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ORIGINAL ARTICLE

Dual mobility hip arthroplasty wear measurement: Experimental accuracy assessment using radiostereometric analysis (RSA)

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KEYWORDS
Radiostereometric Analysis (RSA);
Total Hip Arthroplasty (THA);
Wear;
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Summary
Introduction: The use of dual mobility cups is an effective method to prevent dislocations. However, the specific design of these implants can raise the suspicion of increased wear and subsequent periprosthetic osteolysis.
Hypothesis: Using radiostereometric analysis (RSA), migration of the femoral head inside the cup of a dual mobility implant can be defined to apprehend polyethylene wear rate.
Study objectives: The study aimed to establish the precision of RSA measurement of femoral head migration in the cup of a dual mobility implant, and its intra- and interobserver variability.
Material and methods: A total hip prosthesis phantom was implanted and placed under weight loading conditions in a simulator. Model-based RSA measurement of implant penetration involved specially machined polyethylene liners with increasing concentric wear (no wear, then 0.25, 0.5 and 0.75 mm). Three examiners, blinded to the level of wear, analyzed (10 times) the radiostereometric films of the four liners. There was one experienced, one trained, and one inexperienced examiner. Statistical analysis measured the accuracy, precision, and intra- and interobserver variability by calculating Root Mean Square Error (RMSE), Concordance Correlation Coefficient (CCC), Intra Class correlation Coefficient (ICC), and Bland-Altman plots.
Results: Our protocol, that used a simple geometric model rather than the manufacturer's CAD files, showed precision of 0.072 mm and accuracy of 0.034 mm, comparable with machining tolerances with low variability. Correlation between wear measurement and true value was excellent with a CCC of 0.9772. Intraobserver reproducibility was very good with an ICC of 0.9856, 0.9883 and 0.9842, respectively for examiners 1, 2 and 3. Interobserver reproducibility was excellent with a CCC of 0.9818 between examiners 2 and 1, and 0.9713 between examiners 3 and 1.

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Discussion: Quantification of wear is indispensable for the surveillance of dual mobility implants. This in vitro study validates our measurement method. Our results, and comparison with other studies using different measurement technologies (RSA, standard radiographs, Martell method) make model-based RSA the reference method for measuring the wear of total hip prostheses in vivo.

Level of evidence: Level 3. Prospective diagnostic study.

Introduction

The use of dual mobility cups is effective in avoiding dislocations, as indicated in recent publications [1—6]. However, their specific design increases the surface subjected to friction and can raise the suspicion of increased wear and periprosthetic osteolysis. In total hip arthroplasty (THA), the usual wear rate with metal-polyethylene friction torque is between 0.1 and 0.2 mm/year [7]. Dumbleton et al. [8] demonstrated that osteolysis rates correlated with wear rates and size of debris, and also that osteolysis was rarely observed when wear was less than 0.1 mm/year. To date, there have been few in vivo evaluations of dual mobility cup wear [4,9]. On standard anteroposterior views, the femoral head is the most often invisible because of the metal back, which makes measurement difficult. Radiostereometric analysis (RSA), developed by Selvik in the early 1970s [10], enables precise measurement of femoral head penetration in the acetabular component (representing bedding, wear and creep) [11,12]. This is currently a reference method for quantification of THA wear [13]. This study aimed to establish the precision of radiostereometric measurement of femoral head migration in the implant dual mobility cup, and intra- and interobserver variability.

