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A preliminary hip joint simulator study of the migration of a cemented femoral stem

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Abstract: A hip joint simulator that can be used to evaluate the outcome of the cemented total hip replacement has been designed, manufactured and evaluated. The simulator produces motion of a cemented hip construct in the extension/flexion plane, with a socket to rotate internal/externally. At the same time a dynamic loading cycle is applied to the construct. A validation test was performed on a cemented femoral stem within a novel composite femur. The study demonstrates the value of using a hip joint simulator to evaluate the outcome of the cemented hip construct. A complex migration pattern of the cemented hip prosthesis with respect to load cycling was observed, demonstrated *in vitro* comparable prosthesis migration behaviour, both the stem migration and migration patterns, to that found clinically.

Keywords: hip joint simulator, loosening, stem migration, total hip replacement

1 INTRODUCTION

In the absence of an accepted *in vitro* bench test to predict the outcome of the cemented hip replacement, the evaluation of new materials and prosthesis designs relies upon animal experiments and clinical trials [1–4]. However, using such methods is recognized as an inefficient and costly way to screen out inferior implant designs. Several *in vitro* studies have been reported recently to measure the relative prosthesis/bone movement of the hip joint replacements [4, 5]. The experimental set-up is usually mounted on an Instron servohydraulic materials testing machine using the one-leg standing condition and a compressive sinusoidal load is directly applied on the femoral head, at a frequency of 5 Hz [6–9]. Britton and Prendergast [10] designed a novel loading generating rig that can produce a physiologically realistic loading configuration for walking, including muscle forces and hip contact force, and transmits this load to the implanted femur. McKellop *et al.* [11] measured the relative prosthesis–bone motion in the axial, medial–lateral and rotational directions, with the lower mounting plate swinging in the anterior–posterior direc-

tion while the prosthesis was under simultaneous axial and bending load.

The loading on the hip joint during gait is far more complicated than the loading conditions adopted in the reported *in vitro* tests. The movement within a hip joint replacement includes the femoral flexion, extension, abduction, adduction, internal and external rotations [12, 13]. Moreover, the rotation of the acetabular cup relative to the femoral head exerts a torsion torque on the femoral component. This demonstrates the need for a physiological load simulation in order to test the cemented hip implants *in vitro* safely. However, the reported *in vitro* pre-clinical test procedures simulate only one or two loading conditions.

A hip joint simulator can produce physiological dynamic loading and simulate the human hip activity under a similar environment to that of the human body. The design and validation work of the simulator at Durham has been reported elsewhere [14, 15]. Hip simulators have concentrated on wear and has long been used to assess wear or tribological properties of the artificial joints [16–19]. Clearly, however, a simulator of migration would be an important clinical test in implant designs.

Clinical observation using Roentgen stereophotogrammetric analysis (RSA) suggests that using the subsidence of the prosthesis at two years post-operation can predict the outcome of the cemented total hip

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arthroplasty [7, 20–22]. Pre-clinical test methodologies that can be used to predict the outcome of cemented total hip replacements, paralleling the methods now used in the evaluation of hip joint tribology, is a recognized need [5].

Fundamental to this work is the development of the hip joint simulator that can simulate the human hip both in movement and the loading condition, which can be applied to the study of the migration of the cemented hip prosthesis. A novel composite bone model has been developed by the authors for this purpose and presented here are the hip joint simulator based preliminary results of the cemented femoral stem. It is suggested that the development of the hip joint simulator and the experimental approach show promise in the evaluation of new prostheses and bone cements prior to the clinical introduction.

2 HIP JOINT SIMULATOR

2.1 Motion

The Durham hip joint simulator 3 is a modified version of the Durham hip joint simulator Mk 2. It was designed with the intention of building a simple, station-adjustable (to test different types of prosthesis and synthetic bones) and reliable machine while maintaining a realistic simulation of the hip joint replacements in regard to motion, load and lubrication.

