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3 **Stress Shielding in Periprosthetic Bone Following a Total Knee**
4 **Replacement: Effects of Implant Material, Design and Alignment**
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Abstract

Periprosthetic bone strain distributions in some of the typical cases of total knee replacement (TKR) were studied with regard to the selection of material, design and the alignments of tibial components to examine which conditions are more forgiving than the others to stress shielding post a TKR. Four tibial components with two implant designs (cruciate sacrificing and cruciate retaining) and material properties (metal-backed (MB) and all-polyethylene (AP)) were considered in a specimen-specific finite element tibia bone model loaded in a neutral position. The influence of tibial material and design on the periprosthetic bone strain response was investigated under the peak loads of walking and stair descending/ascending. Two of the models were also modified to examine the effect of selected implant malalignment conditions (7° posterior, 5° valgus and 5° varus) on stress shielding in the bone, where the medio-lateral load share ratios were adjusted accordingly. The predicted increases of bone density due to implantation for the selected cases studied were also presented.

For the cases examined, the effect of stress shielding on the periprosthetic bone seems to be more significantly influenced by the implant material than by the implant geometry. Significant stress shielding is found in MB cases, as opposed to increase in bone density found in AP cases, particularly in the bones immediately beneath the baseplate. The effect of stress shielding is reduced somewhat for the MB components in the malaligned positions compared with the neutral case. In AP cases, the effect of stress shielding is mostly low except in the varus position, possibly due to off-loading of lateral condyle. Increases in bone density are found in both MB and AP cases for the malaligned conditions.

Keywords: total knee replacement, tibial component, stress shielding, finite element, periprosthetic, malalignment

1. Introduction

For advanced degenerative conditions such as osteoarthritis (OA), total knee replacement (TKR) has proven to be the most successful intervention that reduces knee pain and restores physical function in such patients. Loosening of the tibial component is the most common cause of failures in TKR [1-3], typically 2-3 times more frequent than the femoral component [4, 5], although the mechanisms that lead to loosening is not well understood. The predominant mode of failure in a TKR is thought to be mechanical fatigue, where articulation produces polyethylene particles that are larger and more irregular in shape than those resulted from a THA, in the latter the predominant mode of failure is thought to be abrasive and adhesive wear [6]. Fundamental to the longevity of fixation is the integrity of cement-bone interlocking [3-5]. Although periprosthetic bone density change around the components of TKR has been known to occur for some time [7-11], it is only recently that evidence has been presented regarding bone resorption in the bone-cement interdigitated region. Miller *et al* [3, 5] presented some postmortem retrieval studies of metal-backed cemented tibial components with time in service from 0 to 20 years. They found that 75% of the bone-cement interlock was lost within 10 years of service, with extensive bony resorption at the periphery of the tibial trays. Lavernia *et al* [12] reported similar findings on autopsy-retrieved femora. Significantly, these studies are based on autopsy retrievals with time in service ranging from 1 to 22 years, where the loss of cement-bone interlocking is linked with periprosthetic bone loss.

The proximal tibial metaphysis consists of dense bone platforms, supported peripherally by an exterior cortical layer and an interior of cancellous bone. The tibial implant is mainly supported by cancellous bone. Under physiological loading conditions the medial plateau is subjected to a greater proportion of the load, and the stresses in an intact tibia are at a maximum under the surface of the joint and at the proximal metaphysis. According to Wolff's law, bone remodels in response to applied loads by changing its architecture. Stress shielding is likely to occur when insufficient loads are transferred to the bone due to the introduction of a stiffer implant, and bone resorption may occur. The material properties of tibial prostheses are known to influence how the stress is transferred to the underlying bone by both the tray and the stem. Given that a metal backed (MB) tray is several orders stiffer than an all-polyethylene (AP) one, far greater stress shielding is expected of MB components

compared to AP components. A recent study [13] shows that the maximum compressive stress within the cancellous bone under an MB component is only a third of that under an AP component. Furthermore, loading conditions as a result of altered bone/implant condylar surface geometry, load placement and pattern due to tibial component design and malalignment may also have significant impact on periprosthetic bone stress distribution [14-17], although these factors have not been adequately studied. Whilst modern TKR instrumentation allows much improved, reproducible alignment of the components, failure cases in AP components were thought to be likely due to malalignment [18].

