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Validation of a new 2-D technique for radiographic wear measurement of cemented, highly cross-linked polyethylene acetabular cups

Brian Derbyshire*, Bilal Barkatali

Centre for Hip Surgery, Wrightington Hospital, Hall Lane, Appley Bridge, WN6 9EP, UK

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ABSTRACT

A new 2-D radiographic wear measurement system has been developed which enables the low wear of highly cross-linked polyethylene acetabular cups to be accurately and precisely measured from standard, pelvis radiographs. The software was validated using radiographic images of a measurement jig which could vary the cup orientation and simulate the effect of pelvic tilt/rotation. Wear was simulated using accurately measured plastic shims to vary the position of the femoral head relative to the cup. The effects of varying “wear” penetration, “wear” direction, cup orientation and X-ray focus position were assessed. Further direct comparison tests were also carried out using radiostereometric analysis. Inter/intra-observer repeatability of the new system was assessed using clinical radiographs.

The mean (SD) “wear” penetration error was -0.002 mm (0.028 mm). The “wear” penetration precision was 0.055 mm. Changing the position of the X-ray focus point made no difference to the measurement error. Inter/intra-observer repeatability and limits of agreement had similar low values. Comparison tests with RSA showed the accuracy was similar.

1. Introduction

Clinical wear of polyethylene (PE) acetabular cups and cup-liners can be measured from radiographic images. Modern 2-D wear measurement systems were originally developed to measure wear of standard ultra-high-molecular-weight polyethylene cups that had a wear rate of 0.1 mm to 0.2 mm per year. The accuracy and precision of those systems were sufficient to achieve reasonably accurate measurements after the first few years of wear [1,2]. During the past decade, however, manufacturers have been providing highly cross-linked polyethylene (XLPE) cups which wear at a much reduced rate (a few hundredths of a millimetre per year) [3,4]. The current 2-D systems have therefore been severely challenged to detect XLPE wear – even after several years. As a result of this, some researchers have preferred radiostereometric analysis (RSA), which is considered to be the “gold standard” for measuring cup wear [5–9]. However, in order to measure wear of cemented, all-PE cups using RSA, marker beads need to be inserted into the cup face at the time of surgery. In addition, RSA requires expensive software, special training, and a special dual X-ray machine set-up – all of which preclude its routine clinical use.

There is a need for continuous surveillance of XLPE cups due to concerns about long-term *in vivo* oxidation and its possible detrimental effect on the wear rate [10]. A simple, inexpensive, and highly accurate 2D system which could measure routine, antero-posterior (A-P) pelvis radiographs would therefore be very useful. In an attempt to address this problem, we have developed an accurate and precise 2-D system for measuring wear of cemented, all-PE, cups. In this paper we describe the measurement technique and its validation.

2. Materials and method

The measurement software was written in the C^{++} programming language. It uses automatic edge detection to fit circles and ellipses (mathematics based on the Levenberg–Marquardt technique [11]) to the femoral head and wire marker images (Fig.1), and it was designed to minimize measurement errors caused by projection related image distortion, inaccurate ellipse/circle fitting, image “contamination” by local bone/cement, and disruption by prosthesis irregularities (e.g, bone screws, wires, marker beads). Appropriate ellipse fitting was ensured by a series of condition tests: standard deviation (SD) of the residuals; expected (theoreti-

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* Corresponding author.
E-mail addresses: drbrianderbyshire@gmail.com (B. Derbyshire), bilal.barkatali@srft.nhs.uk (B. Barkatali).

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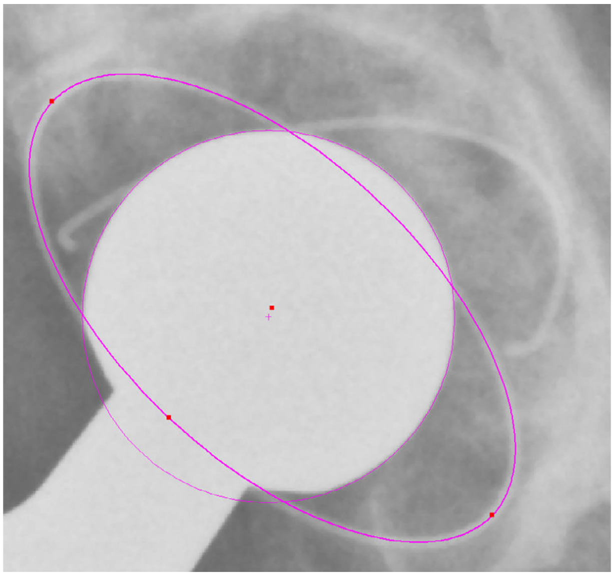

Fig. 1. A measured clinical image.

cal) projection angle of the ellipse; expected shape (major and minor semi-axis lengths: “a” and “b”).

