The final follow-up plain radiograph is sufficient for clinical evaluation of polyethylene wear in total hip arthroplasty
A study of validity and reliability

Maiken Stilling¹, Kristian Larsen³, Niels T Andersen², Kjeld Søballe¹, Søren Kold¹, and Ole Rahbek¹

¹Department of Orthopedics, Aarhus University Hospital; ²Department of Biostatistics, School of Public Health, Aarhus University, Aarhus; ³Orthopedic Research Unit, Department of Orthopedics, Hospital Unit West, Holstebro, Denmark
Correspondence: maiken.stilling@ki.au.dk
Submitted 10-01-10. Accepted 10-04-13

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DOI 10.3109/17453674.2010.506632

Background and purpose Radiostereometric analysis (RSA) is a highly accurate tool for assessment of polyethylene (PE) wear in total hip arthroplasty (THA); however, PE wear measurements in clinical studies are often limited to plain radiographs. We evaluated the agreement between PE wear measured with PolyWare software, which uses plain radiographs, and by model-based RSA, which uses stereo radiographs.

Methods Measurements of PE wear postoperatively and at final follow-up (after mean 6 years) on plain radiographs of 12 patients after cementless THA were evaluated with PolyWare software and the results were compared with those from RSA as the gold standard (Model-based RSA using elementary geometrical shape models; EGS-RSA). With PolyWare, we either used the final radiographic follow-up (PW1) only or both the postoperative follow-up and the final follow-up (PW2).

Results The 2D mean wear measured (in mm) was 0.80, 1.07, and 0.60 for the PW2, PW1, and RSA method. 2D intra-method repeatability was similar for PW1 and RSA with limits of agreement (LOAs, in mm) of ± 0.22, and ± 0.23, respectively. 2D inter-method concurrent validity was best between PW1 and EGS-RSA with LOAs of ± 0.55. For 2D linear wear measurements, the PW1 method had a clinical repeatability similar to that of RSA.

Interpretation PW1 is sufficient for retrospective determination of 2D PE wear from medium-term wear measurements above 0.5 mm, It alleviates the need for baseline plain radiographs, has a clinical precision similar to that of RSA, and is easy and inexpensive to use.

Radiostereometric analysis (RSA) is the most accurate tool for in vivo assessment of PE wear (Kärrholm et al. 1997, von Schewelov et al. 2004, Bragdon et al. 2006), and it is regarded as the gold standard (Ilchmann et al. 1995). However, many radiographic in vivo studies of PE wear in THA are restricted to measurements on plain radiographs because the RSA set-up is expensive and not widely available. Measurement of PE wear on plain radiographs is often limited to 2D analysis because poor quality of cross-table lateral radiographs is a common problem (Syctherz et al. 1999b, 2001). Although PE wear is known to occur multidirectionally (Yamaguchi et al. 1997, Akisue et al. 1999), the bulk of the wear is detectable on the anterior-posterior radiographs alone (Syctherz et al. 1997, Hui et al. 2003, Martell et al. 2003). Based on the availability of radiographs and investigator preferences, some authors favor analysis of serial radiographs (Syctherz et al. 1997, Kim et al. 2001, Hernigou and Bahrami 2003) to describe the pattern of wear and the steady-state wear (Syctherz et al. 1999a, Bragdon et al. 2006), whereas others use 2 radiographic follow-ups (postoperative and latest) (Kraay et al. 2006), or only the latest radiographic follow-up with the assumption of zero wear at baseline (Norton et al. 2002).

Little is known about the conformity between PE wear results measured with RSA and computerized methods using plain radiographs (Ilchmann et al. 1995, von Schewelov et al. 2004, Bragdon et al. 2006). Our group has questioned the conformity of 2D PE wear measurements based on serial, 2, or 1 radiographic follow-up (Stilling et al. 2009b). We determined that there was a statistically significant difference between all approaches, but we were unable to determine which strategy best reflected the true extent of wear (Stilling et al. 2009b). In addition, we recently showed that model-based RSA is an accurate tool for measurement of PE wear in good agreement with the true wear (Stilling 2009).

