAP-coated implant than in an untreated titanium surface. A HAP-coated implant may be helpful for mechanical stability in situations where the cortical bone is inadequate [11]. The mechanical properties of bioactive coatings on Ti6Al4V substrates were investigated by Ou et al. [12]. The aim was to observe the differences in the mechanical properties before and after immersion in collagen solution. The Young’s modulus of the pure hydroxyapatite, the disk and the coatings, was 3.6 GPa. After collagen incubation treatment, the composites had a Young’s modulus of 7.5 GPa.

A new design of the cementless hip stem coating using vertical functionally graded material, FGM, was found by Hedia and Fouda [13], then Fouda [14] studied the effect of changing the FGM hip stem coating material in a horizontal direction. The using of FGM hip stem coating leads to diminishing stress shielding at the medial proximal region of the femur. In addition, it reduces the interface shear stress between the coating and bone that affects the long term stability of the hip implant. However, they also found a new design of dental implant coating which is functionally graded from titanium at the outer shell adjacent to the bone to collagen the inner shell adjacent to the implant, will reduce the maximum von Mises stress by 16% and 13% compared with the conventional coating materials such as collagen and hydroxyapatite coatings, respectively [15].

It is clear from the previous survey that only the concept of using FGM was used only in dental implant and hip prosthesis coatings. It seems that no studies to date have examined the application of FGM on the artificial knee joint coating until now.

2. METHODOLOGY

The total knee replacement joint consists of a tibial base plate or tray, usually made of titanium alloys, stainless steel or cobalt chromium molybdenum (CoCrMo), with a tibial insert (UHMWPE) that acts as the bearing surface. The details of the total knee components and these components which are inserted in a knee joint are illustrated in Figs. 1a, b. In this analysis a mid – coronal plane section of the tibia with implanted prosthesis was studied. Fig. 2 represents this cross section to clear all model components. The tibia represented knee with a medial – lateral width of 74 mm, the tibial plate height equals 8mm with stem length 40 mm and stem diameter 12 mm. All prosthesis components were shown in Fig. 2. The tibial model consisted of the tibial bone (cortical and cancellous), the tibial tray, and the ultra high molecular weight polyethylene (UHMWPE) insert. Linear elastic behavior was assumed for all materials. The heterogeneous material properties of the bone were modeled with six sections of different modulus (cortical diaphyseal, cortical metaphyseal, cancellous epiphyseal, cancellous metaphyseal 1 and 2, and cancellous diaphyseal) [3,16,17]. All these material sections were shown in Fig. 3. The coating material was made of hydroxyapatie (HAP) as an initial design. The properties of all materials were listed in Table 1. The coating material was optimized through this research work using the concept of FGM. The mid – coronal plane section of a tibia with implanted prosthesis was represented using a 2D – axisymmetric finite element model. The model was created using ANSYS 14.5 software package. The finite element model was created using linear isoparametric quadrilateral and triangular elements. The model was rigidly fixed distally at the tibia. Symmetric forces distributed over each condylar surface area equal 1000 N [18]. The load magnitude of 2000 N represents the total joint reaction force equivalent to 3 times the body weight, which is typical during normal level walking [8,10]. The finite element model and the loading conditions were shown in Fig. 4. In this study the coating of the cementless tibia tray was considered to be designed as a FGM with porosity p that is functionally graded from two different materials graded in the vertical direction (model 1), and in the horizontal direction (model 2) as shown in Fig. 5. The volume fraction and rules of mixtures is the most realistic way for representing the continuous gradation of the material properties of FGM. The volume fraction of the first material is V_1, while the volume fraction of the second material is V_2. Theses volume fractions are distributed in the vertical and horizontal directions according to the following relations [13-15]:

$$\text{Model 1: } V_2 = (y/l)^m \tag{1}$$

$$\text{Model 2: } V_2 = (x/w)^m \tag{2}$$

While the volume fraction for the second material for both models calculated as;

$$V_1 = 1 - V_2 \tag{3}$$

where y and x are the vertical and horizontal position of any point along the tibia tray coating, l is the total length of the tibia tray coating, w is the medial – lateral width of the tibia tray coating, and m is a parameter that represents the composition variation between the two different materials along the gradation direction.

