Numerical evaluation of bone remodelling associated with trans-femoral osseointegration
implant - a 68 month follow-up study

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Abstract: Osseointegrated trans-femoral implant is a relatively new orthopaedic anchoring method for connecting a stump with a prosthesis. Through a follow-up study of a patient over six years, significant bone remodelling has been observed. Finite element (FE) simulations were carried out to investigate the relationship between the bone remodelling and the strain re-distribution around the trans-femoral osseointegrated implant system. An initial FE model representing the original status of the femur-implant assembly was created from CT scans of the subject prior to osseointegration. Follow-up X-ray images were acquired at various stages post-surgery, which allowed the changes in bone wall thickness to be measured. By updating the bone thickness in the initial model, a series of follow-up FE models were created. Representative load associated with the subject's body weight was applied to the models, and the strain re-distributions were calculated. The results showed that in order to minimise the adverse effect of bone remodelling, an osseointegration implant made by functionally gradient materials are preferred over homogeneous materials.

Keywords: Bone Remodelling, Finite Element Analysis, Femur, Osseointegration, Implant.

Word count: 2220

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1 Introduction

Trans-femoral osseointegration is a technique that provides a direct transfer of load from an artificial limb to human skeleton rather than via the skin and soft tissue of the stump. Although superficial infection used to be the most frequent complication of the patient, usually they can be treated effectively with oral antibiotics (Brånemark et al 2014). As a result, trans-femoral osseointegration has led to significantly improved artificial limb fitting (Sullivan et al., 2003), minimised the complications such as soft tissue damage, ulceration and pain of the stump due to nerve compression (Brånemark et al., 2001). However, clinical observations showed that significant bone remodelling may occur around the implant (Xu et al., 2006), which was detrimental to the stability of the implant. As a result, the long term benefit of osseointegration may be diminished.

It is well-known that mechanical load is one of the biomechanical stimuli in bone remodelling (Lanyon, 1984). In order to understand the bone remodelling process, various forms of stimuli had been investigated and reported in literature, which included tissue stress level (Fischer et al., 1997), local stress non-uniformity (Tsubota et al., 2002), strain energy density (Kerner et al., 1999), equivalent strain (Stülpmner et al., 1997), strain rate (LaMothe et al., 2005), strain magnitude (Rubin and Lanyon,

1985), strain history (Mosley et al., 1997) and strain gradient (Turner et al., 1997). Tomaszewski et al (2012, 2012) compared the bone remodelling of three different osseointegration implant systems; OPRA (Xu and Robinson, 2008), ISP and a newly designed implants. Most of these stimuli were derived from strains. Therefore our study was also focused on strains, trying to establish a relationship between bone remodelling and the strain around the implant, with a view to improving the implant design.

In this study, multiple femur-implant models were created based on the geometric information of a subject's femur at different stages of time. Firstly, an initial FE model was created to represent the original status of the femur-implant assembly immediately after the surgery. Subsequently, follow-up X-ray images were acquired at three stages (Month 31, 52 and 68) post-surgery. By updating the bone thickness in the initial FE model, three new follow-up FE models were created, representing the development of bone remodelling process. By applying the load associated with the subject's body weight to FE models, strain re-distributions at the three stages were calculated.

2 Method and Materials

2.1 Reconstruction of an initial model

The subject of this study is a male amputee, 55 years old and 70kg with good bone quality. Apart from the superficial infection of stump, no osteoporosis and fractures of cortical bone and cancellous bone were found during the follow-up period according to X-ray images of the patient. The initial femur-implant model was reconstructed

using pre-surgery CT scan images. The femur diaphysis is approximately 120mm long, with the mean anterior-posterior and medial-lateral diameters of 30mm and 26mm. The OPRA (Integrum AB, Göteborg, Sweden) implant is a hollow threaded intramedullary stem which is made of titanium and connected with an external artificial limb by a protruding soft tissue layer element. The fixation of the intramedullary stem with the bone is achieved by the thread of the implant. The length of the implant is 80mm and the hollow part 45mm. In the threaded section, the core diameter is 16mm, the external diameter 18mm, and the pitch size 1.24mm. The abutment is 51mm long, with a core diameter of 11mm.