We have now studied the intra-method repeatability and concurrent validity between 2 methods (PolyWare and EGS-
Implants

All components (femoral stems and acetabular cups) were cementless. The femoral component was a solid Ti6Al4V-alloy collarless, straight-stem Bi-Metric design (Biomet Inc, Warsaw, IN) with circumferential plasma-spray titanium and porous hydroxyapatite coating of the proximal one-quarter. The acetabular component was a plasma-sprayed titanium and hydroxyapatite-coated Mallory head, solid-finned Ringloc metal shell (Biomet). The cups were inserted using the same technique (approximately 2-mm press-fit by coating thickness, line-to-line reaming). The femoral stems were inserted by 2 alternative surgical techniques (bone rasping or bone compaction of the medullar canal) according to randomization in the RCT. The femoral heads (Biomet) were all of chrome-cobalt alloy, and they were 28 mm in diameter in 11 cases and 22 mm in diameter in one case. In all cases, the PE liners were of the Hi-Wall type and consisted of compression-molded, ultrahigh-molecular-weight PE (UHMWPE) resin, consolidated, packed, and sterilized by gamma irradiation in argon gas in the range of 2.5–4 Mrad (ArCom; Biomet).

Radiographs

In the 2 follow-ups, all radiographs were obtained at the same hospital. The primary radiographs (stereo radiographs, anteroposterior pelvis, and cross-table lateral) were obtained during 2001 and 2003 within a week of surgery and after mobilization of the patients. The primary stereo radiographs were digital, but the plain radiographs were hard copy and were digitized to tagged image files at a resolution of 300 dots per inch at 100% scale in a high-resolution optical A3 scanner (Epson Expression 10000xl Pro A3). A standard RSA set-up of 2 synchronized ceiling-fixed roentgen tubes (Arco-Ceil/Medira; Santax Medico) angled toward each other at 40° and a uniplaner carbon calibration box (Box 24; Medis Specials, Leiden, the Netherlands) were used. At final follow-up, all radiographs were fully digital (FCR Profect CS; Fujifilm) and stored without compression. The anteroposterior and cross-table lateral radiographs had a size of 2,364 × 2,964 pixels (grayscale TIFF format) and the stereo radiographs had a size of 2,080 × 2,529 pixels (grayscale BMP format). The final radiographs were collected as double examinations by the same radiographer in January and February of 2009, with complete repositioning of the radiographic equipment and the leg of the patient between examinations (stereo radiographs, anteroposterior pelvis, and cross-table lateral). The quality of the digitized anteroposterior radiographs was generally good; however, in 3 patients the automatic circle fitting and edge detection with the PolyWare software was turned off and overruled by the manual digitizer tablet, as recommended to maintain reasonable reproducibility (Collier et al. 2003).

Methods for PE wear measurement

In the non-weight-bearing pelvic radiographs, the location of the central ray was estimated by penciling diagonals between
the corners of the rectangular exposure on the radiograph. Analysis was performed by an experienced observer (LLA) with a computerized method (PolyWare Pro 3D Digital vs. 5.10; Draftware Developers, Conway, SC). This technique, developed by Devane et al. (Devane et al. 1995a, b), is only applicable to uncemented acetabular cups, and it features a digital edge-detection algorithm to fit circles and ellipses to the peripheral shadows of the femoral head and acetabular component (Figure 1). 2D PE wear is measured in the plane of the anteroposterior radiograph. At first, both the postoperative and the final radiographs were used for measurement of 2D and 3D PE wear vectors (PW2), but later only the final radiographs (PW1) were used.