2.1. Software technique

The software imports a full-size, A-P radiograph of the pelvis (windows bitmap or jpeg format) and stores it in memory as a bitmap. The main on-screen operations are carried out on a zoomed area surrounding the images of the cup wire marker and femoral head. All on-screen point-setting (screen resolution 96 dpi) is translated automatically to the bitmap which has a higher resolution (depending on the A-P radiograph resolution). For the laboratory tests, the resolution of the radiographs was 172 dpi.

An ellipse, created by setting three points, is placed approximately over the image of the wire marker and then adjusted more accurately by dragging “handles” (Fig. 1) which allow the shape, position and orientation of the ellipse to be altered – thereby providing “seed” parameters for the edge-detection algorithm. Before triggering the edge-detection routine and fitting an ellipse to the wire marker image, the image of the femoral head is masked by manually setting points where it intercepts the wire marker image. The shape and orientation parameters of the fitted ellipse enable the calculation of the cup version ($\sin^{-1}(b/a)$) and inclination (corrected for X-ray beam offset [12,13]).

After creating a three-point-circle around the periphery of the femoral head image (to find its seed parameters: x, y, r), the interception positions of the wire marker image with the femoral head image are masked (if necessary) and the head image is then edge-detected. The software automatically calibrates the measurements to the known diameter of the femoral head (inputted at the start of the measurement procedure). A displacement vector is then determined from the co-ordinates of the centres of the femoral head and wire marker images (Fig. 2). The procedure is repeated using a follow-up radiograph and the difference between the vectors enables the wear penetration and wear direction to be calculated. A set of algorithms for estimating wear volume [14] is included in the software.

2.2. Wear simulation

Two UHMWPE cups were specially manufactured for these tests. Each had an outer diameter of 64 mm, but a recess at the cup base enabled a 54 mm diameter circular wire marker to be attached (thus simulating a 54 mm OD cup). The large size of each cup enabled a box-shaped cut-out to be machined centrally into the base. The angle of the cut-out to the plane of each cup base was machined at 80° and 70°, respectively so that the plane of the cut-out was parallel to the horizontal when the cups were fixed in 10° or 20° anteversion (Figs. 3, 4). Plastic shims (www.RS-Components.com) of different, consistent thicknesses were cut to size so that they could be placed on the lateral and superomedial borders of the cut-out. By changing the combined thicknesses of the shims for each setting, the position of a 32 mm diameter metal femoral head (resting against the shims) could be changed – thereby simulating wear of the cup.

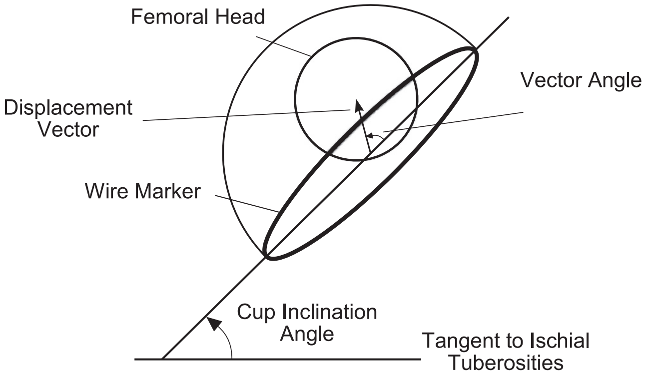

Fig. 2. Diagram showing the measured displacement vector and its direction relative to the wire marker ellipse axis. The centres of the femoral head and wire marker images, together with the inclination and version of the cup are first determined, followed by corrections for the X-ray beam offset projection effect.

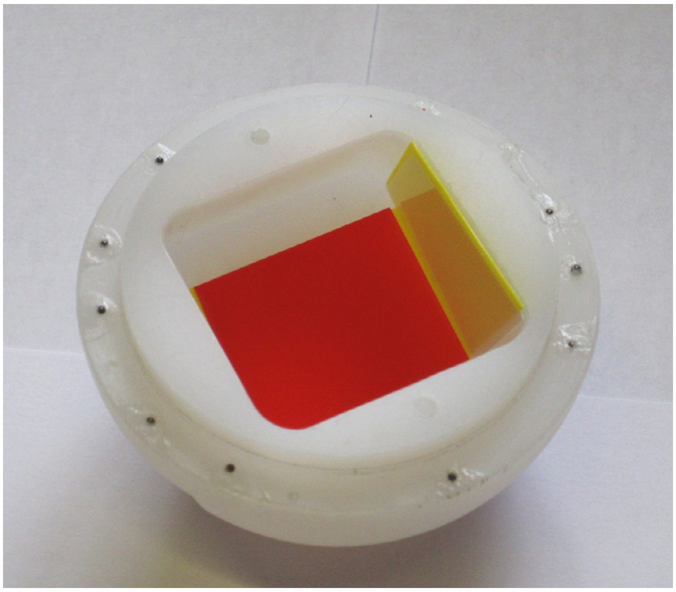

Fig. 3. A box-shaped cut-out enabled plastic shims to be placed at the side (*x*) and bottom (*y*). of the box. Marker beads around the cup edge were used for the RSA comparison measurements.

