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INCORPORATION OF INTERFERENCE FIT AND CYCLIC LOADING IN SIMULATION ALGORITHM FOR BETTER PREDICTION OF MICROMOTION OF FEMORAL STEMS

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Abstract. Aseptic loosening is one of the major causes for revision surgery in hip arthroplasty. This has been attributed to failure in achieving strong primary fixation. Interface micromotion beyond a certain threshold limit inhibits bone ingrowth and favours the formation of fibrous tissue. In this study, an algorithm was constructed to predict micromotion and therefore instability of femoral stems. Based on common physiological loading, micromotion is calculated throughout the bone-implant interface. Press fit stem insertion was modelled using interference fit and cyclic loading was used to better simulate actual loading configuration. An in-vitro micromotion experiment was carried out on four human cadaveric femurs to validate the micromotion algorithm. A good correlation was obtained between finite element predictions and the in-vitro micromotion experiment.

Keywords: hip arthroplasty, primary stability, micromotion algorithm, experimental validation, finite element

Abstrak. Pelonggaran aseptik adalah salah satu daripada sebab utama pembedahan ulangan tulang paha. Ini berlaku disebabkan kegagalan untuk mendapatkan cengkaman pertama yang kuat. Pergerakan antara implan dengan tulang melebihi had tertentu menghalang pertumbuhan tulang dan mengakibatkan pembentukan tisu berbentuk fiber. Dalam kajian ini, satu algoritma dicadangkan untuk meramal pergerakan implan dan seterusnya ketidakstabilan implan. Dengan menggunakan beban fisiologi, pergerakan implan relatif kepada tulang dikira menggunakan algoritma. Implan yang menggunakan sistem cengkaman tekanan telah dibentuk dan beban ulangan dikenakan untuk memberi simulasi yang sebenar. Satu ujikaji 'in-vitro' telah dilaksanakan terhadap empat tulang paha manusia untuk mengesahkan algoritma yang dicadangkan. Keputusan ujikaji telah mengesahkan pergerakan implan yang dijangka oleh algoritma ini.

Kata kunci: tulang paha, algoritma cengkaman, pengesahan ujikaji

1.0 INTRODUCTION

Achieving good primary fixation is of crucial importance in hip arthroplasty to ensure good short-term and long-term results. One of the major direct consequences of a lack of stability is the eventual loosening of the prosthesis [1-3]. The stability, or the lack of it, is commonly measured as the amount of relative motion at the interface

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between the bone and the stem under physiological load. Large interfacial relative movements reduce the chance of osseointegration, and cause the formation of fibrous tissue layer at the bone-implant interface [4, 5]. The shear strength at the interface will reduce significantly as well as the ability to transfer load to the surrounding bone. This will further encourage the formation and thickening of fibrous tissue, which eventually leads to loosening and failure of the arthroplasty.

During repeated physiological load cycles the stem will subside into the bone and after a sufficient number of cycles the stem will settle. Subsidence is the permanent movement of the stem relative to the bone, although biological processes may cause the subsidence to increase over time. Even in this relatively settled state there will continue to be low levels of motion (micromotion) at the stem-bone interface as a result of the continued load-unload cycle. It is high levels of this continued disruption of the interface that is thought to prevent osteogenic cells from bonding to the surface of the stem. Hence, in terms of evaluating the ingrowth potential of an arthroplasty it is the micromotion component rather than subsidence which is the relevant constituent of the overall relative motion between stem and implant.

The threshold value of relative micromotion, above which fibrous tissue layer forms, has been studied in both animals and human, and it varies according to surface state and implants' design. In a review of dental implants in animals, the threshold micromotion value between 50 and 150 μm was found [6]. Femoral stems implanted in animals had a slightly lower threshold value of 30 μm. A similar range of values were reported for orthopaedic implants in human. A micromotion study on eleven cemented femoral specimens retrieved at autopsy found a maximum axial micromotion of 40 μm [7]. Histologic investigation showed intimate osseointegration at the interface with only rare intervening fibrous tissue. The same magnitude of micromotion was found in cementless femoral components with bone ingrowth at the porous coating and a higher micromotion of 150 μm was found on areas of failed bone ingrowth [8]. Another micromotion study comparing the AML and the Mallory-Head prosthesis with surface bone ingrowth showed a micromotion of 80 μm or less [9]. It can be concluded from these reports that the threshold value of micromotion for osseointegration is between 30 and 150 μm.

