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In vitro examination of the primary stability of three press-fit acetabular cups under consideration of two different bearing couples

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Backround: For preclinical statements about the anchoring behavior of prostheses, the primary stability of the prosthesis is of special importance. It was the aim of this study to examine and compare the relevant relative micromotions of three different acetabulum prostheses by introducing three-dimensional torques.
Methods: The cups were implanted under standard conditions into an anatomical artificial bone model. Three-dimensional torques were applied to the acetabular cups. Taking into account the resulting frictional moments of two different bearing couples, ceramic-on-ceramic and ceramic-on-polyethylene, the relative micromotions of the cups were recorded as maximum total micromotion, translational and rotational micromotion, and the primary stability values of the three cups were compared.
Results: Relative micromotion of all cup models was always significantly smaller with the CoC bearing couples than with the CoP bearing couples ($p < 0.001$). The rotational micromotion was always lower ($p < 0.001$) than the translational micromotion, and the rotational as well as the translational micromotions were each always lower than the maximum total micromotion ($p < 0.001$, $p < 0.010$). The thinnest-walled cup system always showed the largest relative micromotions.
Conclusion: The results of our study can be interpreted as indicating that the low relative micromotions of all cups – irrespective of the use of CoC or CoP bearing couples – are within an acceptable range favoring secondary osseointegration of the implants. Furthermore, we were able to show that the cup wall thickness and the surface quality of the cup systems have an influence on the primary stability and the elastic deformability of the examined cup systems.

1. Introduction

Each year, more than 1000,000 total hip replacement (THR) systems, consisting of a stem and an acetabular component, are implanted worldwide [1]. It is therefore not surprising that THR is considered the operation of the century [2]. However, there are always complications that lead to premature failure of the components. The main reason for the failure of both stem and acetabular components is aseptic loosening [3,4], which is mainly due to a lack of initial osteointegration of the implant [5,6] or due to osteolysis caused by polyethylene wear debris [7] in the long term. Primary stability of the implant is considered the most important predictor of good osteointegration of the stem and of the acetabular component [8]. Thus, it makes sense to examine implants preclinically in so-called hip simulator studies in order to be able to evaluate statements about the osseointegration behavior of the implants. In recent decades, in vitro primary stability analysis has become an established preclinical assessment tool [9–20]. However, in these studies, among other things, different hip simulators with different loads and load directions as well as different bone models have been analyzed, so that often a comparison of the results has proved to be rather difficult. In a previous study, we reported on a new concept of a 3D-measuring acetabular simulator set-up [11], which has been extended and optimized within the framework of the present study. One optimization of our set-up was the use of an anatomical bone model with cranial and caudal notches as often used in the literature [21–24] instead of a simplified spherical bone model. Furthermore, it was the aim of this study to investigate the influence of friction moments of two different bearing couples which are commonly used at total hip replacement – in this case ceramic on polyethylene (CoP) and ceramic on ceramic (CoC) – on the primary stability of three

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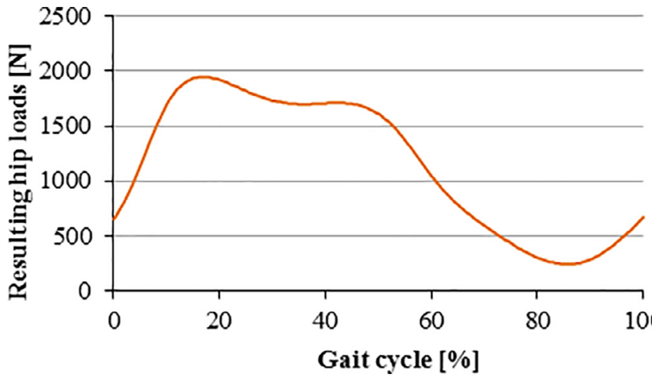

Fig. 1. Resulting hip loads [N] during gait cycle.