2.3. Cup orientation simulation

A specially designed test jig, made from radiolucent acrylic, was developed to enable the cup to be set at different 3-D orientations (Fig. 5). By varying the cup version and its internal/external rotation, the effect of changes in pelvic tilt/rotation in sequential radiographs could be simulated.

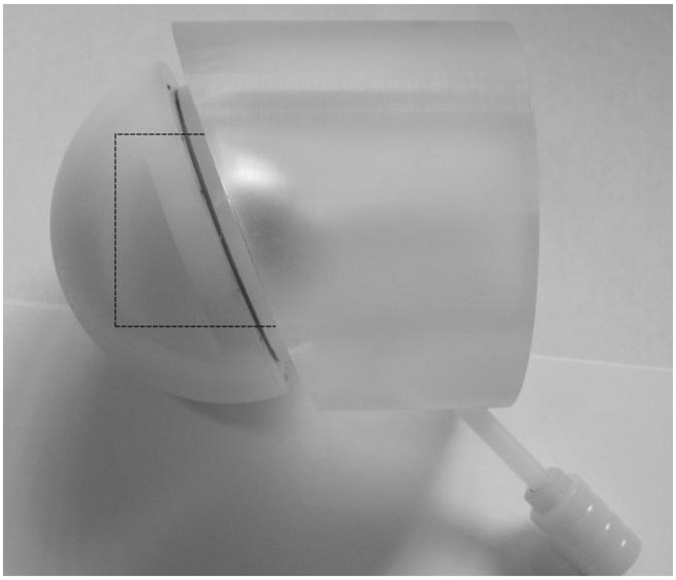

Fig. 4. The cup was pinned at a fixed anteversion to the slanted face of the inner cylinder. Dotted lines show that the angle of the cut-out was parallel to the inner cylinder axis.

The outer cylinder was supported at a height simulating a typical height of a hip above an X-ray machine table. This cylinder could tilt about its centre, and a peg/hole at each end enabled the tilt to be set in 10° increments, thereby changing the fixed version of the cup. The cup was fixed against the slanted face of an inner cylinder which could be inserted into and closely contained by the outer cylinder. Two inner cylinders were manufactured with different face slants to provide 10° and 20° fixed anteversion settings. In this study, the version setting was altered by ±10° relative to the fixed version by changing the outer cylinder tilt. Two diametrically-opposite, aluminium alloy pins in the cup face were used to pin it to holes in the slanted face (Fig. 6). These holes, which were set with a 10° spacing around the face, enabled the internal/external rotation of the cup to be varied. In this study, the rotation was varied by ±10°. The whole jig could be rotated about a pivot at the centre of its base, and a peg at one end of the base enabled the radiographic inclination settings to be changed to 35°, 45° or 55°.

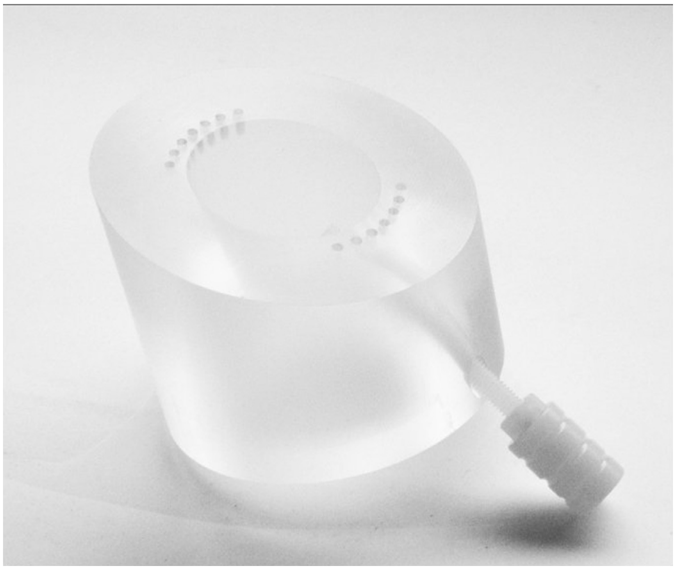

Fig. 6. Holes on the inner cylinder face enabled the cup to be pinned at different internal/external rotations.

2.4. Procedure

The software uses the duo-radiographic technique whereby the vector displacement of the femoral head image relative to the wire marker image is determined in postoperative (reference) and follow-up radiographs and the vector difference is calculated. After measuring a reference radiograph, each “follow-up” radiograph was measured three times and average values of “wear” penetration and “wear” direction were recorded.

For the reference measurement, shims, with a total thickness of up to 1.5 mm, were placed at the end (*y*-direction) and side (x-direction) of the box-shaped cut out. Shims were also placed at the bottom of the cut-out in order to ensure the level of the femoral head centre was approximately coincident with that of the wire marker centre. For the latter, the required shim thickness was determined in a separate radiographic test in which the position of the femoral head relative to the wire marker centre was measured in the x-z plane.