The hip joint simulator 3 has five articulating stations and one creep station, as shown in Fig. 1. The cemented hip complex connects to the load actuator cylinder via the universal joint, a feature that facilitates the self-alignment and adjustment of the mounting angle. The

load actuator sits flatly on the bottom plate and can slide to and is fixed at the required position, so that the femur can be mounted anatomically as required. The acetabular cup, which was inclined at 30° from the vertical, was connected to the cup holder on the top. This approximates the anatomical position of the hip joint as well as providing the desired motion when in operation. The set-up of the station is shown in Fig. 2.

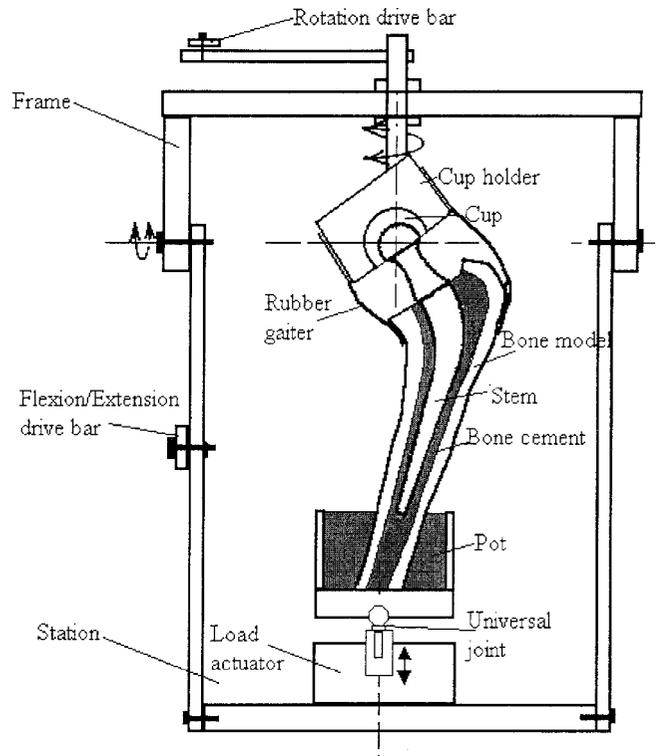


Fig. 2 The schematic of the station set-up

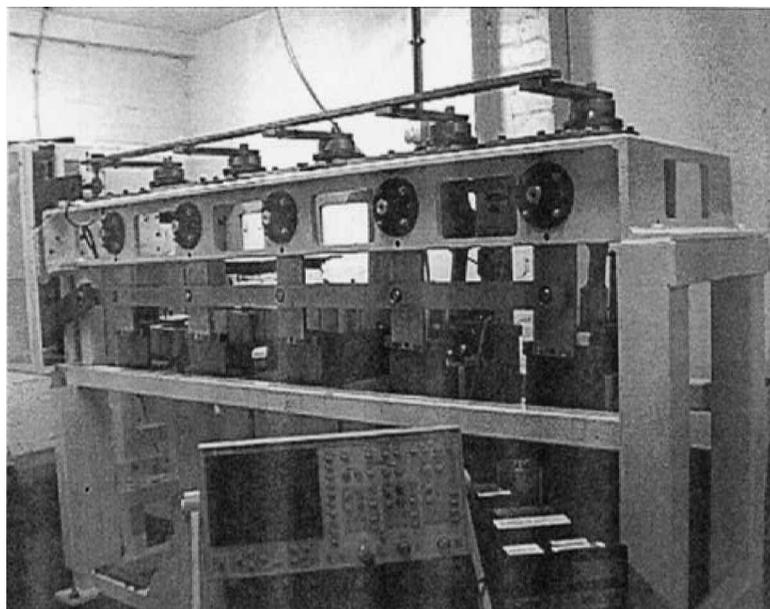


Fig. 1 The Durham hip joint simulator 3 with five articulating stations and one creep station

An a.c. motor drives an output shaft at 1 Hz on which a timing belt pulley and crank arrangement was mounted. The crank arrangement drives the extension/flexion drive bar directly and oscillates the five stations with an approximate sinusoidal motion through -15° to 30° in the extension/flexion plane, as shown in Fig. 3.