In clinical follow-up studies the movement between stem and bone is estimated from inspection of radiographs [10-12]. These are in fact measurements of subsidence and not micromotion. Large subsidence (>2 mm annually) has been shown to correlate with clinical loosening. This clinical measure includes gross loosening subsequent to fibrous tissue ingrowth caused by high levels of micromotion. However, the clinically measured subsidence is representative of an amalgamation of factors in addition to interface micromotion and as such cannot be used as a direct measure of ingrowth potential. In in-vitro experimental studies it is possible to separate the relative movement between the stem and bone into subsidence which is often at the scale of many hundreds of microns and 'micromotion' which is typically much smaller. In this case subsidence is distinctly different from micromotion but compared to the clinical measure of subsidence does not include any time dependent biological effects. All previous finite element studies [13-16] estimate micromotion as the total relative motion between the stem and the bone at the maximum load of the first load cycle and hence do not separate the motion into subsidence and micromotion. As a result, these studies may over predict the micromotion and also the predicted trends in micromotion may be obscured by the trends in subsidence.

The friction coefficient and the interference fit are intuitively essential input parameters in finite element models aimed at predicting interface micromotion of press-fit hip stems. Several previous works [15,17-22] have investigated the effects of friction coefficient and it is possible to estimate with reasonable accuracy the value of this parameter. In contrast there has been very little work on the effect of interference fit and except for one paper which used a simplified cylindrical model [23], previous FE studies did not include an interference fit.

In this study an investigation was carried out on the effect of interference fit on micromotion prediction and to identify a reasonable value of this parameter. An investigation was also made regarding the estimation of micromotion from previous finite element studies by separating the predicted total micromotion into subsidence and micromotion. Thus having established the appropriate method and input variables we will compare the finite element predictions with a parallel in-vitro experiment measuring interface micromotion.

2.0 MATERIALS AND METHODS

A three-dimensional model of the Alloclassic hip stem (Zimmer, Warsaw, IN) was constructed from CAD files received from the manufacturer. The flat surfaces were meshed automatically with triangular elements using MAGICS™(Materialise software), whilst non-flat surfaces (i.e. corners) were meshed manually. This procedure is essential in order to ensure relatively constant triangular mesh size throughout while maintaining the actual geometry of the implant. The surface mesh was thoroughly checked and any distorted elements created using the automated procedure was repaired manually.

The construction of 3D models of the hip was done using AMIRA software (Mercury Computer Systems, Inc.) which allows semi-automated segmentation of 2-dimensional CT images. Segmentation was carried out manually on the Visible Human Project (VHP) CT dataset, and compiled automatically using the software's marching cubes algorithm which generates a 3D triangular surface mesh. The hip stem model was then aligned inside the femur, and the neck of the femur was resected at an indicated line of resection. The completed model was then converted to solid tetrahedrals in Marc.Mentat (MSC.Software) finite element package. A mesh convergence study was carried out, and the model with 56526 elements and 12078 nodes was found to be sufficient for a converged solutions.

A study was also conducted to investigate the effect of friction coefficient. Similar to results of other researchers [13 -15, 20], we found that the effect of friction coefficient on micromotion was relatively minor for friction coefficients higher than 0.15. When comparing finite element predictions of micromotion with experimental measurements, Viceconti *et al.* [22] found that a friction coefficient between 0.3 and 0.5 led to the best correlation with experiments. Rancourt *et al.* [21] experimentally measured friction coefficients between bone and a blasted metal surface and found a coefficient of 0.4. Based on these previous studies we have used a friction coefficient of 0.4 in this study.

There was some difficulty in simulating the press-fit of hip stems because the amount of interference fit and its distribution were unknown. It would be difficult, if not impossible, to exactly measure how much press-fit has been achieved and the actual distribution of the fit post-surgery. During surgery of hip arthroplasty an orthopaedic surgeon will use visual and auditory clues until he 'feels' that the implant is 'firmly' seated. There is no way of telling how much interference fit has been achieved and its distribution – is it mainly in the distal part, the proximal part, or throughout the stem. However, to ignore the interference fit altogether in an FE micromotion study would be inappropriate as the stems are designed with press-fit. Constant interference fit was therefore assumed throughout the contacting bodies, and the values were estimated using a simple cylindrical model that described the interference fit of the long stem and the diaphyseal bone. Based on the geometry and properties of the bone and implant, a value of about 100 μm was found. Three models of the replaced hips were therefore prepared with an interference fit set to 0, 50 and 100 μm respectively. Coefficient of friction was set to 0.4 and all other parameters remained the same. To simulate the actual loading configuration on a replaced hip, a cyclic loading input of 10 cycles was used in this study.

An in-house micromotion algorithm was written in Compaq Visual Fortran (Compaq Computer Corporation) to calculate and display micromotion from MARC.Mentat's post-processing file by subtracting the nodal displacements of the outer surface of the stem from the corresponding nodal displacements of the bone. Material properties for the bone were assigned based on the grey-scale value of the CT images on an element-by-element basis. The models were then loaded in physiological stair-climbing with all relevant muscle forces included and restrained distally.

