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Radiostereometric analysis of hemiarthroplasties of the hip – a highly precise method for measurements of cartilage wear☆

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SUMMARY

Objective: Cartilage wear is a feature of osteoarthritis and rheumatoid arthritis. Precise measurements of wear have been difficult. Cartilage wear caused by an artificial articulating joint surface is a well-known feature of hemiarthroplasties. The aim of this study was to demonstrate that radiostereometric analysis (RSA) may be used for three-dimensional measurements of cartilage wear in hemiarthroplasties of the hip.

Method: We performed a phantom model study to assess the feasibility of a subsequent clinical trial. We showed that the motion of the prosthetic head relative to the pelvis was not influenced by the orientation of the prosthetic head. Twenty-two patients were randomised to treatment with a cemented or an uncemented hemiarthroplasty for an acute femoral neck fracture. Migration of the prosthetic head into the acetabulum was measured using RSA.

Results: A mean migration of the prosthetic head into the acetabulum of 0.62 mm was found at 3 months [95% confidence interval (CI): 0.27–0.97] and a further migration of −0.07 mm at 12 months (95% CI: −0.16–0.32). There were no differences between the groups in prosthetic migration or functional outcome. Between three and 12 months, there was no detectable cartilage wear during the first postoperative year.

Conclusion: Whether the migration during the first 3 months represents a period of bedding in due to a harder opposite surface remains to be shown. RSA may be used for measurement of cartilage wear in hemiarthroplasties of the hip. This study demonstrates a highly precise method for measurements of cartilage wear.

Introduction

Articular cartilage degradation is the main feature of osteoarthritis, and may also occur as a result of cartilage damage in conditions such as rheumatoid or septic arthritis, and after injury[1]. Hemiarthroplasty is a surgical procedure that replaces half the joint with an artificial surface and leaves the other part in its natural state. Hemiarthroplasty is most commonly performed in the shoulder and the hip, and is the most common treatment for displaced femoral neck fractures[2,3]. Although few studies describe the influence of the artificial joint surface on the cartilage in hemiarthroplasties, cartilage degradation and prosthesis protrusion are well-known phenomena in hemiarthroplasties[4]. It has been histologically demonstrated that the acetabular cartilage degrades more rapidly in response to articulation with a metal head[5,6]. Both cemented and uncemented hemiarthroplasties are commonly used, both having good clinical results[7,8]. However, one study has demonstrated acetabular and femoral osteolysis using uncemented hydroxyapatite-coated hemiarthroplasties[9]. Acetabular wear may lead to pain and decreased function, and ultimately a reoperation with conversion to a total hip arthroplasty. Attempts to radiologically quantify the rate of cartilage degradation and relevance to clinical outcome have shown inconsistent results[10,11].

Radiostereometric analysis (RSA) was introduced in 1974[12], and is a well documented method for measuring very small movements in the skeleton with high precision[13,14]. RSA utilizes small (0.5–1.0 mm) radiopaque spherical tantalum (Ta) markers placed into the patient's skeleton. Two simultaneous radiographs of the patient and a calibration object are then obtained at different angles. Measurements of the projected markers are used for

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reconstruction of the three-dimensional (3D) geometries of the markers in the skeleton, and of any implant examined. True 3D movements *in vivo* between one set of markers or implant with respect to another may be calculated with high precision[15]. The method has been used to study micro-motion *in vivo*, including prosthesis migration, joint kinematics, fracture stability, skeletal growth and vertebral motion[13,16,17]. One clinical trial has reported differences in wear between two types of hemiarthroplasties of the hip[18].

The aim of the present study was to demonstrate that RSA may be used for the 3D measurements of acetabular cartilage wear. We used the model of hemiarthroplasties of the hip, measuring the migration of the centre of the prosthetic head relative to the pelvis between examinations. We hypothesized that there would be no difference in the acetabular degradation in patients randomised to a cemented or an uncemented bipolar hemiarthroplasty up to 1 year postoperatively.