An accurate micrometer (Mitutoyo M327-25, with a guaranteed accuracy of ±2 µm) was used to measure the total shim thickness several times in the vicinity of femoral head contact, and the mean

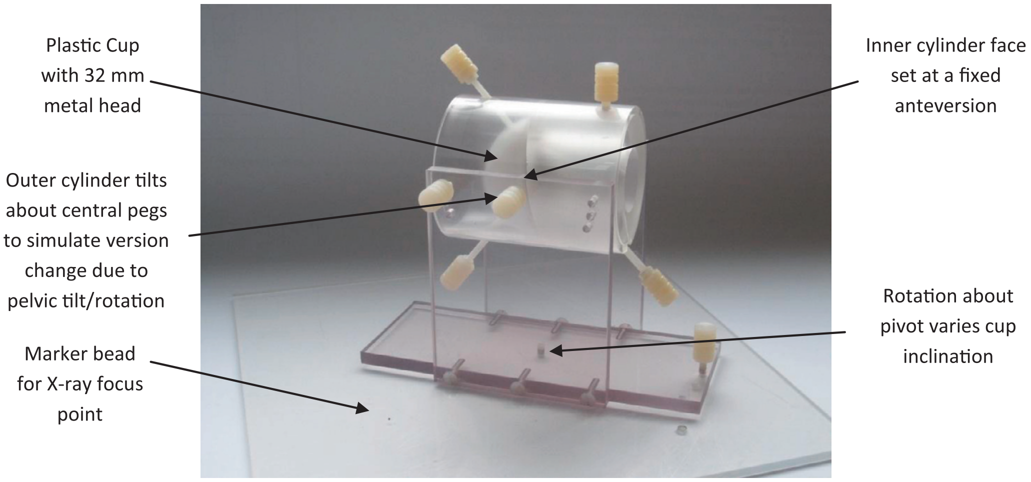

Fig. 5. X-ray test jig.

measurement was recorded. The 32 mm diameter, metal femoral head was carefully placed in the cut-out against the shims and a piece of plastic foam was placed in one corner of the cut-out in order to lightly cushion the head against the shims and maintain it in place. The cup was then located on the face of the inner cylinder in the standard position (no internal/external rotation) and a long plastic screw through the inner cylinder was made to lightly engage a piece of foam plastic glued to the base of the femoral head. This maintained the femoral head position in the y-direction within the cup. The cup/inner cylinder combination were then inserted and pegged inside the outer cylinder. With the outer cylinder tilt set to zero and the jig set at 35°, 45° or 55° inclination, the reference "wear" plane was parallel to the radiographic plane. Radiographs were taken using a Siemens Axiom Luminos dRF digital X-ray machine with a focus-to-sensor distance of 1150 mm. X-ray exposure settings of 64.5 kV and 2 mAs were found to be appropriate. The X-ray beam was focused on a tantalum marker bead fixed to the base sheet at a position simulating the typical location of the pubic symphysis relative to the cup.

For the "follow-up" measurements, the thickness of the shims in the *x* and/or *y* direction was reduced on successive settings. This enabled changes not only in the "wear" penetration but also in the "wear" direction to be simulated. The same procedure as above was then followed except that the internal/external rotation of the cup and also the outer cylinder tilt were varied between ±10° so that the "wear" plane was no longer parallel to the radiographic plane. Random combinations of settings were used and the calculated "wear" penetrations and "wear" directions varied between 0.162 mm to 0.933 mm, and 12.4° to 56.9°, respectively (angles relative to the cup face).

2.5. Variability of X-ray beam focus position

In routine A-P pelvis radiographs, the X-ray focus point location can vary. This change in focus position could slightly affect the projected images (e.g. the size and direction of elliptical projection) – and the software is designed to accommodate this effect. Further tests were therefore carried out to assess whether focus point changes would affect the measurement accuracy.

Radiographs were taken with the X-ray beam focused on the "pubic symphysis" bead and additionally on two extra beads located 100 mm above and 50 mm below that central bead. The latter locations were considered to be extreme cases for the focus point variation. Settings of 10° anteversion, 0° rotation and 35°, 45° and 55° inclination were used. The simulated wear penetration and direction were 0.40 mm and 49.9°, respectively. Focusing on the upper bead caused the elliptical image of the wire marker to be almost closed into a straight line. To obviate that problem, results for the upper focus point were recorded for a fixed anteversion setting of 20° (the penetration settings for that case changed slightly to 0.43 mm and 36.4°).

2.6. Clinical repeatability

The intra- and inter-observer repeatability of the system was tested on paired clinical radiographs (post-op. and follow-up) of 10 patients (10 Stanmore cups).