For validation of the micromotion algorithm an experiment was conducted on human cadaveric femurs. The Alloclassic hip stems were used in this experiment, and two points – one in the proximal and another in the distal – was chosen for micromotion measurement. In order to avoid unnecessary loosening, the two points on the implant were drilled before implantation. A simple jig was made to guide the drilling of the implant (before implantation) and the bone (after implantation) (Figure 1). A linear variable differential transducer (LVDT Model DFg5, DC Miniature

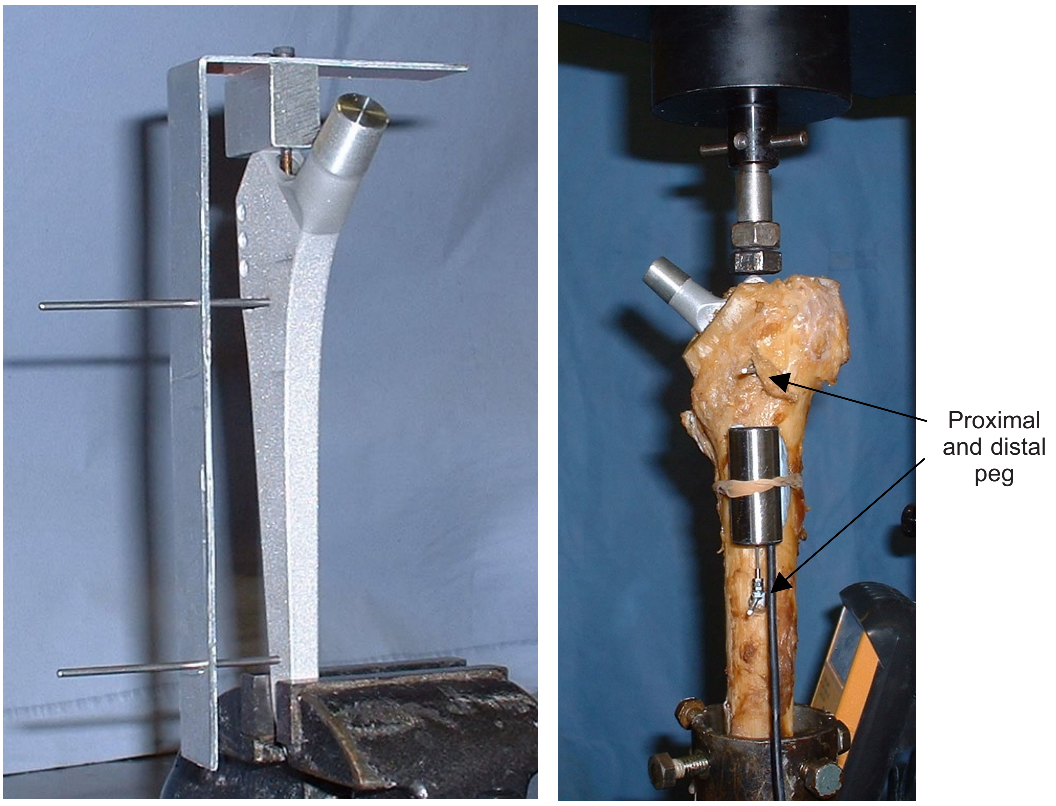

Figure 1 The jig used to position the holes in the bone and the pegs in the implant, respectively (left). The implant-bone specimen with LVDT attached to the femur loaded in compression in the mechanical testing machine (right)

series, Solartron Metrology, UK), was chosen to measure the axial component of displacement of the implant relative to the bone.

Once the holes had been drilled into the implant, implantation was carried out by an experienced orthopaedic surgeon. Four cadaveric femurs (3 left, 1 right) were used in this experiment. The neck of the femur was first resected, and the femur was then reamed with firm impaction using the smallest size reamer to open the canal. The process was continued with the next size increment of the reamer until no further movement of the reamer with impaction could be made and there was a change in pitch during impaction. A femoral stem measuring the same size as the last reamer used was then implanted in the femur. Two femurs had Alloclassic size 4 and another two had size 3.

After the implantation was completed on all four femurs, the jig was used once again to locate the holes in the implant. A ϕ5 mm drill was used on the bone, which was larger than the ϕ2 mm of the implant holes. A ϕ2 mm steel rod 40 mm long was inserted into each hole. The movements of this rod, which represent the movements of the implant relative to the bone, were measured by the LVDT via the connecting rod of the LVDT core. The steel rods were glued into the implant holes to avoid them from moving or becoming loose.

The femur was then sectioned 250 mm distal to the lesser trochanter and placed inside a grease-lubricated cylindrical metal container. The container was then placed onto the table bed of a universal materials testing machine (Instron Corp., Canton, MA) for alignment. The specimen was adjusted so that the long axis of the stem was parallel to the direction of loading. Polymethylmethacrylate (PMMA) was then poured inside the container to ensure that the specimen was securely fixed. The LVDT was placed at the midpoint between the two steel rods, and the connecting rod of the LVDT core was then fixed to the free-end of the steel rod which had been roughened with glass paper.

