

Quantification of clearance and creep in acetabular wear measurements

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Background: This study aimed to measure femoral head penetration before occurrence of real wear, and to quantify the portions attributable respectively to clearance and plastic deformations in various acetabular designs.

Methods: We analyzed CT scans from 15 patients at 'day five' after total hip arthroplasty (THA). All patients received Exafit[®] femoral stems and 28 mm heads: 5 patients had cemented Durasul[®] all-PE cups, 5 patients had uncemented Allofit[®] metal-backed cups, and 5 patients had uncemented Stafit[®] dual-mobility cups. We also analyzed CT scans of samples of the three head-cup combinations to compare *in vivo* and *in vitro* measurements.

Results: The mean femoral head penetration measured on 'day five' was lower for all-PE cups (0.196 mm) than for metal-backed cups (0.551 mm) and dual-mobility cups (0.634 mm).

Conclusions: The present study indicates that isolated measurements of femoral head penetration include 0.15–0.46 mm of radial clearance and 0.05–0.27 mm of creep, and confirms that the majority of so-called bedding-in observed in the first post-operative months is not entirely due to wear.

Keywords: Total hip arthroplasty (THA); polyethylene wear; femoral head penetration

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Introduction

The consequences of polyethylene (PE) wear remain a principal cause of long-term failure in total hip arthroplasty (THA) (1-5). *In vivo* measurements of PE wear are regularly made to identify patients at risk, estimate the time for component wear-through, compare performance of bearing couples, and adjust frequency of follow-up of osteolytic lesions in patients at risk (6,7).

Wroblewski *et al.* (8) and Sychterz *et al.* (9) were among the first to describe the biphasic pattern of wear in THA, which is rapid in an initial "bedding-in" phase, but relatively slow in a later "steady state" phase. The studies highlighted that femoral head penetration during the "bedding-in" phase is not entirely caused by abrasive wear, and that it should be subtracted from annual penetration

measurements, in order to estimate true wear rates. Numerous studies thereafter affirmed that "bedding-in" lasts 6 to 24 months depending on implant design and type of PE (10-18). There is little consensus in the literature, however, on the precise definition of "bedding-in", other than it comprising a combination of creep and abrasive wear of the PE.

A prosthetic hip joint is considered perfectly spherical from a mechanical perspective, but in reality the outer diameter of the femoral head is slightly smaller than the inner diameter of the acetabular liner, and therefore the components articulate with some eccentricity. This eccentricity is termed 'clearance', and is important to ensure smooth tribology, as it prevents jamming and facilitates lubrication with synovial fluid (19-25). Each bearing couple has a unique clearance, which depends on its



Figure 1 The three types of acetabular cup used (all manufactured by Zimmer Inc., Warsaw, IN, USA): (A) cemented Durasul® highly cross-linked all-PE cup; (B) un-cemented Allofit® metal-backed titanium acetabular cup with press-fitted Durasul® highly cross-linked PE liner; and (C) un-cemented Stafit® dual-mobility CoCr acetabular cup with mobile Sulene® conventional PE liner.

articular diameter and materials. Consequently, ‘absolute’ measurements of femoral head penetration (at a specific instant of time) include the clearance, which is not caused by wear nor creep, and this is why ‘relative’ measurements of femoral head penetration (subtraction of two absolute measurements at different instants of time) are required to estimate true wear (13,16,17,26). Numerous authors described clearance qualitatively, but to our knowledge, there are no published studies that analyze clearance quantitatively before the occurrence of true wear.

The aim of this study was to measure the initial femoral head penetration before occurrence of true wear, and to quantify the portions caused respectively by clearance and creep in three types of acetabular component: monobloc cemented all-PE (control), modular uncemented metal-backed PE, and modular uncemented dual-mobility PE. Such data would allow measurement of true PE wear and enable more realistic monitoring and comparison of bearing couples and implant survivorship.

