A novel method to assess primary stability of press-fit acetabular cups

Emilie A Crosnier, Patrick S Keogh and Anthony W Miles

Centre for Orthopaedic Biomechanics, Department of Mechanical Engineering, University of Bath, Bath, UK

Corresponding Author: Emilie Aurélie Crosnier, Centre for Orthopaedic Biomechanics, Department of Mechanical Engineering, University of Bath, Bath, BA2 7AY, UK, Email: E.A.Crosnier@bath.ac.uk, tel. +44 (0)1225 385 961

Abstract

Initial stability is an essential prerequisite to achieve osseointegration of press-fit acetabular cups in total hip replacements. Most *in vitro* methods that assess cup stability do not reproduce physiological loading conditions and use simplified acetabular models with a spherical cavity. The aim of this study was to investigate the effect of bone density and acetabular geometry on cup stability using a novel method for measuring acetabular cup micromotion.

A press-fit cup was inserted into Sawbones® foam blocks having different densities to simulate normal and osteoporotic bone variations, and different acetabular geometries. The stability of the cup was assessed in two ways: (a) measurement of micromotion of the cup in six degrees of freedom under physiological loading; and (b) uniaxial push-out tests.

The results indicate that changes in bone substrate density and acetabular geometry affect the stability of press-fit acetabular cups. They also suggest that cups implanted into weaker, e.g. osteoporotic, bone are subjected to higher levels of micromotion and are therefore more prone to loosening. The decrease in stability of the cup in the physiological model suggests that using simplified spherical cavities to model the acetabulum over-estimates the initial stability of press-fit cups. This novel testing method should provide the basis for a more representative protocol for future pre-clinical evaluation of new acetabular cup designs.

Keywords

Total hip replacement, acetabular cups, press-fit fixation, initial stability, biomechanical study

Introduction

Total Hip Replacement (THR) is one of the most successful orthopaedic surgeries today, with over one million procedures performed around the world every year.[1] It aims to relieve pain and discomfort caused by disease, and to restore the natural function of the hip joint. Aseptic loosening has long been a major cause of failure in THR, accounting for over 50% of all revisions.[2, 3] Acetabular cups are particularly affected by aseptic loosening and have a higher revision rate compared to stems.[4]

There are a multitude of factors that contribute to aseptic loosening, an important one being initial instability of cementless acetabular cups. The hip is subjected to cyclic loading as a result of activity, which can induce micromotion at the bone-implant interface.[5, 6] Studies have reported that osseointegration of cementless acetabular components will occur if the relative micromotion at the bone-implant interface is below 40 µm and may occur up to 150 µm.[7, 8] Micromotions above 150 µm result in fibrous tissue formation, leading to implant loosening and revision surgery.[9]

Acetabular cups are normally assessed *in vitro* using static load-to-failure tests, which essentially investigate the design limits of implants by submitting them to extreme conditions rather than assess their performance in physiological conditions. These methods are relatively simple with well-defined endpoints and use standard equipment. However, they do not relate to physiological conditions and their endpoints are rarely linked to clinical values.

Primary stability of cementless cups can be achieved with press-fit, where the cup is implanted into an under-reamed cavity to provide an interference fit. The contact area between the bone and the cup should be limited to the equatorial rim of the acetabulum, leaving a small gap at the dome.[10] This results in a strong equatorial fit, which produces compressive stresses at the periphery of the acetabulum. These stresses generate compressive forces to stabilise the cup. Furthermore, limiting the contact area to the rim of the cup, and creating a small gap at the dome, results in the majority of the loads being transmitted through the peripheral cortical bone at the acetabular rim, hence recreating the load transfer of the natural hip.[10, 11]

Anatomical features of the acetabulum influence the stability of the cup. Within the pelvis, the acetabulum is essentially supported by the anterior and the posterior acetabular columns (Figure 1(a)). As a result of their gothic architecture the columns act as struts, adding stability, spreading out the pressure, and transferring the forces exerted by the femoral head.[11, 12] The two columns join superiorly to the acetabulum, forming a radiolucent triangle, which gives flexibility to the acetabulum.[11] The acetabular rim is interrupted inferiorly to form the acetabular notch.

Many of the *in vitro* studies use foam blocks with a hemispherical cavity as an acetabular model instead of cadaveric pelvic bones.[13-17] These blocks are more readily available than cadaveric bones. They are also manufactured with constant mechanical properties which reduce interspecimen variability, an inherent problem with cadaveric testing.[18] Modelling the acetabulum as a hemispherical cavity does not, however, take account of the important anatomical features of the acetabulum.