In the present study, detailed finite element analyses were conducted to evaluate the influence of some of the typical factors, including implant material, design and malalignment of the tibial components, on the periprosthetic bone strain response to see which conditions might be more forgiving than the others to stress shielding following a TKR. Bone responses from both the bone-cement interdigitated region, as identified by Miller et al [3, 5], and the whole tibia were considered, together with the potential bone density increase due to implantation.

2. Materials and Methods

A three-dimensional finite element model of an intact proximal segment of tibial bone was developed from the CT images of a female left tibia obtained from the Visible Human Project [19] using Mimics 14.0 (Materialise, Leuven, Belgium). Two common designs of a tibial component (Zimmer NexGen Hi Flex) were considered (Fig. 1): One with cruciate sacrificing (CS), where the polyethylene liner has a central peg so it is posterior stabilised; and one with cruciate retaining (CR), where the polyethylene liner is without the central peg. The 3D geometries of the two implants were scanned using computed tomography (CT) in a STL format, constructed into solid models and virtually implanted into the proximal tibia using Boolean operations in Mimics. A cement layer, of a thickness approximately 2mm, was introduced between the tibial component and the bone (Fig. 2a). The interface between the bone and the cement; and that between the component and the cement were assumed to be fully-bonded. The lower end of the tibial model was fully fixed (Fig 2(b)) and the length of the tibial model is 150mm.

The bone, the tibial components and the cement were simplified as linear elastic and isotropic materials. The heterogeneous properties of the bone were assigned by mapping the CT Hounsfield unit (HU) values to the elastic modulus of each bone element, using an empirical relationship from the literature [20-22]:

$$E = 2017.3 \times ((HU + 13.4)/1017)^{2.46} \quad (1)$$

The range of the Young's modulus values obtained from Eq (1) is from 124 MPa to 4823 MPa, which is within the normal range of cancellous bone in knee [23].

For each implant design (CS and CR), both AP and MB components were examined. For MB components, the material properties of the tibia tray/stem and the spacer were assumed to be titanium and polyethylene, respectively; whilst the AP component was assigned with the properties of polyethylene. The material properties used in the present study are listed in Table 1.

All four tibial components (CS-AP, CS-MB, CR-AP, CR-MB) were implanted in a neutral position to investigate, first of all, the effect of component design and material on the stress shielding of periprosthetic bone. For the neutral position the tibial plateau was cut at 0° posterior slope and 90° to the mechanical axis of the tibia [24]. In addition, the two CS components were also implanted at three malalignment positions (7° posterior, 5° valgus and 5° varus) to examine the influence of malalignment on the periprosthetic bone responses (Fig. 3). The angles were selected to be within the tolerance limits in surgical practice for bone collapse or instability [17, 25].

The average peak axial contact forces of 1960N, 2492N and 2280N, obtained from *in vivo* telemetric measurements for normal walking, stair descending and stair ascending [26, 27], were applied on the top surface of the models. The axial forces were split into medial (F_{med}) and lateral (F_{lat}) components and distributed on the corresponding condyles (intact) or bearing spacers (implanted) of the tibia, respectively (Fig 2(b)). During walking, the ratio of medial-lateral load share was assigned as 60:40 for both the intact and the implanted tibia in the neutral and 7° posterior alignment positions [28]. For the implanted tibia in 5° valgus and 5° varus positions, the ratios of medial-lateral load ratios were assumed to be 45:55 and 75:25, respectively [28]. For the load cases of stair descending and ascending, only the neutral position was considered for the intact and the implanted tibia models and

the medial-lateral load ratios were assumed to be 55:45 [29]. The intact and the implanted tibial models, each with approximately 750,000-800,000 linear tetrahedral elements and element sizes ranging from 0.5 to 2.0 mm, were inputted to Abaqus 6.12 (Dassault Systèmes, RI, USA) for the numerical analysis. Table 2 summaries the analyses carried out in this study.