Both the postoperative and the final stereo radiographs were obtained without weight bearing and with the patient supine. The leg was positioned with the anatomical axis parallel to the y-axis of the calibration box. Analysis of all stereo radiographs was performed by an experienced observer (RM) with the software Model-Based RSA vs. 3.2 (Medis Specials, Leiden, the Netherlands) using elementary geometrical shape (EGS) implant models (EGS-RSA) (Kaptein et al. 2006). This is a newly developed RSA feature alleviating the need for tantalum bead marking of components or for reverse engineering of cup models (Kaptein et al. 2003). By use of the EGS mathematical algorithm in the software, software-generated sphere models were matched to the peripheries of the femoral head and cup with errors of 0.08 mm and 0.13 mm, respectively. PE wear was evaluated with the cup sphere as the reference and the femoral head sphere as the migrating (penetrating) object (Figure 2). The centers of the spheres are automatically defined by the software. The postoperative and final stereo radiographs were used for analysis. The output of EGS-RSA is a standard for RSA with 3 coordinate numbers (X, Y, and Z), and from these, 2D and 3D linear wear vectors can be calculated by Pythagoras’ theorem (as the square root of $(X^2 + Y^2)$ and the square root of $(X^2 + Y^2 + Z^2)$, respectively).

**Economic evaluation**

A cost analysis comparing the PolyWare and RSA methods was performed with a marginal analysis (only differing costs) based on the present study; i.e., computer hardware that was necessary for both methods was not included. We defined 2 cost areas: investment costs and staff costs. The perspective of the analysis was that of the hospital. The investment costs consisted of additional X-ray equipment, calibration box, A3 transparency scanner, software, and education. X-ray equipment, calibration box, and software costs were calculated from actual costs. The staff costs consisted of the time used by the professions involved. The observed time for the radiographer to obtain 1 stereo radiograph was 30 min and 10 min for 1 AP pelvis plain radiograph. The observed time for retrieval and storage of 1 digital radiograph from the database at the radiology department was approximately 15 min, and the observed average time for finding 1 archived hard-copy radiograph and digitizing it in the transparency scanner was 45 min. RSA analysis took 90 min per patient (2 stereo radiographs) and PolyWare analysis took 30 min per patient (2 plain AP radiographs). Hourly salary for the radiographers (35 €) and for the research assistants (51 €) was obtained from the annual salary divided by 1,516 h, which was estimated by the administrative office to be the average number of effective working hours. All costs are based on 2010 prices.

**Statistics**

**Repeatability.** The standard deviation of the difference (SD$_{\text{dif-intra}}$) between the first and the second measurements (double examinations) within a method along with limits of agreement (LOA$_{\text{intra}}$ = SD$_{\text{dif-intra}}$ × ±1.96) were calculated according to Bland and Altman (1986). The systematic variation (bias) between the double examinations followed a normal distribution (Shapiro-Wilk test (Altman 1995)) and were tested with a paired t-test. The measures of repeatability (SD$_{\text{dif-intra}}$ or equivalent the width of LOA$_{\text{intra}}$) of the 3 methods were compared pairwise by looking at the ratios, and tested with an F-test.
LOA_intra provides the same measure as the bias ± the 95% repeatability limit that is specified in the ASTM 177 standard practice for bias and precision (2008). For comparison of RSA precision with that in the literature, we calculated the 95% confidence interval (CI) for translation values of each axis.

Concurrent validity. Concurrent validity defines the chronological correlation between 2 measurement methods (International Epidemiological Association Inc. 1995). The RSA method was considered to be the “gold standard”. An average value from double examinations was calculated and used to estimate the bias between methods. The bias followed a normal distribution (Shapiro-Wilk test) and was tested with a paired t-test. Furthermore, the standard deviation of the difference (SD_dif_inter) between methods and the agreement limits between methods (LOA_inter) were calculated according to Altman (1995) (LOA_inter = SD_dif_inter × ±1.96).

Statistical significance was assumed at p < 0.05. Intercooled Stata software version 10.0 (StataCorp, College Station, TX) was used for statistical computations.