The aim of this study was to develop and assess a novel method to test acetabular cup stability under physiological loading. This method comprised a system to measure the micromotion of the cup in six degrees of freedom and a more physiological acetabular model which replicated the mechanical support present in the acetabulum. The effect of bone density on the micromotion of the cup was also assessed.

Methods

Acetabular component

All tests were carried out using a single hemispherical Trident acetabular component (Stryker, Mahwah, NJ, USA). The component comprised a 54 mm titanium shell with a hydroxyapatite coating, and its corresponding polyethylene liner (X3, Stryker, Mahwah, NJ, USA) with an inner diameter of 28 mm.

To limit the effect of repeated use, the cup was cleaned using a soft nylon brush after every test to remove any debris, which could have affected the surface finish of the cup. Visual inspection of the acetabular shell was also performed after every test to ensure the cup was not scratched or damaged. Preliminary work showed no changes in stability with repeated use of the same acetabular component under similar conditions.

Acetabular model

Polyurethane foam blocks (Sawbones®, Malmö, Sweden) were used as a synthetic bone substrate. Twelve high density foam blocks (density of 0.48 g/cm³, compressive strength of 18 MPa, #1522-04) and twelve low density foam blocks (density of 0.24 g/cm³, compressive strength of 4.9 MPa, #1522-02) were used to simulate two qualities of bone. These foam blocks were chosen for two reasons. Firstly, their properties are within the range of trabecular bone properties reported in the literature: bone density ranges between 0.17 g/cm³ and 0.50 g/cm³, and compressive strength ranges between 2 MPa and 50 MPa.[19, 20] The chosen high density foam is near the top of the bone density range, simulating normal bone; whilst the chosen low density foam is near the bottom of this range, simulating weak, e.g. osteoporotic, bone. Secondly, these foam blocks are commonly used to model the acetabulum in similar studies.[13-17]

Two different acetabular cavity geometries were machined using foam blocks comprising both densities. The first geometry was a 1 mm under-reamed hemispherical cavity (High Density Spherical and Low Density Spherical). The acetabular cavity was designed with a 1 mm offset, making it slightly deeper compared to its width (53 mm peripheral diameter and 27 mm depth). This was done to ensure that the cup did not bottom out before peripheral fixation occurred. The second geometry was similar to Spherical with two extra cavities superiorly and inferiorly to the acetabulum (Figure 1(b); High Density Physiological and Low Density Physiological). The Physiological geometry aimed to model the mechanical support of the posterior and anterior acetabular columns, and the non-supportive areas of the acetabular notch and the radiolucent triangle, inferiorly and superiorly to the acetabulum, respectively. The width of both the acetabular notch and the radiolucent triangle was 27 mm, which corresponds to a 60° angle.[21, 22]

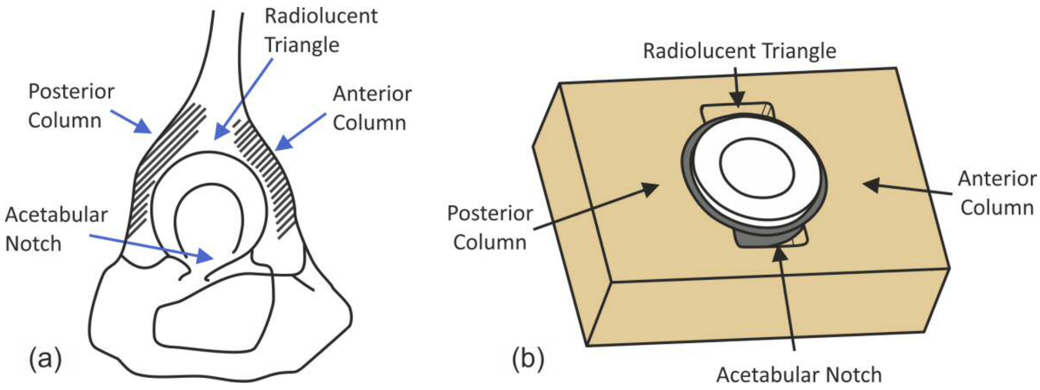

Figure 1. The acetabular columns, the acetabular notch and the radiolucent triangle labelled on both the pelvis (a) and the Physiological Sawbones® foam block (b).

Similarly to previous studies, a 1 mm press-fit was chosen, rather than a 2 mm press-fit, to ensure full seating of the cup in the high density foam blocks. [14, 15, 23] Furthermore, studies have reported significant variations when using reamers with errors up to 2.9 mm in some cases. [24, 25] The acetabular cavities were therefore machined using a CNC machine in order to ensure accuracy and reduce variability caused by reaming between each specimen. The peripheral diameters were measured using a digitiser (Incise, Renishaw, Wotton-under-Edge, UK) prior to testing to confirm the accuracy of the manufacturing. The mean peripheral diameter was 52.93 mm ± 0.05 mm.

