

In-vitro method for assessing femoral implant–bone micromotions in resurfacing hip implants under different loading conditions

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Abstract: Although prosthesis–bone micromotion is known to influence the stability of total hip replacement, no protocol exists to investigate resurfacing hip implants. An *in-vitro* protocol was developed to measure prosthesis–bone micromotions of resurfaced femurs. In order to assess the effect of all loading directions, the protocol included a variety of *in-vitro* loading scenarios covering the range of directions spanned by the hip resultant force in the most typical motor tasks. Gap-opening and shear-slippage micromotions were measured in the locations where they reach the maximum value. The applicability of the protocol was assessed on two commercial designs and different head sizes. Intra-specimen repeatability and inter-specimen reproducibility were excellent (comparable with the best protocols for cemented hip stems). Results showed that the protocol is accurate enough to detect prosthesis–bone micromotions of the order of a few microns. Statistically significant differences were observed in relation to the direction of the applied force. Using the whole range of hip loads enabled detection of maximum micromotions for any design (the peak value could be different for different loading directions). Application of the protocol during a test to failure indicated that the system could track micromotion up to the last instant prior to failure. The protocol proposed is thus completely validated and can be applied for preliminary screening of new epiphyseal designs.

Keywords: preclinical *in-vitro* testing, implant–femur micromotion, implant primary stability, resurfacing epiphyseal prosthesis, hip replacement

1 INTRODUCTION

Hip resurfacing was used in the earliest attempts to treat hip osteoarthritis [1], but the initial, encouraging outcomes soon revealed unacceptable failure rates [2–5]. However, hip resurfacing designs allow surgeons to preserve more bone tissue, providing easier revision procedures [5–8] if compared with the standard technique. For these reasons, the resurfacing technique, properly revisited, was re-proposed in more recent designs. Hip resurfacing has been reintroduced in the surgical practice [9, 10] as a beneficial solution even for active patients, becoming fairly popular in some countries in the last few years.

Preliminary short-term clinical results for this new type of hip prosthesis are encouraging [6, 11, 12]. A potentially concerning failure scenario in the short term is aseptic loosening of the femoral component (in addition to neck fractures, which can account for up to half of the failures) [7]; in some cases, extensive radiolucency was observed around the short femoral stem, probably indicative of early loosening. A randomized clinical trial [13] resulted in several failures, including a number of early femoral component loosening.

The primary stability obtained with a prosthetic device plays a critical role in aseptic loosening [14]. Additionally, early micromotion is a potential predictor of failure [15]. Thus, each new design should be subjected to preclinical tests specifically designed to assess its stability under physiological loads. The assessment of primary stability *in vitro* is a quite

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well-established procedure for conventional hip stems [16–19]. However, to the present authors' knowledge, no protocol has been proposed to test the stability of the femoral component of hip resurfacing *in vitro*.

Knowing that implant–bone micromotion is a reliable indicator of implant primary stability and that early micromotion is a potential predictor of long-term outcome, the aims of this work were as follows:

- (a) to develop a protocol for the preclinical evaluation of micromotion of the femoral component in hip resurfacing with the following features: firstly, such a protocol should be able to assess implant micromotions under different loading scenarios covering the physiological range; secondly, the amount of load applied and the number of loading cycles must be limited, to avoid bone and prosthesis damage, in order to allow the same specimen to be tested under several loading scenarios; thirdly, the set-up must be adaptable to different prosthetic designs;
- (b) to assess the ability of the protocol to measure implant micromotion in the elastic region (subcritical load values);
- (c) to assess the suitability protocol to evaluate the implant micromotions up to failure, to elucidate the failure mechanism.

2 MATERIALS AND METHODS

2.1 Micromotion measurements

The implanted femur specimens were instrumented with two high-precision waterproof spring-preloaded linear variable-differential transducers (LVDTs) (D5/40AW, RDP, Wolverhampton, UK; accuracy, 1 μm), to measure bone–prosthesis micromotion, following a protocol derived from previous experience [16]. Two components of prosthesis–bone relative motion were measured: gap opening and shear slippage. In order to measure the maximum values of such components, the LVDTs were positioned where these motions reached the respective peak values in a preliminary finite element study [20] (Fig. 1).