The effect of stress shielding on the periprosthetic bone was assessed by examining both the whole tibia and a 3 mm layer of bone volume of interest (VOI) from the resected surface underneath the baseplate (Fig. 2(a)). Three cases were considered: (i) The percentage of bone volume at the risk of resorption; (ii) the percentage of bone volume with increased bone density and (iii) the percentage of “failed” bone volume. For case (i), the relative change of strain energy density (SED) in the implanted tibia from that of the intact tibia was computed as a predictor for potential bone resorption post operation [30]. A threshold level, s , was set at 75%, and it was assumed that the bone resorption will occur if the relative reduction of SED is above this value [31]:

$$1 - \frac{SED_{implanted}}{SED_{intact}} \geq s \quad (2)$$

The percentage of bone volume at a risk of resorption was then calculated for the selected conditions to evaluate the impact of implant material, design and alignment on the strain response of the periprosthetic bones. For case (ii), bone density increase was assumed when [31]:

$$\frac{SED_{implanted}}{SED_{intact}} - 1 \geq s \quad (3)$$

Bone failure (case (iii)) was assumed when either the maximum principal strain is over 0.6% or the minimum principal strain is over 0.8% [32].

3. Results

Fig. 4 shows a comparison of the distributions of the predicted absolute maximum values (the largest (positive, maximum) or the smallest (negative,

minimum), with signs retained) of the principal strains in the bones of the intact tibia model (Fig 4(a)) and the implanted tibia models (Fig 4(b)(c)) with a CS component and in a neutral position under the loading case of walking. It is clear that the MB component significantly altered the strain distribution in the periprosthetic bone, with the metal tray offloaded the bone under the baseplate while the majority load was transferred through the stem causing compressive stress concentration in the bone surrounding its distal end (Fig 4(b)). Comparatively, the strain distribution for the AP component (Fig 4(c)) is more evenly and closer to that of the intact tibia model (Fig 4(a)). More detailed comparisons of the predicted maximum values of the principal strain in the VOI are shown in Fig. 5 (with CS) and Fig. 6 (with CR) for the intact and the implanted models in a neutral position under the load case of walking (a) and stair descending (b). In all cases, MB component significantly reduced the maximum values of the principal strains in the proximal tibia compared with the AP component.

The whole tibia model and the VOI were further examined under the peak loads of the three load cases, and the percentages of the bone volume affected are shown in Fig. 7 (whole bone) and Fig. 8 (VOI) for (a) at risk of resorption (Eq. 2) and (b) increase in bone density (Eq. 3). Overall, there seems little difference in the bone responses to the different load cases. No bone failure was identified based on the simple criterion [32], hence only the results from cases (i) and (ii) are presented. It is clear that MB components led to significantly higher percentage of bone resorption in both the whole tibia and the VOI, particularly in the latter, between 40-50% bone resorption was found, as opposed to under 10% for AP components. The influence of implant type (CS vs CR) on the risk of bone resorption, on the other hand, appears to be small. The highest bone resorption is predicted in the VOI for CS-MB component (49.7%), followed by CR-MB component (45.2%). The estimated bone density increase in the whole tibia appears to favour CS design and somewhat material insensitive (Fig. 7(b)), although in the VOI (Fig. 8(b)) significantly higher increases in the bone density are found in AP than those of MB components.