Materials and methods

Phantom model study

A phantom model study was undertaken to ensure that the rotation of the bipolar head in the acetabulum did not affect our analyses, and to analyse the methological error in our RSA laboratory. We used the same equipment and examination method intended for the patients, and simulated the rotation of the bipolar head that necessarily occurs between examinations in patients. Since penetration of the head into the acetabulum was not simulated, the study assessed the accuracy and precision of measuring zero migration of the prosthetic head into the acetabulum. The phantom model was created using a replica of the pelvis (Sawbones, Pacific Research Labs, Vashon, WA, USA), a Corail bipolar hemiarthroplasty (DePuy/Johnson and Johnson, United Kingdom) and an elastic band to ensure the contact surface between the bipolar head and the acetabulum was maintained regardless of the rotation of the head (Fig. 1). Seven standard 1.0 mm Ta markers (RSA BioMedical, Umea, Sweden) were inserted into the pelvis; four around the acetabulum and three in the anterior superior iliac spine. An RSA calibration cage (cage 43, RSA BioMedical, Umea, Sweden) containing Ta markers for creation of 3D coordinates and built-in film cassette holders were placed behind the phantom. Eight digital radiostereometric examinations were performed using two fixed X-ray sources angled approximately 40 degrees in relation to each other. Between each examination, the bipolar head was manually rotated about its axis of symmetry in the acetabulum with approximately 10–30 degrees in all three dimensions. The motion of the centre of the head was calculated relative to the rigid body segment created by the Ta markers in the pelvis, and expressed as the total point movement (TPM). The centre of the bipolar head was determined by edge detection of the outer metal shell[15]. The first examination was used as the reference and was compared with the subsequent examinations for a total of seven analyses. Analyses were performed using UmRSA (Digital measurement 6.0, RSA Biomedical, Umea, Sweden).

Patients

The clinical trial was conducted at a university hospital from March 2006 to December 2007. We started recruiting patients from a larger randomised controlled trial of 230 hips, comparing a cemented and an uncemented hemiarthroplasty for the treatment of femoral neck fractures[8] (ClinicalTrials.gov Identifier: NCT00491673) and continued recruiting after completion of the large RCT. Recruitment was from March 2006 to December 2007. Patients aged 65 years or older who were admitted with a displaced intracapsular femoral neck fracture were eligible for inclusion. Patients with previous symptomatic hip pathology such as osteoarthritis, a fracture caused by malignant disease, or ongoing infectious disease were excluded. Patients with cognitive impairment or those in need of walking aids before the fracture were included in the larger RCT but excluded in this trial. Randomization was performed using a computer random number generator. Allocation was done by the surgeon on call using sealed, numbered, opaque envelopes. All patients provided informed consent. The protocol was approved by the regional ethics committee.