The equivalent elastic modulus at different regions of the tibia tray calculated from the following equation [13-15]:

$$E = \frac{E_0(1-p)}{1+p(5+8\upsilon)(37-8\upsilon)/\{8(1+\upsilon)(23+8\upsilon)\}} \tag{4}$$

where:

$$E_o = E_2\left[\frac{E_2+(E_1-E_2)V_1^{2/3}}{E_2+(E_1-E_2)(V_1^{2/3}-V_1)}\right] \tag{5}$$

$$\nu = \nu_1 V_1 + \nu_2 V_2 \tag{6}$$

where ν_1 and ν_2 are the Poisson's ratio of the two-phase FGM, respectively and ν is the Poisson's ratio for FGM.

p is the porosity of the FGM tibia tray coating calculated from the following equations:

for the first model: $p = A\,(y/l)^{n}\,[1- (y/l)^{z}]$ (7)

for the second model:

$$p = A\,(x/w)^{n}\,[1- (x/w)^{z}] \tag{8}$$

where A represents the porosity in the mixture calculated using the following equation:

$$\frac{((n+z)/n)^{n}}{1-(n/(n+z))^{z}} \geq A \geq 0 \tag{9}$$

where m, n, z are arbitrary constants.

The main goal of this study is to find the optimal material gradation of the tibia tray coating and the optimal gradation direction. The purpose of using FGM coating is to overcome the mismatch between the tibia tray stiffness and the natural bone. The objective of the current study is to maintain the stress in the bone within the physiological levels of the original tibia, at the same time minimize the stress concentration along the bone/implant interface especially at the distal region of the tibia. In order to have the optimal material gradation the optimization technique applied through the ANSYS package. The computer programs were written with the ANSYS Parametric Design Language APDL to calculate the material properties at each layer of the graded coating.

The objective function is to maximize von Mises stress in the proximal cancellous diaphyseal bone under the tibia tray, to minimize stress shielding at this region of cancellous bone.

The Design Variables are:

(1) Change the elastic modulus of the two-phase composites of FGM tibia tray E_1 and E_2 within a large different values of biomaterials $1GPa \leq E_1, E_2 \leq 210\ GPa$,

(2) Change the parameter of the composition variation, m within a range $0 < m \leq 10$ obtained from literature [13-15].

The state variables are:

(1) The maximum von Mises stress in cortical diaphyseal bone at coating / bone interface using the FGM coating to be more than the maximum von Mises stress using HAP coating. However, it is maximum value does not exceed the value of von Mises stress at this part of tibial natural bone.

σ HAP coating cortical bone ≤ σ FGM coating cortical bone ≤ σ natural tibial cortical bone

(2) The maximum von Mises stress in cancellous epiphyseal bone at coating / bone interface using the FGM coating to be more than the maximum von Mises stress using HAP coating. However, it is maximum value does not exceed the value of von Mises stress at this part of tibial natural bone.

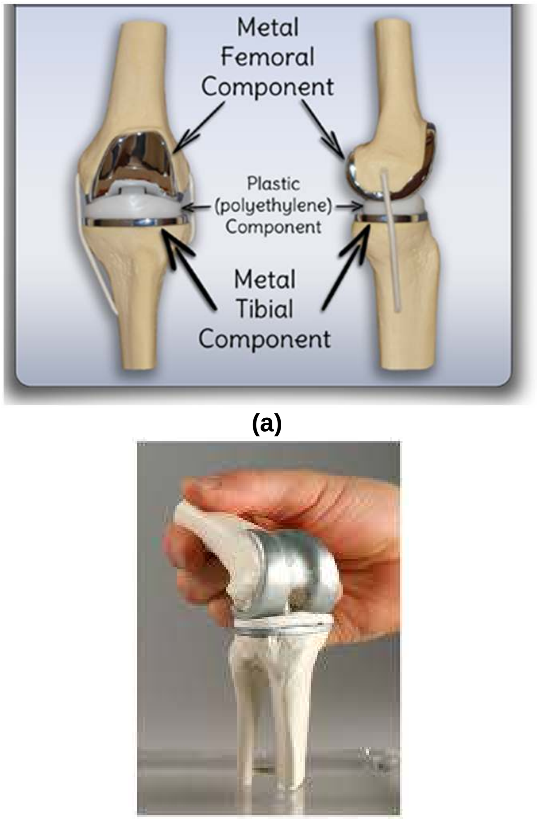
σ HAP coating epiphyseal bone ≤ σ FGM coating epiphyseal bone ≤ σ natural tibial epiphyseal bone

(3) The maximum von Mises stress in the distal cancellous diaphyseal bone at coating/bone interface to be less than the maximum von Mises stress using HAP coating. However, its minimum value is an arbitrary small value (e.g. 0.01MPa).