Methods

From the database of patients operated for THA between May and July 2015 by the senior author (EV) at our centre, we studied post-operative computed tomography (CT) scans of 15 patients, recruited from a routine surgery waiting list for treatment of primary hip arthritis. For both ethical and cost considerations of exposing patients to additional radiation for the purpose of this research, special permission was approved in advance from our institutional review board, and signed informed consent was obtained from each patient.

The patients included 7 men and 9 women aged 57 to 82 years. All patients received the same cemented Exafit® cobalt-chromium (CoCr) femoral stem (Zimmer, Warsaw, IN, USA), assembled with a diameter 28 mm Exafit® CoCr femoral head (Zimmer, Warsaw, IN, USA), but received one of three different acetabular cups (*Figure 1*):

Group A: five patients received a cemented Durasul® highly cross-linked all-PE acetabular cup (Zimmer Inc., Warsaw, IN, USA). The mean weight of patients was 71.4 kg. The engineering drawings indicate that this cup has an articular centre of rotation 3.3 mm above the equatorial titanium ring of cross-sectional diameter 0.8 mm, which is press-fitted in slot of 0.7 mm (*Figure 1A*).

Group B: five patients received an un-cemented Allofit® metal-backed titanium acetabular cup (Zimmer Inc., Warsaw, IN, USA), with a press-fitted Durasul® highly cross-linked PE liner (Zimmer Inc., Warsaw, IN, USA). The mean weight of patients was 74.4 kg. The engineering drawings indicate that the cup is not a perfect hemisphere but that its articular centre of rotation coincides with the center of its rim (*Figure 1B*).

Group C: five patients received an un-cemented Stafit® dual-mobility CoCr acetabular cup (Zimmer Inc., Warsaw, IN, USA), with a mobile Sulene® conventional PE liner (Zimmer Inc., Warsaw, IN, USA). The mean weight of patients was 72.4 kg. The engineering drawings indicate that the cup is not a perfect hemisphere but that its articular centre of rotation coincides with a plane passing through half of its rim (*Figure 1C*).

The engineering drawings of all femoral and acetabular implants were made available by the manufacturer (Zimmer, Warsaw, IN, USA). The nominal articular diameters and

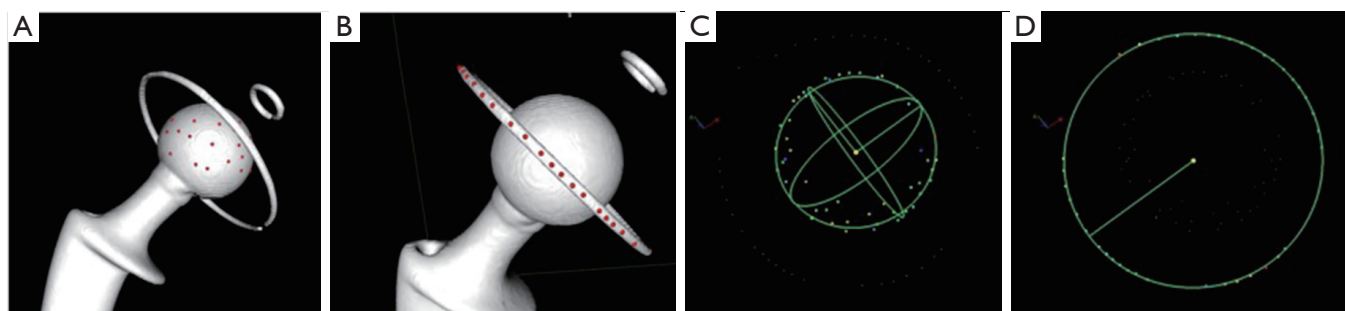


Figure 2 The principle stems of image processing method: (A,B) digitization of 40 points evenly on three-dimensional image reconstructions of each component of CT scanned implants using OsiriX; (C,D) calculation of centre and diameter of a spherical femoral head and of circular metallic ring of PE acetabular component using by the method of least squares in 3DReshaper software.

tolerances indicated were mm for the CoCr femoral head and 28.5 ± 0.1 mm for all the PE acetabular liners. The three implant combinations therefore have a clearance between the CoCr femoral head and the PE acetabular liner in the range 0.400 to 0.690 mm diametrically (0.200 to 0.345 mm radially). The dual-mobility cups have an additional clearance, between the outer surface of the PE acetabular liner and the inner surface of the metallic cup, in the range 0.750 and 1.050 mm diametrically, or 0.375 to 0.525 mm radially.