Results

Repeatability evaluated within methods revealed no clinically relevant or statistically significant bias between any 2 pairs of radiographic double examinations of PE wear. The 2D intra-method repeatability (LOA, mm) was ± 0.22, ± 0.23, and ± 0.53 for PW1, EGS-RSA, and PW2, respectively. The 3D intra-method repeatability (LOA, mm) was ± 0.31, ± 0.62, and ± 0.87 for EGS-RSA, PW2, and PW1, respectively (Table 2 and Figure 3). The relative repeatability between 2D PW1 and 2D EGS-RSA (the “gold standard”) was 1.02 (p = 0.95) (Table 3). Precision (95% CI, mm) was 0.14, 0.26, and 0.29 for the x-, the y-, and the z-axis, respectively.

Concurrent validity showed a statically significant (p < 0.04) bias between all pairwise comparisons of methods, except between 2D PW2 and 2D EGS-RSA. The 2D inter-method concurrent validity (LOA, mm) was ± 0.55, ± 0.89, and ± 0.68 for PW1 relative to EGS-RSA, PW2 relative to EGS-RSA, and PW1 relative to PW2, respectively. The 3D inter-method concurrent validity (LOA, mm) was ± 1.13, ± 1.06, and ± 0.90 for PW1 relative to EGS-RSA, PW2 relative to EGS-RSA, and PW1 relative to PW2, respectively (Table 3 and Figure 4).

The total investment costs were €132,982 for RSA, €7,217 for PW2, and €2,052 for PW1 using only the final radiographic follow-up (Table 4). The total staff costs for the 12 patients in this study were €1,644 for RSA, €1,068 for PW2, and €612 for PW1 (Table 4).

Discussion

Although RSA is considered to be the most accurate and precise analysis method for PE wear (the gold standard) (Ilchmann et al. 1995, von Schewelov et al. 2004), many radiographic in vivo studies, especially retrospective studies, have been restricted to wear measurements on plain radiographs. Several computer-assisted methods for assessment of PE wear on plain radiographs are available (von Schewelov et al. 2004, McCalden et al. 2005, Geerdink et al. 2008), but few have been compared clinically with RSA (Ilchmann et al. 1992, 1995, von Schewelov et al. 2004, Bragdon et al. 2006), and to our knowledge no previous studies have evaluated the concurrent validity of RSA and the commonly used PolyWare method for plain radiographs (Devane and Horne 1999). Specifically, we wanted to determine whether it was more accurate (in agreement with RSA) to use only the final radiographic follow-up or to use both the postoperative and
Figure 3. Bland-Altman plots and scatter plots, with lines of equality for repeatability measures for each of the 3 methods. Bland-Altman plots (columns 1 and 3); x-axis: average of two measurements; y-axis: the difference between 2 measurements (y = measurement 1 − measurement 2); red lines: 95% limits of agreement; dashed line: bias from 0; solid green line: y = 0 line; dots: individual double measures. Scatter plots (columns 2 and 4); x-axis: first measurement; y-axis: second measurement; maroon lines: lines of equality; EGS-RSA: radiostereometric analysis using sphere models; PW1: PolyWare using only the final follow-up radiographs; PW2: PolyWare using the postoperative and final follow-up radiographs.

Table 3. Comparison of repeatability and concurrent validity between methods

| Analysis method | Repeatability | Concurrent validity |
|-----------------|---------------|---------------------|
|                 | Repeatability ratio | p-value | SD_{dif-inter} (mm) | Bias ± (±LOA) | CI 95% of true bias | p-value |
| 2D measurements |               |          |                    |               |                         |         |
| PW1 relative to EGS-RSA | 1.02 | 0.95 | 0.27 | 0.48 (±0.55) | 0.30–0.65 | < 0.001 |
| PW2 relative to EGS-RSA | 2.32 | < 0.001 | 0.44 | 0.21 (±0.89) | -0.08–0.49 | 0.14 |
| PW1 relative to PW2 | 2.36 | < 0.01 | 0.34 | 0.27 (±0.68) | 0.05–0.49 | 0.02 |
| 3D measurements |               |          |                    |               |                         |         |
| PW1 relative to EGS-RSA | 2.80 | 0.002 | 0.56 | 0.73 (±1.13) | 0.37–1.09 | < 0.001 |
| PW2 relative to EGS-RSA | 2.00 | 0.03 | 0.53 | 0.36 (±1.06) | 0.03–0.70 | 0.04 |
| PW1 relative to PW2 | 1.40 | 0.28 | 0.45 | 0.36 (±0.90) | 0.08–0.65 | 0.02 |