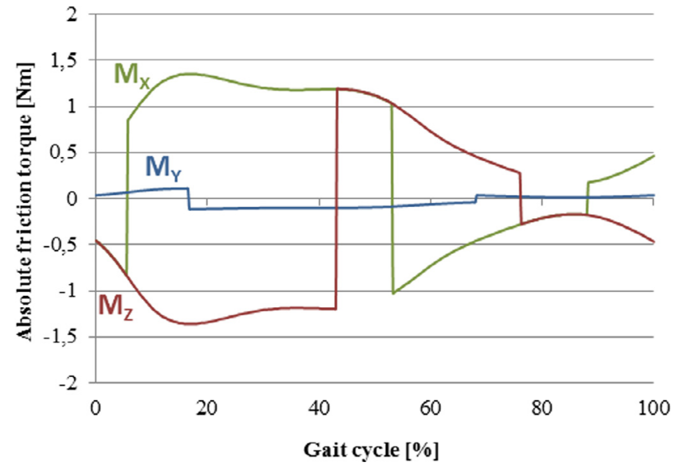

Fig. 2. Calculated frictional torque curves [Nm] during gait cycle.

different cementless acetabular cups, taking into account the relative micromotions and comparing them preclinically.

2. Methods

2.1. Theoretical background

The frictional forces of the physiological gait cycle at the X, Y, and Z levels have been calculated on the basis of the forces acting on the acetabular cup measured by Bergmann et al. [25] and the average friction factors as they are common in the orthopedics sector. The speed-independent and constant friction coefficient was set at μCoC = 0.044 for ceramic-on-ceramic bearing couples (CoC) and at μCoP = 0.063 for ceramic-on-polyethylene bearing couples (CoP). These tribological properties were investigated by Brockett et al. [27] both on CoC and CoP bearing couples which in orthopedics are commonly used, in 25% bovine serum lubrication, which is the ISO standard for tribological in vitro tests of artificial friction couples of the hip joint. Against this background, the friction coefficients of Brockett et al. are being used hereinafter. Furthermore, these values correspond to average values also found in literature (range CoC: 0.02–0.10, CoP: 0.05–0.08) [11,26–29]. In order to obtain the frictional torque acting in the artificial hip joint with CoC and CoP bearing couples, 400 interpolated force values occurring under physiological load [25] were determined (Fig. 1) and multiplied by the two friction coefficients μCoC and μCoP. The respective physiological friction force curves were calculated based on these values. The resulting friction torques were determined from these frictional forces, taking into account a 32 mm femoral head. Subsequently, the directions of rotation of the acting moments were determined by means of a standardized gait cycle (Fig. 2). Here, only the maxima and minima of the angular positions of the hip joint under flexion and extension, adduction and abduction as well as internal rotation and external rotation were considered, since these represent the turning points of the sense of rotation. Furthermore, the resulting torques for taking into account the inclinational and anteversional positions of the acetabular cup were transformed according to Lewinnek et al. [30].

2.2. The acetabulum simulator

The calculated torques around the transformed X, Y, and Z axes were applied onto the acetabular cup using three ISK 3104.30/230 synchronous servomotors (IGAS, Echterdingen, Germany). The servo motors have a standstill torque of 3.7 Nm, a nominal torque of 3.0 Nm and a maximum torque transmission of 11.0 Nm. The average deviation between nominal and actual torques of all axes combined of CoP is 0.035 ± 0.015 Nm (9.1 ± 1.7%) and of CoC 0.023 ± 0.010 Nm (10.0 ± 4.0%). The deviation repetition of CoP is 0.014 ± 0.006 Nm (4.1 ± 1.6%) and of

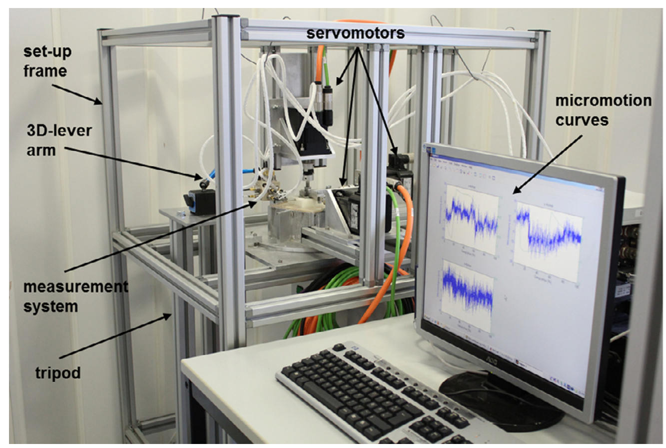

Fig. 3. Overview of the 3D-measuring acetabular simulator set-up.