Implantation

The acetabular component was inserted into the testing blocks using a single-axis hydraulic test machine (Dartec, Series HC10), and following a protocol of 5 cycles of loading at a frequency of 1 Hz to replicate the effect of hammer blows. Maximum loads of 5.0 kN and 2.0 kN were used for the high and low density foam blocks, respectively.[13] A custom-made fixture, consisting of a disk fitting over the rim of the component, was used to ensure that the load was distributed evenly around the rim of the cup during implantation. The insertion protocol was based on a method used by both MacKenzie et al.[24] and Kim et al.[26], which provided a controlled process to ensure repeatability.

Prior to implantation, a rod was threaded into the dome screw hole at the apex of the acetabular cup. This attachment site was chosen for two reasons. Firstly, this allowed the rod to be attached to the cup without modifying or damaging the cup. Any modifications could have changed the mechanical properties of the cup, and hence its behaviour when implanted. Secondly, since research has suggested that press-fit primarily relies on peripheral fixation, it was assumed that a hole at the bottom of the acetabular model through which the rod passed would not affect the stability of the cup.

Micromotion testing

The implanted cup was placed on a custom made rig to measure the micromotion in the six degrees of freedom of the acetabular cup under cyclic loading (Figure 2(b)). A triangular mount with three target spheres was attached to the protruding rod, rigidly connecting the triangular mount to the cup (Figure 2(a)). The configuration of the six linear variable differential transformers (LVDTs; Red Crown LVDT, range ±0.5 mm, linear error ≤3 µm, Marposs, Bentivoglio, Italy) allowed the measurement of the position of all three spheres at the same instant. These measurements were then used to calculate the three translational ranges of micromotion of the cup in the orthogonal axes (X, Y and Z) and the rotation about these axes (θ_X, θ_Y and θ_Z) from a single point, which was defined as the centre of rotation of the cup (Figure 2(b)). This LVDT configuration was adapted from a frequently used method developed by Berzins et al.[27] to assess the stability of femoral stems.[28-34]

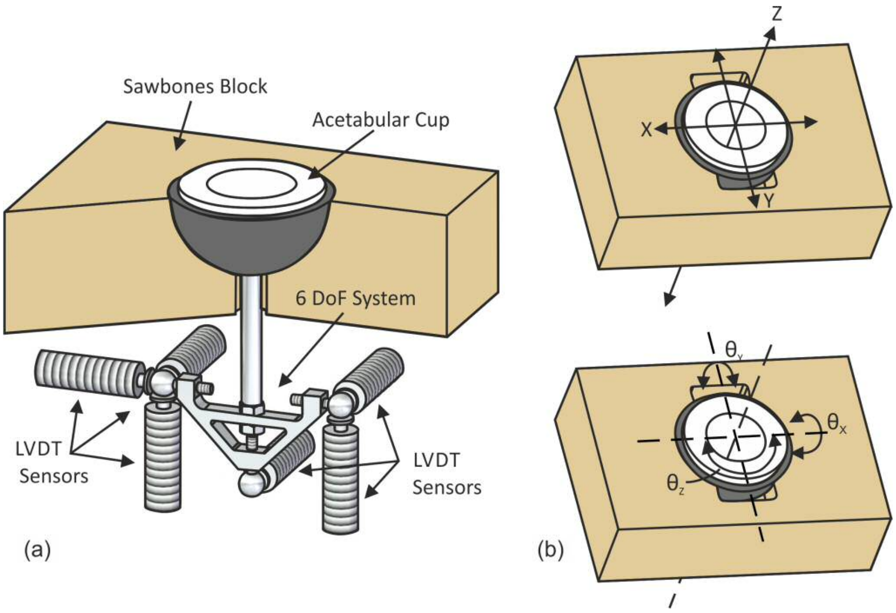

Figure 2. a: Setup to measure the six degree of freedom (DoF) of the acetabular componen. b: Six degrees of freedom of the acetabular cup.