a Repeatability ratio: ratios of variance.
b p-value: test of variance between methods (F-test).
c SD_{dif-inter}: random variation from the 2 different methods.
d Bias: systematic variation between methods.
e LOA: limits of agreement around the bias (95% prediction interval = SD_{dif-inter} x 1.96).
f 95% confidence interval for the bias.
g p-value (paired t-test) bias between methods.

h PW1: PolyWare PE wear analysis using only the final follow-up radiographs.
i EGS-RSA: radiostereometric analysis of PE wear using sphere models (the “gold standard”).
j PW2: PolyWare PE wear analysis using the postoperative and final follow-up radiographs.
Several variables in the clinical set-up may, in theory, influence the amount of wear measured. Small changes in the radiographic set-up from follow-up to follow-up, under- or overexposure of radiographs that can affect the quality and sharpness of the component borders, patient position and leg rotation, body size and soft tissue mass of the patients, and angulations and size of components are just some of the variables that may affect clinical radiographs. Wear measurements based on uncalibrated plain radiographs would naturally be more sensitive to these changes than calibrated stereo radiographs. Despite all these potential problems with plain radiographs, we did not exclude any patients or radiographs because the border of the femoral head was sufficiently visible in all radiographs.

When only the final follow-up plain radiograph (PW1) is used to estimate wear, the primary position of the femoral head in each patient (zero wear) is assumed by the PolyWare software based on CAD-based knowledge of the cup and head, the final radiograph follow-ups with the PolyWare method (Stilling et al. 2009b).

### Table 4. Marginal cost analysis in € (euros) for polyethylene wear analysis by EGS-RSA and with PolyWare as used in this study. For easy comparison, the staff costs are listed per patient

| Cost area                  | EGS-RSA | PW2  | PW1  |
|----------------------------|---------|------|------|
| Investment costs (1 time)  |         |      |      |
| Additional X-ray equipment | 80,604  | 0    | 0    |
| Calibration box            | 10,075  | 0    | 0    |
| A3 transparency scanner     | 0       | 5,165| 0    |
| Software                    | 34,595  | 510  | 510  |
| Education of radiographer  | 1,542   | 0    | 0    |
| Education of research assistant | 6,166 | 1,542| 1,542|
| Total investment costs      | 132,982 | 7,217| 2,052|
| Staff costs per patient     |         |      |      |
| Radiographer                | 35      | 12   | 12   |
| Research assistant          | 102     | 77   | 39   |
| Total staff costs per patient | 137  | 89   | 51   |

*EGS-RSA: radiostereometric analysis of PE wear using sphere models (2 stereo radiographs were used).*  
*PW2: PolyWare PE wear analysis using the postoperative and final follow-up plain radiographs.*  
*PW1: PolyWare PE wear analysis using only the final radiographic follow-up plain radiographs.*
and the keyed-in information on sizes. For PW2 and RSA, the 
postoperative radiographs provide the baseline. The algorithms 
for determination of wear by use of plain or stereo radiographs 
are not identical. Consequently, exact agreement between PE 
wear measurements based on different angle radiographs evalu-
ated with different software packages cannot be anticipated, 
but some similarity can be expected. Both EGS-RSA and 
PolyWare are shadow-casting methods (Collier et al. 2003), 
and PolyWare relies on the marking of a beam center in the 
radiographs. We used only pelvic anteroposterior plain radi-
ographs at postoperative and final follow-up; thus, the center 
of the ray should have been similar at different follow-ups. 
The resolution of the scanned primary hard copy plain radiographs 
and the follow-up digital radiographs we used followed the 
recommendations in the instruction manuals.