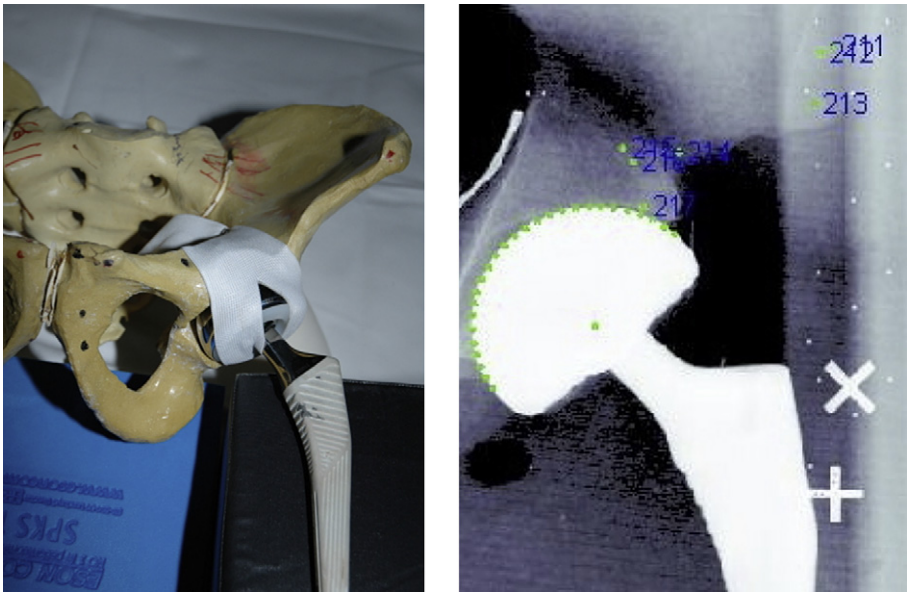

Fig. 1. The phantom model (left) and a radiostereometric image (right) with Ta markers in the pelvis (numbered) and in the calibration cage. The centre of the prosthetic head has been computer-calculated using edge detection.

Intervention

Patients underwent a bipolar hemiarthroplasty with either a cemented femoral stem (Spectron, Smith & Nephew, Memphis, TN) using Palacos R + G cement (Heraeus Medical GmbH, Wehrheim, Germany) or an uncemented press-fit hydroxyapatite-coated femoral stem (Corail, DePuy/Johnson and Johnson, United Kingdom). All patients received a 28 mm cobalt–chromium head and the same bipolar head (Mobile Cup, DePuy/Johnson and Johnson, United Kingdom). The bipolar head is a one-piece polyethylene hemispherical cup covered with a thin metal shell available in sizes from 43 to 58 mm diameter, all with an inner diameter of 28 mm. Arthroplasty was performed through a posterior approach with the patient in the lateral decubitus position, using spinal anaesthesia. Five or six 1.0 mm Ta spherical markers were inserted in the pelvis around the acetabulum and three in the anterior superior iliac spine using an UmRSA Injector (RSA BioMedical, Umea, Sweden) (Fig. 2). All patients were given preoperative intravenous cefalotin 2 g and a further three doses the first 16 h after the operation. All patients received 5000 IU low molecular weight heparin subcutaneously daily for at least 7 days. Six surgeons carried out the procedures. Early mobilization was encouraged in all patients, with weight bearing as tolerated.

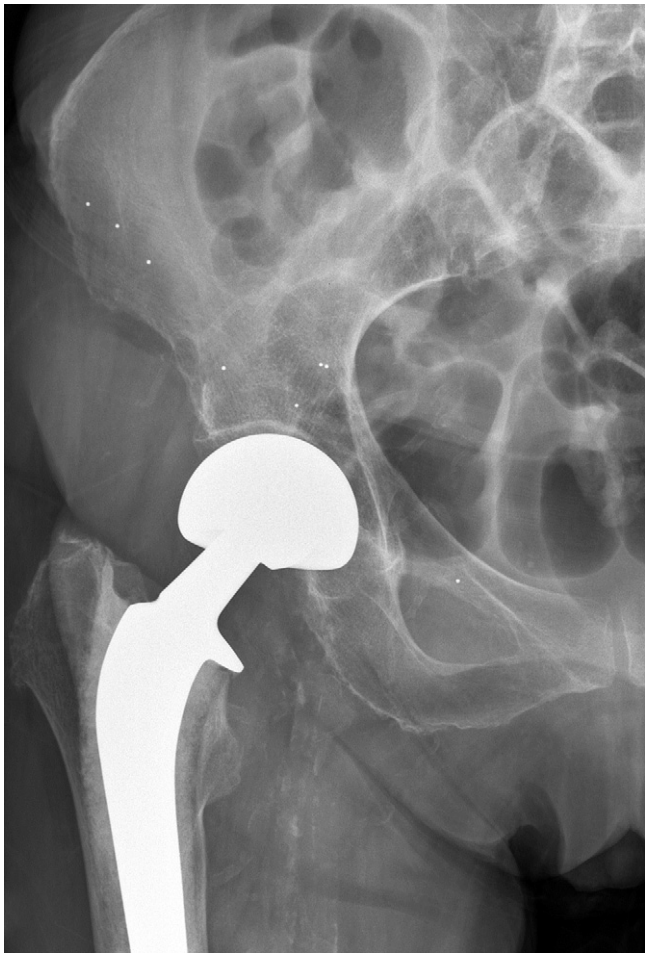

Fig. 2. A radiograph showing a cemented bipolar hemiarthroplasty of the right hip. Ta markers have been implanted around the acetabulum, in the anterior superior iliac spine, and in the superior pubic ramus.