A cyclical axial compression load of 0 to 2 kN was then loaded to the specimen for 50 cycles at a rate of 1 kN/min using a 5 kN load cell. All implanted femurs were subjected to cyclic pre-load with the same magnitude and rate until there was no major fluctuation in the readings of the voltmeter. This protocol ensured that no significant axial subsidence was recorded during the experiment by achieving maximum press-fit and ensured repeatability of results. Once the voltmeter readings had stabilised, the experiment started. Readings from the digital voltmeter were taken manually at maximum load of 2 kN and when fully unloaded at each cycle. Measurements for the distal part were performed first and after 50 cycles had completed, the direction of the magnetic core of the LVDT was reversed for micromotion measurement of the proximal part.

For comparison with FE predictions, one of the femurs was CT scanned twice – one whilst intact and another after implantation. An FE model of an intact femur was constructed from the first CT dataset, and another FE model of the resected femur with implant was constructed from the second CT dataset. The intact bone model was then aligned to the implanted femur model. An Alloclassic hip stem model, created separately from a 3D CAD drawing, was then placed inside the intact bone model with the implanted bone model used as a guide for alignment. This alignment is important in order to ensure that the hip stem model, which was created separately, was in exact location of the one found in the experiment. The implanted model created from the second CT dataset could not be used in FE analysis mainly due to the artefacts from the metal stem. A coefficient of friction of 0.4 was assigned to the stem-bone interface and an interference fit of 0.05 mm was assumed. The FE model was then axially loaded at the centre of the shoulder of the stem with 2 kN of load to simulate the loading configuration in the experiment.

3.0 RESULTS

Figures 2 and 3 below show that interference fit affected relative micromotion significantly. The relative micromotion reduced by up to 15 times in areas of cortical

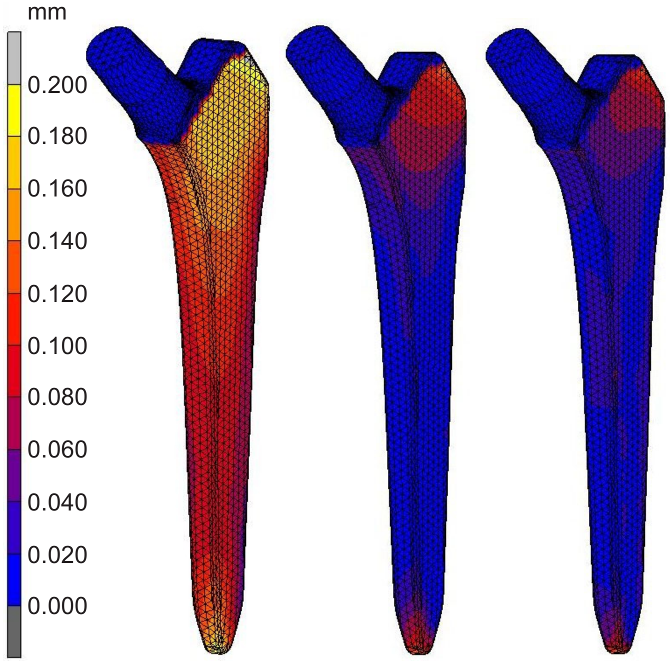

Figure 2 Contour plots of micromotion for the Alloclassic stem with interference fits of (from left to right): 0 μm, 50 μm, and 100 μm, respectively

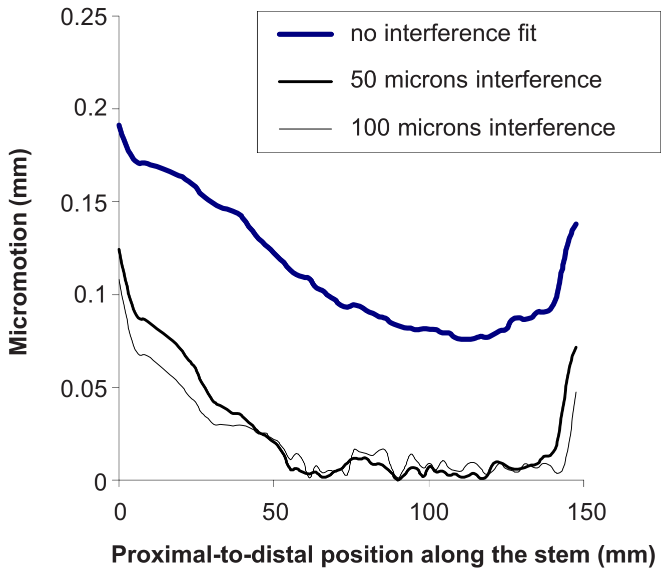

Figure 3 Micromotion along the posterior side of the rectangular tapered type implant with different levels of interference fit

contact when maximum interference fit of 0.1 mm was included, and up to 3 times in the proximal area of cancellous contact. The results also showed that there was not much difference in magnitude and distribution of micromotion between interference fit of 0.05 mm and 0.10 mm.