2.2 Reconstruction of follow-up models

Three follow-up models representing Month 31, 52 and 68 post-surgery were reconstructed. As CT images at the post-surgery stages were not available, only X-ray images of the subject were used to measure the bone thickness changes. Before bone thickness measurement, the distorted X-ray images were stretched such that the horizontal and vertical image scales were identical. The bone thickness at each point was the average over three measurements, with accuracy at approximately 0.1mm. The lateral and medial bone thicknesses are shown in Fig. 1.

The follow-up models were reconstructed by adding the bone thickness change ΔT to the radius R of the initial model, i.e. the radius of the bone in a follow-up model is $R_f = R + \Delta T$. Since the X-ray images only provided the lateral-medial bone thickness changes, the bone thickness change around the periphery was approximated by an interpolation:

$$\Delta T = \Delta T_M \cdot \frac{1 + \cos \theta}{2} + \Delta T_L \cdot \frac{1 - \cos \theta}{2}$$

where ΔT_M and ΔT_L are the bone thickness changes from X-ray image at the medial and lateral sides, θ is the angle of each point on the periphery. When θ is 90° or 270° , ΔT represents the bone thickness change at anterior or posterior side.

The above bone thickness changes were used to update the bone thickness in the initial model via a dedicated computer programme, resulting in three follow-up models to represent bone remodelling at these stages.

2.3 FE modelling

2.3.1 Material properties

As an anisotropic material, the bone properties vary along different orientations (Lanyon, 1984). However, the difference in Young's modulus along the radial and longitudinal directions in the middle shaft of a femur is deemed small (Xu et al., 2000). In the current study, the bone remodelling was found to occur around the diaphysis region. Hence the cortical bone was assumed to be transversely isotropic, with the longitudinal Young's modulus set at 18GPa and the radial and circumferential moduli at 13GPa. The shear modulus of the bone was 7GPa, and the Poisson's ratio at 0.3 (Cowin et al., 2000). The Young's modulus of the titanium implant and abutment was 115GPa and the Poisson's ratio 0.3.

2.3.2 Convergence test

The ABAQUS software package was used to perform FE analysis. Before simulations on bone remodelling, a mesh convergence test was carried out. Without losing generality, axisymmetric models were used in this test to represent the bone-implant assembly. Four models with quadrilateral elements and four models with tetrahedron elements were generated. For each mesh, strain data was extracted at the top of the screw thread and along a path in the bone. Along the path, the von Mises equivalent strain ϵ_{effect} was calculated using the following definition:

$$\epsilon_{effect} = \left(\frac{2}{3} \epsilon' : \epsilon' \right)^{\frac{1}{2}}$$

where $\epsilon'_{ij} = \epsilon_{ij} - \frac{1}{2} \delta_{ij} (\epsilon_1 + \epsilon_2 + \epsilon_3)$, ϵ_{ij} is the strain tensor, and $\epsilon_1, \epsilon_2, \epsilon_3$ are the principal strains. Results showed that the equivalent strain variations along the path were very close among the different meshes. Therefore only tetrahedron element with free mesh was used in subsequent FE analyses for the bone remodelling process.

2.3.3 Mesh of the femur-implant models

All the models were freely meshed using four-node isoparametric tetrahedral elements as shown in Fig. 2. The average element size was 1mm. Table 1 shows the mesh summaries. The femur and implant were deemed to share the same nodes along the femur-implant interface in the models. This assumption is consistent with a previous clinical study and histological assessment (Brånemark et al., 1983).

2.3.4 Load and boundary conditions

Different approaches (Graichen et al., 2007, Taylor and Walker, 2001, Bergmann et al., 2014) were used to determine the load on the femur. However, the load from Taylor and Walker's (2001) study was obtained closer to the transfemur location of our implant abutment. Therefore, in the absence of real time loads upon the subject's implant system, Taylor and Walker's was adopted in this study to determine the body weight (BW) associated load on the implant abutment. In their study, multiple gait cycles were recorded, which allowed determining the maximum axial force, torsion and bending moments. Hence, the four load components in our study were set at: axial force 1.90 BW, axial torque 0.82 BW·cm, A-P moment 6.68 BW·cm, and M-L moment 3.90 BW·cm. This load case was similar to the study carried out by Tomaszewski (Tomaszewski PK, et al 2010).

3 Results

Fig. 3 shows the von Mises equivalent strain distributions along two circumferential paths, one near the distal end (at 5mm) and the other at the proximal end (at 80mm). The radius of the path was 10.5mm. The outward offset between the femur-implant interface and the circumferential path was 0.5mm. The path starts from the medial side (0°) and passes through the anterior, lateral, posterior sides and back to the medial side.