1. The gap opening was measured between the most medial point of the rim of the prosthetic components and the adjacent bone.
2. The shear slippage was measured between the bone and the prosthesis on the posterior side. The relative positions of the two transducers were scaled by the head diameter.

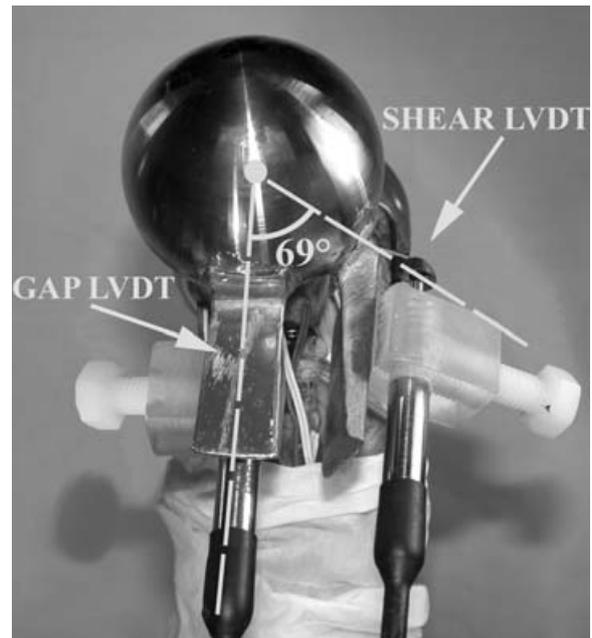


Fig. 1 Medial view of the proximal implanted femur: the two LVDTs were accurately aligned so as to lie in the plane of the edge of the prosthesis, with the line of action respectively in a radial direction (for the LVDT measuring gap-opening micromotion), and in a tangential direction (for the LVDT measuring shear-slippage micromotion). To allow consistent positioning with different head sizes, the relative positions of the two transducers were calculated considering a polar reference system centred on the head centre; thus the angular distance was constant through the specimens (69°). The body of the transducers was connected with a small fixture to the lowest point of the prosthesis (at the medial and posterior sides respectively) and close to the prosthesis rim. The moving probe of the LVDTs were instrumented with a spherical tip of 2 mm diameter in contact with a target metal plate (L shaped for the shear LVDT) glued on to the bone, with the surface perpendicular to the axis of the LVDT

The bodies of the LVDTs were mounted on the prosthesis (within 2 mm from the rim of the prosthetic head) by means of custom adjusted fixtures and bicomponent epoxy glue. The probe of the LVDTs was equipped with a custom-designed pin that targeted a small metal plate glued on to the bone surface within 2 mm from the rim of the prosthetic component (and perpendicular to the axis of the LVDT). The set-up and the assembling technique for the transducers were optimized using the first set of two specimens (implanted with two different prosthetic designs; see below).

The LVDT signals were logged in a multi-channel unit (model 34970A, Agilent Technologies, Santa Clara, California, USA) together with load and position signals from the testing machine. Continuous recording from the LVDTs allowed the inducible micromotion (which was recovered within seconds after unloading) and the permanent migration (not recovered after load removal) to be measured.

2.2 Mechanical *in-vitro* testing

In order to explore implant micromotions under all possible loading conditions, a set of five loading directions [20] was selected. Such loading angles were designed to cover the physiological range of maximum hip reaction angles recorded in hip patients [21] during a wide range of activities (including level walking at different speeds, single-leg stance, stair climbing and descending, and standing up from a seated position), and to generate bending in different planes, axial loading, and torsion. These configurations (load cases 1 to 5 in Fig. 2) do not represent any specific motor task but they correspond to the extreme directions of the resultant hip joint force in the frontal and sagittal planes. With the aim of exploring the effect of different loading conditions on the head–neck region, it was decided not to include the action of any muscle, which would mainly affect the femur distal to the lesser trochanter [22, 23].