The predicted maximum values of the principal strains in the VOIs in the selected malalignment conditions are shown in Fig. 9 for MB and AP components with CS. For comparison purposes the results from the models in a neutral position are also included. The percentages of bone resorption in the VOIs due to the selected alignment conditions are shown in Fig. 10(a). Overall the strains in the malaligned conditions differ significantly from those in the neutral position. The

strains in the periprosthetic bones vary significantly even for a small variation in the alignment. Incidentally, the altered loading conditions with a MB component appear to have increased the periprosthetic bone strains hence reduced the effect of stress shielding somewhat compared with that in a neutral position, especially for a posteriorly aligned component. With a malaligned AP component, however, the effect of stress shielding seems to be similar to that in a neutral position, except when the component is aligned at 5° varus, when the risk of bone resorption may be increased due to significant off-loading on the lateral condyle. In this position, the predicted percentages of bone resorption using a MB and an AP component are nearly the same (30.9% vs. 27.8%), indicating an orientation that might be predisposed to bone resorption. Increases in bone density in the VOI were found for both MB and AP components in all three malalignment conditions (Fig. 10(b)), although the increases for the AP component are consistently greater.

4. Discussion

4.1 Influence of implant material and design

In this study, a specimen-specific FE tibial model has been developed to investigate the effects of selected implant materials and designs of tibial components on stress shielding of periprosthetic bones. The results reveal that the influence of tibial tray material is far more significant than that of implant design for the cases studied. Although it has been well known that the MB components cause stress shielding, most previous studies mainly concerned with the maximum stress/strain values [13, 14] in the periprosthetic bones, which are sensitive to local irregularities and not representative of the overall bone response. In the present study, we examined the whole periprosthetic bones and adopted a predicted percentage of bone volume with resorption risk, which provides a more quantitative measure for the potential risk of bone resorption, hence more informative of the effect of stress shielding on the periprosthetic bone in proximal tibia post a TKR operation.

Modern TKRs generally have low failure rates and revisions are infrequent in short and medium terms, although data for long term performance are not readily available. With increasingly younger patients receiving knee replacements, the impact of such implants on bone quality should not be underestimated. Although few symptoms post operation may present clinically following a successful replacement

procedure, the influence of implant materials/design on the periprosthetic bone stock over time is largely unknown. Miller *et al* [3, 5] reported significant bone resorption in apparently well-fixed MB implants retrieved from autopsies after up to 20 years of service. Although in these cases bone resorption did not appear to lead to clinical failures at the time of death of the patients, the impact of such significant bone losses on the long-term stability and future revision could not be underestimated. The severe loss of bone stock near the metal baseplate would present problems when revisions are needed in later years, and this is particularly relevant for younger, more active recipients, where preservation of bone stock is just as important as restoration of function. A further analysis was carried out by replacing the titanium in a CS-MB component with a cobalt-chrome (assuming $E = 200\text{GPa}$). The percentage of bone resorption was predicted to be 58.0%, even higher than that under a titanium tibia tray (49.7%). It seems that higher risk of bone resorption is expected for stiffer implants.

As a first step towards implant design beyond restoration of functions, we hope the current results will raise more awareness for implant manufacturers and clinicians on the effects of implant materials on bone quality, so that this factor may be considered in future implant development and surgical decision towards long term success of TKR.

4.2 Influence of malalignment

Tibial tray malalignment has been associated with abnormal medial-lateral force distribution, which overloads the bone-implant interface as well as the bone itself, resulting in loosening of the implant [28]. Although a number of studies have been published regarding the effects of malalignment of tibial component, only the peak stresses/strains were reported, and only MB components were considered [24, 33-36]. In addition, most of these studies focused on the effect of malalignment in coronal plane (i.e. varus/valgus orientation). Perillo-Marcone *et al.* [33] compared the stresses in cancellous bone of an implanted tibia due to malalignment of tibial component in both coronal and sagittal planes, and concluded that the bone stress in a valgus position was the lowest. However, the axial force was applied in the centre of the medial condyle in that study, without the consideration of medial-lateral load share distribution. In the present study, the variation of medial-lateral force distributions due to the alignment positions was considered and the performance of