Further strain distributions along two longitudinal paths were also produced. Fig. 4 shows the longitudinal paths on the medial and lateral sides, both along the external surfaces of the femur. The strain distributions along the paths are shown in Fig. 5.

4 Discussions

From Fig. 3(a), it can be seen that the overall strain distribution around the distal path was similar for all models. During the bone remodelling process, bone loss at the medial and lateral sides resulted in decreases in bone thickness, as indicated in Fig. 1. However, the strain on the circumferential path did not increase dramatically. This is probably because fewer loads were transferred to the femur in the extreme distal region as the femur thickness decreased. The maximum strain can be found around the 30° region, which was the position of maximum bending stress caused by the A-P and M-L moments. The bone thickness around the region between 180° and 230° became very thin (less than 0.5mm, the offset of circumferential path from the implant) 50 months after the implantation. As a consequence, no strain data was available for the Month 52 and 68 models between 180° and 230°.

Fig. 3(b) shows the strain distribution around the circumferential path at the proximal end of the femur. Compared to strain distribution around the distal end, the differences in strain level between the earlier and later models were evident. After a long period of time, massive bone growth was observed around the proximal end as indicated in Fig. 1. As a result, the strain levels for the 31, 52 and 68 month models were much lower than the initial model. As with the strain distribution at the distal end, the peak strain occurred at around the 30° region.

On the lateral side of the initial model (Fig. 5(a)), the strain increased dramatically to round 0.0007 at the 30mm. Then the strain distribution remained uniform for a short length approximately 20mm, after which it increased gradually to a peak of 0.0013 at around the 90mm-100mm region. For the follow-up models, the region with uniform

strain distribution was larger. It started at around the 10mm position and ended at nearly the 70mm position. The strains in the follow-up models were slightly higher than that of the initial model around the distal end, while it was significantly lower around the proximal end.

Similar strain distributions can be found along the medial side as shown in Fig. 5(b). As this path was close to the maximum strain surface (at 30°), the strain was higher than that along the lateral side. The peak strains for the initial and follow-up models were found at around the 90mm-100mm region.

It can also be seen from Fig.5 that the strain increased around the distal end and decreased around the proximal end. The decrease in bone thickness around the distal end led to an increase in strain in this region. The bone growth in the proximal end resulted in an increase in bone thickness and hence a decrease in strain within the region. However, there was almost no strain change around the mid-region (from 40mm to 50mm). This indicated that this mid-region maintained the equilibrium status.

From a clinical application point of view, the bone loss around the distal end could lead to bone fracture. If this happened, the amputee would be in a much worse condition than those with the traditional stump-socket-prosthesis connection technique, as the residual femur could fracture. Therefore in designing an implant for osseointegration, functionally gradient material should be preferred to homogeneous materials. A properly designed functionally gradient implant with low stiffness at the distal end would help to maintain a sufficient strain to prevent significant bone loss.

190

191 It should be notated that there are limitations in this study. As bone remodelling is
192 understood to occur on the free surface of bone (Martin , 1972), one of the limitations
193 in this study is that only dimensional change of the bone is simulated without
194 considering density change of the cortical bone. Also the bone thickness of the other
195 follow-up models was approximately calculated from the measured bone thickness at
196 the lateral and medial sides. This inevitably resulted in an inaccuracy to the simulation.
197 In addition, the loading rate and number of cycles per day were not taken into account
198 in this study. A more realistic loading situation should be based on the daily usage of
199 the prosthetic limb by the subject. Further studies are needed to address these
200 limitations so that more conclusive findings can be made. Nevertheless, the current 68
201 month follow-up study provided some insights to bone remodelling.

202

203 **5 Conclusions**

204 Through a follow-up study over six years, significant bone remodelling was observed
205 and evaluated using FE method. Strain distributions along the circumferential paths of
206 the femur did not change significantly during the bone remodelling process. In
207 contrast, significant strain re-distribution occurred along the longitudinal direction of
208 the femur, which led to bone remodelling that correlated with the observation of the
209 bone thickness change at the proximal and distal end. All these results provided
210 fundamental biomechanical justification to develop an osseointegration implant with
211 functionally gradient material over a homogeneous material. As the currently study
212 suffered from limitations on X-ray images and simplified load conditions, more work

is needed in order to improve the accuracy of FE simulation so that more conclusive results can be obtained.