T arbitrary value ≤ T FGM diaphyseal bone ≤ T Ti diaphyseal bone

Table 1. Material property of the tibia and tibial prosthesis

Material	Elastic modulus (MPa)	Poisson's ratio
Diaphyseal cortical bone	17000	0.3
Metaphyseal cortical bone	5000	0.3
Cancellous epiphyseal bone	400	0.3
Cancellous metaphyseal bone 1	320	0.3
Cancellous metaphyseal bone 2	300	0.3
Cancellous diaphyseal	100	0.3
polymethylemetacrylate (PMMA)	2000	0.23
UHMWPE	1000	0.3
Stem / tray (titanium alloy)	110000	0.33



(a)

(b)

Fig. 1. (a) The details of the total knee components (b) The total knee components are inserted in a knee joint

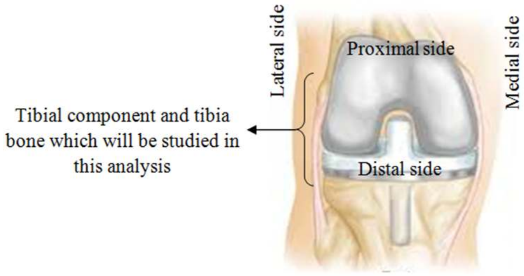


Fig. 2. The cross section of a tibial component inserted in the natural knee

3. RESULTS AND DISCUSSION

The optimization process was started using cementless titanium tibia tray coated with HAP as an initial design. The optimal materials were found to be hydroxyapatite and collagen due to their excellent biocompatibility and also were used before by Hedia et al. [13,15]. The optimal FGM for the first model was graded vertically from hydroxyapatite at the distal layers of the coating to collagen at the upper layer of the coating under the tibia plate. However, the optimal FGM for the second model was graded horizontally from hydroxyapatite at the inner layers of the coating adjacent to tibia stem to collagen at the outer layers of the coating adjacent to the tibia bone. Both optimal FGM models have a composition variation parameter *m* equals 0.1 which mean that both FGM compositions were rich in collagen.

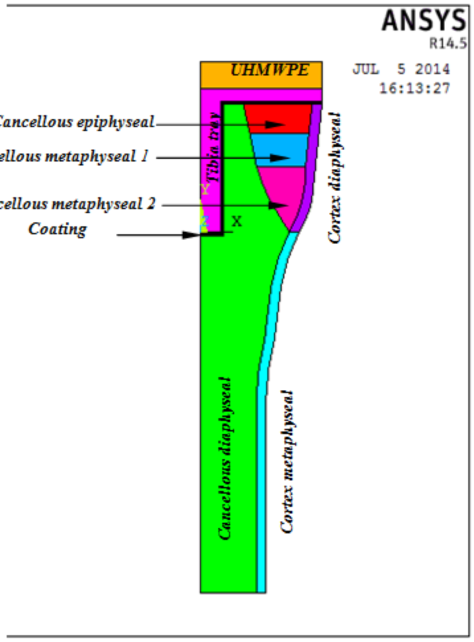


Fig. 3. The components of the tibia and tibial prosthesis

A comparison between the stresses of the initial cementless tibia tray coated with HAP and the two FGM designs is illustrated through the following figures. The von Mises stress were used for this analysis because it's a combination of principal stresses σ_1 and σ_2 and also is a good representation for theory of failure. The von Mises stress in distal tibia at tibia/coating interface is illustrated in Fig. 6. The stresses increased gradually from the coating center towards the stem tip. The maximum Von Mises stress is increased by 9% for the vertical FGM compared to HAP coating. However, the stresses are identical for both horizontal FGM and HAP coating along tibia/coating interface.

Fig. 7 illustrates von Mises stress in cortex metaphyseal bone at coating/bone interface. It is found that the maximum von Mises stress is increased by 11% for the vertical FGM coating and by 14% for the horizontal FGM coating compared to HAP coating.

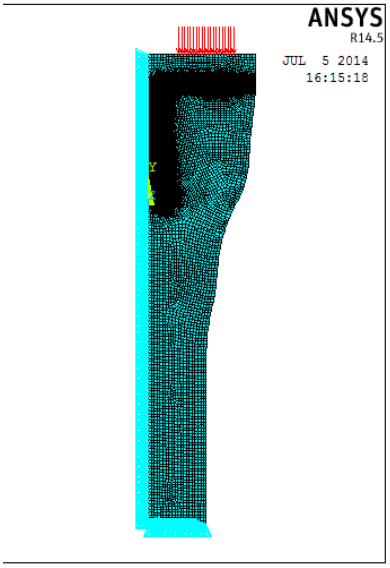
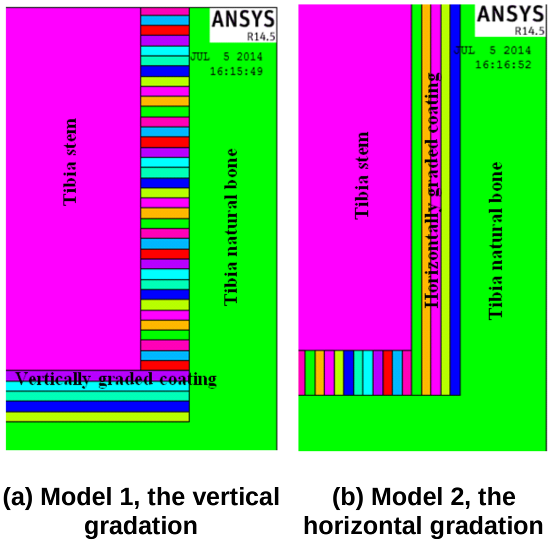


