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ORIGINAL PAPER

No clinical difference between large metal-on-metal total hip arthroplasty and 28-mm-head total hip arthroplasty?

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Abstract
Purpose We aimed to test the claim of greater range of motion (ROM) with large femoral head metal-on-metal total hip arthroplasty.
Methods We compared 28-mm metal-on-polyethylene (MP) total hip arthroplasty with large femoral head metal-on-metal (MM) total hip arthroplasty in a randomised clinical trial. ROM one year postoperatively was determined in 50 patients. Mean head sizes were 28 mm (MP) and 48 mm (MM).
Results After one year, the large head MM group showed greater improvement in internal rotation (14 degrees) than the 28 mm group (seven degrees).There were no significant differences in the absolute values of postoperative internal rotation, external rotation, flexion, extension, abduction and abduction.
Conclusions Absolute postoperative range of motion did not differ between the two groups. The improvement in internal rotation was greater after large femoral head metal-on-metal total hip arthroplasty. It is however questionable whether this difference is clinically relevant.

Introduction

Traditionally, metal-on-polyethylene (MP) total hip arthroplasty (THA) has been using 28-mm femoral heads, as larger heads were associated with increased polyethylene wear. With the introduction of highly cross-linked polyethylene, 32-mm heads have become increasingly popular. Alternative bearings such as ceramic-on-polyethylene, ceramic-on-ceramic and metal-on-metal make even larger femoral heads possible. In hip simulator and biomechanical studies, large femoral heads can increase range of motion (ROM). Crowninshield et al. [1] showed that ROM increased by 30 degrees as the femoral head size increased from 22 to 40 mm. Femoral heads over 32 mm provided greater ROM and virtually complete elimination of component-to-component impingement [2]. A 38-mm femoral head increased hip ROM compared to the 28-mm head and this improvement was 5.3 degrees [3]. All in all, a large head–neck diameter ratio might be the crucial factor for obtaining large ROM [2, 4].

Whether the results of these preclinical studies also apply in a clinical setting is debatable. We found only three clinical studies comparing hip ROM after large femoral head hip arthroplasty with conventional THA. Vail et al. [5] compared hip resurfacing patients with 28- or 32-mm THA patients and found that resurfacing patients had larger ROM postoperatively. This was not a randomised study. Le Duff et al. [6] compared within-subject ROM in 35 patients after hip resurfacing to contralaterally implanted THAs and found no difference. Lavigne et al. [4] showed greater ROM of large femoral head THA over 28-mm THA and hip resurfacing, but this study was not randomised. Hence, randomised controlled evidence is still absent.

The aim of our randomised clinical trial was to determine whether large femoral head metal-on-metal total hip total arthroplasty has greater ROM at one year postoperatively compared to 28-mm metal-on-polyethylene THA.

Methods

Study design

A randomised controlled trial was conducted. Concealed allocation was used and the randomisation procedure was

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based on sequentially numbered opaque sealed envelopes, produced by an external institution. The study design, procedures and informed consent were approved by the local Medical Ethical Committee (registration number 2005–42). The trial was registered in the Netherlands Trial Registry (NTR1399). Guidelines of the Consort Statement were followed [7].

Study population

The study was conducted at the Martini Hospital, Groningen, the Netherlands. The patients included suffered from non-inflammatory degenerative joint disease of the hip including osteoarthritis, avascular necrosis and traumatic arthritis, and were aged between 50 and 70 years. Patients with active infection, revision arthroplasty, marked bone loss, and unwillingness or inability to follow instructions were excluded. Participation in the study was voluntary and informed consent was required.

Interventions

Large femoral head metal-on-metal total hip arthroplasty (MM)

Patients in this group received a cementless plasma-sprayed porous-coated titanium alloy acetabular component with a cobalt-chromium liner (M2a-Magnum™, Biomet) and a cobalt–chromium femoral head with a carbon concentration between 0.20% and 0.30%. Radial clearances varied between 17.5 and 150 micrometers. The head sizes could vary from 38 to 60 mm, depending on the shell sizes which ranged from 44 to 66 mm. The geometry of the patient determined the largest possible shell size and head size to be implanted.

28-mm metal-on-polyethylene total hip arthroplasty (MP)

Patients in this group received a cementless plasma-sprayed porous-coated titanium alloy acetabular component (Mallory-Head®, Biomet) with a polyethylene liner (ArCom™, Biomet) and a 28-mm cobalt–chrome femoral head with a carbon concentration between 0.20% and 0.30%. In both the MM and MP groups the same cementless femoral component was used: a proximally plasma-sprayed porous-coated titanium alloy (Ti_6Al_4V) stem (Mallory-Head®, Biomet).