Conflict of Interest Statement

The authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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Figure Legends

Figure 1 Outer and inner bone thickness in lateral side (A) and medial side (B)

Figure 2 Anteroposterior (AP) views of the meshed femurs and implant model

Figure 3 Strain distributions along distal (a) and proximal (b) circumferential paths

Figure 4 Anteroposterior (AP) view of the femur model with outer longitudinal paths

Figure 5 Strain distributions along the outer longitudinal path on external surface. (a) Lateral side. (b) Medial side.

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(a)

(b)

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(a)

(b)

Tables

Table 1 Meshing summaries of the femur-implant models

		0 month	31 st month	52 nd month	68 th month
Femur Model	Average Element				
	Edge Length	1.46mm	1.22mm	1.25mm	1.26mm
	Element Number	56837	111049	110503	116884
Abutment & Implant Model	Average Element				
	Edge Length			1.26mm	
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1 Introduction

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Fig. 3(b) shows the strain distribution around the circumferential path at the proximal end of the femur. Compared to strain distribution around the distal end, the differences in strain level between the earlier and later models were evident. After a long period of time, massive bone growth was observed around the proximal end as indicated in Fig. 1. As a result, the strain levels for the 31, 52 and 68 month models were much lower than the initial model. As with the strain distribution at the distal end, the peak strain occurred at around the 30° region.

On the lateral side of the initial model (Fig. 5(a)), the strain increased dramatically to round 0.0007 at the 30mm. Then the strain distribution remained uniform for a short length approximately 20mm, after which it increased gradually to a peak of 0.0013 at around the 90mm-100mm region. For the follow-up models, the region with uniform

strain distribution was larger. It started at around the 10mm position and ended at nearly the 70mm position. The strains in the follow-up models were slightly higher than that of the initial model around the distal end, while it was significantly lower around the proximal end.

Similar strain distributions can be found along the medial side as shown in Fig. 5(b). As this path was close to the maximum strain surface (at 30°), the strain was higher than that along the lateral side. The peak strains for the initial and follow-up models were found at around the 90mm-100mm region.

It can also be seen from Fig.5 that the strain increased around the distal end and decreased around the proximal end. The decrease in bone thickness around the distal end led to an increase in strain in this region. The bone growth in the proximal end resulted in an increase in bone thickness and hence a decrease in strain within the region. However, there was almost no strain change around the mid-region (from 40mm to 50mm). This indicated that this mid-region maintained the equilibrium status.

From a clinical application point of view, the bone loss around the distal end could lead to bone fracture. If this happened, the amputee would be in a much worse condition than those with the traditional stump-socket-prosthesis connection technique, as the residual femur could fracture. Therefore in designing an implant for osseointegration, functionally gradient material should be preferred to homogeneous materials. A properly designed functionally gradient implant with low stiffness at the distal end would help to maintain a sufficient strain to prevent significant bone loss.

190

191 It should be notated that there are limitations in this study. As bone remodelling is
192 understood to occur on the free surface of bone (Martin , 1972), one of the limitations
193 in this study is that only dimensional change of the bone is simulated without
194 considering density change of the cortical bone. Also the bone thickness of the other
195 follow-up models was approximately calculated from the measured bone thickness at
196 the lateral and medial sides. This inevitably resulted in an inaccuracy to the simulation.
197 In addition, the loading rate and number of cycles per day were not taken into account
198 in this study. A more realistic loading situation should be based on the daily usage of
199 the prosthetic limb by the subject. Further studies are needed to address these
200 limitations so that more conclusive findings can be made. Nevertheless, the current 68
201 month follow-up study provided some insights to bone remodelling.

202

203 **5 Conclusions**

204 Through a follow-up study over six years, significant bone remodelling was observed
205 and evaluated using FE method. Strain distributions along the circumferential paths of
206 the femur did not change significantly during the bone remodelling process. In
207 contrast, significant strain re-distribution occurred along the longitudinal direction of
208 the femur, which led to bone remodelling that correlated with the observation of the
209 bone thickness change at the proximal and distal end. All these results provided
210 fundamental biomechanical justification to develop an osseointegration implant with
211 functionally gradient material over a homogeneous material. As the currently study
212 suffered from limitations on X-ray images and simplified load conditions, more work

is needed in order to improve the accuracy of FE simulation so that more conclusive results can be obtained.

Conflict of Interest Statement

The authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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