The timing belt pulley allowed the drive to pass to a parallel shaft above and drove the internal/external rotation drive bar via the crank arrangement on the shaft. This caused the acetabular components to be oscillated with an approximate sinusoidal motion through -5° to 5° in the internal/external rotation. Thus in the biaxial motion, the femoral component swings in the extension/flexion plane and the acetabular component rotates internally/externally, which simulates the movement of the hip in level walking. The timing belt and slots on the internal/external rotation crank fastenings allowed a phase difference of 90 between the two motion cycles to be accurately set, as shown in Fig. 4.

2.2 Load and loading profile

On the top shaft, a slot disc was used to activate three optoswitches, used to control the loading cycle. Rotating the slotted disc position relative to the internal/external rotation crank allowed the loading cycle to be synchronized with the motion cycles. The optoswitches control a Norgren pneumatic proportional valve via a programmable interface controller. The output from the Norgren proportional valve was amplified pneumatically using an SMC booster valve. A manifold then supplied pressure equally to a Hoerbiger pneumatic actuator in each of the stations. Load is applied on at maximum flexion

(equivalent to heel strike) and off at maximum extension (toe off).

The resultant forces of the normal hip were varied in the range 150–800 per cent of body weight depending on the walking speed, walking modes and measuring techniques [13, 23]. Saikko *et al.* [24] observed joint loading over the first 30 months following implantation, and the peak forces increased with walking from about 280 per cent of the patient's body weight (BW) at 1 km/h to approximately 480 per cent BW at 5 km/h. Jogging and very fast walking both raised the forces to about 550 per cent BW. About 200–250 per cent BW forces were recorded *in vivo* using a telemetric technique by English *et al.* [25]. In this study, the compressive load level peaking at 2500 N was chosen, which is 3.5 times BW of 75 kg body mass, to approximate the stress level that a well-bonded stem may reach *in vivo*. The load waveform was taken from Crowninshield *et al.* [26], except that the valley between the two peaks is omitted for simplicity. In their waveform the duration of the loaded part of the cycle, from heel strike to toe off, is about 63 per cent of the length of the cycle. This was preserved in the present study so that the load on the stem remains close to the physiological loading at heel strike and toe off. The pneumatic output from the stations followed a square wave loading cycle at a frequency of 1 Hz, as shown in Fig. 5.

The acetabular component was firmly connected to the cup holder, and the high part of the acetabular component was carefully calibrated according to the procedures described in reference [27] in order to make sure that the centre of the stem head is in line with the hinge of the articulate station when the stem head comes in contact with the acetabular cup. The cemented hip

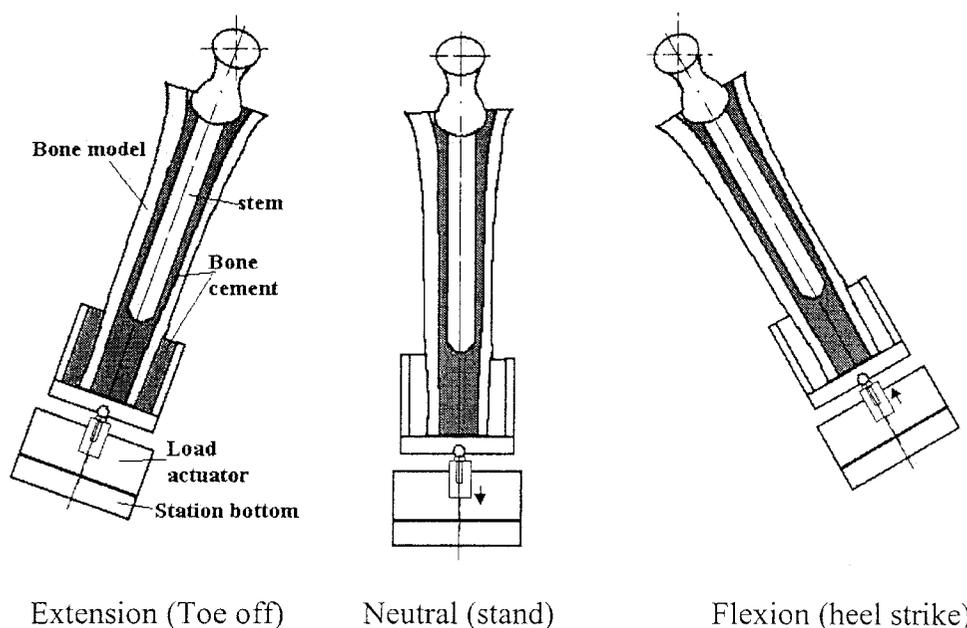


Fig. 3 The crank arrangement drives the femoral component which swings through -15° to 30° in the extension/flexion plane

