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Metal Ion Levels and Functional Results Following Resurfacing Hip Arthroplasty Versus Conventional Small-Diameter Metal-on-Metal Total Hip Arthroplasty; a 3 to 5 year Follow-Up of a Randomized Controlled Trial

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ABSTRACT

We present an update of a randomized controlled trial on 71 patients (<65 years) who received either a resurfacing hip arthroplasty (RHA) ($n = 38$) or cementless 28-mm metal-on-metal (MoM) total hip arthroplasty (THA) ($n = 33$). Metal ion levels and functional outcome scores were analyzed with a mean follow-up of 58 months (SD 8.1). No clear shifts in relatively good outcome was encountered between RHA and THA. Metal ion levels appear to equalize between groups after 3 years. Median cobalt and chromium remained below 1.3 μg/L throughout follow-up in both groups. Six revisions were performed, of which three for pseudotumor formation (one THA, two RHA). In conclusion there were no clinical differences between the two groups and metal ion levels were lower than other series remained low, however, pseudotumor formation was not eliminated.

The resurfacing hip arthroplasty (RHA) has been marketed as the latest advancement in hip arthroplasty and was targeted at young active patients who needed a hip that would last a lifetime. Based on all (theoretical) advantages [1–8] RHA and metal-on-metal (MoM) bearings were appealing concepts to both surgeon and patients. The potential disadvantages, however, like the more technical demanding procedure, the subsequent potential risk of femoral neck fractures, the occurrence of excessive metal ion release and the adverse reactions to metal debris (ARMD) [2,9–12] were less widely specified and in hind view may have been underestimated. In the rapidly emerging market of RHA, we felt that there was a lack of literature where this new concept was balanced against the 'gold standard' of conventional total hip arthroplasty (THA). In a period with considerable promotion for the use of these MoM implants we undertook a randomized clinical trial to assess the proposed benefits of RHA compared to an established THA (with a small-diameter MoM bearing). On the short term, up to 2 years, we found that all functional outcome scores improved highly significant for both groups [13]. RHA patients scored significantly higher on UCLA, OHS and VAS satisfaction at some intervals, however, it may be argued whether these encountered differences were clinically relevant. Chromium and cobalt blood levels were significantly higher for RHA during the running in phase of 1 year with a tendency towards decreasing levels up to 2 years follow-up. No pseudotumors were encountered in either group at the earlier short-term follow-up report. One RHA was revised for early aseptic loosening and in two THA's a cup insert was exchanged for recurrent dislocation [13].

In this RCT we questioned whether the functional results of RHA would indeed be superior to a conventional metal bearing THA and whether a large diameter RHA bearing would induce more metal ion release than a relatively small 28 mm diameter similar bearing in a conventional THA. Since there is an ongoing international debate on the surplus value of RHA against conventional THA we felt it appropriate to provide an update of a previous report [13] with now 3 to 5 year follow-up of a randomized trial comparing RHA with a small diameter metal-on-metal THA.

Patients and Methods

Study Design and Randomization Procedure

In the original exploratory study [13] patients with osteoarthritis of the hip were randomized to receive either a resurfacing total hip arthroplasty (RHA) or a conventional uncemented small diameter MoM total hip arthroplasty (THA). The study is designed to compare the functional results and metal ion blood levels of patients after RHA versus THA at (the now presented) short and medium follow-up, and eventually the long-term interval.

From June 2007 until January 2010 eighty-two patients were randomly assigned to receive one of two hip implants (RHA versus THA). A computer-generated variable block schedule was used for

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randomization. An independent statistician generated the randomization list and the resulting treatment allocations were stored in sealed opaque envelopes. Randomization occurred at the outpatient consultation by the orthopaedic surgeon at the time of planning a hip arthroplasty. Patient and the surgeon could not be blinded for the eventual type of implant; neither could, however, influence the randomization outcome. The criteria for inclusion were patients under 65 years, who needed a primary hip arthroplasty for hip arthritis. Patients were excluded if they had (previous) infection of the hip or other sites, hip fracture, avascular necrosis with collapse, osteoporotic bone mineral density, neoplasm, or renal failure. Inclusion and subsequent follow-up of patients are summarized in the consort statement (Fig. 1). A per-protocol was used in this study, because revised patients could be followed for metal ions. Two patients were lost to follow-up because of lack of motivation, one in each group (RHA after 12 months, THA after 24 months). Two patients deceased in the THA group, of conditions not related to the implantation of the THA. Ten patients also had a metal-on-metal implant on the contralateral side and thus their metal ion blood levels were evaluated separately. The revision cases are described in detail in the results section. Approval from the regional ethics committee from the Radboud University Nijmegen Medical Centre was obtained, with issue number LTC 419–071206, Committee Human Research number (CCMO) 2007/015 and date of approval 01/02/2007. All patients agreed to sign an informed consent. This study was performed in compliance with the Helsinki declaration. The EudraCT trial register number consigned to this study was 2006-005610-12.