The femurs were mounted on the load cell of the testing machine (model 8502, Instron, Canton, Massachusetts, USA). A system of cross-rails was provided to avoid application of undesired horizontal force components. In order to measure initial implant stability, a quasi-static scenario was preferred, rather than fatigue testing. The load was applied in 25 s and was held for 30 s to allow settling and repeatable measurements [24]. The load was sufficiently low (75 per cent of the body weight) to allow repeated loading without bone–cement damage (based on the finite element method [20]).

In order to compare the effect of the different loading directions, each implanted femur specimen underwent all loading scenarios. Only five loading cycles were applied for each loading configuration so as to avoid specimen damage and to allow the same specimen to be tested under different scenarios without a sequence effect (in fact, the scope of this study was not to investigate loosening with high numbers of cycles). The specimen was allowed to recover for at least 5 min between replicates. The whole loading set-up was dismantled and realigned between replicates.



Fig. 2 The load cases simulated on a right femur (lateral view on the left, and posterior view on the right). The angles define only the relative positions of the femur specimens under the testing machine, which are needed to obtain the correct *in-vitro* loading and do not correspond to any specific anatomical position. Load cases 1 to 5 were applied in the non-destructive tests. Load case F was used to simulate spontaneous head–neck fractures

Finally, a failure test was performed to evaluate micromotion until the instant prior to implant failure [23]. An additional loading scenario was thus designed (load case F in Fig. 2) to replicate the loading associated with the highest risk of spontaneous fractures. A preliminary finite element study [20] explored the condition (among the motor tasks reported by Bergmann *et al.* [21]) under which the stresses are highest in the head–neck region. This study showed that the most suitable scenario was when the force was at 8° in the frontal plane [25]. The load rate was set so as to cause fracture in 1–3 s from load application.

2.3 Specimens

A total of six fresh frozen human cadaveric femurs were obtained from the International Institute for the Advancement of Medicine (Jessup, Pennsylvania,

USA), excluding donors with musculoskeletal pathologies. Donor data were as follows:

- (a) sex: five males;
- (b) age: average, 62.4 years; range, 51–80 years;
- (c) height: average, 176.2 cm; range, 175–178 cm;
- (d) weight: average, 99.8 kg; range, 75–164 kg;
- (e) head diameter: average, 50.6 mm; range, 48.0–54.4 mm.

A visual inspection and radiographic assessment – including dual-energy X-ray absorptiometry and computer tomography scanning – confirmed the absence of abnormalities, defects, or damage. The femurs were wrapped in cloth soaked with physiological solution and stored sealed at -25°C when not in use; they were constantly moistened by means of wet cloths during testing.

The femurs were prepared with a set of reference axes to allow for reproducible alignment throughout the test, following a validated protocol [24, 26]. The femoral condyles were placed in a steel box with dental cement.

Implantations were carried out by experienced surgeons, following the recommended surgical techniques for each device. The femoral head and neck were reamed so that the axis of the prosthetic component was aligned with the neck axis (alignment was checked in the post-operative radiographs). A first set of two specimens was used for optimizing the testing set-up and LVDT fixtures, and to verify that the method could be adapted to different resurfacing designs. They were implanted with the following devices (one each):

- (a) Conserve Plus (Wright Medical Technology Inc., Arlington, Tennessee, USA) (this specimen was tested as part of another study [27]);
- (b) Birmingham hip resurfacing (BHR) prosthesis (Midland Medical Technologies, Birmingham, UK).

Both prostheses are manufactured from Co–Cr alloy. The inner geometry of the dome differs for the two types, as also does the design thickness of the cement layer.

Once the testing method was consolidated, the remaining four femur specimens were used to assess the repeatability of the method. Thus, they were implanted with suitably sized BHR prostheses. Pre-chilled ($+4^{\circ}\text{C}$) vacuum-mixed (Mixevac II, Stryker, Mahwah, New Jersey, USA) low-viscosity bone cement (Surgical Simplex P, Stryker) was used.