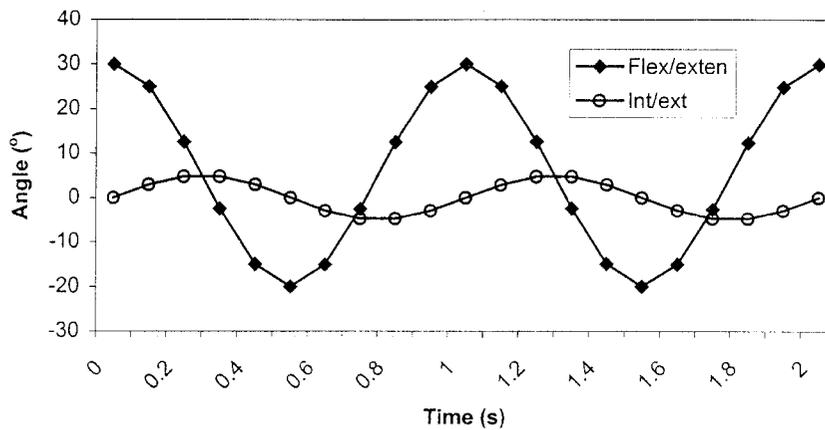


Fig. 4 The motion cycles used on the simulator 3

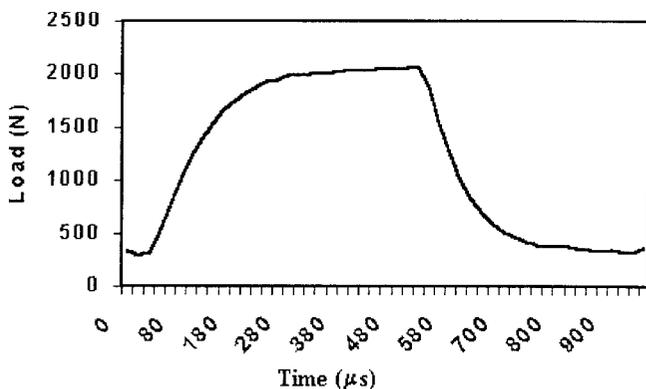


Fig. 5 Loading cycle at a frequency of 1 Hz was applied on each station. Heel strike is located at the end of the zero-load phase and toe off at the start of the zero-load phase

construct was mounted on to the station of the simulator, via a universal joint, at an adduction angle of 11° , chosen to allow a comparison with other studies [28, 29]. The femur was oscillated with an approximate sinusoidal motion through -15° to 30° in the extension/flexion plane. The acetabular components were oscillated with sinusoidal motion in the internal/external rotation plane through -5° to 5° . The articulating station combined flexion/extension of the femoral component, with internal/external rotation of the acetabular cup. The load vector was not simply in the vertical direction, but oscillated with the angle of swing of the femur. The combination of motion and loading cycles resulted in a three-dimensional locus of the load vector over the acetabular component, as observed *in vivo* and as used by Brummit and Hardaker [30].

2.3 Lubrication

The use of synovial fluid to replicate the *in vivo* lubricant exactly in the simulator is not viable due to the cost and difficulty of obtaining the quantities required for testing. A previous study [31] revealed that a carboxymethyl

cellulose (CMC) fluid with a viscosity of 9.9 cp demonstrated a similar friction factor to that of synovial fluid. Thus CMC fluid with a viscosity of 9.9 cp was chosen as the lubricant in the present study. The space between the acetabular component and the femoral component was sealed using a rubber gaiter filled with CMC fluid. Evaporation of the lubricant is compensated for using a replenishment bottle. Thus, the articulating surface was immersed in the lubricate to ensure that the articulation remains lubricated during the test.