Objectives and outcome measures

The primary outcome was the acetabular wear expressed by the 3D TPM between the centre of the prosthetic head and the pelvis at 12 months, calculated by the UmRSA software. Hip function was rated with Harris hip score (HHS)[19] ranging from 0 to 100 points covering a maximum of 44 points for absence of pain, 47 points for function and nine points for range of motion and absence of deformity. The Barthel Index (BI) was used to rate ability to perform activities of daily living (ADL)[20]. Health related quality of life was rated by the patient-assessed EQ-5D (Euroqol)[21].

Data collection

Data were collected during hospital stay, and at three and 12 months. The surgeon on call collected data during admission. A trained research nurse who was blinded to the intervention collected data at follow-up visits at three and 12 months. The radiostereometric examinations used as a reference were done postoperatively after mean 3 days (range 2–6) after the patients were mobilized, and were compared with the examinations at three and 12 months. To determine the precision of our measurements, all examinations were done in the supine position and repeated on the same day with repositioning of the patient between the scans. The precision was then calculated from the difference in 3D TPM between these double-examinations at all time intervals. For analyses of acetabular wear, double-examinations of all patients at two time intervals were compared, and the mean result of the analyses was recorded.

Statistical methods

Sample size calculations were based on an assumed precision of 0.2 mm of our RSA measurements and a proposed clinically relevant difference in acetabular wear of 0.5 mm. Using the equivalence criterion[22], six patients in each group were required to have a power of 95% to show the mean wear is the same in both groups, using a two-sided alpha set to 0.05. To compensate for some loss of follow-up and mortality, we decided to include 22 patients. To avoid including RSA measurements of patients that may have been reoperated, all analyses were conducted on a "per-protocol" basis[22]. We used the two-tailed Fisher's exact test for dichotomous variables and *t* tests for HHS and EQ-5D index score. For comparisons of migration data between the groups, we used the independent-samples Mann–Whitney *U* test. SPSS version 17 for Macintosh (SPSS Inc, Chicago, IL) was used for statistical analyses.

Results

Phantom model study

The ability to properly determine the edge of the outer metal shell of the prosthetic head using RSA is expressed as the mean error of elliptic fitting[23], which was mean 0.024 mm [Standard deviation (SD) = 0.006], calculated from all eight double-examinations. From the seven analyses simulating prosthetic head rotation but no migration into the acetabulum, the accuracy of measuring zero migration, expressed as the mean TPM of the prosthetic head, was 0.195 mm [95% confidence interval (CI): 0.100–0.289]. For the three cardinal axes, the precision (mean difference between all double-examinations with 95% CI for the mean) was, for the *X*-axis −0.049 (−0.150–0.052), for the *Y*-axis 0.001 (−0.051–0.053), and for the *Z*-axis 0.034 (−0.140–0.208). We concluded that the centre of the bipolar head would be calculated precisely, and that the rotation of the head about its axis of