2.4 Statistics

Only the series of four BHR specimens tested once the protocol was consolidated were subjected to the statistical analyses below. Micromotion data were preliminary screened with the Chauvenet criterion for outliers (no data needed to be discarded). Linearity of the load–micromotion data was checked. Finally data were processed statistically to assess the following:

- (a) correlation between the two measurement locations (gap opening and shear slippage) – correlation analysis;
- (b) correlation between the inducible micromotion and permanent migration – correlation analysis;
- (c) significance of the loading scenario: one-factor analysis of variance (ANOVA).

3 RESULTS

The results below cover the series of four BHR specimens tested once the protocol was consolidated (assessing protocol repeatability). The results from the preliminary test (one Conserve Plus and one BHR specimen) are not reported owing to the slightly different testing set-ups.

3.1 Micromotion during non-destructive testing

Micromotion measurements were successfully performed on all the implanted specimens for all the loading conditions. The recorded values were in the predicted direction [20], consistent with the direction of the applied load, both in gap opening and in shear slippage. Load–micromotion linearity was good ($R^2 \geq 0.98$), confirming the linear behaviour of the measurement system and the bone. Gap-opening and shear-slippage micromotions were highly correlated (correlation coefficient, 0.765; Fisher test P value, less than 0.0001).

The displacement readouts for the four BHR implants were very low (always lower than $20\ \mu\text{m}$) with the reduced-load simulation (Fig. 3). Measurement repeatability was good in all specimens; variability between repeats on the same specimen, under the same loading condition, ranged from less than $1.0\ \mu\text{m}$ to $3.7\ \mu\text{m}$, depending on the specimen and loading condition. Inter-specimen variability (four specimens) for the same loading scenario ranged between 1.6 and $5.3\ \mu\text{m}$.

The peak values under load for each loading condition were quite different; the largest inducible micromotions were found for load case 4 (with the force slightly tilted from posterior towards anterior).

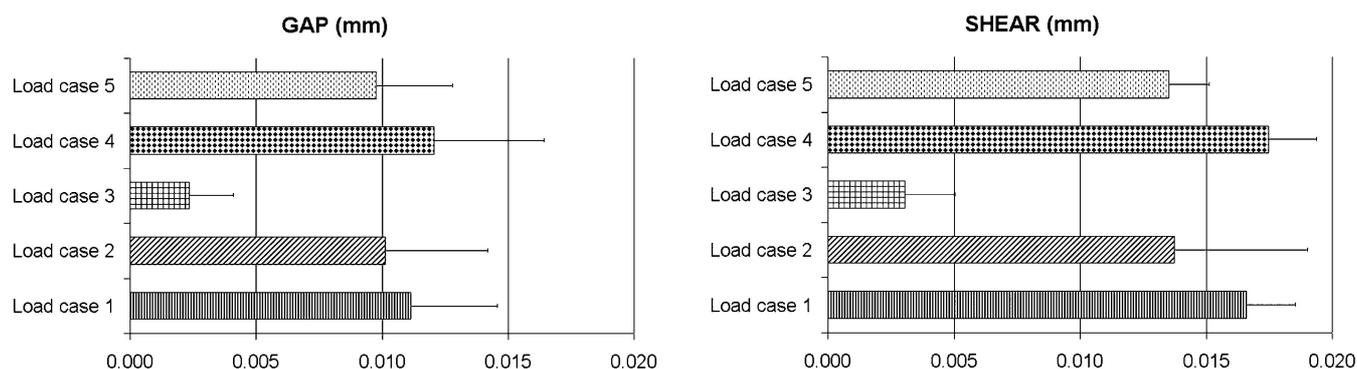


Fig. 3 Gap-opening and shear-slippage inducible micromotions for the five loading conditions tested non-destructively (different directions of the hip joint force; loaded with 75 per cent of the body weight): average between specimens \pm standard deviation. Results are reported only for the four similar BHR specimens tested once the protocol was finalized

Similar micromotions were recorded for load cases 1, 2, and 5. The smallest inducible micromotions were found for load case 3 (with the force at 24° in the frontal plane); these micromotions were much smaller than those recorded in any other direction. Owing to the high repeatability, the effect of the loading scenario on inducible micromotions was statistically significant for the gap-opening measurement direction (ANOVA, $P = 0.048$) and almost significant for the shear-slippage direction (ANOVA, $P = 0.073$).