2.7. RSA study

Tantalum marker beads were glued into holes drilled around the surface of the cup flange in order to prepare the cup for RSA measurements using the UmRSA technique (http://www.rsabiomedical.se). Two neighbouring radiography rooms were employed: one with an RSA set-up, the other with a standard, pelvis X-ray set-up. Using the 20^0 anteversion inner cylinder and a 32 mm diameter, metal, femoral head, the " wear" penetration and direction, version, rotation and inclination settings were varied as previously described. The range of "wear" penetrations was 0.114 mm to 0.835 mm, and the "wear" directions ranged between 0^0 and 50.5^0. For each setting, the RSA radiographs were taken first and then, keeping the same settings, the measurement jig was transferred to the adjoining room for standard radiography (note: those standard radiographs were not the ones already described previously in the first test). Finally, in order to check that the femoral head material had no effect on the accuracy of the measurements, 9 tests (both systems) were carried out using a 32 mm ceramic femoral head. For those tests, the "wear" penetrations ranged between 0.157 mm and 0.752 mm, and the directions ranged between 25.7^0 and 50.4^0.

2.8. Statistics

StatsDirect statistical software was used for analysis (www.StatsDirect.com). Normality of data distribution was tested used the Shapiro−Wilk test [15]. Statistical significance was determined using the single sample *t*-test or Wilcoxon's signed ranks test. Precision was calculated using the method of Ranstam et al. [16] using a Student's *t* value (i.e. $t \times$ SD). Inter/intra-observer repeatability and agreement were determined using the intra-class correlation coefficient and Bland−Altman plots [17], respectively.

3. Results

3.1. Standard tests

For the first tests, three measurements were taken for each of 49 different radiographs/settings (total of 147 measurements). The overall mean (SD) penetration error (bias) was −0.002 mm (0.028 mm) and was not significantly different from zero ($p = 0.587$, CI: −0.010 to 0.006 mm). Ninety-five percent of the errors were within ±0.044 mm (Fig. 7). The precision (intra-observer repeatability) of the penetration measurements was 0.055 mm. The wear direction errors were not normally distributed. The median "wear" direction error was 1.15° (CI: 0.127° to 1.987°). The direction error was greatest at very low penetrations (less than about 0.25 mm) and reduced to within ±10° thereafter (above 0.25 mm, excluding the possible outlier at 19.8°, the median, 5th and 95th percentiles for the wear direction error were 1.7°, −5.5°, and 9.6°, respectively).

3.2. Effect of X-ray focus position

Changing the X-ray focus (Fig. 8) still gave a penetration error within ±0.05 mm (similar to that in Fig. 7a at penetrations of just over 0.4 mm). Wear direction errors were generally the same as in Fig. 7b, with a median (5%, 95% percentiles) of −0.5° (−10.5°, 8.0°).

3.3. Inter/intra observer repeatability

For the repeatability tests of clinical radiographs, the mean wear penetration was 0.35 mm (range: 0.16 mm−0.57 mm). For the intra-observer repeatability test the intra-class correlation coefficient was 0.99, the mean difference was 0.0028 mm and the 95% limits of agreement were −0.044 mm to 0.050 mm (Fig. 9a). For the inter-observer repeatability test, the intra-class correlation coefficient was 0.98, the mean difference was 0.016 mm, and the 95% limits of agreement were −0.038 mm to 0.070 mm (Fig. 9b).

3.4. RSA comparisons

For the RSA comparison tests, three standard pelvis measurements were carried out for each of 33 different radio-

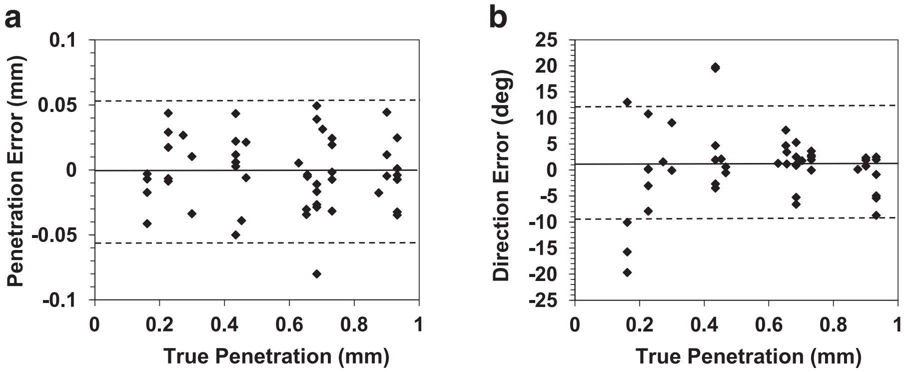

Fig. 7. “Wear” penetration error (a) and direction error (b). Each point represents the mean of 3 repeated measurements. Solid line: (a) Mean; (b) median. Dashed lines: (a) mean ±2SD; (b) 5th and 95th percentiles.