both MB and AP components was examined. The results show that, all the malalignment orientations of a MB component considered seem to reduce stress shielding in the bone, especially a posteriorly orientated component. Other factors should be considered also, however. For example, a MB component in a varus position, although the stress shielding effect is lower than that in a neutral position, the potential risk of failure in the medial condyle due to increased peak strain (Fig. 9d), as found in previous studies [24, 33-36], may compromise this positive effect. For an AP component, the effect of orientation of tibial component on stress shielding seems to be insignificant, except in a varus position, when the risk of failure in medial condyle may be increased due to the increased strain (Fig. 9g) and increased stress shielding due to the offloading of lateral condyle (Fig. 10a). It seems that the correct alignment of an AP component in a varus position is particularly important. Interestingly, increases in bone density are predicted for all the malalignment cases, particularly for AP components.

4.3 Limitations

There are a number of limitations in the present work. The specimen-specific tibial FE model developed in the current study was based on the CT images from an open source [19], thus the validation of the model was not attempted. The female cadaver was selected for the model as the age of the donor (59) is within the range of the age profile of patients for TKR. As the same technique has been utilised for FE model development of human tibia [37], the results are thought to be reasonable. The study was based on only one specimen, however, hence the robustness of the model in terms of the variability in implants and material properties used in TKR could not be tested or if the results are statistically significant, although the study does shed lights on the effect of selected two implant materials, two implant designs and three alignment conditions on the periprosthetic bone in the proximal tibia and whole tibia. The articular cartilage and menisci were not modelled in the intact tibia, where the contact force acting on the condyles in a normal knee joint will be different from that of an implanted knee, thus the ratios between the SED predicted for the implanted tibias and the intact one are only indicative of the degree of stress shielding/increase in bone density due to implantation for bench marking purposes. Fully bonded conditions were assumed between bone-cement and cement-tray interfaces, and the residual stresses within the cement due to the exothermic

reaction of cement polymerization were not considered. The static analyses were carried out assuming average peak joint contact forces during normal walking and stair descending/ascending [27], whilst the effects of physiological dynamic loading and more routine load cases were not considered. Simplified loading conditions were assumed for the cases of malalignment [28] due to the lack of detailed information on the load share distribution of other load cases. Lastly, only the initial post operation strain distributions are reported in present study, whilst long-term effects due to bone remodelling [33, 35] are beyond the scope of this work. Evidence has been presented, however, on the positive correlation between the stress/strain distributions immediate post operation and long-term clinical outcome on bone remodelling [38], hence the predictions obtained from this study may be useful for the purpose of bench marking in prosthesis design and clinical decision-making. The length of stem is known to have an effect on the stress distribution of periprosthetic bone in proximal tibia [39], although this effect was not considered by using two tibial components with an identical length.

Admittedly stress shielding may be only one of the factors affecting the long-term fixation integrity. It remains a challenge for developing new implants with comparable stiffness to the bones as well as excellent strength, toughness and wear resistance.

5. Conclusions

The periprosthetic bone strain distributions in some of the typical cases of TKR have been examined, considering two implant materials, two implant designs and three implant malalignment conditions post a TKR. Metal-backed components seem to have significantly greater effects on stress shielding than those of all-polyethylene components for walking and stair load cases. Comparatively, the influence of the tibial component design on stress shielding appears to be secondary. Malalignment of a MB component appears to reduce somewhat the impact of stress shielding, as opposed to an AP component, where a good alignment in the varus position is important to secure the benefits of its low stiffness. The varus position was found to be the worst for AP as well as MB components for its increased potential risk for bone resorption.

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471

Figures

Figure 1 The two tibial component designs considered in this study:

(a) Cruciate Sacrificing (CS); (b) Cruciate Retaining (CR).