CoC 0.011 ± 0.004 Nm (5.2 ± 4.0%). The servomotors were placed orthogonally to each other and represent the transformed acetabular coordinate system. In order to apply the M_X, M_Y and M_Z torques onto the acetabular cup, a 3D lever arm was attached to the cups and connected with the servomotors (Fig. 3) via low friction couplings (Giunti Oldham GOS-32, Orbit GmbH, Wolfenbüttel, Germany) [11].

2.3. Prostheses

The Plasmafit® acetabular cup system (BBraun, Aesculap, Tuttlingen, Germany) is a cement-free, press-fit cup made of a Ti-6Al-4 V alloy. Thanks to its special surface coating, which consists of a porous pure titan alloy with precise and fine tooth geometries, and the roughness resulting thereof, this cup system is designed to facilitate osteointegration. The wall thickness of the Plasmafit® cup has an average of 4.9 ± 0.1 mm. The Trinity® acetabular implant (Corin Group PLC, Cirencester, England) is also made of a Ti-6Al-4 V alloy and is used as a cementless, press-fit implant. The implant has a pure titan coating applied by vacuum plasma, which in turn is covered with a bioactive calcium phosphate coating of microcrystalline structure and has an average equatorial cup wall thickness of 5.4 ± 0.1 mm. The EcoFit® EPORE® acetabulum is a cement-less, press-fit acetabular cup that also consists of a Ti-6Al-4 V alloy exhibiting a stochastic open-cell surface modification produced by selective melting of powder materials. This surface structure has a porosity of 60%, a rod thickness of 330–390 µm and a relative Young's modulus of 3 GPa. The wall thickness of the cup

Fig. 4. The examined cup models (a) Plasmafit®, (b) Trinity® and (c) EPORE®.

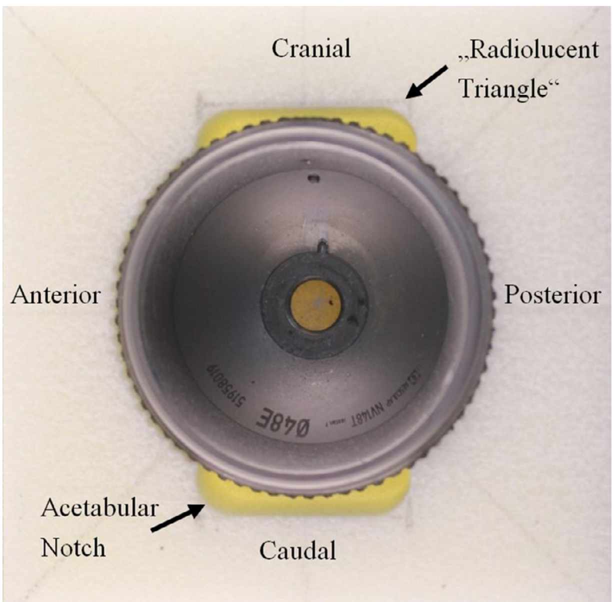

Fig. 5. The anatomical bone model with notches.

is 6.0 ± 0.1 mm. The present study series analyzed all acetabular cup models with a cup size of 48 mm (Fig. 4).