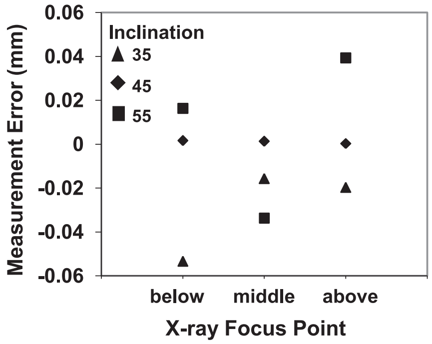

Fig. 8. “Wear” penetration error when the “follow-up” X-ray beam was focused at the middle (reference) position or 10 cm above or 5 cm below it.

graphs/settings (99 measurements) and 33 RSA radiographic pairs were analysed. The mean number of visible marker beads on the cup was 6 (max. 7, min 4), the mean of the mean error of rigid body fitting was 0.088 (SD 0.043), and the mean condition number was 33 (max. 53). The mean 2D penetration error for the standard radiography (Fig. 10a) was 0.0002 mm (SD: 0.029 mm, CI: −0.01 mm to 0.01 mm). With 2D RSA (i.e. measurements in the radiographic x, y plane), the mean penetration error was −0.014 mm (SD: 0.044 mm, CI: −0.03 mm to 0.001 mm). With 3D RSA (i.e. the same as 2D RSA but including the out-of-plane, z-direction measurements), the mean penetration error (Fig. 10b) was −0.0029 mm (SD: 0.046 mm, CI: −0.019 mm to 0.013 mm). For the tests using the ceramic femoral head, 9 radiographs/settings were used. The mean number of visible markers was 5 (max. 6, min 3), the mean of the mean error of rigid body fitting was 0.078 (SD 0.034), and the mean condition number was 40 (max. 54). The mean 2D penetration error for the standard radiographic measurements (Fig. 11a) was 0.0038 mm (SD: 0.023 mm; CI: −0.013 mm to 0.020 mm) and the mean 3D penetration error for the RSA measurements (Fig. 11b) was 0.085 mm (SD: 0.050 mm; CI: 0.039 mm to 0.120 mm).

4. Discussion

Many researchers and clinicians have chosen to use 2-D wear measurement systems instead of RSA because they are less expensive [18], easier to use, and enable wear measurement from standard A-P radiographs of the pelvis in both retrospective and prospective studies. In addition, marker beads do not need to be fixed to all-PE cups prior to surgery– as they do with RSA [8]. The purpose of this study was to develop and test a new 2D system that was sufficiently accurate to measure wear of cemented XLPE acetabular cups from standard A-P radiographs.

We acknowledge limitations to our technique and to our study. The main limitation of the technique is that the all-PE cups need to have fully-circular wire markers. Accurate and consistent measurements are difficult to achieve if the cups have semi-circular or “double-D-shaped” wire markers [19]. A further limitation is that wear cannot be measured accurately if the radiographic version of the cup is very low (few degrees) because an ellipse cannot be fitted to the wire marker image due to merging of its opposite sides. In general, this should not be a problem since most cups are set with a radiographic anteversion of at least 10° in order to avoid impingement problems.

Limitations of the study are that the measurements were from radiographic images of a “wear phantom” and with a femoral head of just one size of (32 mm diameter). It could be argued that the

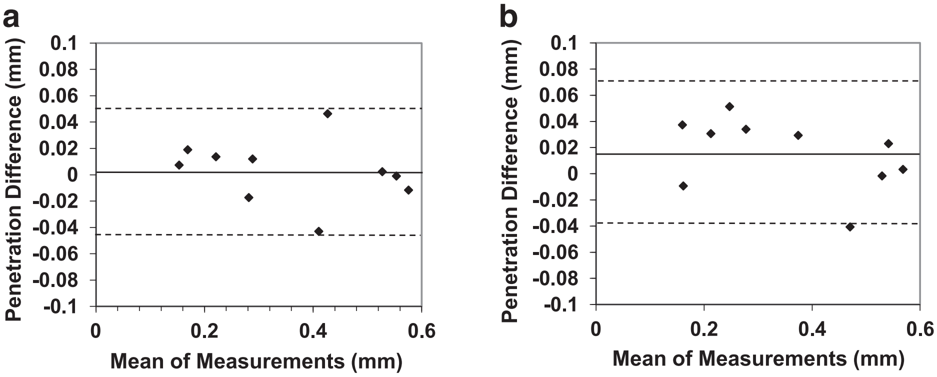

Fig. 9. Bland−Altman plots of (a) Intra-observer agreement, and (b) inter-observer agreement for clinical wear penetration measurements.