Materials and methods

Experimental model

A dual mobility THA phantom implanted in synthetic bone (Sawbones™, Pacific Research Laboratories, USA) was built for this study (Fig. 1). A replica of the pelvis in which the cup corresponding to the mobile part of the assembly was impacted, and a replica of a left femur in which the femoral component was implanted. The Novae E™ (Serf, Décines, France) metal back acetabular component in stainless steel (X18M25W), dual-coated with alumina (Al_2O_3) and hydroxyapatite ($CA_{10}(PO_4)_6(OH)_2$), 57 mm in diameter, was positioned in 45° abduction and 15° anteversion, to reproduce the usual implantation in vivo. This was a dual mobility cup with two concentric articulations. The external surface of the metallic cup had an equatorial zone with macrostructure in relief, and a slightly flattened polar zone (of 0.5 mm) to free constraints leading to expulsion (Fig. 2). Four different mobile polyethylene liners (PE-UHMW) were used. All had an exterior diameter of 50.6 (±0.1) mm. The femoral component was a size 11-3 Dédicace ™ stem (Stryker, Pusignan, France), associated with a modular V40™ head 22.2 mm in diameter with a standard neck in stainless steel alloy (Orthinox™, Pusignan, France).

To simulate polyethylene liner wear, specially manufactured liners were used, with different concentric wear of the small articulation. Ordered directly from the manufacturer (Serf, Décines, France), and processed to the same tolerances as standard liners, these four liners measured either 0 mm, 0.5 mm, 1 mm, or 1.5 mm more than the internal diameter of a standard liner of 22.4 mm. Concerning the measurements, these corresponded to femoral head penetration of 0 mm, 0.25 mm, 0.5 mm and 0.75 mm, respectively. The four liners all had an external diameter of 50.6 (±0.1) mm; thickness of the polyethylene was thus 14.01 mm, 13.76 mm, 13.51 mm and 13.26 mm, respectively. The entire assembly bore a load of 200 N to simulate standing position.

Protocol for repetition of radiostereometric films

A series of radiostereometric films were performed: one series corresponded to films of the four different implants (with 0 mm, 0.5 mm, 1 mm and 1.5 mm wear). Seven different series were performed, on different days, each time under different conditions of model positioning in relation to the calibration cage. The RSA setup (placement of X-ray beam tubes and the calibration cage) was new for each series. All the series were analyzed 10 times by each examiner. The results represented migration of the center of the femoral head compared with the center of the cup. As recommended in previous studies [20], migration was expressed in millimeters (mm), as for global migration (corresponding to Maximum Total Point Motion [MTPM] in English-language articles), equivalent to the sum of migrations:

$$\text{global migration} = \sqrt{(x_i \times x_i) + (y_i \times y_i) + (z_i \times z_i)}.$$

Three examiners reviewed the images: an experienced examiner (Ex 1) specially trained in MBRSA technology at the Leiden University in the Netherlands; a trained examiner (Ex 2), and an inexperienced examiner (Ex 3). All performed independent and non-consecutive measurements; they were blinded to the level of wear.

Radiostereometric measurements

The model was placed in the center of the RSA assembly that consisted of two synchronized X-ray tubes, placed at approximately 1.5 m from the digital films. The assembly comprised a tube integrated in the examination room (Siemens Iconos R200), and a mobile device (Siemens Mobilett XP). Each X-ray beam was directed towards a different film with an angle of approximately 20° compared to the perpendicular [14]. A carbon calibration cage was positioned between

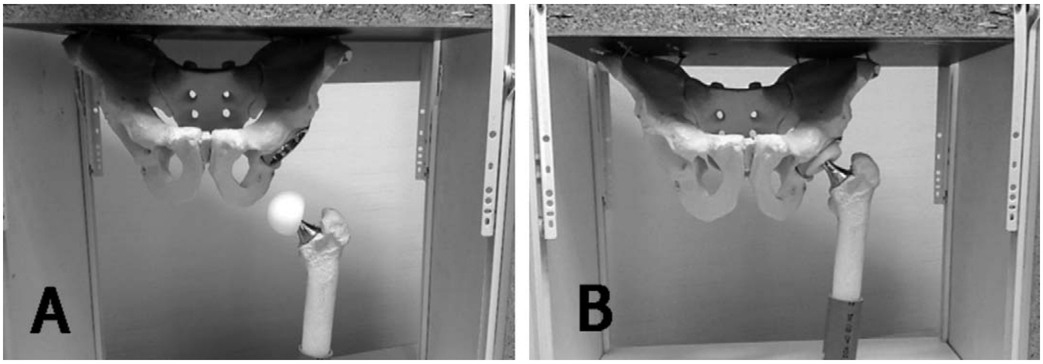

Figure 1 Experimental model with all components in place. A: the upper part is removed to replace the polyethylene liner. B: model under weight loading (200 N).