All patients were allowed to walk on the second post-operative day, and had a pelvic CT scan taken on the fifth post-operative day ('day five'), just before they were discharged. The patients were scanned following the same protocol using a 64 Slices Multi-Detector Scanner (General Electric, Waukesha, WI). The CT scans were taken with a contiguous thickness of 0.625 mm with settings of 12 kV and 70–120 mA. Each CT scan contained 200 to 350 DICOM images and was recorded on a separate CD-ROM. We used the image processing software OsiriX (Pixmeo SARL, Bernex, Switzerland), dedicated to DICOM images, to generate 3D bone reconstructions of each CT scan (27,28). The 3-D surface reconstructions were created using the surface rendering function in OsiriX with software settings optimized for metal (pixel value, 2,000; high resolution, 0.50; smooth iterations, 80). This CT technique has a proven accuracy of 0.050 mm and repeatability of ± 0.040 mm, using cemented all-PE Acoplot implants (Zimmer Inc., Warsaw, IN, USA) or uncemented metal-backed PE Pressfit Kappa Acora implants (Zimmer Inc., Warsaw, IN, USA) (29).

To enable comparison of pre- and post-operative femoral head penetration in the three different acetabular cups, we gathered samples of the three head-cup combinations (groups A, B and C) assembled tightly without application

of additional load, and scanned them following the same CT protocol described above.

The resulting 18 CT scans (15 post-operative hips and 3 non-implanted samples) were analyzed as follow: we compared the 3D coordinates of center of the femoral head and the center of the acetabular cup (*Figure 2*). Forty digitized points were evenly placed on a 3D reconstruction of the femoral head, the metal ring of the all PE cup and the equatorial plane of the metal-backed cups. The coordinates of digitized points were exported using OsiriX to a file as comma-separated variables (CSV). A geometric analysis software, 3D Reshaper[®] (Technodigit, Gleizé, France), was used to deduce the coordinates of the articular head center by fitting a sphere to its points, and the center of the acetabular component by fitting a circle to its points, in both cases using the method of least squares. The point coordinates were further manipulated in spreadsheets using Microsoft Excel[®] (Microsoft Corp, Redmond, WA, USA) to calibrate all coordinates to the known femoral head diameter and to deduce the head-cup eccentricity as is the case with Muller-type all-PE acetabular components, with reference to the engineering drawings of each acetabular component.

The 3D surface rendering was different for each type of acetabular cup (*Figure 3*). For the all-PE implants, both the metallic femoral head and the metallic equatorial ring were perfectly visualized, despite few irregularities on the metallic ring. For metal-backed cups, both the CoCr femoral head and the Titanium cup were perfectly visualised without beam-hardening artifacts, but the proximity of components created an equatorial band of increased thickness. Our CT scan analysis remained valid as long as the points were not placed on artifacts. The dual-mobility cups were not well visualized because of beam-hardening artifacts, created by