Figure 4 shows a contour plot of micromotion for the first 5 cycles of the Alloclassic and Figure 5 shows a graph of two stems modelled with and without an interference fit with 10 cyclic loadings. When modelled without an interference fit, the total micromotion increased as the load cycle was increased and stabilised after the 6th cycle. The graph also shows that convergence for the reversible micromotion modelled with an interference fit is achievable much sooner than the stems modelled without the interference fit.

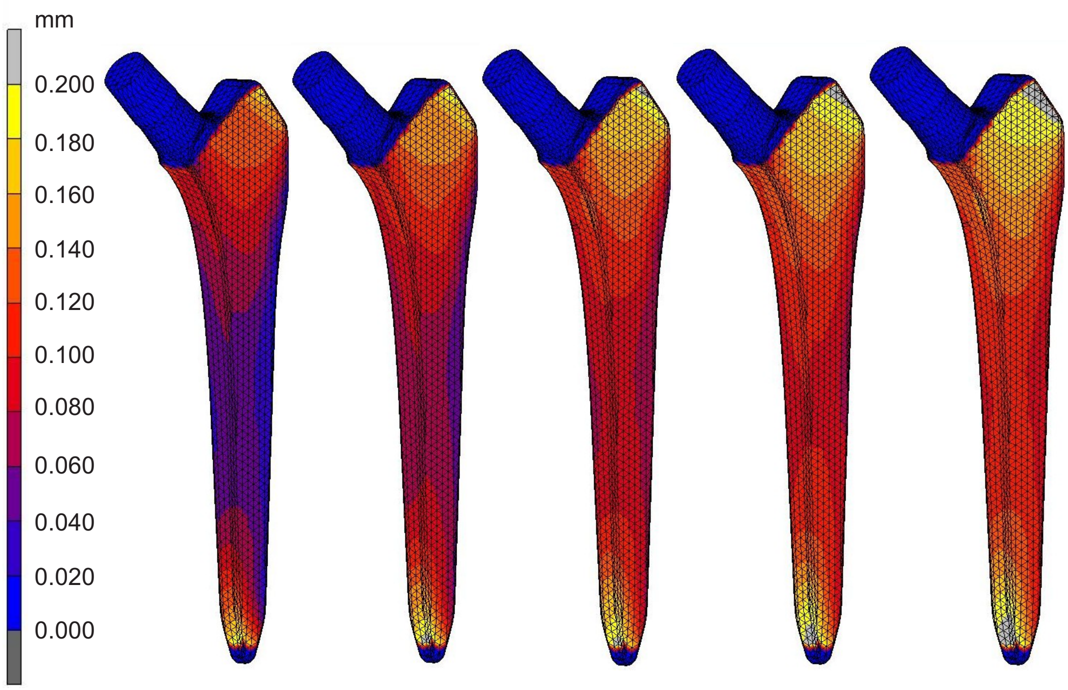

Figure 4 The progression of total micromotion up to 5 cycles

For the micromotion experiment, the recorded voltage readings from the voltmeter were converted into displacements using a linear relationship obtained during calibration. Micromotion results for each specimen were then plotted against load cycles for the distal and proximal part (Figure 6). Specimens 1 and 2 were Alloclassic size 4, and specimens 3 and 4 were size 3. Overall, elastic micromotion in the distal region reduced gradually from 26-50 µm at the first cycle to a value between 16-20 µm after 50 cycles. For the proximal side, elastic micromotion gradually reduced from 20-40 µm after 50 cycles to 12-24 µm after 100 cycles. Elastic micromotion was