The rig was inclined at 30° to the horizontal and the cup was loaded vertically with a 28 mm femoral head component attached to the single-axis hydraulic test machine (Figure 3(a)). The acetabular component was cyclically loaded in compression from 0.01 kN to 2.0 kN for 1000 cycles at a frequency of 1 Hz. The chosen maximum load corresponds to 2.5 times body weight of an 80 kg person.[35]

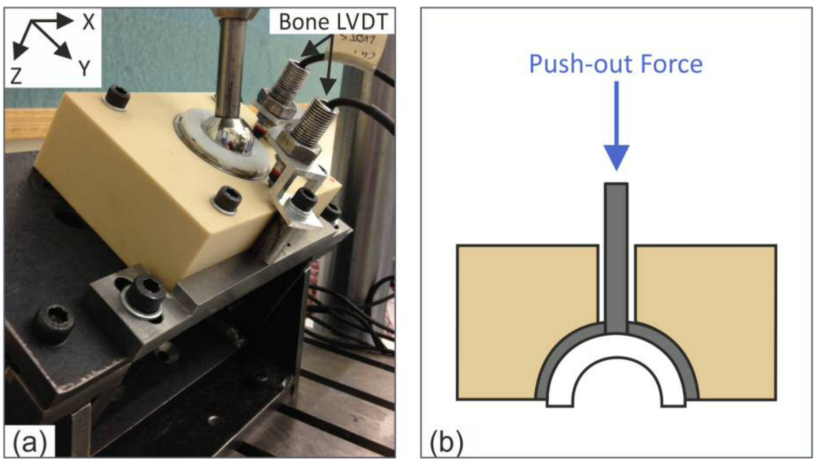

Figure 3. a: Cyclic loading of the acetabular cup in a High Density Spherical block. b: Diagram of the push-out test.

Elastic deformation of the foam was expected during cyclic loading. The six degree of freedom measurement system was connected to the cup via the dome screw hole, and the rig holding the LVDTs was attached at the bottom of the foam block. This meant that under loading, the measurements taken by the six degree of freedom system were a combination of both cup motion and elastic deformation of the foam blocks. For this reason, two extra LVDTs were placed on the Sawbones® blocks near the acetabular cup (Figure 3(a)) to measure its elastic deformation in the Z direction during cyclic loading (one superiorly and one posteriorly). In the case of the Physiological model, only the posterior LVDT was used to measure foam deformation as the foam at the superior measurement site was removed to model the radiolucent triangle.

Push-out test

Following the micromotion test, the acetabular cup was removed from the cavity using a uniaxial push-out test. Once removed from the micromotion measurement rig, the foam block with the implanted cup was placed upside-down, on a custom made rig, under the single-axis hydraulic test machine. The rod attached to the bottom of the cup, and protruding from the back of the foam block, was loaded in compression at a speed of 0.008 mm/s until the cup was dislodged from the cavity, and the peak failure load was recorded (Figure 3(b)).

Statistics

The number of foam blocks used per group was six (n = 6). However, one repeat from Low Density Physiological had to be omitted (n = 5) due to an error in the micromotion data collection.

The sample size was too small to prove normality, hence non-parametric tests were used. The Friedman and the Wilcoxon signed ranks post hoc tests ($\alpha = 0.05$) were used to assess the any difference amongst translations and rotations within the groups. Differences in micromotion and push-out forces when comparing density and acetabular geometry were assessed using the Mann-Whitney test ($\alpha = 0.05$). All analyses were carried out using SPSS (IBM, New York, USA).

Results

Sawbones® deformation

The mean elastic deformation of the Sawbones® foam blocks measured in the relative Z direction during the micromotion tests were: 44±5 µm superiorly and 43±5 µm posteriorly in High Density Spherical; 83±6 µm superiorly and 76±7 µm posteriorly in Low Density Spherical; 37±3 µm posteriorly in High Density Physiological; and 76±2 µm posteriorly in Low Density Physiological.

There were no significant differences in foam deformation between the posterior and superior measurement sites for both High and Low Density. Hence, comparison between the different groups was performed using the measurements obtained from the posterior LVDT only. Foam deformation was also not statistically different between Spherical and Physiological for both densities. However, foam deformation was significantly higher in Low Density compared to High Density for both acetabular geometries (Spherical: $P = 0.037$, Physiological: $P = 0.006$).

General pattern in micromotion

Similar patterns in micromotion were observed regardless of foam density or acetabular geometry (Figure 4). In translation, micromotions in X were always lower much lower than in Y and Z. In rotation, micromotions in θ_X were always the greatest while micromotions in θ_Z were always the smallest. The rotations were much smaller compared to the translations (0.08° in rotations corresponds to a 40 µm displacement in the direction of the arc of rotation for this specific implant geometry and size). Hence, it can be deduced that the main direction of motion of the cup was between the Y and Z translation, which closely matches the direction of loading.

Spherical versus Physiological acetabular geometry

There was a change in the dominant direction of micromotion when comparing acetabular geometry (Figure 4). Micromotion in Y was either significantly greater ($P = 0.046$) or similar to micromotion in Z in High Density Spherical and Low Density Spherical, respectively, while micromotion in Z was always significantly greater than that in Y for both High and Low Density Physiological ($P = 0.046$ and $P = 0.043$, respectively).