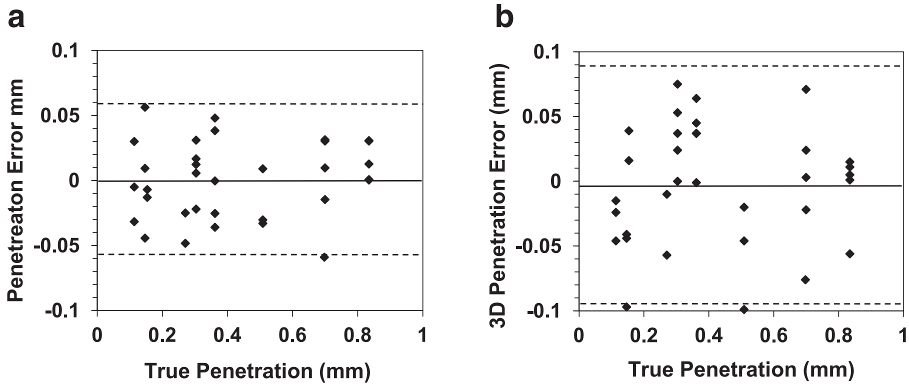

Fig. 10. (a) Standard, 2D "wear" penetration error (new measurement system), using a metal femoral head. (b) RSA, 3D "wear" penetration error, using a metal femoral head. Solid line: mean; dashed lines: mean ±2SD.

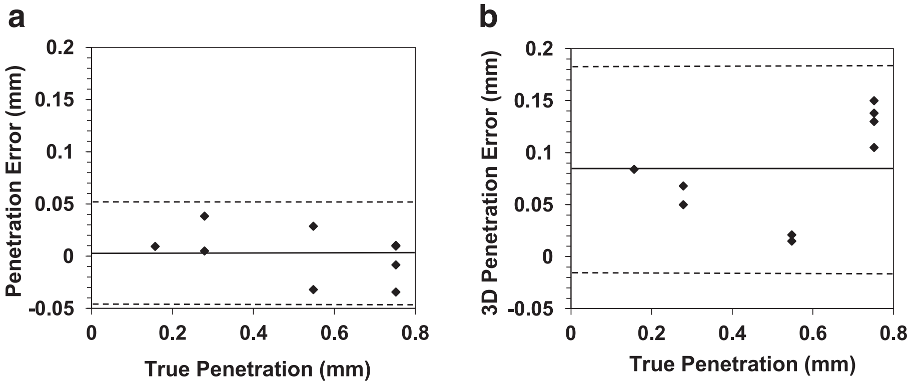

Fig. 11. (a) Standard, 2D "wear" penetration error (new measurement system), using a ceramic femoral head. (b) RSA, 3D "wear" penetration error, using a ceramic femoral head. Solid line: mean; dashed lines: mean ±2SD.

image quality under such laboratory conditions was better than that found in clinical radiographs [20]. The test jig was designed to obviate this limitation to some extent by using multiple layers of acrylic to create local X-ray scatter similar to that produced by soft tissue (Fig. 5). In addition, the X-ray machine settings were adjusted in an attempt to simulate the appearance of clinical images. On a radiograph of an all-PE cup, the femoral head image is usually relatively sharp over most of its periphery. This facilitates automatic edge-detection and ensures a high accuracy of the head image co-ordinates. The wire marker image (used as a reference for the changing position of the head image) is usually not as sharp but it is often of good quality if a modern, digital X-ray machine is used. The clinical images (scanned from film) that we used for the repeatability tests in our study were not of high quality – the wire marker image was locally "contaminated" by bone cement in some cases. However, the software incorporates a function which enables manual masking of certain regions that automatic edge-detection has not successfully avoided and this enabled us to achieve very repeatable results (Figs. 9a, b).

In this study, a single measurement of the reference (baseline) image was taken at each setting. The mean of three repeated measurements of the "follow-up" image was then compared to the reference measurement in order to calculate the "wear". For the many settings used in this study, this technique seemed to work. Even though the variation in the three "follow-up" penetration measurements was generally only a few hundredths of a millimetre, it was found that the mean value was generally closer to the "true" setting than the individual measurements. At each particular setting, variations in the measurements would have been caused by slight differences in manual point taking. The "seed" parameters of the fitting routines would therefore have varied slightly. The mathematical fitting of an ellipse to a series of data points, for example, depends upon five "seed" parameters (x, y, a, b, θ) which are created manually, and slight variations in these can cause the start/finish locations of the evenly spaced, edge-detected points to vary for each repeated measurement. In other words, slight variations in the manual seed parameters can also cause variations in the data set of edge-points. These point co-ordinates are unlikely to sit on a perfect elliptical shape due to effects such as image resolution, local variations in pixel intensity (image sharpness), and quality of the image shape (due, for example, to the wire marker not being perfectly circular). In such circumstances, a "best fit" is not necessarily a perfectly repeatable fit. Repeated, fitted ellipses would, therefore, have slightly different centre co-ordinates, shapes and orientations.

Most of the modern, computerized wear measurement techniques have been validated for uncemented cups only. One exception is the EBRA technique which has been validated for cemented cups using RSA as the reference standard [21]. The mean (SD) measurement error was found to be 0.11 mm (0.12 mm) – or 0.08 mm (0.11 mm) if some of the radiographs were rejected because of the presence of pelvic tilt. This accuracy is several times worse than that determined for our system.