Fig. 4. An axisymmetric finite element model with the loading conditions

A comparision between the maximum von Mises stress in cortex metaphyseal bone for HAP coating, vertical FGM and horizontal FGM is illustrated in Fig. 8. Von Mises stress in cancellous epiphyseal bone at coating/bone interface is illustrated in Fig. 9 which shows that maximum von Mises stress in cancellous epiphyseal bone is increased by 77% for the vertical and horizontal FGM compared to HAP coating. The stresses are increased along whole interface for the horizontal FGM compared to vertical FGM and HAP coating.



(a) Model 1, the vertical gradation **(b) Model 2, the horizontal gradation**

Fig. 5. The gradation direction of the FGM coating

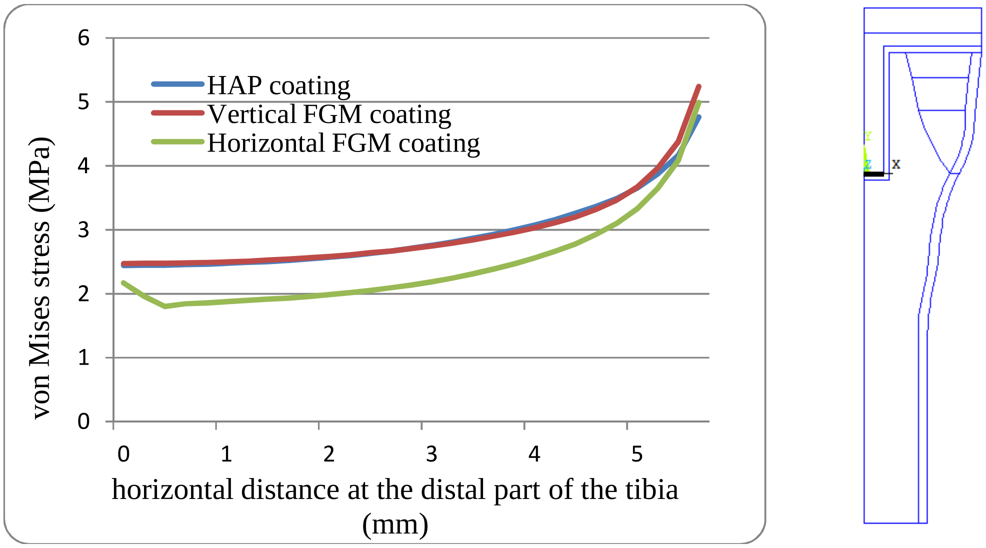


Fig. 6. Von Mises stress in distal tibia at tibia/coating interface, the bold line on the right figure represents this interface

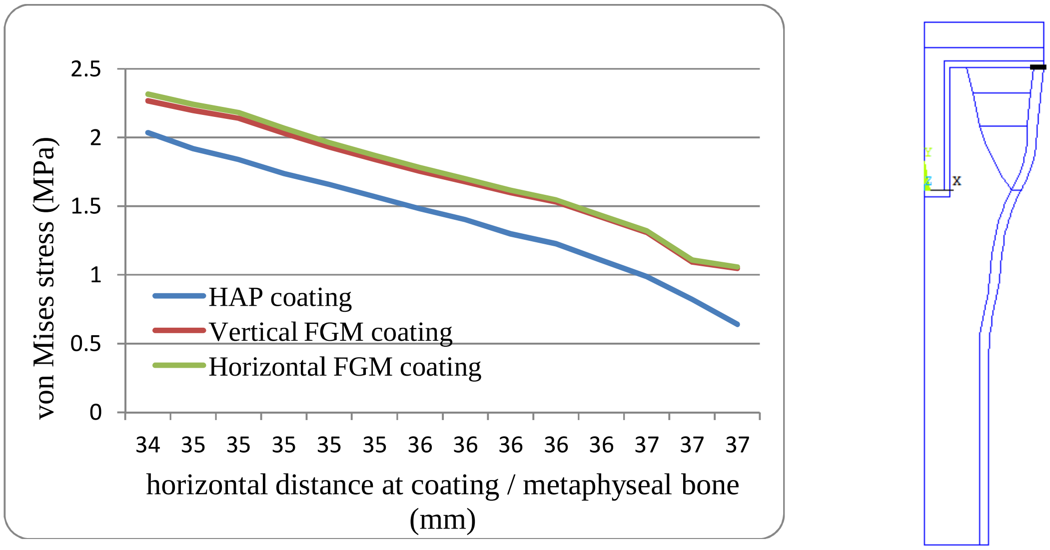


Fig. 7. Von Mises stress in cortex metaphyseal bone at coating/bone interface, the bold line on the right figure represents this interface