2.4. Bone model and implantation

A bone model which is based on the anatomical acetabular geometry was examined. The artificial bone models, serving as a substitute for the cancellous bone of the human pelvis, were made of a polyurethane foam (ROHACELL® 200WF, Evonik Goldschmidt GmbH Rewo, Steinau an der Strasse, Germany) with a Young's modulus of 350.0 MPa and a density of 221.7 kg/m^3 and thus with mechanical properties similar to the human acetabulum (bone density: 348.3 ± 173 kg/m^3, Young's modulus: 116.4 ± 86.7 MPa) [31]. Milling of the anatomical bone model site was performed under standardized conditions with a self-centering drilling machine with a speed of 150/min and a feed rate of 10 mm/min using the original instrumentation. The anatomical bone model was provided with a caudal and a cranial notch each with a width of 27 mm in the a-p direction, a total height of 52 mm from cranial to caudal and a depth of 22 mm [10,21,22,24] using a precision milling machine to create a so called two-point pinching cavity [21]. Subsequently, spherical milling was carried out providing a press-fit of 1.5 mm. Afterwards, the cups were implanted each into $n = 5$ bone foams (Fig. 5) under standardized conditions using a guided dropweight ($m = 2.5$ kg). The weight was dropped three times from a rod level of 1.0 m and three times from 0.5 m. After implantation of the cups the bone foam was rigidly fixed with plaster and the cup-bone compound was adjusted into the 3D-measuring acetabular simulator set-up.

2.5. Measurement method

During the simulation of the physiological gait, a measurement system consisting of nine eddy current sensors type NCDT 3010-S2 (Micro-Epsilon Messtechnik GmbH & Co. KG, Ortenburg, Germany), with an individual resolution of 0.1 µm, continuously recorded the micromotions of the cup and the bone foam [11,19]. The sensors are mounted in an outer coordinate system in the form of an adjustable measuring frame. Depending on the torques applied, the relative micromotions of the bone and that of the acetabular cup are measured at a measuring point on the equatorial cup rim. For recording these relative micromotions, the measurement cube is connected to a measuring pin and the relative micromotion of the acetabular cup in the main anchoring zone is recorded in the equatorial press-fit area.

In order to fix the measuring system in the cup and in the bone foam, prior to implantation, a hole with a diameter of 1.9 mm was drilled into the acetabular cups. The measuring pin was fixed in this hole with superglue. The hole was set 8 mm below the cup rim in the area of the equatorial press-fit. In order to measure the spatial micromotions of the bone foam, the foam was initially left with a remaining foam wall thickness of 5 mm between measuring pin and acetabular cup. After the bone foam measurements, an irreversible recess of 7 mm diameter was made so that the cup and the existing cup hole were exposed and thus could be measured. The measuring cube was attached to the measuring pin, which in turn was fixed with superglue either on the dorsal and cranial bone foam measurement point or on the cranial acetabular cup measurement point (Fig. 6). The measuring frame was parallelly aligned to the measuring cube, resulting in an orthogonal measuring distance of 1.0 mm for each sensor. In each case, $n = 50$ gait cycles with $n = 3$ measurement repetitions were applied onto the acetabular cup and the micromotion of both the acetabulum and the bone foam were recorded. For quantitative assessment of the primary stability, we used the maximum total micromotion, the translational and rotational micromotions of the cup as well as those of the bone foam. From these micromotions, each differences of the maxima between bone foam and cup are determined. The resultant maximum total micromotion was calculated by vectorial summation of the simultaneous maximum translational and the maximum rotational relative micromotions by point-to-point comparison of the mean micromotion value curve of the gait cycle [11].

2.6. Statistics

The results are shown as mean values of the maximum total micromotion, rotational as well as translational micromotion of all cups, including the related standard deviation (SD), depending on the respective bearing couples. In order to detect potential differences between the respective cup models, taking into account their relative micromotions, we used a multi-factorial variance analysis with log transformed original values. The paired comparisons were performed using an LSD post-hoc test and adjusted on the basis of multiple testing by means of the Sidak correction. A p-value $< .05$ was considered statistically significant.