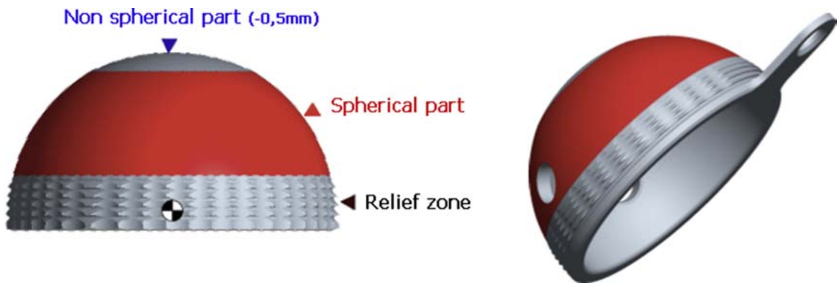

Figure 2 Diagram of the Novae E® metal back cup; spherical surface in red. A: strict profile view. B: anterior view in ''anatomical'' position.

the phantom and the films. This calibration cage enabled definition of the three dimensional space with its coordinates, for calculation of focus points. In this study, the *x*, *y* and *z*-axes corresponded to the mediolateral, craniocaudal and anteroposterior directions, respectively. All the images were processed on the radiology unit workstation, to adjust their properties and thus obtain proper visualization of the femoral head; they were then transmitted via the intrahospital network to the Center for Research in Clinical Orthopedics in Caen, France.

All the images were processed using contour detection software (MBRSA v3.2, Medisspecial, The Netherlands), validated by Garling et al. [15]. This technique is based on the capacity to minimize the difference between the virtual projection of a 3D surface model of an implant and the actual projection of the implant on the radiographs. The actual contours of the implant on the radiographs were detected using Canny's algorithm [16]. The 3D model was projected on the planar image and the virtual projected contour was calculated [14]. The actual contour and the virtual contour were defined as a chain of beads. The difference between the two contours was defined as the mean distance between the beads in the two chains [17]. To minimize these differences, the first positioning of the implant was performed manually by the operator. Secondarily, a computerized algorithm was used (Iterative Inverse Perspective Matching [IIPM]). This algorithm is based on studies by Wunsch [18] and Besl [19]. To finalize contour optimization, we used the Valstar algorithm, improved by Kaptein et al. [17]. This procedure was performed for the two components: femoral head and cup (Fig. 3).

Each implant was represented by a rudimentary geometric model: the cup corresponded to a sphere 57 mm in diameter, while the femoral head corresponded to a sphere 22.2 mm in diameter. During manual detection of the cup contours, the non-spheric parts of the implant were not taken into account (pole and equatorial zone with protrusion and relief).

Statistical analysis

The aim of this study was to establish the precision of radiostereometric measurement of femoral head migra-

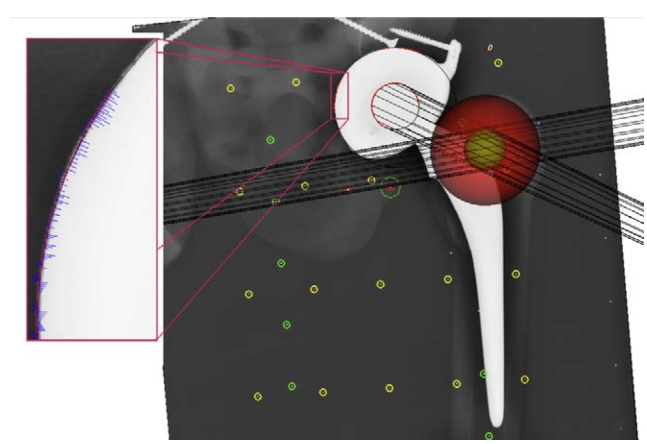

Figure 3 Contour detection. Box: exponential representation of the difference between virtual and effective projections (blue lines).