More recently, the Hip Analysis Suite (HAS) [2] has been updated for measuring wear of cemented (all-PE) cups more accurately. It fits a circle/ellipse to the image of the cup surface in order to provide a cup reference point. However, even with good quality radiographs and image enhancement, the cup-cement interface can often be indistinct and non-circular (Fig. 12) and so accurate and repeatable circle/ellipse fitting could be difficult to

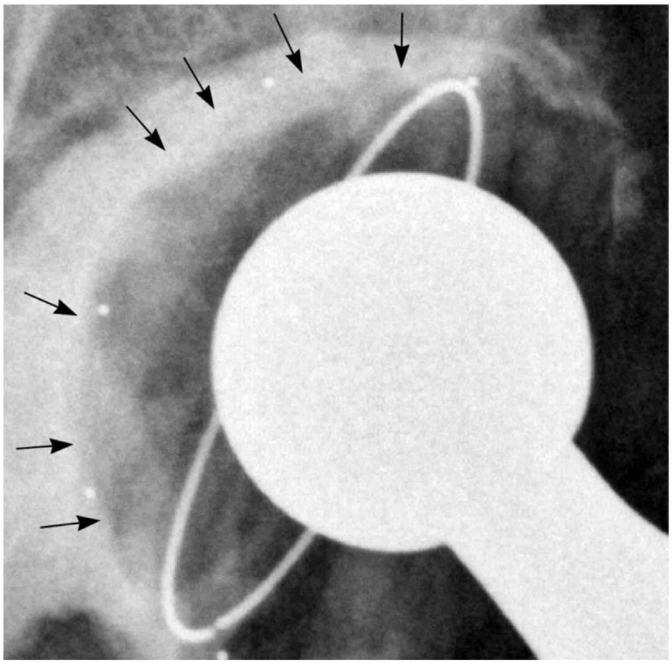

Fig. 12. An enhanced image of a clinical radiograph of a cemented cup. The cup outline is barely distinct, non-circular and disappears in several regions (arrows). Note the clarity of the wire marker. Marker beads in the cup surface were not used in the present study.

achieve. In a laboratory validation study of the new system, Langlois et al. [22] found that its repeatability was inferior to RSA but its accuracy "approximates RSA techniques". They reported a mean (SD) bias of 0.089 mm (± 0.06 mm) and a repeatability (95% limit) of 0.106 mm (0.292 mm) [22]. No clinical radiographs were assessed. Their radiographic measurements were of a single cup maintained at a constant orientation (i.e. same cement interface image), and with a constant position of the central X-ray beam. In order to simulate wear, the XY position of the femoral head was accurately incremented relative to the cup using a micrometer controlled platform [22] and so no out-of-plane wear was simulated. In our view, this technique of using exactly the same settings for all radiographs does not sufficiently simulate clinical conditions.

It is widely held that the key advantage of RSA is that it can measure out-of-plane wear and can compensate for variations in pelvic tilt and/or rotation in serial images. However, several studies have shown that wear occurs mainly in the coronal (A-P radiographic) plane [23–25] or that out-of-plane wear is not statistically significant [8,26]. In addition, the clinical measurement precision of RSA in the out-of-plane direction has ranged between 0.2 mm [27] and 0.34 mm [8], which is very large compared to the magnitude of XLPE wear. This is probably why some researchers refer to the proximal (i.e. 2D) wear in their publications [6–9]. In the present study, a mixture of cup orientation settings (version and internal/external rotation) was used in an attempt to simulate the possible range of pelvic tilt and rotation effects on the measured 2-D wear vector. In addition, the effect of different X-ray focus positions was assessed. Because our 2-D system corrects for changes in cup orientation and projection, these variations had no appreciable effect on the calculated wear vectors. Wear penetration errors in our laboratory tests (Fig. 7) and in measurements of clinical radiographs (Fig. 9) were similar to those found in our RSA tests (Figs. 10, 11). "Wear" direction errors were generally within ±10° but were worst at very low wear penetrations (Fig. 7b). Since wear volume is estimated using the wear direction angle [14], its accuracy would also be worse at very low penetration values. However, it should be borne in mind that creep accounts for much of the early penetration (about 0.1 to 0.2 mm [28,29]) and is usually subtracted when calculating the wear rate.

Clinical cup wear measurement has an important use in the assessment of different types of polymer that manufacturers introduce. To date, the majority of studies on different types of XLPE have used uncemented cup liners. Since radiographic measurement techniques for uncemented cups rely on the cup shell as a reference datum, movement or "backside wear" of the PE liner within the shell could exaggerate the wear measurements. Wear studies of all-PE, cemented cups are therefore advantageous in this respect [7–9].

Conflict of interest

None.

Ethical approval

Not required.

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Software enquiries

The software is owned by the funding charity (Arthritis Research UK). To apply for a copy, please contact research@arthritisresearchuk.org mentioning the above grant numbers.

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