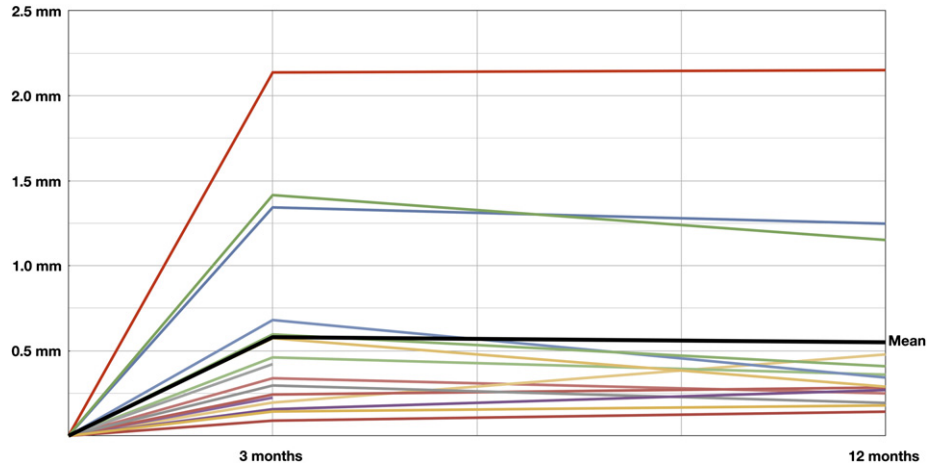

Fig. 3. Graph showing the 3D TPM of 16 patients at 3 months and 14 patients at 12 months. Each line represents one patient. Black line represents the mean TPM of all patients.

symmetry would not influence on our analyses if acetabular wear of more than 0.5 mm was to be measured.

Clinical trial

We recruited 22 patients (19 women) with mean age 78 years (range 65–88). Before the first follow-up, three patients had died (one in the cemented and two in the uncemented group), one withdrew from the trial not disclosing the reason, one withdrew after being treated for a deep wound infection, and one was excluded from analyses after being reoperated for a dislocated prosthesis with conversion to a total hip arthroplasty, leaving eight patients in each group for analyses at 3 months. Between the two follow-ups, one patient withdrew from the trial and one was excluded from analyses after being reoperated for a dislocated prosthesis, leaving seven in each group for analyses at 12 months.

For the whole group, the mean TPM between the prosthetic head and the pelvis was 0.62 mm at 3 months (95% CI: 0.27–0.97) and 0.55 mm at 12 months (95% CI: 0.22–0.88). All variability between patients occurred between the reference examination and 3 months (Fig. 3). From three to 12 months, the TPM was −0.07 mm (95% CI: −0.16–0.32). Migration data for the three cardinal axes and TPM are presented in Table I. The precision of the measurements expressed by the mean difference between all double-examinations was, for the *X*-axis 0.024 mm (99% CI: −0.010–0.058), for the *Y*-axis −0.019 mm (99% CI: −0.037–0.000), and for the *Z*-axis −0.013 mm (99% CI: −0.046–0.019). The distribution of the markers in the pelvis was assessed using the condition number which was below 150 in all cases (mean 44; range: 14–127). The stability of the markers was assessed using the mean error of rigid body fitting, which was below 0.35 in all cases. There was no significant difference in TPM from three to 12 months between the cemented and the uncemented groups ($P = 0.95$). No acetabular wear was detected on plain radiographs at three or 12 months.

There were no significant differences in baseline data or in any outcome measures between the two groups throughout the trial (Table II), though the trial was underpowered to detect any potential differences in these data. The HHS, BI and EQ-5D scores were comparable to the larger randomised trial from which the patients were recruited[8]. There were no correlations between functional outcome measures or weight, and rate of acetabular wear.

Discussion

In this study we demonstrate a highly precise method for measurements of cartilage wear in the human body. The most important finding was the consistent measurements of no acetabular degradation between three and 12 months, with a narrow CI and no outliers. From the postoperative RSA examinations up to 3 months, the results were more widespread, suggesting that the initial postoperative period involves a variation in settling of the prosthetic head in the acetabulum during weight bearing, or that the true initial wear is larger for some patients than for others. Geometrical differences between the spherical prosthetic head and the acetabulum, differences in cartilage thickness, differences in cartilage elasticity, and presence of intra-articular blood may explain this phenomenon. This early period may be similar to the period of plastic deformation (creep) or “bedding in” seen in RSA studies of polyethylene wear in prosthetic acetabular cups, that is followed by a slower rate of polyethylene wear[24]. It is, as far as we know, impossible to differentiate between plastic deformation and wear in cartilage and subchondral bone.