Table 1 Mean RMSE according to wear studied.

Wear	*n*	Mean RMSE	Difference (*S if p < 0.05*)
A(0.25 mm)	210	0.0314	A < B (S)
B (0.5 mm)	210	0.0391	A < C (NS)
C(0.75 mm)	210	0.0320	B > C (S)

S: significant; NS: non significant; RMSE: Root Mean Square Error.

tion in the dual mobility implant cup, and its intra- and interobserver variability. Many publications use these terms but with different meanings [21,22]. In this study, the following definitions were used: precision of the measurement method is defined as the closeness of agreement between repeated independent test results *(precision* = ± *1.96* × *standard deviation)*; accuracy is defined as the closeness of a measurement to the true value; the difference between the result obtained and the true value corresponds to the bias. The Root Mean Square Error (RMSE) corresponds to accuracy.

Statistical analysis was performed using Medcalc®, version 10.4 (Medcalc Software, Mariakerke, Belgium) software. Mean error for measurements was calculated as the difference in measurement compared with the true value. Accuracy of the protocol was evaluated using RMSE. These results have been presented as histograms of frequency distributions. Concordance correlation coefficient (CCC) was used, as well as regression graphs, to analyze correlations between the various results. CCC evaluated the tendency for pairs of observers to be situated on a straight line at 45° passing through the origin [23]. Interobserver reproducibility was also assessed using Bland-Altman plots. In this type of analysis, the difference between two observers is plotted according to the evolution of the parameter studied [24]. To study intraobserver reproducibility, the first interpretation for each series served as the reference for other interpretations of the same series. Intra Class Correlation Coefficient (ICC) was calculated for each examiner to estimate intraobserver agreement [25]. Likewise, RMSE differences (calculated to study intraobserver reproducibility) between the various examiners were analyzed to evaluate possible disparities that could indicate a steep learning curve. In all cases, a difference was considered significant if $p < 0.05$.

Results

Precision and accuracy

Mean error for all measurements ($n = 630$), for all examiners, was 0.023 mm, CI 95% [0.019—0.026]. Among the 630 measurements, the highest value for measurement error was 0.16 mm. Precision was 0.072 mm. To assess the accuracy of our measurement protocol, Root Mean Square Error (RMSE) for all measurements compared with the true values was 0.034 mm, CI 95% [0.032—0.036] (Fig. 4). Study of RMSE according to wear (i.e. depending on the various liners), found accuracy was significantly less when wear was 0.5 mm (Table 1). However, measurement of wear was strongly correlated with true value, whatever the liner studied, with a CCC of 0.9772 (Fig. 5).

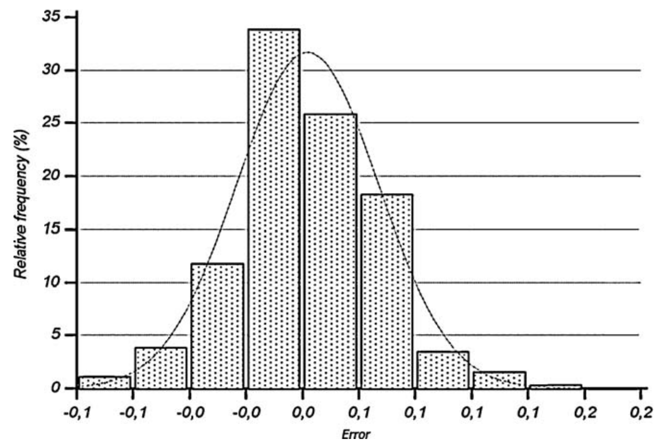

Figure 4 Distribution of error values for all measurements ($n = 630$).