A posterolateral or straight lateral surgical approach in lateral decubitus position was used. Six different orthopaedic surgeons performed the operations. Antibiotic prophylaxis with an intravenous first-generation cephalosporin was given preoperatively and during the first 24 hours postoperatively. All patients were treated postoperatively following a standardised protocol in terms of analgesia and mobilisation. Weight bearing was progressively increased and combined flexion (>90 degrees), adduction and internal rotation (posterior approach)/external rotation (straight lateral approach) was prohibited for six weeks. As prophylaxis against thrombosis, low molecular weight heparin was given for six weeks.

Measurements

Hip ROM was assessed preoperatively and one year postoperatively, as part of the Harris Hip score assessment [8]. The assessors were orthopaedic surgeons and senior orthopaedic registrars. Neither the observers nor the patients were blinded. We employed the neutral-zero-method in three planes, i.e. flexion/extension, abduction/adduction, and internal/external rotation (supine) using a goniometer. Maximum ROM was defined by the point of soft tissue resistance or pelvic movement on passive motion.

Supine anteroposterior (AP) pelvic hip radiographs (115% magnification) were taken preoperatively and at regular intervals postoperatively. The one-year postoperative radiographs were reviewed by an orthopaedic registrar (MJMZ) and a senior orthopaedic surgeon (JJAMVR) using the Gruen [9] and DeLee & Charnley [10] classifications for signs of bone resorption, subsidence, osteolysis, interface deterioration, cysts, radiolucencies, reactive line formation, bone sclerosis, cortical hypertrophy, tip sclerosis and pedestal formation. We also looked at cup and stem osteointegration, as well as femoral component varus and valgus alignment. We used the definitions published by Gosens et al. [11]. The acetabular component abduction angle (inclination) was measured and periarticular ossifications were noted [12].

Sample size

It was our hypothesis that large head metal-on-metal arthroplasties would show larger ROM compared to the 28-mm metal-on-polyethylene articulations. In order to detect at least a clinical relevant difference in ROM of 10° with a standard deviation of 10 (SD based on a pilot study), 15 patients were needed in each group (alpha 0.05, power 0.80). We included 25 patients in each group.

Statistical analysis

The Statistical Package for the Social Sciences version 14.0 for Windows (SPSS Inc., Chicago, IL, USA) was used. Patient characteristics and outcome measures are presented in means and standard deviations or in numbers. Differences between groups were tested using independent-samples *t*-tests for continuous variables with normal distribution and Mann Whitney U tests in case of non-normal distribution, and Fishers exact tests for dichotomous variables. Differences between preoperative and postoperative ROM values were tested with paired-samples t-tests for each group separately. The pre-to-post improvement in ROM was calculated for each patient and the mean difference was tested between the two groups using independent-samples t-tests. A p-value of <0.05 was considered to be statistically significant.

Results

Preoperatively, both groups were comparable regarding gender, age and ROM in five of the six ROM measures (Tables 1, 2 and 3). In the MP patients preoperative extension was significantly less than in the MM patients (difference 2°; $p=0.024$). Preoperative flexion, abduction, adduction, internal and external rotation were equal (all p-values>0.05). Harris hip score was similar ($p=0.644$). Mean head size in the MM patients was 48 mm (range 44–54 mm). Postoperatively, there were no dislocations.

In both groups, the Harris hip score increased significantly from preoperatively to one-year postoperatively (Tables 2 and 3). From preoperatively to postoperatively, flexion improved significantly in the MM group, but not in the MP group. Extension on the other hand did improve in the MP patients, but not in the MM patients. Abduction, adduction, internal and external rotation all significantly increased in both groups.

The pre to postoperative improvement in internal rotation was significantly larger after the large femoral head MM arthroplasty (14°) compared to the 28-mm MP procedure (7°; Table 4). There were no differences between the two groups with respect to improvement of flexion, extension, abduction, adduction or external rotation. The absolute value of postoperative ROM did not differ between groups (all p-values>0.05).

Radiological analysis one-year postoperatively revealed that all stems and cups were osteointegrated. We did not observe subsidence, tip sclerosis, pedestals, bone resorption or bone sclerosis. One patient (MP) showed cortical hypertrophy. Evaluation showed no periprosthetic osteolysis, no interface deterioration, no reactive line formation, one cyst in DeLee & Charnley zone 3 (MM) and one radiolucency in Gruen zone 6 (MP). Varus femoral malalignment (>5°) was present in four MM patients; no stems were malaligned in valgus. Periarticular ossifications were seen in 12 patients (grade I: 4 MM, 4 MP; grade II: 2 MM, 2 MP). Seventy-six percent of patients had acetabular abduction angles between 40 and 55° (range 24–64°). Mean abduction angle was similar in the MM and the MP patients (resp. 51° [SD 6] and 48° [SD 9]; $p=0.243$).