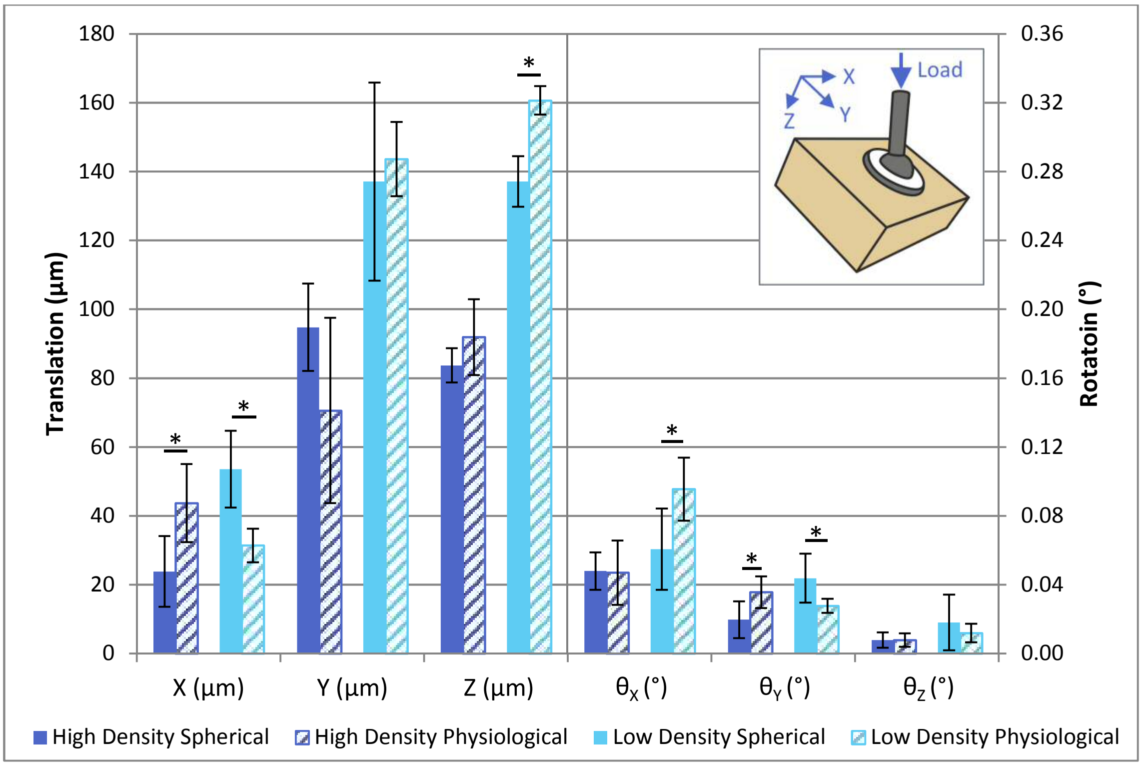

Figure 4. Comparing the micromotion of the acetabular cup in six degrees of freedom when implanted in Spherical and Physiological (0.08° corresponds to 40 µm with this specific implant). Values expressed as mean and standard deviation. * Statistically significant difference ($P = 0.05$) with Mann-Whitney test.

In general, micromotions tended to be higher in Physiological compared to Spherical (Figure 4). Micromotions in X and θ_Y were statistically greater ($P = 0.016$ and $P = 0.034$, respectively) in High Density Physiological compared to High Density Spherical. Micromotions in Z and θ_X were higher in Low Density Physiological compared to Low Density Spherical ($P = 0.006$ and $P = 0.041$, respectively). In contrast, micromotions in X and θ_Y were higher in Low Density Spherical than in Low Density Physiological ($P = 0.006$ and $P = 0.028$, respectively).

The push-out forces were significantly higher in Spherical compared to Physiological (Figure 5) for both densities (High Density: $P = 0.004$, Low Density: $P = 0.006$).