Surgical Technique

The surgical technique, after-treatment and rehabilitation protocol have been described in the previous report on this study [13]. In the RHA group a resurfacing prosthesis was implanted with both components made of a cast, heat-treated solution-annealed Co–Cr alloy (Conserve plus; Wright Medical Technology, Arlington, Tennessee, USA). In the THA group, an uncemented tapered stem and threaded titanium cup with a polyethylene insert with a metal liner were placed (Zweymuller Classic) together with a metal 28 mm head (Metasul) (Zimmer Orthopaedics, Warsaw, Indiana, USA).

Clinical Evaluation

Questionnaires that included the SF-12, Oxford Hip Score (OHS) and VAS implant satisfaction were taken pre-operatively and at 6, 12,

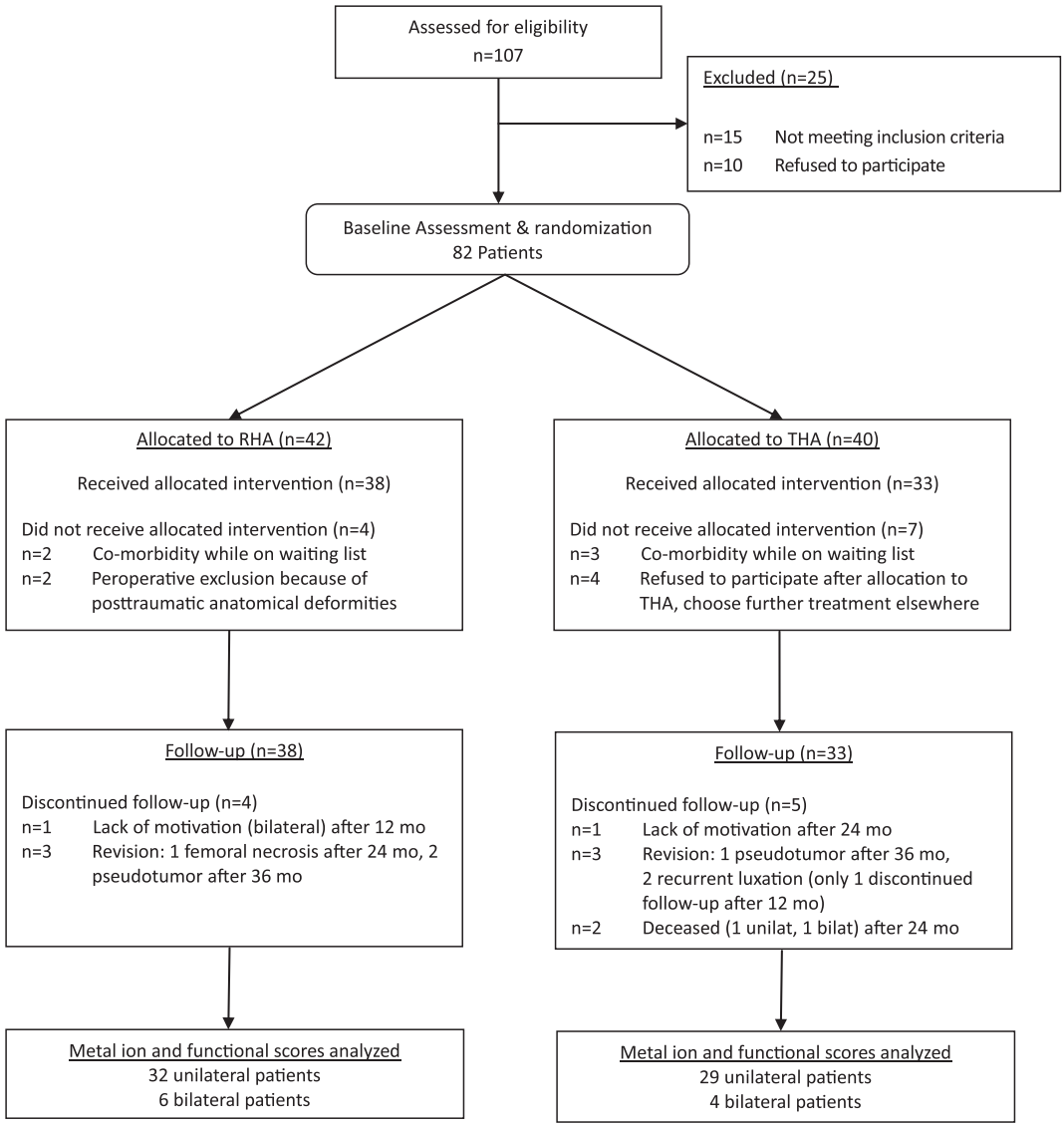

Fig. 1. Consort statement.