The permanent migrations after load removal for the four BHR implants never exceeded $7 \mu\text{m}$ for both LVDTs, and for all the tested specimens under all loading conditions. Differences between load cases were not tested statistically for the permanent migrations, as these values were comparable with the accuracy of the measurement system. Permanent migrations did not correlate significantly with the inducible micromotions (correlation coefficient, less than 0.3; Fisher test P value, greater than 0.1).

3.2 Micromotion during destructive testing

Micromotions were successfully acquired during the whole tests to failure. In all cases, a non-linear trend was observed in the last instants prior to failure (Fig. 4), showing that the measurement system is capable of tracking the failure pattern. Bone–prosthesis maximum micromotion recorded at failure for the four BHR implants ranged between 123 and $218 \mu\text{m}$ medially (gap opening), and between 169 and $599 \mu\text{m}$ posteriorly (shear slippage).

4 DISCUSSION

A new protocol was developed to measure micromotion *in vitro* in resurfacing hip implants with the

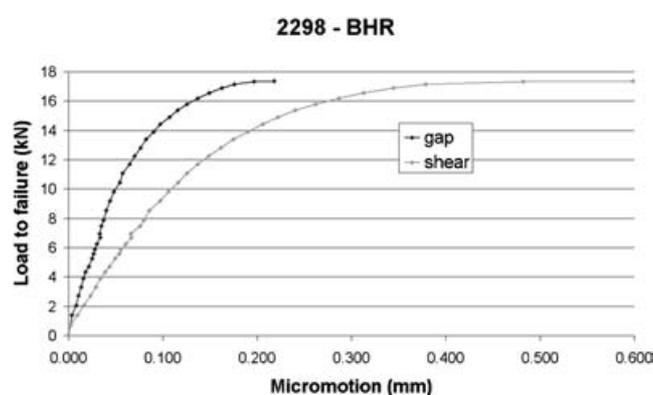


Fig. 4 Typical load–micromotion curve for a BHR implant, when loaded to failure: the two curves correspond to the two transducers recording gap opening (medially) and shear slippage (posterior side)

following features. The protocol included different loading scenarios to explore micromotions in the physiological range of hip joint force. Thus each specimen was subjected to five mechanical loading configurations under the testing machine. The loading protocol and micromotion measurement system were first tuned on two different designs implanted in cadaveric femurs. The intra-specimen repeatability and inter-specimen reproducibility were then assessed on four more human cadaveric femurs, implanted with BHR resurfacing prostheses.

The flexibility of the protocol was demonstrated by applying it to two different prosthetic designs, and to different head sizes during the preliminary tests. It must be emphasized that only components implanted in the correct position and alignment were tested.

Micromotions were successfully measured in the elastic range (low load values). Also, micromotions were tracked until specimen failure, obtaining

different patterns in relation to the implant type. The values measured under load for the tested prosthesis for both peak and permanent micromotions are comparable with those found for cemented hip prostheses [16].

The prosthesis–bone inducible micromotion under load caused a gap opening in the medial region, and shear slippage in the posterior region. This confirms that the protocol is capable of assessing the two main components of prosthesis–bone relative micromotion in the areas where they reach the maximum value [20]. The direction of the applied load affected the amount of micromotion quite significantly. The smallest micromotions were found for load case 3; for this loading scenario the direction of the applied load was closest to the femoral neck axis (and thus possibly further stabilized the prosthetic component (Fig. 2)). Conversely, differences were relatively small for all other loading cases. However, this specific trend might be related to the design features of the prosthetic component tested in this study (BHR). What can be assumed as a general pattern is that the micromotion is severely affected by the direction of the applied load. Therefore, in order to investigate possible loosening of a resurfacing component, different loading scenarios should be explored.