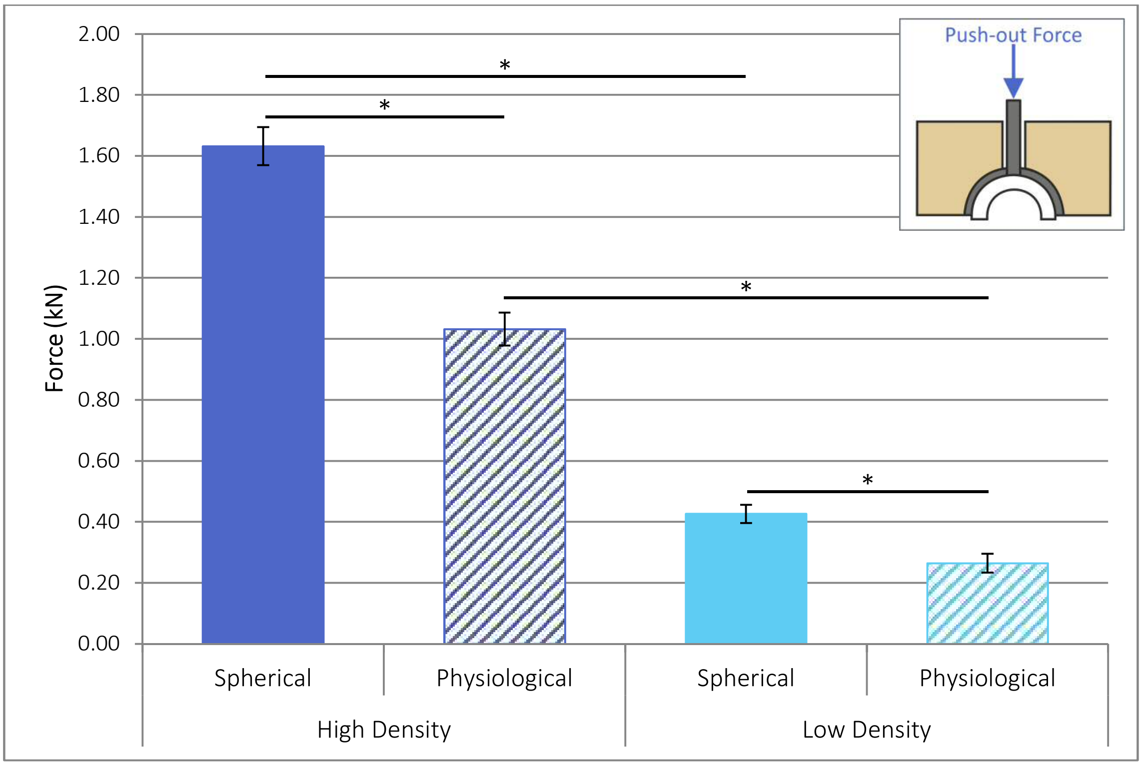

Figure 5. Comparing the cup push-out forces. Values expressed as mean and standard deviation. * Statistically significant difference ($P = 0.05$) with Mann-Whitney test.

High Density versus Low Density bone substrate

In general when comparing groups with the same acetabular geometry, the micromotion in Low Density was higher compared to that in High Density (Figure 6). In Spherical, the micromotion was statistically greater in all translations (X: $P = 0.006$, Y: $P = 0.025$, Z: $P = 0.004$) and in θ_Y ($P = 0.014$). In Physiological, the micromotion in Low Density was statistically greater than in High Density in Y, Z and θ_X ($P = 0.025$, $P = 0.004$ and $P = 0.008$, respectively). The exceptions to this trend was micromotion in X, which was statistically lower ($P = 0.045$) in Low Density Physiological compared to High Density Physiological.