The radiographic set-up and the leg of the patient were re-
positioned between the double-examination radiographs in our 
study, and the calculated inter-method repeatability therefore 
reflects the contribution of variance from the radiographic set-
up, the leg position, and the method of PE wear analysis. All 3 
methods had small biases (range -0.09–0.06 mm), which were 
of no clinical or statistical significance. The best intra-method 
repeatability was obtained with 2D PW1 and 2D EGS-RSA, 
with approximate limits of agreement of ± 0.22 mm and ± 0.23 
mm. Repeatability for all the 2D PE methods of wear mea-
surement had limits of agreement below ± 0.5 mm, whereas 
repeatability of all 3D PE methods of wear measurement had 
limits of agreements above ± 0.5 mm.

In a clinical study, Digas et al. (2003) assessed double exami-
nations of 45 patients and reported that precision absolute 
mean ± 2.7 SD (99% CI) for the 3D total was 0.22 mm. This 
is somewhat better than our observation for 3D EGS-RSA 
(LOA: ± 0.31 mm). These authors also reported translational 
precision of marker-based RSA to be 0.13 mm for the trans-
verse axis, 0.10 mm for the longitudinal axis, and 0.22 mm for 
the sagittal axis. Röhrl et al. (2004) evaluated double exami-
nations of patients with slight repositioning between exposures 
and found a longitudinal axis precision of 0.15 mm (95% CI). 
We used a model-based RSA method and observed a similar 
precision (95% CI) for the x-axis (0.14 mm) but a poorer pre-
cision for the y- and z-axis (Kaptein et al. 2006). It has already 
been emphasized that a 3D precision is mathematically dif-
ficult to present, as the precisions of the different directions 
cannot easily be added (Ryd 1986). Yet, this was necessary for 
a direct comparison of the repeatability of RSA and PolyWare.

In a retrieval study, PolyWare has been shown to underesti-
mate 2D linear wear by 20% and dimensional 3D wear by 18% 
(Hui et al. 2003). We found the opposite tendency; that is, over-
estimation of wear by PolyWare in comparison to EGS-RSA as 
the gold standard. The relative mean difference between the 2D 
and 3D PE wear measured by PolyWare using two radiographic 
follow-ups (PW2) and EGS-RSA was 21% and 30%, respec-

Comparing PolyWare using one radiographic follow-up 
(PW1) and EGS-RSA, the relative difference for 2D and 3D 
wear was even larger (40% and 46%, respectively). As a con-
sequence of these large differences in measured mean wear, 
we only established concurrent validity of the mean bias with 
EGS-RSA and PW2 based on statistical testing. However, the 
 systematic variation (bias) can be corrected for when known, 
whereas the random variation cannot, and thus the methods 
with the concurrent smallest LOA are the ones in closest agree-
mement. In our study, this was EGS-RSA and PW1.

A clinical threshold of interest for the detection of PE wear 
that leads to long-term osteolysis and implant failure has been 
established to be 0.2 mm/year (Dowd et al. 2000, Sochart 2001). 
This is at the lower limit of clinically measurable wear 
with the best 2D wear methods used in our study. When total 
wear measurements close to 0.2 mm are of interest (i.e. cross-
linked liners at medium-term follow-up), the images should 
be analyzed several times, with the average value representing 
the true value (Vickers 2003). For PE wear analysis, however, 
the number of repeat wear measurements that is optimal is 
not known at present. Using the most accurate method (EGS-
RSA), the medium-term wear rate was 0.12 mm/year, which 
is in accordance with a recent report (Skoldenberg et al. 2009). 
We have previously determined the medium-term PE wear 
rate (0.25 mm/year) in similar ArCom PE liners articulated with 
28-mm cobalt-chromium femoral heads by wear analysis 
on serial radiographs (Stilling et al. 2009a). Later, we were 
able to show that the use of serial radiographs for wear analy-