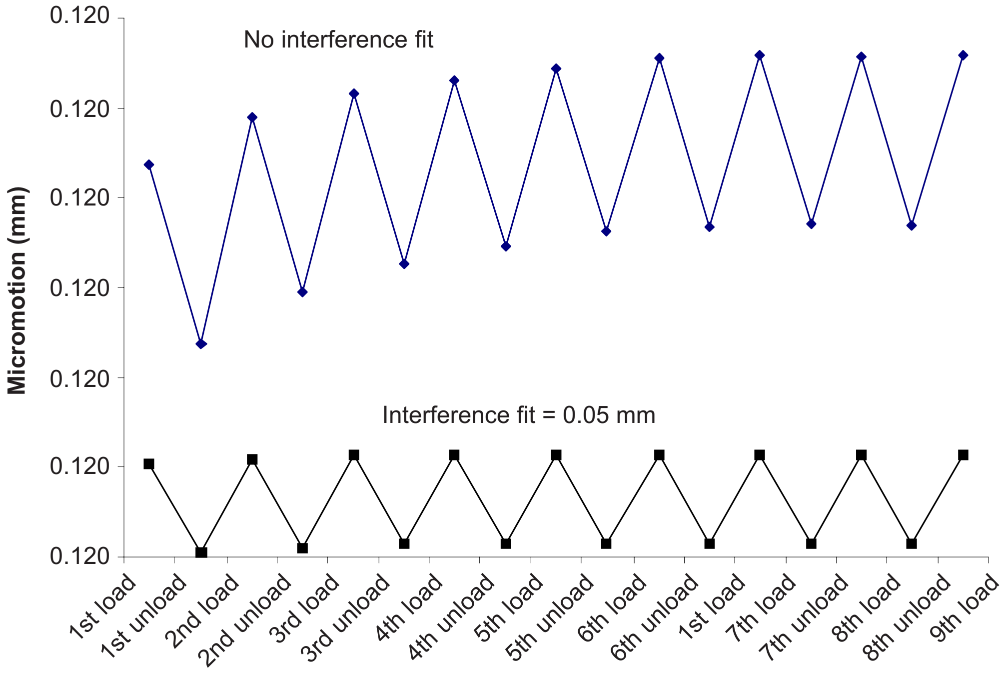

Figure 5 Graph of predicted micromotion (averaged over the stem surface) to show total relative motion, subsidence and micromotion at two levels of interference fit

larger proximally than distally for specimens 2, 3 and 4. In terms of the different implant sizes used in the experiment (two size 3 stem and two size 4 stem), there were no major differences in micromotion found between them.

The result of the FE analysis simulating the experiment is shown in Figure 7. The distribution of micromotion was similar between the anterior and posterior side, and the proximal half had relatively larger magnitude of micromotion than the distal half. The proximal half of the stem had a range of micromotion between 24-29 μm whilst in the distal half micromotion reduced gradually from 28 to 14 μm. For micromotion result at similar location to the experiment, the value of micromotion was 26-28 μm for the proximal part and 21 μm for the distal part. Figure 8 shows a graph comparing the FE results at a specific point in the proximal and distal part and the range of elastic micromotion values obtained from the experiment after 50 cycles. The graph shows that the FE results correlate well with the experimental findings, with larger micromotion proximally than distally.

4.0 DISCUSSION

Modelling the press-fit characteristic of hip stems is crucial in an FE study of hip arthroplasty as it significantly affects the interface micromotion. Ignoring the