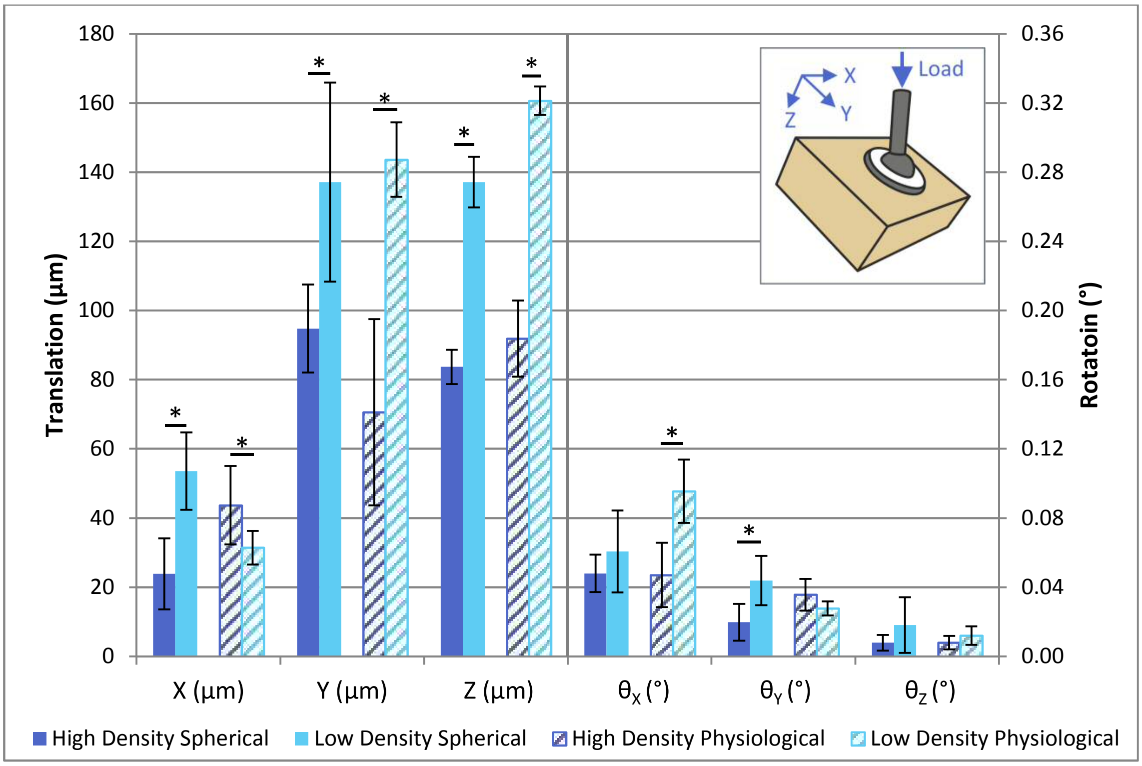

Figure 6. Comparing the micromotion of the acetabular cup in six degrees of freedom when implanted in High and Low Density foam blocks (0.08° corresponds to 40 μm with this specific implant). Values expressed as mean and standard deviation. * Statistically significant difference (P = 0.05) with Mann-Whitney test.

The push-out forces were significantly higher in High Density compared to Low Density (Figure 5) for both acetabular geometries (Spherical: P = 0.004, Physiological: P = 0.006).

Discussion

The aim of this study was to develop and assess a novel *in vitro* method to measure acetabular cup micromotion in six degrees of freedom under physiological loading to investigate the effect of bone density and of a more physiological acetabular model on cup stability. This study had three significant findings. Firstly, the results showed that using a spherical cavity to model the acetabulum may overestimate the stability of press-fit acetabular cups. Secondly, press-fit acetabular cups are less stable when implanted into weaker bone. Finally, micromotion of the cup is not dominant in one direction and therefore should be measured in the six degrees of freedom.

Elastic deformation of the Sawbones® foam blocks was measured in the Z direction during the micromotion tests. Foam blocks of the same density had similar levels of deformation regardless of the acetabular geometry. However, bone deformation was higher in Low Density than in High Density. This was because the Low Density foam blocks had a lower compressive strength. They were therefore more likely to undergo deformation than the High Density foam blocks under the same loading.

There was a substantial decrease in stability with the Physiological model compared the Spherical model: nearly all micromotions were greater and the push-out forces were smaller (Figures 4 and 5). As described previously, the press-fit relies primarily on peripheral fixation. The presence of the acetabular notch and the radiolucent triangle in the Physiological model reduced the available contact area at the rim between the bone substrate and the cup compared to the Spherical model (Figure 1(b)). The compressive stresses exerted at the rim of the cup were comparable between acetabular geometries because the cup was implanted with the same press-fit. Hence, the decrease in contact area resulted in a decrease in compressive forces around the cup rendering it less stable within the bone substrate. The reduction in contact area was also responsible for the change in direction of the dominant micromotion since there was less foam present to resist the load in the Z direction in Physiological compared to Spherical. There were some exceptions to this trend where some micromotions were greater in Low Density Spherical compared to Low Density Physiological. A possible explanation for this is that because of the weaker properties of the Low Density foam and the reduced amount of foam present in Physiological compared to Spherical, the cup embedded itself more into the foam. This may have increased its stability in directions of micromotion that were not affected by the loading cycles, such as X and θ_Y micromotions. Furthermore, they were small and none were in the direction of the dominant micromotion, therefore these micromotions are unlikely to contribute to implant loosening.

An objective of this study was to develop an acetabular model that replicated the important structural properties of the acetabulum as well as being easily reproducible and with low interspecimen variation. The Physiological model is easily manufactured and better replicates the structural support present in the acetabulum compared to the Spherical model. A similar model to Physiological was validated in another study using cadaveric pelvic bones[36]. Furthermore, the use of Sawbones® foam blocks and a CNC machine to manufacture the acetabular cavity ensured low interspecimen variability in both mechanical properties and acetabular cavity geometry. It can therefore be assumed that the data from the Physiological model are the more appropriate ones. It is therefore likely that the simplified Spherical cavity over-estimated the stability of press-fit cups.

There was a clear decrease in stability of the cup when it was implanted in Low Density compared to High Density foam blocks: micromotions tended to be greater and push-out forces were smaller (Figures 5 and 6). There was one exception in Physiological where micromotion in X was higher in High Density compared to Low Density. Here again, this can be explained by the cup embedding itself more in the weaker foam and therefore is more stable in the direction unaffected by the loading cycles.