3 FEMUR MODEL AND STEM MIGRATION MEASUREMENT

The bone model comprised a commercial bone cortex (Bone Models Limited, UK) filled with an epoxy resin cancellous bone model (CBME Durham, UK). The femoral canal was prepared according to the procedures described elsewhere [32, 33]. Vacu-Mix Plus pre-packed with CMW 1 radiopaque bone cement (CMW, UK) was used in the present study to cement the prostheses and its compositions and mechanical properties are discussed elsewhere [34]. The bone cement was introduced into the prepared femur canal in a retrograde fashion and kept at constant pressure. The Charnley FLNGD 40 stem was inserted into the femur at a cross-head speed of 500 mm/min to a pre-set position.

The migration measurement device was based on the concept employed by Maher *et al.* [5] to measure the migration of a cemented hip prosthesis *in vitro* test, in which they used six linear variable differential transformer displacement transducers (LVDTs) and specially built LVDT holders to measure the migration of the target device. The design developed in the present study use a depth micrometer with a resolution of $1 \mu\text{m}$, instead of LVDTs, to measure the relative migrations of the measuring device.

A purpose-built measuring device (Fig. 6), a three-ball measuring jig, was rigidly attached to the femoral component, while the reference window was rigidly

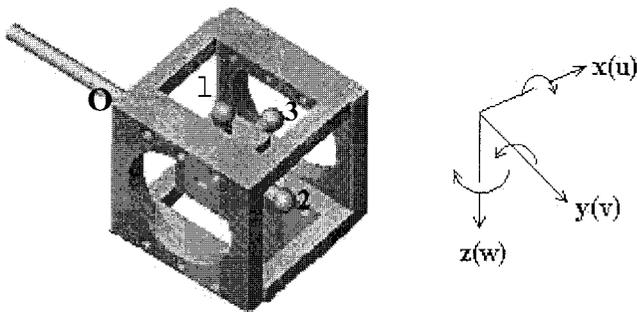


Fig. 6 The coordinate of the migration measuring protocol

attached to the femur. Thus the relative migration between the femoral component and the bone cortex can be obtained by measuring the displacement of the three-ball jig relative to the reference window. The fixed coordinate axis x of the jig is aligned with the line joining the centre of ball 3. The fixed coordinate axis y of the body is aligned with the line joining the centre of ball 2 and the centre of the attaching rod between the jig and the prosthesis. The jig fixed axis z is mutually perpendicular to the x and y axes and is aligned with the line joining ball 1. Point O is the reference point of the jig. A matrix representing the $\{x, y, z\}$ coordinates of the centres of each of the balls 1, 2 and 3 is constructed, where $\{0, 0, z_1\}$, $\{0, y_2, 0\}$ and $\{x_3, 0, 0\}$ are the centre coordinates of balls 1, 2 and 3 respectively.

As the measuring jig was rigidly attached to the prosthesis, the jig will migrate with the prosthesis. If the prosthesis migrates, when subject to loading cycles, the migration can be described as a rotation (θ_x, θ_y and θ_z is the rotation angle around axes x, y and z respectively) and a translation ($\{u_0, v_0, w_0\}$ is the translation of the origin O in axes x, y and z respectively). Then, the displacement of the three balls can be expressed as follows:

$$\begin{Bmatrix} u_1 & u_2 & u_3 \\ v_1 & v_2 & v_3 \\ w_1 & w_2 & w_3 \end{Bmatrix} = [\mathbf{R}] \begin{Bmatrix} 0 & 0 & x_3 \\ 0 & y_2 & 0 \\ z_1 & 0 & 0 \end{Bmatrix} + \begin{Bmatrix} u_0 & u_0 & u_0 \\ v_0 & v_0 & v_0 \\ w_0 & w_0 & w_0 \end{Bmatrix} - \begin{Bmatrix} 0 & 0 & x_3 \\ 0 & y_2 & 0 \\ z_1 & 0 & 0 \end{Bmatrix} \quad (1)$$

where

$$[\mathbf{R}] = \begin{bmatrix} 1 & -\theta_z & \theta_y \\ \theta_z & 1 & -\theta_x \\ -\theta_y & \theta_x & 1 \end{bmatrix}$$