All RSA examinations in this trial were conducted with the patient in the supine position. We do not know whether RSA examinations during weight-bearing would differ from our findings, however, one trial found no differences between supine and standing RSA measurements of wear of total hip arthroplasties[25].

The patients in this trial were generally more healthy than the average patient in the larger randomised trial from which they were recruited[8]. Although we did not quantify their level of activity, number of steps or walking distance between follow-up intervals, the functional outcome scores indicate a functional level similar to,

Table I
Migration in mm (95% CI) along each cardinal axis and TPM at three and 12 months

	X-axis	*Y*-axis	*Z*-axis	TPM
3 months	−0.19 (−0.59–0.24)	0.13 (−0.02–0.29)	−0.08 (−0.28–0.12)	0.62 (0.27–0.97)
12 months	−0.16 (−0.55–0.22)	0.15 (0.02–0.28)	−0.10 (−0.29–0.08)	0.55 (0.22–0.88)

Table II
Characteristics and functional outcome for patients according to treatment. Figures are numbers* (percentages) of patients unless stated otherwise

	Cemented	Uncemented	Mean difference or relative risk (95% CI)	*P* value
Perioperative details				
Mean (SD) age at fracture (years)	78.4 (7.1) ($n = 11$)	78.2 (7.7) ($n = 11$)	0.18 (−6.4–6.8)	0.96
Mean (SD) weight at fracture (kg)	68.9 (8.9) ($n = 10$)	66.2 (13.6) ($n = 10$)	2.7 (−9.2–14.5)	0.64
Mean (SD) duration of surgery (min)	78.3 (17.6) ($n = 11$)	70.4 (9.9) ($n = 11$)	7.9 (−6.9–22.7)	0.27
Mean (SD) diameter of prosthetic head (mm)	48.1 (2.7) ($n = 11$)	47.0 (2.4) ($n = 11$)	1.1 (−1.2–3.4)	0.33
Mean (SD) intraoperative blood loss (ml)	360 (184) ($n = 11$)	340 (151) ($n = 11$)	20 (−138–178)	0.79
Mean (SD) HHS				
Baseline	94.0 (5.5) ($n = 11$)	96.4 (4.5) ($n = 11$)	2.4 (−3.4–8.3)	0.38
At 3 months	83.6 (8.6) ($n = 8$)	87.4 (7.0) ($n = 8$)	3.9 (−5.2–13.0)	0.37
At 12 months	80.7 (11.9) ($n = 7$)	84.7 (15.9) ($n = 7$)	4.0 (−12.4–20.4)	0.60
No (%) with BI of 19 or 20				
Baseline	11 (100) ($n = 11$)	11 (100) ($n = 11$)	n/a	n/a
At 3 months	5 (63) ($n = 8$)	7 (86) ($n = 8$)	0.71† (0.39–1.30)	0.57
At 12 months	5 (71) ($n = 7$)	6 (86) ($n = 7$)	0.83† (0.47–1.45)	1.00
Mean (SD) EQ-5D index score				
At 3 months	0.71 (0.12) ($n = 8$)	0.82 (0.10) ($n = 8$)	0.10 (−0.03–0.24)	0.13
At 12 months	0.62 (0.28) ($n = 7$)	0.80 (0.19) ($n = 7$)	0.18 (−0.10–0.46)	0.18
Mean (SD) EQ-5D visual analogue scale				
At 3 months	57 (20.4) ($n = 8$)	71 (13.6) ($n = 8$)	13.3 (−6.4–33.0)	0.17
At 12 months	65 (20.7) ($n = 7$)	79 (14.4) ($n = 7$)	14.1 (−6.6–34.9)	0.16

* Number varies because some information was missing for some patients.
† Relative risk.

or higher than, what is normal for elderly patients treated for femoral neck fractures[2,8].