3. Results

The relative micromotion of all cup models was always significantly smaller with the CoC bearing couples than with the CoP bearing couples ($p < .001$) due to lower friction forces of CoC. Even the respective type of motion was always significantly different. The rotational micromotion was always lower ($p < .001$) compared to the translational micromotion, and the rotational as well as

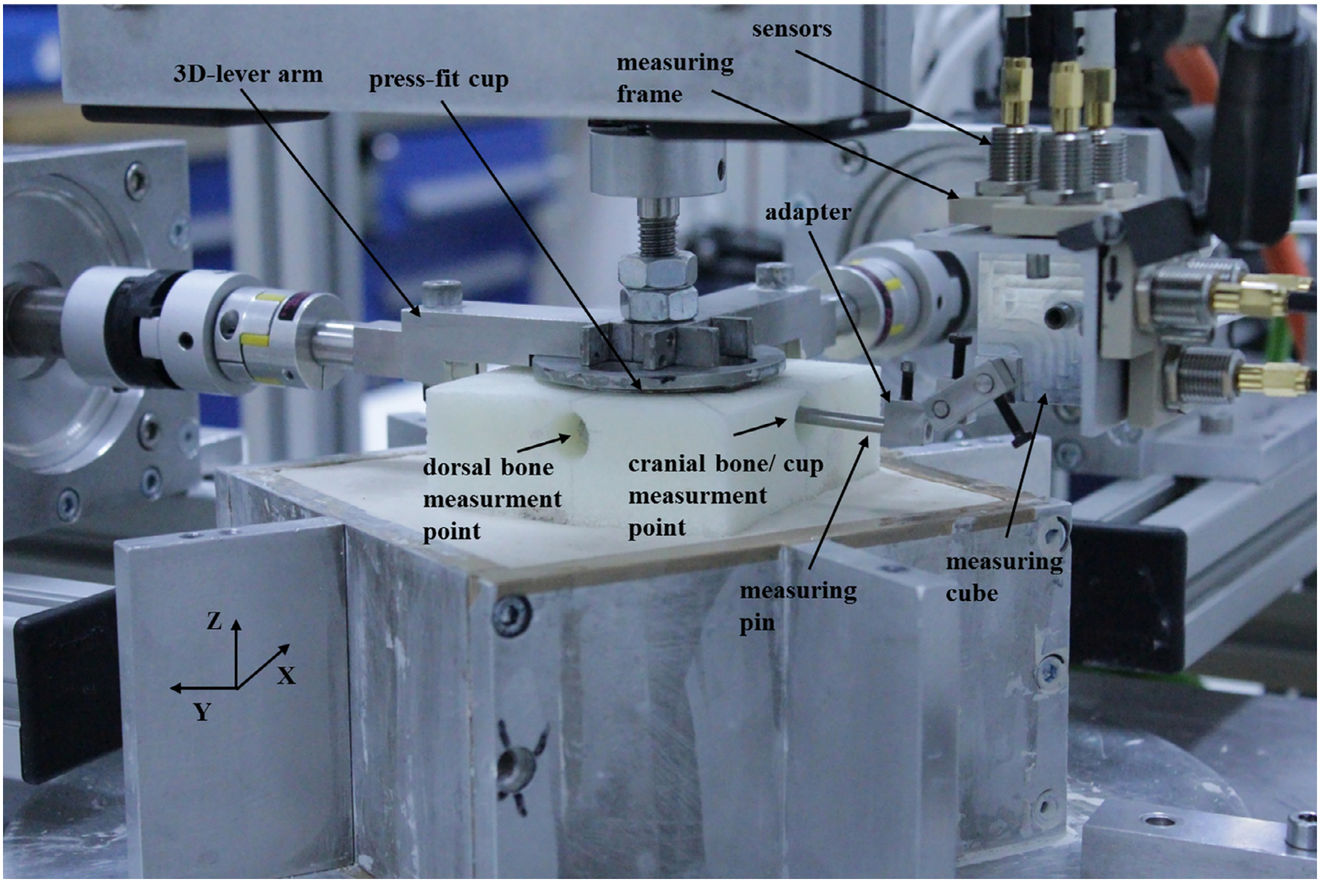

Fig. 6. The measuring principle in detail.