Solving the above equation gives the migration of the

jig origin O as

$$\begin{aligned} u_0 &= u_3 \\ v_0 &= v_2 \\ w_0 &= w_1 \\ \theta_x &= \frac{v_0 - v_1}{z_1} = \frac{w_2 - w_0}{y_2} \\ \theta_y &= \frac{u_1 - u_0}{z_1} = \frac{w_0 - w_3}{x_3} \\ \theta_z &= \frac{u_0 - u_2}{y_2} = \frac{v_3 - v_0}{x_3} \end{aligned} \quad (2)$$

By incorporating equations (2) and (1), the migrations of the jig centre can be obtained. The migrations of the prosthesis head centre and distal end are evaluated geometrically and calculated correspondingly.

4 PRELIMINARY RESULTS

Two cemented hip prostheses were tested in the present study, and the subsidence variations of the stem with the loading cycles are shown in Fig. 7. This figure shows that the stem subsides with respect to the loading cycles. The subsidence of the stem for both the stem head and the distal stem increased with the number of loading cycles. It was observed that a difference existed between the subsidence of the stem head and the distal stem. The stem head demonstrated a higher subsidence than the distal stem at each loading cycle. Total subsidence after 3 million loading cycles reached 176 and 70 μm for the stem head and distal stem respectively.

With reference to Fig. 7, two subsidence stages, an initial higher subsidence stage followed by a steady subsidence stage, can be identified. The subsidence of the stem head and distal stem reached 76 and 42 mm respectively at 100 000 loading cycles, representing about 43 and 60 per cent of the total subsidence respectively at 3 million cycles. The subsidence of the stem head increases dramatically with the loading cycles in the initial stage until about 100 000 loading cycles and was about 1.8 times higher than that of the distal stem. The subsidence reaches a steady stage and thereafter increases slowly with the number of loading cycles.

As a rigid body, the difference in the subsidence of the stem head and the distal stem may be a result of the stem rotation. Figure 8 shows the measured stem rotations with respect to the loading cycles. Stem rotation contributed to the three-dimensional migration of the stem with loading over the test duration. Typically, the stem rotated within the composite bone about the y axis, which results in the stem head migrating medially and the distal stem laterally. The stem internal rotation about the z axis, added by rotation about the

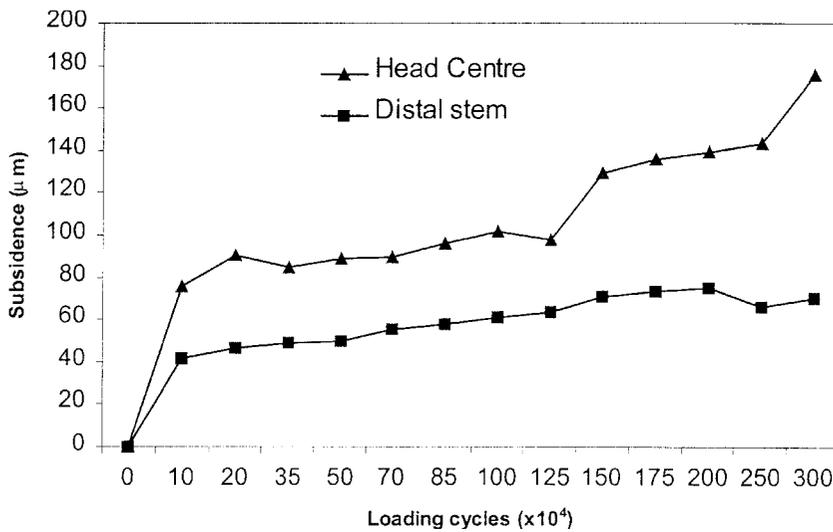


Fig. 7 The migration of the stem head and the distal stem with the loading cycles