There were some exceptions in High versus Low Density Physiological, but these micromotions were below the 40 µm and 0.08° limit (using trigonometry, 0.08° of rotations equates to 40 µm of micromotion for all rotations with this specific implant). These motions should therefore not inhibit osseointegration. As previously discussed, foam deformation was greater in Low Density than in High Density. This resulted in smaller compressive stresses around the rim of the implant. Therefore, the cup implanted into an acetabulum with weaker bone would be less stable and therefore more likely to become loose than when implanted in normal bone. This finding is in agreement with other studies assessing cup stability using both cadaveric pelvic bones and Sawbones® foam blocks.[13, 14, 17, 23, 37]

Micromotions measured using the high density foam blocks in this study were comparable to those measured in other studies which use cadaveric pelvic bones. In one study, Kwong et al.[38] measured the stability of a 1 mm press-fit cup using a rod attached to the dome of the cup. Only the micromotion along the axis of the rod was measured, which was equivalent to the Z micromotion in this study. Their study reported a mean micromotion of 40 µm, which is smaller than the micromotion reported here. This difference can be attributed to the lower load used (1.112 kN) in their study and that the measurements did not include bone deformation. Stiehl et al.[39] reported micromotions below 125 µm for 1 mm press-fit cups, similar to the micromotions measured in this study. Finally, Won et al.[6] reported micromotions between 16 µm and 46 µm for 1 mm press-fit cups. These micromotions were equivalent to the resultant micromotion in the X and Y direction in this study (Figures 2 and 4). The micromotions are slightly higher in this study, probably due to the higher load used (1.5 kN vs. 2.0 kN).

This study is the first to accurately measure and report the micromotion of the acetabular component in six degrees of freedom. Previous studies either measured the micromotion of the cup only in one direction and/or one rotation, or reported the resultant micromotion.[6, 37-42] Most studies reported in the literature only include measurement of the micromotion in the Z direction, based on the assumption that it is dominant. This study, however, showed that this was not always the case (Figure 4). For this reason, it is essential to consider all degrees of freedom when investigating micromotion of press-fit cups.

The push-out forces measured in this study (Figure 5) are similar to the pull-out forces reported by Antoniades et al.[23] using the same implant and similar foam blocks with a spherical cavity (densities: 0.45 g/cm³ and 0.22 g/cm³). For the 1 mm press-fit component implanted in the high density substrate, their mean pull-out force was 1.553 kN. The push-out forces recorded in this study have a similar mean force and are within their range of values (1.039 kN – 2.195 kN). For the cup implanted in the low density substrate, the pull-out forces recorded were higher (mean = 0.668 kN) than in this study. This is because the cup was inserted with a 2 mm press-fit instead of a 1 mm press-fit.

There were some inherent limitations as this was a bench-top study using polyurethane foam blocks as a bone substrate and micromotion reported were the sum of micromotion of the cup and elastic deformation of the foam. The foam blocks used in this study only model trabecular bone and do not replicate the rim of cortical bone present at the periphery of the acetabulum. The absence of this cortical bone may affect the overall stability of the acetabular cup however, previous studies have reported similar results when comparing Sawbones® foam blocks and cadaveric pelvises[14-16], and Jin et al.[36] showed that the geometry used for the Physiological model best recreates the mechanical and structural properties of the acetabulum. The micromotion of the foam was measured in the Z direction and the results were consistent with elastic deformation of the foam under load. Therefore, even though the micromotions reported in this study overestimate the true micromotion of the acetabular cup, comparisons between each group can still be made. Hence, this testing method can be used to assess changes in cup design and provide an insight on what happens *in vivo*.

Conclusions

The novel *in vitro* method presented in this study offers an insight into the behaviour of press-fit acetabular components under physiological loading. This method also provides a more accurate method to investigate cup stability compared to the simplified methods currently more widely used. Comparison of the results between the two different acetabular geometries shows that the spherical cavity over-estimates the stability of the cup; therefore a more physiological model should be used to assess *in vivo* risk of failure. Finally, the results indicate that cups inserted into weaker, e.g. osteoporotic, bone would be more prone to micromotion. For this reason, it may be recommended that either additional fixation, such as screws or pegs, or cement be used in patients with weaker bones. This method should form the basis of a key method for pre-clinical testing.

Funding

This study was supported by the Victoria Wells PhD Studentship in collaboration with the Enid Linder Foundation.

Acknowledgments

The acetabular component was donated by Stryker UK.

Declaration of conflicts of interest

The authors declare that there is no conflict of interest.

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