Table 1 Demographics and surgical characteristics in the 28-mm metal-on-polyethylene (MP) and large femoral head metal-on-metal (MM) groups

Characteristic	MP (N=25)	MM (N=25)	P-value
Male/female ratio	13/12	13/12	1.000
Age, mean (SD)	61 (5)	60 (5)	0.710
Surgical approach (posterolateral / straight lateral)	16/9	15/10	1.000
Femoral head size, mean (SD)	28 (0)	48 (3)	0.000

P-values were calculated by independent-samples t-test, except male/female ratio and surgical approach; these were calculated by chi-square (Fisher's exact) tests

Table 2 Pre and postoperative hip scores and range of motion (ROM) in the 28-mm metal-on-polyethylene (MP) group

Hip scores and ROM	Preoperative (N=25)	Postoperative (N=25)	P-value
Harris hip score	51 (14)	86 (11)	0.000
Flexion	102° (14)	106° (13)	0.148
Extension	0° (1)	2° (4)	0.024
Abduction	26° (11)	41° (8)	0.000
Adduction	18° (7)	27° (10)	0.001
Internal rotation	10° (8)	17° (11)	0.001
External rotation	21° (12)	29° (11)	0.031

All values given as mean and standard deviation (SD). P-values were calculated by paired-samples t-tests and refer to the difference between the preoperative and postoperative values

Discussion

The primary goals of THA are pain relief and restoration of mobility. With a rising number of young, active osteoarthritis patients, these mobility demands have become higher and obtaining natural hip motion remains an ultimate goal. Normal healthy hips have a mean 133° flexion, 19°

Table 3 Pre and postoperative hip score and range of motion (ROM) in the large femoral head metal-on-metal (MM) group

Hip scores and ROM	Preoperative (N=25)	Postoperative (N=25)	P-value
Harris hip score	49 (13)	88 (8)	0.000
Flexion	102° (12)	110° (10)	0.020
Extension	2° (6)	2° (5)	0.979
Abduction	24° (9)	40° (8)	0.000
Adduction	16° (8)	26° (8)	0.000
Internal rotation	6° (6)	20° (10)	0.000
External rotation	21° (12)	28° (10)	0.023

All values given as mean and standard deviation (SD). P-values were calculated by paired-samples t-tests and refer to the difference between the preoperative and postoperative values

Table 4 Preoperative to postoperative improvement in hip score and range of motion (ROM) in the 28-mm metal-on-polyethylene (MP) and large femoral head metal-on-metal (MM) groups

Hip scores and ROM	MP (*N*=25)	MM (*N*=25)	*P*-value
Harris hip score	35 (16)	39 (13)	0.276
Flexion	5° (15)	8° (16)	0.470
Extension	2° (5)	0° (8)	0.229
Abduction	15° (15)	17° (13)	0.673
Adduction	9° (12)	10° (10)	0.702
Internal rotation	7° (10)	14° (13)	0.044
External rotation	8° (17)	7° (15)	0.929

All values given as mean and standard deviation (SD). *P*-values were calculated by independent-samples *t*-tests and refer to the differences between groups

extension, 40° abduction, 30° adduction, 41° internal endorotation and 39° external rotation [13]. It is suggested that ROM after THA should be 120° flexion, 20° abduction and 20° external rotation [14]. After THA mean flexion improved from 82° to 101°, abduction from 10° to 22°, internal rotation from 3° to 16° and external rotation from 16° to 21° [15]. Thus there is a need for improvement in hip ROM after THA.

Hip simulator and biomechanical studies suggest that large femoral heads can lead to greater ROM than 28-mm arthroplasties due to a favourable head–neck ratio [1, 2, 4]. To our knowledge this has not been proven clinically in a randomised study. We performed a randomised clinical trial and postulated that large femoral head metal-on-metal THAs would yield greater ROM one-year postoperatively compared to 28-mm metal-on-polyethylene THAs.

The most important findings of our study are: (1) the improvement in internal rotation was greater after the large femoral head metal-on-metal arthroplasty (14°) compared to the 28-mm arthroplasty (7°); (2) absolute postoperative internal rotation and other ROM measures did not differ; and (3) there were no differences with respect to improvement of flexion, extension, abduction, adduction and external rotation.

Theoretically, greater internal rotation could result from a posterolateral surgical approach. In the Cochrane Database [16], the average range of internal rotation in extension of the hip was significantly higher with a posterior compared to a direct lateral approach. However, the distribution of both approaches was equal between our two prosthetic groups (MM: 16 posterior, 9 lateral; MP: 15 posterior, 10 lateral). Furthermore, we compared the internal rotation improvement in both groups and found no statistically significant difference.