Intraobserver reproducibility

RMSE was calculated for each examiner (called RMSE *intra*). For examiners 1, 2 and 3, RMSE *intra* was respectively 0.039 mm, CI 95% [0.035—0.044], 0.036, CI 95% [0.033—0.040], and 0.038, CI 95% [0.033—0.044]. The RMSE *intra* differences between observers were however not significant (Table 2). ICC between the measurements and true values was calculated for the three examiners. It was

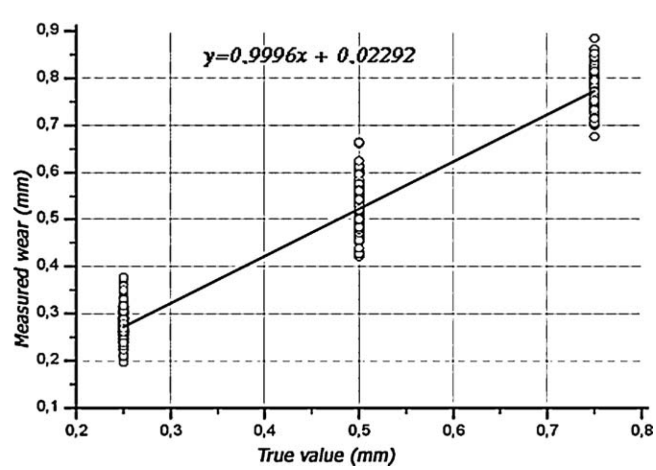

Figure 5 Regression line showing excellent correlation between wear measurements and true values.

Table 2 Comparison of RMSE *intra* [CI 95%], depending on examiner.

	RMSE *intra*	Difference not significant
Ex 1	0.039 [0.035 – 0.044]	Ex 1 vs Ex 2: *p* = *0.34*
Ex 2	0.036 [0.033 – 0.040]	Ex 1 vs Ex 3: *p* = *0.82*
Ex 3	0.038 [0.033 – 0.044]	Ex 2 vs Ex 3: *p* = *0.53*

RMSE: Root Mean Square Error; Ex: examiner.

0.9856, 0.9883 and 0.9842, respectively for examiners 1, 2 and 3.

Interobserver reproducibility

Analysis of the three examiners' results enabled evaluation of interobserver reproducibility for our measurement protocol. On comparing the results of examiner 2 (trained) with those of examiner 1 (expert), we found excellent correlation with a CCC of 0.9818. The mean difference between measurements by examiner 2 and examiner 1 was very low: −0.0034 mm, CI 95% [−0.0088−0.0019] (Fig. 6). Likewise, excellent correlation was found between the results of examiner 3 and those of examiner 1, with a CCC of 0.9713; the mean difference between measurements by examiner 3 and those by examiner 1 was −0.0075 mm, CI 95% [−0.01426−−0.00075]. We found less difference between examiners 2 and 1 than between examiners 3 and 1, but this was not significant.

Discussion

Two major questions remain unresolved concerning dual mobility THA. The first is implant wear when subjected to friction and compression forces; the second is periprosthetic osteolysis caused by release of polyethylene particles due to wear. To date, few studies have succeeded in precisely quantifying wear in these implants, and in all cases, the studies concerned polyethylene implants removed during revision; until now, wear of dual mobility cups has rarely been evaluated in vivo [4,9,26]. The aim of this study was to establish the precision of radiostereometric measurement of femoral head migration in the dual mobility implant cup, and its intra- and interobserver variability. The precision and accuracy of RSA measurements, in this experimental protocol, were 0.072 mm and 0.034 mm (CI 95%). Error was always random, as shown on the Bland-Altman plots. Correlation between wear measurement and true value, whatever the measure, was excellent with a CCC of 0.9772. Among the 630 measurements performed under this protocol, the highest value for measurement error was 0.16 mm. This is an important fact to be taken into consideration in future clinical studies. As the confidence interval for our results was very short, this probably corresponded to an aberrant measurement. We recommend in practice the performance of systematic double interpretation as the best method to avoid aberrant measurements.