Permanent migrations were quite small (never exceeding $7\ \mu\text{m}$). Such residual migration could be associated with minor cement damage, with permanent deformation of the cancellous bone underlying the implant, or with interface failure (or with a combination of the modes above). Permanent migrations did not exhibit any significant correlation with the inducible micromotions (this can be due either to an actual lack of correlation, or to the fact that the permanent migration is close to the sensitivity of the measurement system).

The failure tests confirmed that the protocol allowed the prosthesis micromotion to be measured up to failure, being able to distinguish the elastic region from the non-linear trend typical of the instants prior to failure.

Comparison of the present results against clinical outcome is favourable: experimentally measured micromotions were small; roentgen stereophotogrammetric analysis studies indicated small or non-significant migrations during the first year [28, 29].

As no other *in-vitro* study has been published on micromotion of resurfacing implants, this protocol can be reasonably compared only with the protocols for conventional stemmed prostheses [18, 19, 30–32]. The accuracy of such validated protocols ranges from a fraction of a micron to several microns. The

accuracy of the present protocol was equal to the precision of the transducers, which was better than $1\ \mu\text{m}$. Linearity and repeatability were checked, and showed values consistent with those reported in other *in-vitro* tests [19].

Furthermore, *in-vitro* protocols for total hip replacement usually measure micromotions when the specimen is subjected to a torsional load (alone or with axial components). In the present investigation, five different loading configurations were considered in order to cover the physiological range of maximum hip reaction angles recorded in hip patients [20, 21]. This guarantees that, even if different micromotions occur for different loading directions, the highest value is detected by the protocol proposed.

Some limitations of the proposed method must be discussed.

Firstly, the action of the muscles was not included in the set-up. This simplification, which improves test set-up reproducibility, was based on the observation that the head–neck region is negligibly affected by the action of the thigh muscles [22]. This decision was confirmed by previous finite simulations [20, 23, 25]. Although such simulations were performed only on intact femurs, the present authors cannot see any reason why there should be a significant effect of the muscles in the implanted femur, if there is no effect in the head–neck region of the intact femur.

Secondly, a limited number of loading cycles was applied (five for each loading direction). This is the only option if different loading directions must be applied to the same specimen to investigate whether there is one specific loading direction that is more critical for the implant. In fact, as the test protocol includes assessment of the fracture mode, cadaveric specimens must be used (composite femurs are unsuitable for fracture tests [33]). As cadaveric specimens cannot withstand many loading cycles without non-physiological damage, this study was limited to a few loading cycles for each loading direction. A limited number of loading cycles is acceptable, as the goal of this study was that of investigating the primary stability (as opposed to long-term loosening). This decision is consistent with other *in-vitro* protocols in which only few loading cycles were applied [18, 30]. However, it must be noted that this set-up could be modified to include several loading cycles (if the fracture test is given up) by using composite femur models (similarly to reference [16]).

Thirdly, micromotions were measured at only two locations. Such locations were chosen as they corresponded to the points where the largest shear and

gap micromotions were expected on the basis of a previous finite element study [20]. On the one hand, this prevented resolving the three-dimensional bone–implant micromotion [17]; on the other hand, it enabled relative prosthesis–bone motions in the spots where they reached their peak to be measured with the highest accuracy. Because of the presence of a very thin layer of cement, the prosthesis–bone relative motions could not be separated in the two prosthesis–cement and cement–bone components (as happens in standard hip stems [34]). Thus, the overall prosthesis–bone relative motions were measured.

In conclusion, a protocol has been developed (on the basis of previous exploratory finite element studies) and thoroughly validated, confirming its ability to measure the largest micromotions occurring at the prosthesis–bone interface in a number of loading scenarios covering the physiological range, including when the specimen was brought to failure. To the present authors' best knowledge, no other similar protocol has ever been proposed for investigating micromotions of resurfacing hip implants.

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