With respect to clinical results, randomised clinical studies on ROM after large and small femoral head THA's have not been done as far as we know. Two heterogeneous, non-randomised studies compared hip resurfacing to conventional THA with respect to ROM and found mixed results [5, 6]. One randomised blinded study compared hip resurfacing to THA, but showed no differences in postoperative ROM [17]. A recent cohort study proved that large femoral head arthroplasty had greater total hip ROM compared to 28-mm THA [4]. The total arc of rotation was greater in the large femoral head group, but only when measured in prone or legs hanging position. In the supine position, which is the position we used in our study, hip rotations did not differ. This suggests that the improvement in internal rotation in our large femoral head patients might have been even greater if measured in prone or legs hanging position. This study lacks randomisation and a description of component positioning.

Component positioning can influence hip ROM. D'Lima et al. [18] found that steeper cups lead to increased flexion, extension and abduction but to decreased adduction and rotation. Internal rotation was not influenced by component positioning: it always remained larger than 45 degrees. For maximum ROM and stability with a 28-mm head, the authors advised a cup abducted at 45–55°, anteverted at least 15° with 15° of femoral anteversion. Our surgeons generally aim for 40–55° of abduction and this is reflected in the mean radiological abduction angles of 51° and 48° in the MM and MP groups, respectively. We did not find any significant correlation between abduction angle and ROM improvement in any direction. We therefore believe it is unlikely that component positioning acted as a large confounder in our study.

Our study has some limitations. Most importantly, our clinical method for assessing hip ROM may lack high reliability. In the literature, interobserver reliability of visual (not goniometric) measurement of hip ROM was found to be moderate (intraclass correlation coefficient (ICC) 0.48–0.56) [19]; another study calculated a goniometer internal rotation ICC of 0.48 [20]. Intraobserver reliability of the goniometer on the other hand proved excellent and similar to that of an electromagnetic tracking system: ICC for internal rotation was 0.95 and standard error (SEM) was 2.4°; flexion had the highest SEM (3.9°), concurrent validity was good [21]. Although we did not perform a reliability assessment on our data, we estimate our standard measurement error to be at least 4°. A second limitation is that the patients and the observers were not blinded. Thirdly, our surgeons used two different approaches (posterolateral and straight lateral). The two prosthetic groups did however not differ with respect to surgical approach. We therefore do not think surgical approach acted as a confounder.

In clinical practice, postoperative improvement of flexion is probably more important than internal rotation [4]. However, a greater internal rotation of large femoral heads could facilitate the postoperative rehabilitation of patients after a posterior approach by allowing more hip motion before dislocation. It could also benefit patients prone to dislocation, for instance those with high physical demand jobs, muscular disorders, cognitive dysfunction, dysplasia, previous femoral neck fracture or rheumatoid arthritis [22]. It is questionable whether these benefits may be expected clinically, given the small (7°) improvement in internal rotation.

Whether or not metal-on-metal is an attractive large femoral head bearing is debatable given the concerns over long-term biological effects [23]. If this bearing is chosen, a minimum 46-mm head size seems advisable since wear rates decrease with increasing head size (>40 mm) [24] and small head sizes have been associated with early failures. For ceramic on highly cross-linked polyethylene however, a 32-mm head may suffice in terms of range of motion and a 36-mm head in terms of wear. Cinotti et al. [3] have shown that 36- and 38-mm heads increased ROM compared to 28-mm heads, but these sizes added little to the ROM gain that the 32-mm head had already accomplished. Fisher et al. [25] saw 50% less wear comparing 36-mm ceramic to cobalt-chrome heads on highly cross-linked polyethylene. As regards dislocation risk (tested in the lab as impingement), 38+ heads appeared preferable over 28- and 32-mm heads in one study [2], but the added value of the 36- and 38-mm heads proved negligible over the 32-mm head in another study [3]. Thus, increasing femoral head sizes beyond 36 mm probably does not bring any additional clinically significant benefit, except for metal-on-metal bearings where a minimum of 46 mm seems preferable.

In summary, our study demonstrates that improvement in internal rotation is greater after large femoral head metal-on-metal arthroplasty compared to 28-mm metal-on-polyethylene THA (14° versus 7°). This is in accordance with hip simulator and biomechanical studies, but has never been shown previously by means of a randomised clinical trial. However, no differences in absolute postoperative internal rotation or other ROM measures were found. Whether this difference is therefore clinically relevant is open to discussion, especially since we estimate the standard measurement error to be at least 4°.

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Conflict of interest The authors declare that they have no conflict of interest.

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