The results for inter- and intraobserver reproducibility were excellent. The difference between the experienced examiner and the others was very small, with a very short confidence interval of 95%. In all cases, we found very good correlation between the results of the various examiners. This was explained by the effectiveness of software assistance in calibration and contour detection. Only Börlin et al. [27], in an experimental study on the precision of RSA measurements of femoral implant positioning, had evaluated inter and intraobserver reproducibility. Mean error between 2 examiners was 0.056 mm. However, our results are not comparable because we studied relative migration of an implant compared with another, whereas Börlin et al. [27] measured the position of one implant with two repeated measurements.

Our aim was to be as close as possible to in vivo conditions. Nevertheless, the system did not reproduce soft tissue attenuation, which can impair X-ray image quality, and thus disturb detection of the tantalum cage markers and implant contours. Likewise, the contour of the femoral head was always visible, despite the metal cup 3 mm in thickness. In everyday practice, we recommend meticulous adjustment of the X-ray tube constants, adapted to each patient's morphology, to obtain the same images. The preparation stage and installation of the patient must also be precise and producible, and performed by experienced staff.

We present results close to other RSA measurement studies of THA wear. Bragdon et al. [28] performed mea-

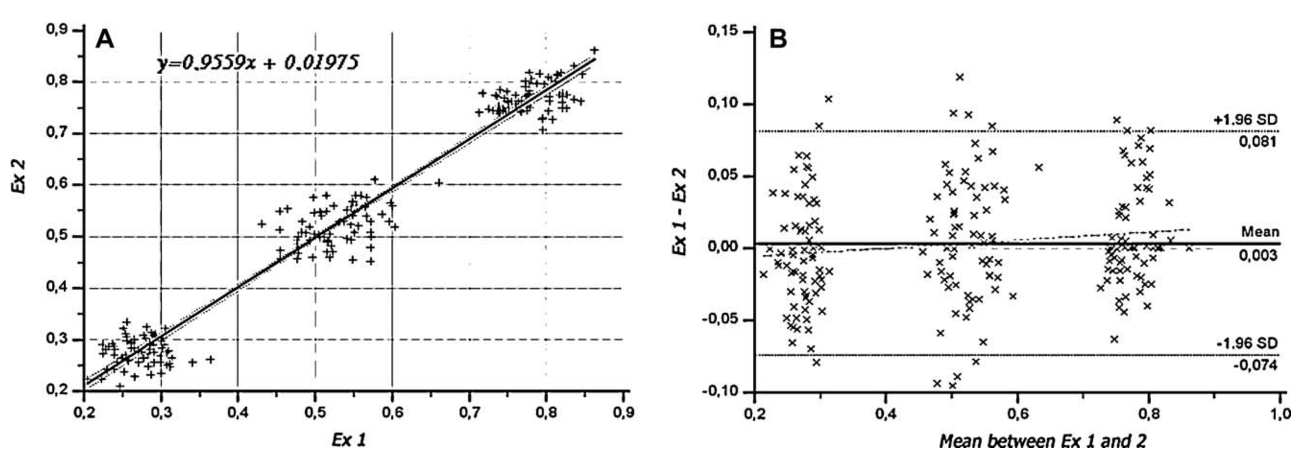

Figure 6 Interobserver reproducibility. A: regression line showing excellent correlation between examiner 2 and examiner 1. B: Bland-Altman plots showing dispersion of measurement differences between examiner 2 and examiner 1.

Table 3 Comparison of various results published in the literature concerning the accuracy and precision of hip prosthesis wear measurement.