The pathogenesis of osteoarthritis is not fully understood, but involves destruction of chondrocytes, disruption of the extracellular matrix, and subsequent proteoglycan depletion – as a possible result of acute trauma, overuse, or altered mechanics[26,27]. In hemiarthroplasties of the hip, reviews of patient series have suggested that the rate of cartilage degradation and subsequent acetabular protrusion of the prosthesis may be specific to the characteristics of the implant[11]. Animal studies have suggested several elements in the pathogenesis: In a study of hip hemiarthroplasties in 24 dogs, Cruess (1984) showed an early loss of proteoglycan, subsequent breach of the superficial layer of the cartilage after 2–4 weeks, and growth of pannus from the articular margins[28]. In a study of six sheep, Field (2009) found changes in chondrocyte distribution and morphology as well as histological signs of apoptosis, and a femoral head penetration of up to 5.5 mm within 6 months measured with RSA[29]. Minihane (2005) found a 2.6-fold increased porosity of the subchondral plate when compared with the untreated side in eight dogs, but no difference in the subchondral plate thickness[30]. Other animal models have shown similar results, and also confirm a more rapid time course than in humans[31,32]. Prostheses using a ceramic articulating surface have been studied in animals and in humans, but no advantages over metal prostheses have been found[33,34].

In this trial, we used bipolar hemiarthroplasties in both the cemented and the uncemented groups. There is some evidence of reduced wear and better function when using bipolar hemiarthroplasties[18,35], and many patient series with short- and long-term follow-up have shown less pain and decreased protrusion of the acetabulum than previous reports on models without an additional articulating joint between the stem and the head of the prosthesis[11,36–45]. Revision rates of hemiarthroplasties for acetabular wear differ greatly between reports[38,46]. One randomised trial showed less wear with a bipolar prosthesis measured with RSA[18], but the clinical advantages of the bipolar design have yet to be proven in randomised trials[47–50]. There are several types of hip hemiarthroplasties available, and the possible differences between designs have not been properly assessed. Unanswered questions include whether the prosthetic head should be spherical or slightly aspherical, whether the diameter of the prosthetic head should match the femoral head exactly or be slightly larger or smaller, and if there are certain patients who should be considered unfit for hemiarthroplasty based on their age or the radiological geometry of the acetabulum. Neither of the hemiarthroplasties used in this study seem to inflict significant wear of the acetabulum in the short term. Future randomised controlled trials may be able to assess the differences between types of hemiarthroplasties, using RSA, functional outcome measures, and longer follow-up.

In conclusion, RSA is a highly precise method for measuring cartilage wear in hemiarthroplasties of the hip *in vivo*. Studies on other joints should be preceeded by a phantom model study assessing the feasibility of a clinical trial.

Role of the funding source

The sole funding source of this trial was Oslo University Hospital, Orthopaedic Department.

Author contributions

We hereby declare that all authors have made substantial contributions to the conception and design of the study, or acquisition of data, or analysis and interpretation of data. All authors have contributed substantially to draughting of the article or revising it critically for important intellectual content, and all authors have approved the final version to be submitted. The authors have contributed as follows:

Conception and design: WF, JD, FS, JEM, LN; Analysis and interpretation of the data: WF, JD, FS, FF, SR, JEM, LN; Draughting of the article: WF; Critical revision of the article for important intellectual content: JD, FS, FF, SR, JEM, LN; Final approval of the article: WF, JD, FS, FF, SR, JEM, LN; Provision of study materials or patients: WF, JD, FS, FF, SR; Statistical expertise: WF, FF, SR; Obtaining of funding: WF, LN; Administrative, technical, or logistic support: WF, JD, FS, JEM, LN; Collection and assembly of data: WF, JD, FS, FF, SR.

Conflict of interest

WF has received lecture fees from DePuy, travel support from Biomet and Stryker; JD: None; FS: None; FF has received lecture fees from Amgen CO and Stryker, travel support from Smith & Nephew and Synthes; SR: None; JEM: None; LN has received lecture fees and travel support from Biomet, DePuy, Novartis, Amgen CO and Stryker.

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