Table 1
Absolute values of the maximum total micromotion, the rotational as well as the translational micromotion of the acetabular cups. Small superscript letters indicate the *p*-values in pairwise comparison between the prostheses.

	CoC				CoP			
	Plasmafit®	Trinity®	EPORE®	*p*-values	Plasmafit®	Trinity®	EPORE®	*p*-values
Rotation [μm] ± SD	20.86± 3.04^{a,b}	15.75± 1.82^{a}	15.16± 0.95^{b}	a = 0.013; b = 0.004	31.34± 4.03^{a,b}	22.79± 2.69^{a}	23.14± 1.47^{b}	a = 0.003; b = 0.006
Translation [μm] ± SD	69.53± 6.25^{a,b}	48.61± 2.65^{a}	52.96± 5.60^{b}	a = 0.001; b = 0.014	105.06± 9.77^{a,b}	71.57± 2.85^{a}	81.08± 9.60^{b}	a<0.001; b = 0.021
Total motion[μm] ± SD	76.60± 7.52^{a,b}	53.17± 2.78^{a}	57.81± 5.91^{b}	a = 0.001; b = 0.011	115.91± 11.21^{a,b}	78.57± 3.93^{a}	88.74± 10.01^{b}	a<0.001; b = 0.017

the translational micromotions were always lower than the maximum total micromotion ($p < 0.001$, $p < 0.010$), as we would have expected.

Table 1 lists the maximum total micromotions and the translatational as well as rotational maximum micromotions. In each case, these result from the subtraction of the maxima of $n = 50$ gait cycles of averaged micromotion curves between the bone foam and the acetabular cup. The superscript letters represent the indicators of the *p*-values of the paired comparisons. The Plasmafit® cup consistently has the largest relative micromotions (total movement CoC=76.60 ± 7.52 and CoP=115.91 ± 11.21) in the bone-implant interface compared to the EPORE® (total movement CoC=57.81 ± 5.91 and CoP = 88.74 ± 10.01) and the Trinity® cup (total movement CoC=53.17 ± 2.78 and CoP=78.57 ± 3.93), regardless of the bearing couples or the type of motion. No significant differences can be detected between the EPORE® and the Trinity® cup (Table 1).

4. Discussion

The results of our study show that the rotational type of motion consistently causes the lowest relative micromotions and is substantially lower than the translational component. The maximum total micromotion resulting from the summation of these two simultaneous motion types is the largest motion type of each cup system. We were able to show that the relative micromotions of the CoP bearing couples always were larger than those of the CoC bearing couples, as we would have expected. As a logical consequence, these findings result from the higher friction torques of the CoP bearing couples, which in turn are due to the higher friction coefficient of $\mu CoP = 0.063$ vs. $\mu CoC = 0.044$. This has already been proven in a previous study, in which the initial commissioning of the test set-up used in the present case was described in detail [11].

The working group Crosnier et al. investigated a direct comparison between a spherical and an anatomical bone model, taking into account various bone densities. For the spherical bone model with high density, they could show that the translational relative micromotion on all axes was on average about 67.0 ± 40.2 µm. On the other hand, the anatomical model with high bone density showed 72.0 ± 17.5 µm. For the low bone density spherical bone model, the average relative micromotion was 107.67 ± 47.3 µm and for the low bone density anatomical bone model it was 112.33 ± 70.22 µm. Regardless of the respective bone density, Crosnier et al. were also able to show that the maximum rotational relative micromotions were lower than 40 µm. Only the rotational micromotion around the X-axis of the anatomical bone model with low density was greater than 40 µm. They concluded that loss of primary stability of the acetabular cup in the anatomical model is more in line with real clinical conditions and that the use of a simplified spherical bone model is therefore inadequate [23].