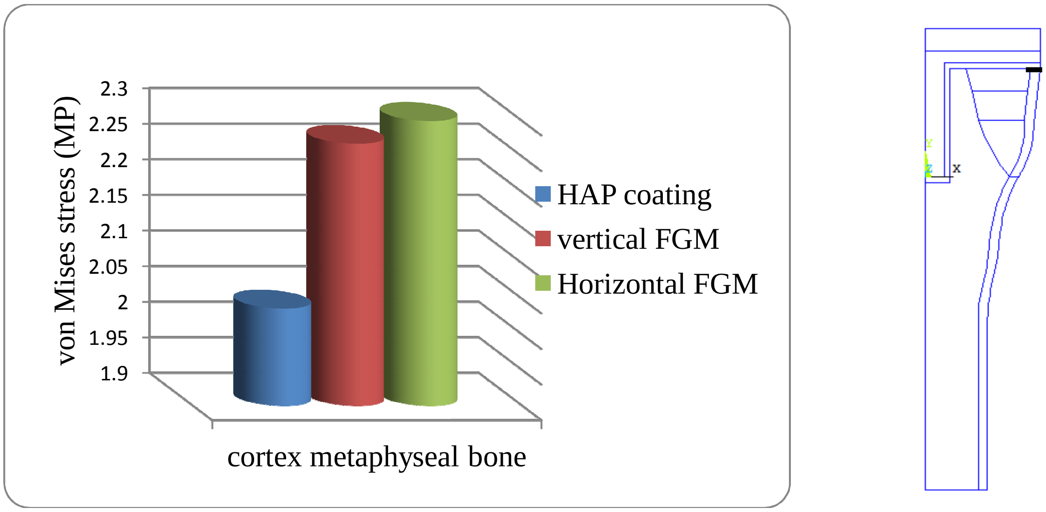


Fig. 8. Maximum von Mises stress in cortex metaphyseal bone for HAP coating, vertical FGM and horizontal FGM

A comparison between the maximum von Mises stress in cancellous epiphyseal bone for HAP coating, vertical FGM and horizontal FGM is illustrated in Fig. 10. Von Mises stress in distal cancellous diapyseal bone at coating/bone interface is illustrated in Fig. 11. It is shown that the stresses increased gradually towards the stem tip for all coating types. The stresses for vertical FGM and HAP coating are the same along whole coating/bone interface. However the stresses increased for small values along whole interface except at the stem tip for horizontal FGM compared to vertical FGM and HAP coating.

Fig. 12 illustrates von Mises stress in cancellous diaphyseal bone at the vertical coating/bone interface. It is shown that stresses decreased gradually from distal to proximal regions. The stresses have the same values along whole interface for vertical FGM and HAP coating. The stresses are reduced for horizontal FGM coating along whole interface except at the stem tip compared to vertical FGM and HAP coating. von Mises stress in proximal cancellous diapyseal bone at coating/bone interface is illustrated in Fig. 13. It is found that the maximum von Mises stress is increased by 39% for the vertical FGM coating and by 57% for the horizontal FGM coating compared to HAP coating. A comparison between the maximum von Mises stress in proximal cancellous diaphyseal bone for HAP coating, vertical FGM and horizontal FGM is illustrated in Fig. 14.

The model did not include some effective elements such as ligaments and muscles. Also, the positions of the components have been considered theoretically and the applied load has been assumed constant. Additionally, in the present analysis, all materials used in the tibial prostheses assumed isotropic and linearly elastic. Heterogeneous bone properties modeled by considering different properties for cortical bone (diapyseal and metaphyseal) and cancellous bone (epiphyseal, metaphyseal 1 & 2 and diaphyseal). Furthermore, a rigidly bonded interface assumed between implant components, coating and bone. This simplified model was used before by many researchers [3,16,17,19, 18]. These assumptions were made in order to