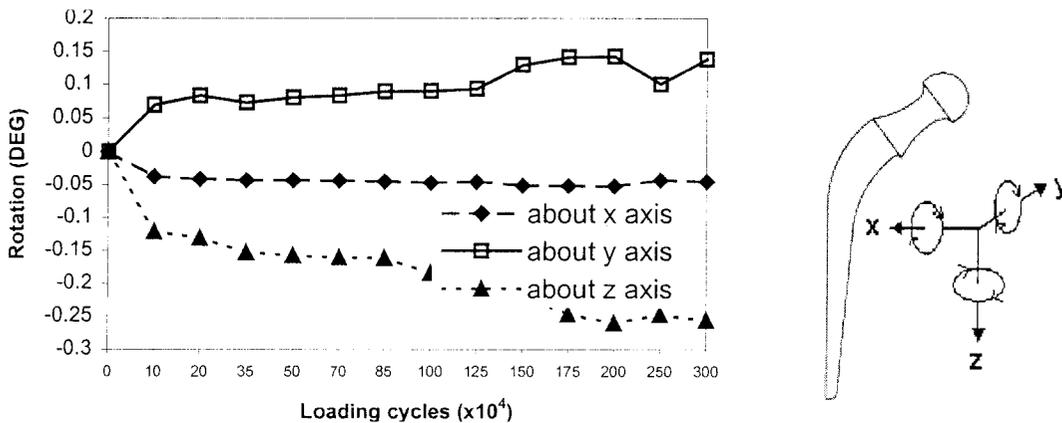


Fig. 8 Rotation of the prosthesis with the loading cycles (positive for right-hand rule and negative for left-hand rule)

x axis, contributed to the head migrating posteriorly. The total angle of rotation at 3 million cycles for the stem was 0.046°, 0.14° and 0.26° about the x, y and z axes respectively. The rotation of the stem also featured with two rotation stages, i.e. a higher rate stage of rotation followed by a lower rate stage of rotation. For the rotation about the x axis, about 92 per cent of the total rotation occurred during the first 0.2 million cycles; 60 and 51 per cent of the total rotation angle were recorded for the rotation about the y and z axes respectively at 0.2 million cycles. Beyond that, the rotation rate seemed to decrease to a steady stage.

5 DISCUSSION

Failure of total hip replacement (THR) is a complex process and is currently poorly understood. The long-term endurance of total hip arthroplasty depends on lasting mechanical integrity of the bone between the implant and the bone, the implant–bone cement interface. The

migration of cemented femoral components is a complex combination and translation in three dimensions. Clinical studies using radiostereophotogrammetry have shown that those cemented hip prostheses that migrate rapidly in the first two post-operative years are the ones that require early revision [35]. Loudon and Older [36] reported that subsidence of the femoral component was related to the long-term outcome of hip replacement. An unsatisfactory outcome was associated with subsidence of more than 5 mm, when clinical failure is likely. Karrholm *et al.* [37] measured the migration at two years and found that those femoral components that failed had subsided more than 2 mm in two years. Those that functioned well had a mean migration of 0.08 mm. In the present study, the subsidence of the stem was far from reaching the 2 mm threshold. Does this result suggest that the stem tested in this study was stable? As a general assumption, 1 million loading cycles is a realistic estimate of the number of walking cycles endured by the hip joint annually. In comparing the present data to the clinical measurements, it is clear that the average

migration measured in this study is comparable to that in the clinical data, as observed in Table 1.

The substantially larger migration of the femoral component at an early test stage confirms other clinical observations [35, 38, 39]. The rapid early migration *in vivo* is probably caused by resorption of the bone layer, which has been injured by surgical trauma and the heat of polymerization of polymethylmethacrylate (PMMA) cement. After the initial stage, when the initial settling is complete, the implants tend to migrate slowly without substantial bone loss and probably result from a combination of cement creep, allowing the implant to sink within its mantle. In comparing the variation of the stem subsidence with the loading cycles to the creep variation of cement with the loading cycles [40, 41], a clear similarity was observed. This may suggest that the later migration pattern could be creep driven.

Several *in vitro* studies [5, 39, 42] have attempted to measure the prosthesis/bone movement of femoral hip replacements. Various methods have been devised using custom-designed machines. The experimental set-up comprised an Instron servohydraulic materials testing machine. The femur was clamped to the base of the machine using the one-leg standing condition and a compressive sinusoidal load was directly applied on the femoral head, at a frequency of 5 Hz [6–9]. Britton and Prendergast [10] designed a novel loading generating rig that could produce a physiologically realistic loading configuration for walking, including muscle forces and hip contact force, and transmits this load to the implanted femur. However, none of the reported studies realized the physiological simulation of the hip joint conditions with regard to motion, load and lubrication.