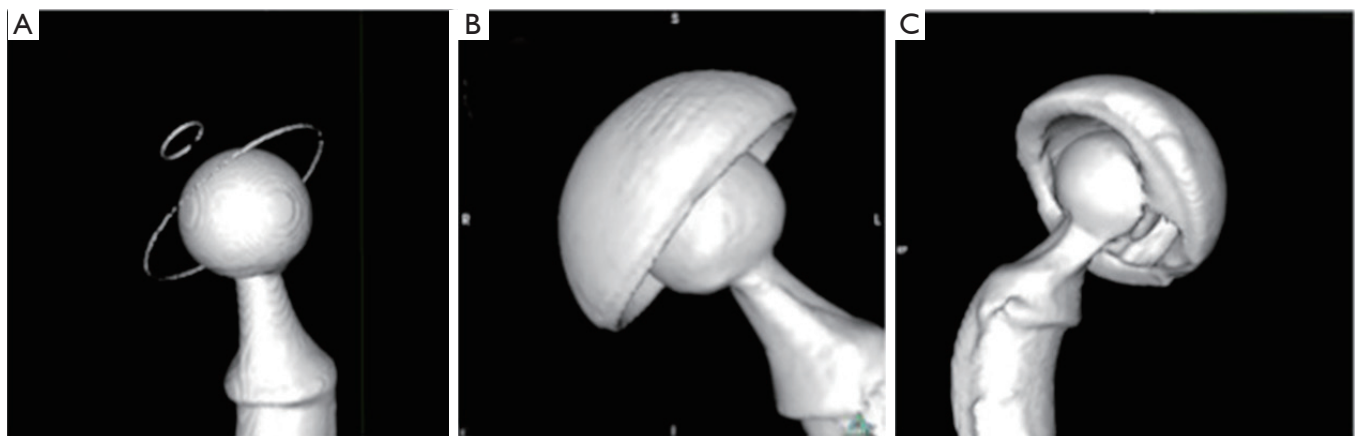


Figure 3 Three-dimensional surface reconstructions by OsiriX from CT scans of three types of acetabular component: (A) cemented Durasul® highly cross-linked all-PE cup; (B) un-cemented Allofit® metal-backed titanium acetabular cup; and (C) un-cemented Stafit® dual-mobility CoCr acetabular cup.

Table 1 3D penetration of CoCr femoral heads in PE acetabular liners calculated from patient CT scans taken on ‘day five’

Acetabular cup (patient group)	Patient	Weight (kg)	Penetration (mm) (mean ± SD)
Durasul® all-PE (group A)	N 1	72	0.199±0.054
	N 2	76	0.187±0.049
	N 3	60	0.216±0.021
	N 4	80	0.181±0.055
	N 5	69	0.197±0.039
Allofit® metal-backed (group B)	N 6	66	0.508±0.108
	N 7	80	0.538±0.083
	N 8	68	0.582±0.084
	N 9	78	0.551±0.135
	N 10	80	0.576±0.098
Stafit® dual mobility (group C)	N 11	56	0.567±0.063
	N 12	68	0.609±0.089
	N 13	73	0.676±0.066
	N 14	80	0.719±0.057
	N 15	85	0.597±0.098

PE, polyethylene.

the proximity of the two metallic parts, which degraded the sphericity of the femoral head and rendered it impossible to position points on the femoral head and the PE liner using the 3D reconstructions. We therefore used the 2D orthogonal reconstructions created by OsiriX to calculate the eccentricity between the head and cup for dual-mobility

implants.

We studied the intra-observer error of our method by blindly repeating the measurement procedure ten times on all 18 CT scans by the same senior surgeon (EV). Statistical analyses were done using SPSS (IBM Corporation, Armonk, New York, USA) and its statistical module.

Results

The total femoral head penetration in PE acetabular liner, measured *in vivo* from CT scans taken after weight bearing on ‘day five’ (Table 1), was considerably lower for Group A (Durasul® all-PE cups) (0.196 mm) than for Groups B (Allofit® metal-backed cups) (0.551 mm) and C (Stafit® dual-mobility cups) (0.634 mm).

The clearance measured *in vitro* from CT scans of assembled implant samples (Table 2) was also lower for the cemented Durasul® all-PE cups (0.149 mm) than for the un-cemented Allofit® metal-backed cups (0.455 mm) and the un-cemented Stafit® dual-mobility cups (0.367 mm).