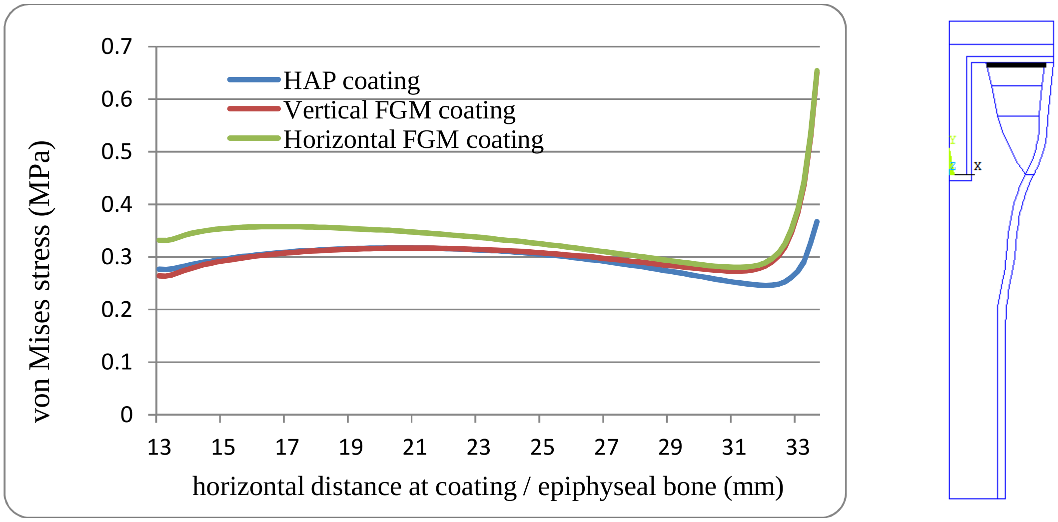


Fig. 9. Von Mises stress in cancellous epiphyseal bone at coating/bone interface, the bold line on the right figure represents this interface

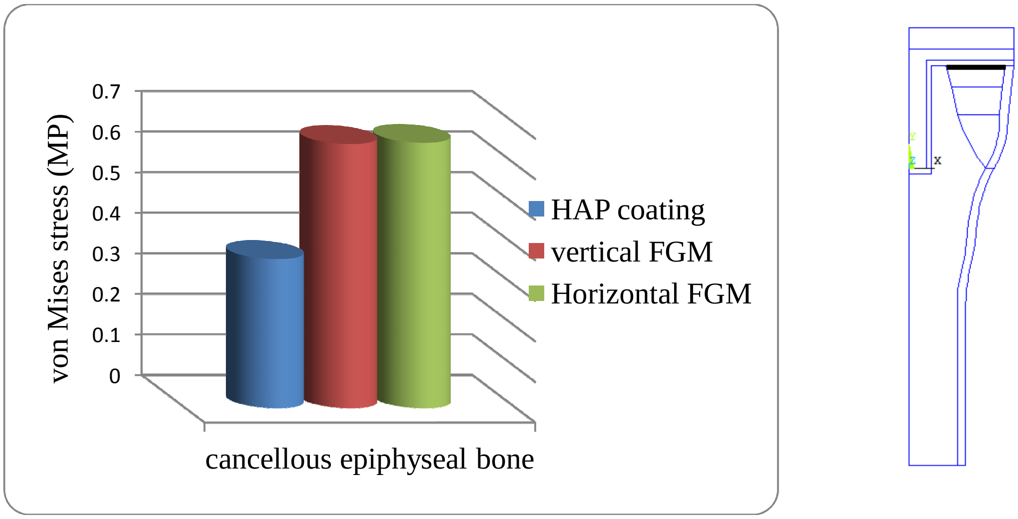


Fig. 10. Maximum von Mises stress in cancellous epiphyseal bone for HAP coating, vertical FGM and horizontal FGM, the bold line on the right figure represents this interface

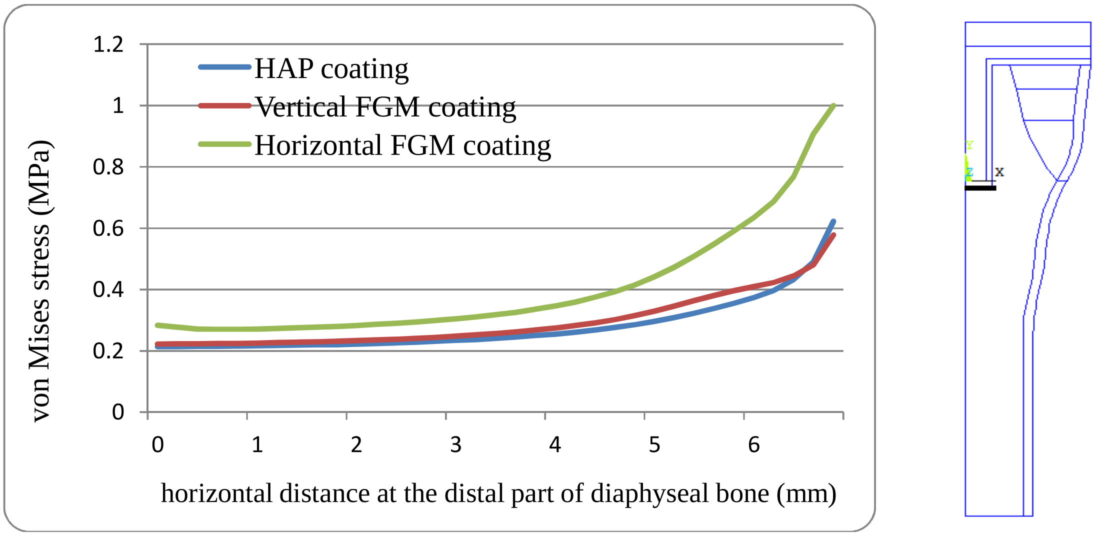


Fig. 11. Von Mises stress in distal cancellous diapyseal bone at coating/bone interface, the bold line on the right figure represents this interface