Assessing concurrent validity, the mean PE wear measured 
with PolyWare (PW1 and PW2) was greater than wear mea-

sured by EGS-RSA. This is similar to the report of Bragdon 
et al. (2006) who compared marker-based digital RSA and 
the Martell method on plain radiographs. They suggested a 
calculation and comparison of the steady-state wear between 
methods. In our patient series no 1- or 2-year radiographic 
follow-ups were available, so this was not possible.

The accuracy of 2D PE wear measurement by the EGS-
RSA method was recently shown to be in very good agree-
mement with the true wear (Stilling et al. 2009b). Thus, based 
on the present results, the use of only the final plain radiographic 
follow-up with the PolyWare method (PW1) comes within 
± 0.55 mm of the true value. This is sufficient for comparative 
studies assessing differences between 2 groups, and if desired, 
the systematic error can be corrected for. Furthermore, limit-
ing the assessed plain radiographs to the final follow-up will 
 improve repeatability and also provide the chance of good-
quality digital radiographs. Also, it permits definition of a pre-
study protocol for the last follow-up radiographs, thus ensur-
ing that there is less projection variation between radiographs 
in a retrospective clinical study targeting PE wear. This could 
also reduce the number of patients needed for evaluation.

The marginal cost analysis favors PolyWare over RSA con-
cerning both investment costs and staff costs; however, some
designations of the costs shown may be needed in another institution depending on the additional equipment needed. PE wear analysis with PolyWare, where only the final (and digital) radiograph is used, is the lowest priced method overall. However, because PolyWare is a less precise method than RSA, a 2–3 times larger sample size will be needed for this method (Stillinger 2009), which evens out the staff costs for a prospective clinical study with the 2 methods. Yet, investment costs are 20 to 60 times more expensive for RSA, and to be cost-effective the RSA system should be used for more than 1 study. Furthermore, and something that was not included in the marginal analysis, plain radiographs are needed for documentation after surgery, whereas stereoradiographs are additional and therefore add to the total radiation dose per patient studied.

We expect our findings to have good external validity and to be applicable to good-quality radiographs of various brands of hemispheric metal shells with polyethylene liners and metal femoral heads. The PolyWare method using only final radiographic anteroposterior images is inexpensive and easy to use, is applicable for 2D wear measurements above 0.5 mm in total, and offers a simple and fast set-up that is applicable for the assessment of PE wear in most hospitals. The PolyWare method using only final radiographic anteroposterior images has a clinical repeatability similar to that of EGS-RSA (“the gold standard”) and is ideal for retrospective research because it alleviates the need for baseline images that are often lost, stored in hard copy, and of variable quality. For assessment of low PE wear (i.e. with new cross-linked liners), PolyWare software does not supply the accuracy required, and for such situations we recommend RSA. For assessment of medium-term or long-term wear measurements in larger groups of patients, the PolyWare method is optimal, simple, and in relatively close agreement with the gold standard of RSA.

Designed the study: KS, OR, MS, and SK. Operated on the patients: KS. Gathered the data: MS, OR, and SK. Analyzed the data: MS, NTA, and KL. Wrote the initial draft: MS and KL. Revised the initial draft: KS, SK, OR, and KL. Ensured the accuracy of the data and analysis: NTA and KL.

The authors thank Rikke Mørup for performing radiostereometric analyses on all patients and Lone Løvgren Andersen for performing wear analyses with PolyWare on all patients.

No competing interests declared.

ASTM: Standard Practice for Use of the Terms Precision and Bias in ASTM Test Methods E177. Subcommittee E11 20 on Test Method Evaluation and Quality Control, ASTM International, West Conshohocken, PA, USA 2008.

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