The intra-observer repeatability of measurements is indicated by the standard deviation (SD), which was generally less than 0.1 mm. For *in vitro* measurements, the intra-observer repeatability was best for the Durasul® all-PE cups (SD 0.035 mm) and worst for the Stafit® dual-mobility cups (SD 0.098 mm). For *in vivo* measurements, the intra-observer repeatability was again best for the Durasul® all-PE cups (SD 0.044 mm) but worst for the Allofit® metal-backed cups (SD 0.102 mm).

Table 2 3D penetration of CoCr femoral heads in PE acetabular liners calculated from CT scans of sample implants (*in vitro*) and of patients (*in vivo*) on ‘day five’

Acetabular cup	Weight (kg)	Penetration (mm)		Difference (mm) (Creep + thermal expansion)
		<i>In vitro</i> (clearance only) (mean ± SD)	<i>In vivo</i> (clearance + creep + thermal expansion) (mean ± SD)	
Durasul [®] all-PE (group A)	71.4	0.149±0.035	0.196±0.044	0.047
Allofit [®] metal-backed (group B)	74.4	0.455±0.036	0.551±0.102	0.096
Stafit [®] dual-mobility (group C)	72.4	0.367±0.098	0.634±0.075	0.267

PE, polyethylene.

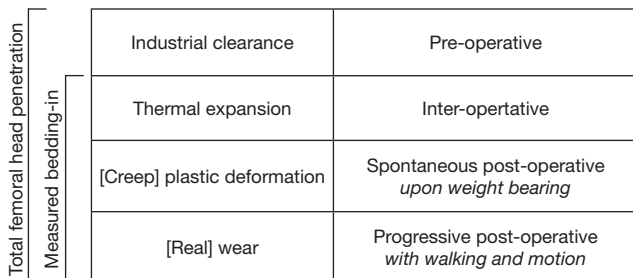


Figure 4 Constituents of femoral head penetration in a polyethylene acetabular insert. Only 3 of 4 components (industrial clearance, thermal expansion, and plastic deformation) are measurable on ‘day 5’.

Discussion

The aim of this study was to measure the initial femoral head penetration in THA before occurrence of true wear, and to quantify the portions attributable to clearance and plastic deformation of PE, in three types of acetabular component. The results revealed that femoral head penetration on ‘day five’ amounts to 0.2 to 0.6 mm, of which 58% to 83% could be attributed to ‘clearance’. The extent of this initial penetration depends on the type of acetabular cup, and is considerable when compared to total ‘bedding-in’ observed in the first years after implantation (8,11).

The total femoral head penetration in a PE liner during the lifetime of a THA could be considered as the sum of four factors (*Figure 4*): (I) clearance between articular components; (II) thermal expansion of the PE liner upon implantation; (III) rapid creep or plastic deformation upon weight-bearing; and (IV) slow true wear from walking and motion. The penetration measured on ‘day five’ includes only the first three factors and excludes the fourth factor. The existence of multiple factors could explain the usual overestimation of radiological wear measurements

in comparison to direct measurement (30). It remains difficult, however, to estimate with certainty the portions due to clearance and to plastic deformation, notably because the effects of thermal expansion are unknown. The *in vitro* samples were scanned at room temperature around 22 °C, whereas the *in vivo* implants were scanned at body temperature around 37 °C. This temperature difference of 15 °C would change the liner thickness by 0.2% to 0.3%, through exact dimensional increases cannot be predicted for complex shapes (21). Thermal expansion is an issue rarely raised in orthopedic literature, although PE has one of the highest coefficients of thermal expansion among plastics, about 10 to 20 times greater than that of metals (31).

It is worth noting that material properties, including mechanical strength and thermal expansion coefficients, are not identical for all implanted PE liners. Groups A and B received Durasul[®] highly cross-linked PE liners, whereas Group C received Sulene[®] conventional PE liners. The elastic limit and creep resistance of highly cross-linked PE is greater than the mechanical strength of conventional PE. This probably explains why the difference between *in vitro* and *in vivo* penetration (*Table 2*) is considerably smaller for Groups A and B than for Group C—and inversely—why the proportion of penetration attributed to clearance is greater for Groups A and B than for Group C. Lee and Pienkowski (32) observed that creep occurs in less than three days, whereas Deng *et al.* (33) argued that it progresses over the first month. It is therefore possible that our measurements at ‘day five’ may not represent the full extent of creep that those implants could exhibit after the first month.