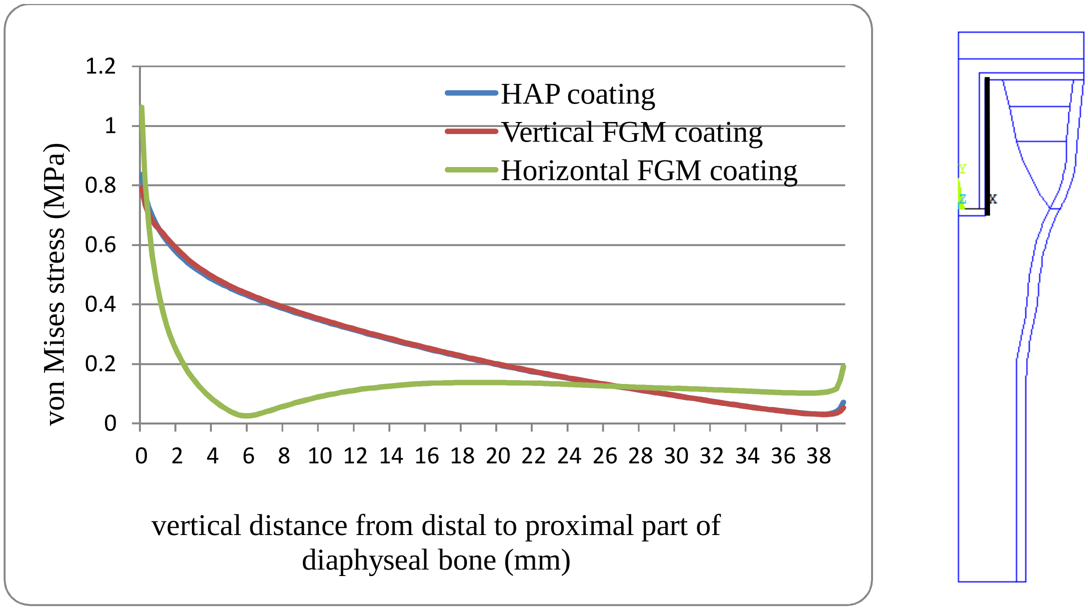


Fig. 12. Von Mises stress in cancellous diaphyseal bone at coating/bone interface, the bold line on the right figure represents this interface

make it possible to find the optimal FGM tibia tray design. Then the optimal FGM design can be applied on any real 3D tibia prosthesis model. In order to illustrate the validity and limitations of the 2D – axisymmetric finite element model, the results obtained from this model were compared to results obtained from more detailed 3D – finite element model [20]. Also, a comparison between the results of this model was compared also with other 2D models that have been carried out through other studies [3,16] which have approximately the same properties, dimensions, and the same loading conditions. There is a good agreement in von Mises stresses between the model of this study and those other models. The stress values are not exactly identical, but the trends of the stresses in each model are significantly similar.