	Method	Accuracy (mm) (RMSE)	Precision (mm) (according to ASTM)
Kang (2003) [34]	Simple X-ray	1.64	0.62
Ilchmann (2006) [35]	EBRA	0.11[a]	ns
Martell (1997) [36]	Martell	0.033	0.48
Bragdon (2002) [28]	RSA	0.065	0.067
Digas (2003) [37]	RSA	ns	0.1 – 0.22[a]
Börlin (2006) [29]	RSA	0.053	0.125
This study (2010)	RSA	0.034	0.072

RMSE: Root Mean Square Error; ASTM: American Society for Testing Materials; ns: not specified.
[a] Results presented by the author and calculated using a method other than that of ASTM.

surements of precision and accuracy on an experimental model with RSA based on detection of markers. They showed very good results with 0.065 mm and 0.067 mm for accuracy and precision. Börlin et al. [29], in an experimental model closer to ours, based on simple geometric models (hemisphere or sphere) found precision of 0.053 mm and accuracy of 0.125 mm. A summary of various studies of radiographic measurement of THA wear is presented in Table 3. However, the results are not all comparable, because of the different methods used and the different prosthesis models studied. Many figures have been published on the precision and accuracy of RSA, but cannot be compared because of considerable variety in calculation methods. To remedy these disparities, uniformity in RSA study protocols is required [20].

The precision of a measurement depends a great deal on the technology used. The choice of RSA method, among the two currently available, is crucial, with advantages and disadvantages in both cases. The contour detection method (model-based RSA) is increasingly opted for in clinical practice. In comparison with the reference RSA technique, based on marker detection (marker-based RSA), it has several advantages. Marker-based RSA requires modifications in prosthetic implants: the tantalum markers must be affixed to the implant, or directly inserted in the implant. Several studies have shown the good precision of model-based RSA, though slightly inferior to marker-based RSA [14,17,30,31].

We decided to use simple geometric models to represent the cup and femoral head. In 1997, Valstar et al. [32] had already proposed the use of simple geometric models (hemisphere + a circle), but only to study the position and orientation of the cup. They found a mean error for cup center positioning of 0.04 mm. Börlin et al. [29] also used a hemispheric model in their study of wear measurement in 2006. In one experimental study involving contour detection of a tibial implant in a knee prosthesis using model-based RSA, Hurschler et al. [30] showed that the reduction in the proportion of contour detected had very little effect on measurements. We thus decided to represent the cup with a sphere, which considerably simplified the models. Despite the flattened pole of 0.5 mm and the equatorial zone with projections of the Novae E^{TM} cup, the spherical part was sufficiently large and detectable on the RSA films to obtain the precision expected. Using this method, we freed ourselves from the need to use Computer Assisted Design (CAD) or Reverse Engineered (RE) files [14,17].

We propose a measurement protocol allowing quantification of femoral head penetration in the cup. However, this measurement is only an approximation of polyethylene wear. In addition to wear, there are the phenomena of bedding (early) and creep (distortion of materials under constant constraint). In the literature reporting radiographic measurements of wear, creep is often described [13,33]. To date, no methods have been standardized for estimation of the proportion of creep compared with true polyethylene wear; the factors involved are so numerous and varied (cup design, polyethylene manufacturing quality, patient population studied, etc.). Moreover, measurement of femoral head penetration cannot differentiate between wear of the small or the large articulation. Also, when studying polyethylene wear in mobile liners in dual mobility implants, potential wear due to contact between the femoral neck and the retention collar of the liner (''third articulation'') must be taken into account. This wear is not measurable using radiographic techniques, but can be responsible for the release of polyethylene particles at the origin of osteolysis.

This study reports validation of a radiostereometric measurement protocol of a dual mobility cup. This was prerequisite knowledge for implementing an in vivo study of such an implant compared with a fixed liner. The accuracy, precision, reproducibility, and the low doses of radiation, make model-based RSA the technique of choice for analysis of our arthroplasties. An international standard currently in development could become an indispensable tool before the marketing of or after modification of orthopedic implants.

Conflict of interest statement

The companies SERF, Stryker Europe and Mathys contributed to part of the cost of academic studies using RSA in an institutional research account.

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