Regardless of the bone density or material properties of the bone foam used in the present study, these results are quite comparable. Our current study findings also indicate that the anatomical model with its caudal and cranial notch has an influence on the anchoring of the acetabular cups and thus may lead to more realistic results compared to our predecessor study where we examined a spherical bone model. It has been shown that the anatomical bone model - regardless of the particular cup model, the bearing couples and the respective type of motion - causes increased relative micromotions in the bone-implant interface [11,23]. This finding can be explained by the reduced equatorial contact surface between cup and bone, which is based on the human anatomy, and by the reduced press-fit resulting thereof. The anatomical bone model should therefore continue to be used in following studies. This statement is supported by the comparability of the measured relative micromotions with the results of further in vitro and FEM studies with micromotions in a range between 20–160 µm testing the primary stability of different cup designs [9,10,13,23,32].

In general, comparing all cup systems we could show that the Trinity® cup behavior was almost equivalent to the EPORE® cup behavior, regardless of the type of movement and the respective bearing couples, and thus an identical osteointegration behavior can be assumed. Only the Plasmafit® cup deviated slightly but consistently from the other two cups, regardless of the type of motion and the bearing couples, and it consistently exhibited higher relative micromotions in the bone-implant interface.

This might be explained by greater rigidity of these other two cups due to larger cup wall thicknesses and thus an increased press-fit in the bone-implant interface or by different frictional forces due to the different surface structures of the acetabular cups. Thus, the Plasmafit® cup has a lower wall thickness compared to the other two cup systems, which consequently also leads to a higher deformability of the cup under load conditions. Although the absolute wall thickness of the EPORE® is significantly higher than that of the Trinity® cup, the EPORE® cup has an open-cellular macrostructure with a relatively low Young's modulus of 3 GPa, thus approaching in its periphery the periprosthetic cancellous structure. This in turn could lead to a slightly higher elastic deformability of the EPORE® cup in the bone-implant interface and, consequently, to marginally higher relative micromotions of the implant compared to the Trinity® cup, although the latter has a smaller wall thickness.

Due to the notches of the anatomical bone model and due to the relative small cup wall thicknesses, the Plasmafit® cup has higher elastic deformability and consequently more relative micromotions, while the other two cup systems may compensate the applied forces thanks to their rigidity which is due to the thicker walls and their surface quality.

5. Limitations

It is a limitation of our study that a constant and simplified friction model was used, although in vitro and in vivo studies have shown that during the human gait cycle, a speed-dependent and dynamic coefficient of friction is effective [26–29,33]. Nevertheless, the coefficients of friction used in this study are still in the range of the studies already mentioned. In addition, the maximum resulting friction coefficients (CoP = 1.9 Nm) used here are comparable with values from literature (for example CoP = 1.8 Nm) [33]. The applied friction torques of our study result from in vivo measured forces and kinematics of a hip joint and were taken into account in the calculation of the friction coefficients [14,27]. The application of three hip joint forces could probably reduce the cup motion and therefore the cupś primary stability would improve. Nevertheless, the results of our study are comparable with the results of other studies [9,10,13,23,32] so that we are convinced that the resulting torques have a greater impact on the primary stability of the cups than axially induced forces. The present study is an in vitro study using a bone-like polyurethane foam to reduce the variability. Statements about biological bone remodeling processes, that is, the demonstration of a possible osteointegration of the implants, are therefore only conditional and should be confirmed in clinical long-term studies or registry data.

6. Conclusions

The present in vitro measurement set-up for the determination of relative micromotions of different acetabulum cup systems is a novel concept of preclinical analysis of acetabular primary stability. The results of our study can be interpreted as indicating that the low relative micromotions of all cups – irrespective of the use of CoC or CoP bearing couples – are within an acceptable range favoring secondary osseointegration of the implants. Finally, we were able to show that the cup wall thickness and the surface quality of the cup systems have a significant influence on the primary stability and the elastic deformability of the examined systems. However, whether a stiffer cup or a more elastic one would be beneficial should be investigated in further in vitro studies and validated by long-term clinical studies.

Declaration of conflicts of interests

The authors declare that there is no conflict of interest.

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Competing interests

None declared.

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Ethical approval

Not required.

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