It is also worth noting that the clearances are not identical for all implanted PE liners: Group A received monolithic all-PE liners which exhibit a single ‘primary’ head-liner clearance, whereas Groups B and C received modular PE liners assembled within metallic shell and thus exhibit an additional ‘secondary’ liner-shell clearance (34). This

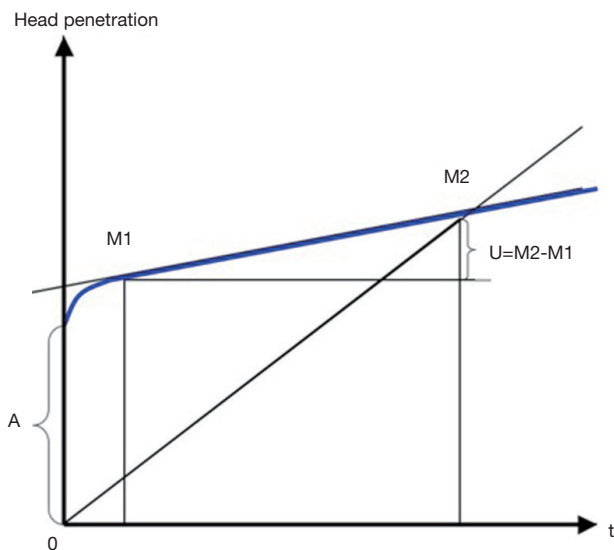


Figure 5 Graphic illustration of femoral head penetration over time. The graph does not start at the origin because of clearance and post-operative creep (A). A relative measurement (U) comparing head penetration at two time intervals (M1 and M2) would eliminate errors and indicate true wear.

probably explains why both *in vivo* and *in vitro* penetration (Table 2) are considerably lower for Group A than for Groups B and C. Barrack *et al.* (30) reported that the liner-shell clearance is in the range 0.1 to 0.6 mm for a particular implant model, whereas Sychterz *et al.* (9) argued that this gap reduces over time with creep.

The repeatability of our measurements is consistent with values reported for the method of Vandebussche *et al.* (29) which has a proven accuracy of 0.050 mm and repeatability of ± 0.040 mm. The method used in the present study had been validated by comparison with direct measurements, which in our opinion are the Gold Standard, but was not compared to the accuracy of radiological measurement methods such as RSA or other digitized radiological methods such as that of Martell and Berdia (35). The advantages of our method are the use of open-source software, and its rapidity and applicability to all types of acetabular cups whether all-PE or metal-backed. Furthermore, there were no significant weight differences among patients, which implies that head penetration due to plastic deformation under weight bearing is comparable among the three groups. The disadvantages of our method are the need for the engineering drawings of the implants used and the need for postoperative pelvic CT scans with thin 0.625 mm slices.

The impact of clearances is virtually unknown in the orthopaedic community because it has little or no impact on clinical practice. Surgeons may be aware of some clearance to avoid jamming and facilitate lubrication, but they seldom relate this clearance to wear measurements. Few surgeons realize that the average diameter of a “28 mm” ceramic femoral head is 27.975 mm ($28^{+0}_{-0.05}$), and for a cobalt-chromium femoral head is 27.955 mm ($28^{+0}_{-0.05}$). Penetration of a femoral head in PE over time is usually represented on graphs starting from a zero value on the ordinate (13,16,17,26). It would seem more appropriate to indicate the clearance on such graphs (Figure 5).

The present study indicates that isolated measurements of femoral head penetration include 0.15 to 0.46 mm of radial clearance and 0.05 to 0.27 mm of creep. The study also confirms that the majority of so-called bedding-in observed in the first post-operative months or years is not entirely due to wear.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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