Figure 2 (a) An illustration of the implanted tibia model, where the implant, the cement layer, a 3mm bone volume of interest (VOI) selected at the resected surface and the tibia bone are indicated; (b) The loading and boundary conditions applied. The axial force was split into medial (F_{med}) and lateral (F_{lat}) components, and distributed on the corresponding condyles (intact) or bearing spacers (implanted) of the tibia. The ratios of medial to lateral load share were assigned based on [28, 29]; the lower part of the tibia model was fully fixed.

Figure 3 The 3D tibial models representing the selected alignment conditions with a CS component: (a) The natural tibia; (b) the tibial component implanted in the neutral position; (c) the tibial component implanted at 7° posterior position; (d) the tibial component implanted at 5° valgus position and (e) the tibial component implanted at 5° varus position.

Figure 4 A comparison of the predicted absolute maximum principal strain distribution under walking in the proximal tibia for the intact natural tibia (a) and implanted tibias: (b) The model with a metal-backed (MB) tibia tray; (c) the model with an all PE (AP) tibia tray. The implants are of CS type and are implanted in a neutral position.

Figure 5 A comparison of the predicted absolute maximum principal strain distribution in the VOI for the natural tibia and the implanted tibia (CS component) under walking and stair descending: (a1) The intact model under walking; (a2) the model with a MB tibia tray under walking; (a3) the model with an AP tibia tray under walking; (b1) The intact model under stair descending; (b2) the model with a MB tibia tray under stair descending; (b3) the model with an AP tibia tray under stair descending.

Figure 6 A comparison of the predicted absolute maximum principal strain distribution in the VOI for the natural tibia and the implanted tibia (CR component) under walking and stair descending: (a1) The intact model under walking; (a2) the model with a MB tibia tray under walking; (a3) the model with an AP tibia tray under walking; (b1) The intact model under stair descending; (b2) the model with a MB tibia tray under stair descending; (b3) the model with an AP tibia tray under stair descending.

(a)

(b)

Figure 7 The predicted percentage volumes of (a) bone resorption and (b) bone density increase in the whole tibia bone for the implanted tibias of the two component designs under the selected loading activities.

(a)

(b)

Figure 8 The predicted percentage volumes of (a) bone resorption and (b) bone density increase in the VOI for the implanted tibias of the two component designs under the selected loading activities.

LE, Max. Principal (Abs)
(Avg: 75%)

Red	+8.8e-04
Orange	+8.8e-04
Yellow	+5.9e-04
Light Green	+3.0e-04
Green	+1.6e-05
Dark Green	-2.7e-04
Blue	-5.6e-04
Dark Blue	-8.5e-04
Light Blue	-1.1e-03
Medium Blue	-1.4e-03
Dark Blue	-1.7e-03
Very Dark Blue	-2.0e-03

Figure 9 A comparison of the predicted absolute maximum principal strain distribution in the VOI for the selected alignment conditions (CS component): (a) MB component (neutral); (b) MB component (7° posterior); (c) MB component (5° valgus); (d) MB component (5° varus); (e) AP component (neutral); (f) AP component (7° posterior); (g) AP component (5° valgus); (h) AP component (5° varus).

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(a)

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(b)

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Figure 10 The predicted percentage volumes of (a) bone resorption and (b) bone density increase in the VOI for the selected alignment conditions.

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Table 1 The materials properties assigned for the components of the FE models

Component	Young's modulus (MPa)	Poisson's ratio
Bone ^[20-22]	$E = f(HU)$	0.3
Titanium tray ^[37]	110,000	0.3
Polyethylene ^[37]	1,000	0.3
Cement ^[31]	2,200	0.3

Table 2 A summary of the analyses performed in this work

	Intact Tibia	CS Implanted Tibia		CR Implanted Tibia	
		MB	AP	MB	AP
Neutral	√	√	√	√	√
7° posterior		√	√		
5° valgus		√	√		
5° varus		√	√		

CS: Cruciate sacrificing
CR: Cruciate retaining
MB: Metal-backed
AP: All-polyethylene
At neutral alignment position, walking, stair descending and stair ascending were considered; whilst at malalignment conditions only walking was considered.