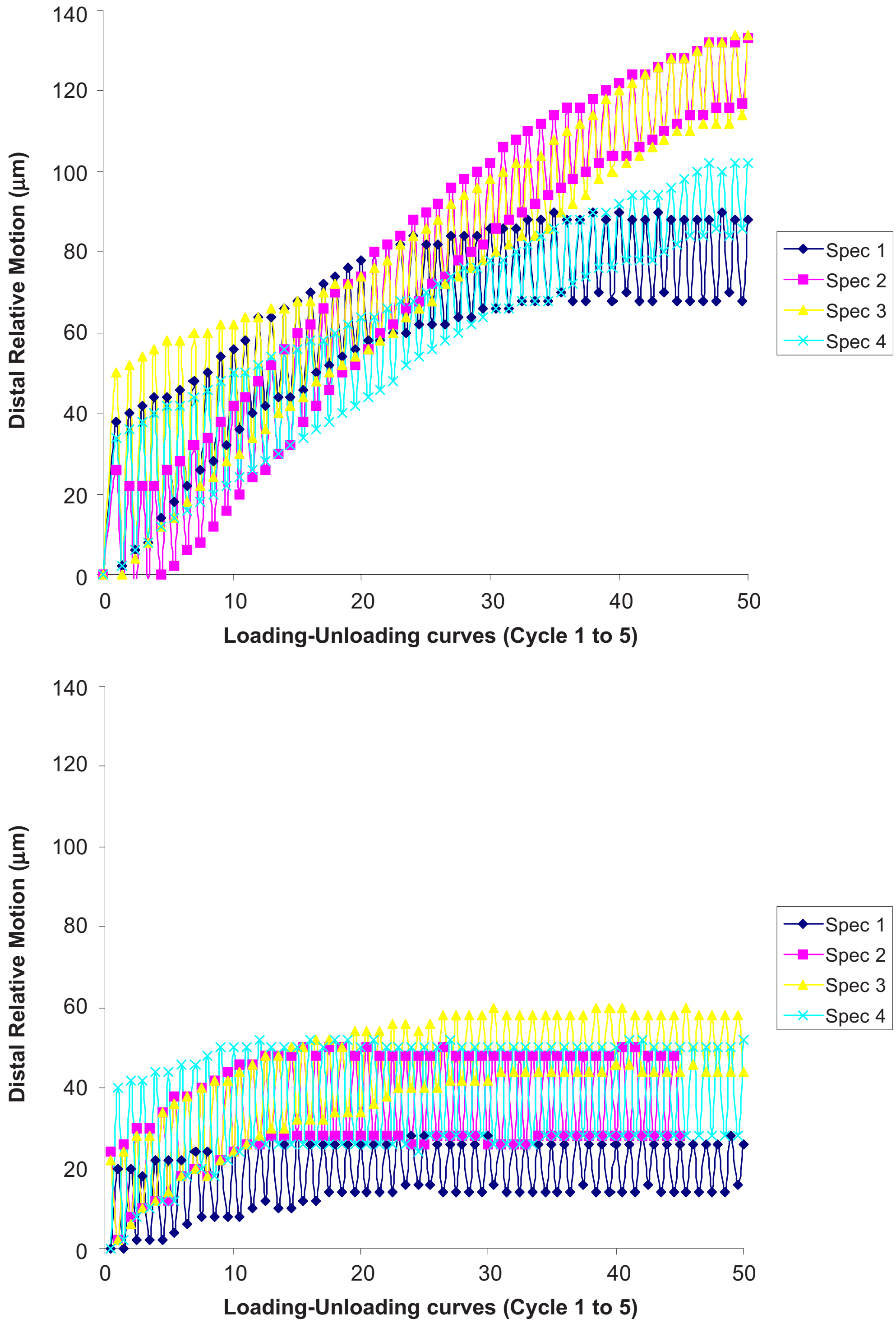

Figure 6 Distal micromotion (top) and proximal micromotion (bottom) results from the experiment

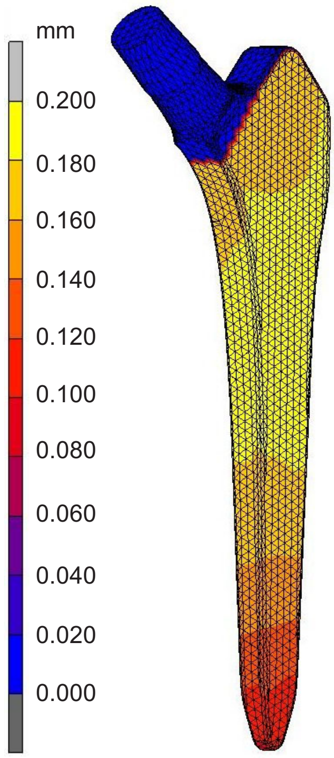

Figure 7 Predicted micromotion of the tapered rectangular stem under an axial load of 2kN, using interference fit of 50 microns and evaluating the micromotion from just one static load

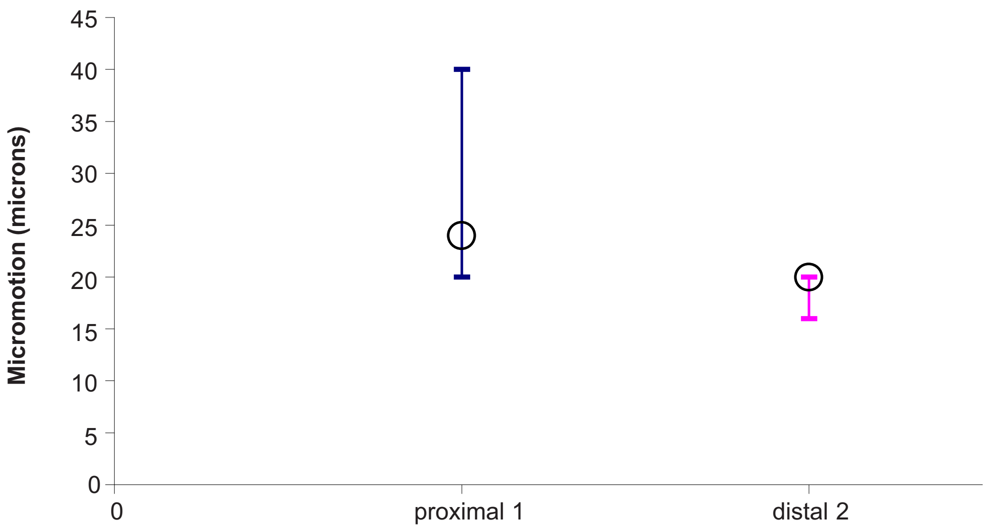

Figure 8 Graph showing the experimental range of values for the proximal and distal region after 50 cycles compared to the FE results

interference fit will overestimate the predicted relative micromotion and therefore underestimate the stability of the stem. The results also show the importance for an orthopaedic surgeon to try and achieve the designed press-fit during implantation as interference fit of just 50 μm throughout would increase the stability of the implant by a factor of 10.