Several factors, including bone quality, loading locus, stem and cement types, cementing techniques, etc., should be considered when interpreting the data and comparing with the published results. The current study was carried out on a hip joint simulator, in which the femur are subjected to compressive loads of varying magnitude, with the direction varying in a cycle; the rotation of the acetabular component exerted a torsional moment to the femoral component. *In vivo*, the femur also experienced muscle forces, which counterbalanced the contact force. The counterbalance effect of the muscle forces acting on the femur may have an influence

on the load distribution, such as a reduced bending moment. This may cause the stem to migrate in a different way or produce a different movement. However, there has been no literature report on the effects of muscle on stem migration. As the femoral component swings in the extension/flexion plane and the acetabular component rotation is internal/external, which was added by the lubrication regime adopted in this study, attempts to apply the muscle forces to the femur in a simulator test have proved to be difficult at the present stage.

As a simplified loading simulation, the square wave loading profile has been widely adopted in the evaluation of biomaterials. Smith and Unsworth [43] compared the simplified motion and loading to that of the physiological loading of a hip joint simulator. Visual inspection of the worn surface of the cups revealed that no notable difference was observed between these two motion and loading modes in regard to the wear of the hip joints, and it was concluded that simplified loading is therefore an acceptable mode in simulator testing. It has a clear advantage over the sinusoidal loading profile of the physiological loading. Therefore a compressive sinusoidal load was adopted in the reported *in vitro* test of the hip replacements and the simplified load profile was adopted in the present study. However, no literature reports the effect of the loading profile on stem migration and more evaluation work should be carried out in the future.

Previous *in vitro* studies [27, 44] revealed that the bone quality (mechanical strength and modulus) and creep behaviour of a cement mantle plays a very important role in the migration of the cemented hip prosthesis and the remodelling process of the bone cortex. The stems within a weak bone cortex migrate much more than those within a strong bone cortex. The pattern or direction of migration changed with loading cycles, and this change in pattern is larger than the change in rate, which is also observed clinically [35]. The difference suggests that different mechanisms cause the migration at different periods and different restrained conditions.

As a first-attempt *in vitro* test, the hip joint simulator has demonstrated clear advantages over the reported *in vitro* test methods [4, 5, 42, 45, 46] with regards to loading locus, motions and lubrications, the test shows a very

Table 1 Comparison of the stem migration between the present study and clinical measurements

Sites	Experimental data			Clinical data [35]	
	1 million	2 million	3 million	First year	After first year
Stem head (mm)	0.101	0.139	0.176	0.54 ± 0.16	0.09 ± 0.04
Distal stem (mm)	0.061	0.07	0.07	0.04 ± 0.14	0.15 ± 0.05
Rotation angle (°)					
θ_x	-0.045	-0.052	-0.046	-0.1 ± 0.14	0.10 ± 0.08
θ_y	0.18	0.26	0.26	1.17 ± 0.69	0.20 ± 0.29
θ_z	0.09	0.14	0.14	0.32 ± 0.12	-0.02 ± 0.04

promising method for pre-clinical evaluation of the outcome of cemented hip replacements.

6 CONCLUSIONS

A new design of hip joint simulator and a method for measuring the migration behaviour of a cemented hip prosthesis *in vitro* has been described. The study demonstrates the value of using a hip joint simulator to evaluate the outcome of the cemented hip construct. A complex migration pattern of the cemented hip prosthesis with respect to load cycling was observed. This experimental outcome is significant because it is the first study using a hip joint simulator that has demonstrated *in vitro* comparable prosthesis migration behaviour, both the stem migration and migration patterns, to that found clinically, suggesting that the reported experimental set-up and the method can be used for pre-clinical evaluation of the biomaterials in cemented hip replacements. Work is ongoing using matched moduli cortex and cancellous elements of the bone model, developed to better replicate the physiological situation.

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