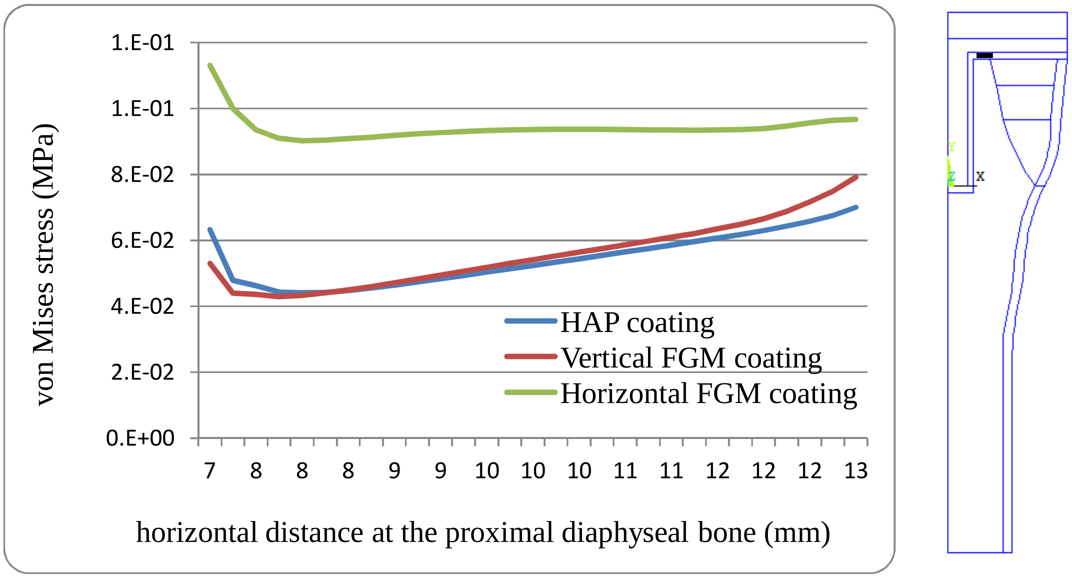


Fig. 13. Von Mises stress in proximal cancellous diapyseal bone at coating/bone interface, the bold line on the right figure represents this interface

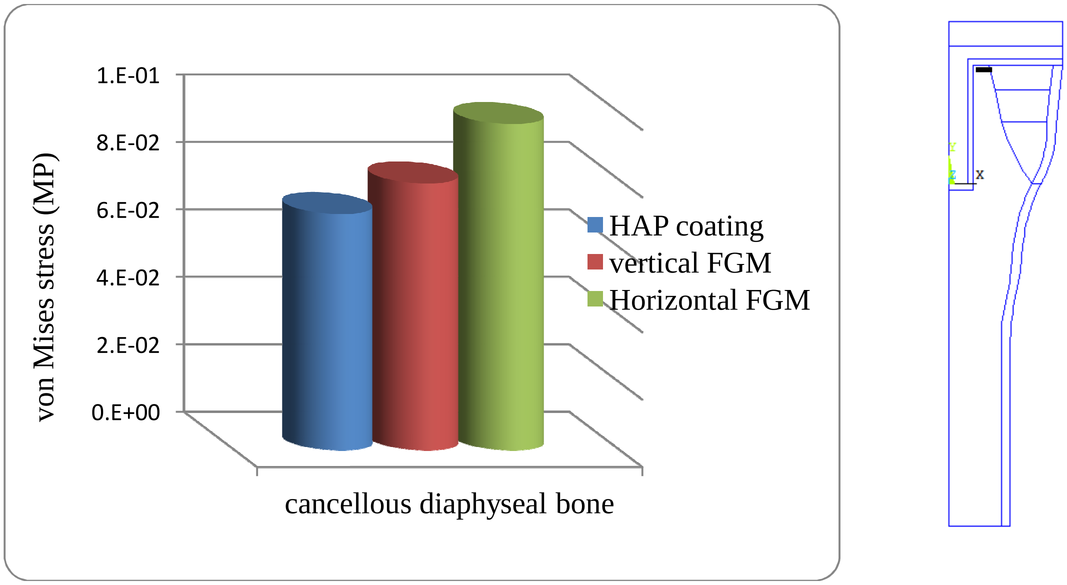


Fig. 14. Maximum von Mises stress in proximal cancellous diaphyseal bone for HAP coating, vertical FGM and horizontal FGM, the bold line on the right figure represents this interface

4. CONCLUSIONS

Cementless tibia tray material coating can be optimized using HAP/collagen FGM instead of using HAP coating. Both vertical and horizontal FGMs eliminate the stress shielding problem at the proximal region of the tibia bone under the tibia tray. This optimal design leads to positive success of implantation and and increase the life of the joint implant. The material gradation can be changed from hydroxyapatite at the lower coating layers to collagen at the upper layer of the tibial coating for the vertical FGM model. However, the material gradation can be changed from hydroxyapatite at the inner layers of the coating adjacent to the tibial stem to collagen at the outer layers of the coating adjacent to the tibia natural bone for the horizontal FGM models.

Both models have an optimal value of composition variation parameter *m* equals 0.1 which means that both designs are rich in collagen. The maximum von Mises stress is increased in the cortex metaphyseal bone by 11% for vertical FGM coating and 14% for horizontal FGM coating compared to HAP coating. However, the maximum von Mises stress is increased in the cancellous epiphyseal bone by 77% for both vertical and horizontal FGM coating compared to HAP coating. While the maximum von Mises stress is increased in the cancellous diaphyseal bone by 39% for vertical FGM coating and 57% for horizontal FGM coating compared to HAP coating. Coating with vertical FGM has the same effect on the stress concentration at the stem tip and along whole distal stem interface as the HAP coating. However, coating with horizontal FGM reduces the stress along whole distal stem interface compared to HAP coating except the stress concentration at the distal stem tip.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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