In this study, the amount of press-fit was assumed to be similar throughout the interface. The actual degrees of press fit, however, varies depending on the design of the stem and the surgical techniques involved [24]. Hip stems with distal fixation design such as the AML hip stem are more likely to have press fit distally than proximally. Proximal fixation design such as the ABG hip stem, on the other hand, relies on press-fit in the proximal part of the stem because the endosteal cortex is over-reamed distally to avoid cortical contact. The surgical techniques for preparing the femoral canal could also produce different amount of press-fit. The under-reaming technique, where the size of the last reamer used in preparing the canal is slightly smaller than the actual implant size inserted into the canal, would theoretically produce larger interference fit than the line-to-line reaming technique [25, 26]. However, the under-reaming technique may not achieve the intended press-fit because gaps at the interface may occur due to surgical error during bone preparation [27]. Reaming and broaching of the femoral canal causes bone damage to the supporting cortical and cancellous bone. Together with the viscoelastic behaviour of bone, the actual interference fit obtained after successful surgery is unlikely to achieve the intended press-fit. All these uncertainties together with the difficulty in measuring the achieved press-fit after surgery caused most researchers to omit this important parameter in their predictions. This study shows that in any FE analyses related to micromotion and stability of hip stems, any values up to 100 μm could be used to model press-fit. The actual value to be used in an analysis depends on the one that is most appropriate or best illustrate the effect of a particular investigation or a particular design.

Similar to in-vitro experiments, micromotion results from FE analyses can be categorised through cyclic loading. Reversible micromotion is the difference of the measured minimum and maximum values for one loading cycle, and permanent micromotion is the non-recoverable micromotion when the stem is unloaded at a particular time. The reversible micromotion is of particular importance because if the threshold limit is exceeded, fibrous tissue will form at the interface and fixation of the stem will be compromised. Permanent micromotion, on the other hand, is one of the predictors for aseptic loosening, but predicting long-term instability using this technique may not be feasible because many cycles would have to be simulated with accordingly long solution times. It should also incorporate biological factors into account which is beyond the scope of this study.

Our FE results showed that reversible micromotion did not change much throughout the ten load cycles for both stems modelled with and without an interference fit. However, for the stem modelled without an interference fit, the reversible micromotion must be calculated from one complete cycle, i.e. the difference between the minimum and maximum of one loading cycle. Micromotion measurements based on just the first peak load may over-predict micromotion by more than 100%. On the other hand, permanent micromotion was negligible when an interference fit was included. The micromotion result at the first maximum load was therefore a good estimate of the reversible micromotion. This is effectively simulating the settled-state of the stem within the femoral canal where no further bone crushing is taking place.

In the validation experiment, cyclic pre-load was performed until no significant jump in micromotion in each cycle was observed and readings from the voltmeter had stabilised. This was to ensure that the implant had been firmly seated and measurement for reversible micromotion could then be carried out. This was simulated in the FE analysis by assigning an interference fit between the hip stem and the femur with a value of 50 μm. Considering the limitations of the finite element models as well as the experimental study (due to deformation of the bone) the FE micromotion predictions based on the first peak load compared remarkably well with the experiments.

The experiment showed larger micromotion proximally than distally for specimens 2, 3 and 4. Lesser variations in axial micromotion were also found for the distal region (16-20 μm) than the proximal region (12-24 μm). The FE prediction was in agreement with the experimental results where similar magnitudes were observed and proximal micromotion was found to be relatively larger than distal micromotion. This is as expected because the Alloclassic is a distally-fixed hip stem. It was press-fitted into the canal with its distal part anchored onto the endosteal cortices. These results were also similar to the experimental micromotion comparison between a custom-made stem and an Alloclassic hip stem [28]. Though the loading configuration simulated in their experiment was for single leg stance, the authors did report larger micromotion proximally (24-34 μm) than distally (5-8 μm) for the Alloclassic hip stem. Another in-vitro experimental study comparing between several designs of cementless hip stems [29] which included the Alloclassic also showed that the Alloclassic produced relatively small rotational micromotion distally under torsional load.

A direct comparison of the FE results with other published FE results that used similar hip stem design is not available. Comparison is made even more difficult due to the variety of loading configurations and magnitudes, material properties used, the values of coefficient of friction and the exclusion of interference fit. Nevertheless, the magnitudes were in similar order of magnitude as the one reported by Ando *et al.* [13] and Biegler *et al.* [14].

5.0 CONCLUSION

An algorithm was constructed to predict instability of femoral stems. Based on common physiological loading, micromotion was calculated throughout the bone-implant interface of a rectangularly tapered femoral stem. Press fit stem insertion was modelled using interference fit and cyclic loading was used to simulate actual loading configuration. Larger micromotions were found in the proximal part of the stem indicating a possible loosening in this region. The algorithm was validated through an in-vitro micromotion experiment where good correlation was obtained.

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