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Cluster Hole Versus Solid Cup in Total Hip Arthroplasty: A Randomized Control Trial

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ABSTRACT

Acetabular osteolysis has been linked to polyethylene debris that is generated in the hip migrating through screw holes in the acetabular component. Solid-backed acetabular components were designed to decrease this osteolysis. This prospective trial randomized 100 patients undergoing total hip arthroplasty to either a solid-backed or a cluster-hole acetabular component—all without screws. At 5 years post-surgery, 34.4% of all patients had osteolytic lesions that were visible on CT. There was no significant difference in either presence or volume of the osteolytic lesions, cup migration or functional outcomes (OHS) between the groups. There may no longer be a detriment to using cluster-hole cups instead of solid cups in all hips. This would then give the surgeon the option to use screws for stability as required.

Uncemented acetabular components are increasingly used in total hip arthroplasty. In the 2012 Australian Joint Registry, 94.9% of hip arthroplasties used an uncemented acetabular component [1]. These rely on press-fit fixation, which may be augmented with screws for additional stability.

Acetabular osteolysis has been linked to screw holes in the acetabular component. They allow polyethylene debris that is generated in the hip to gain access to the ilium [2]. Furthermore, wear particles released into the joint fluid may cause inflammation and contribute to the development of an effusion [3]. Chronic inflammation causes fibrosis and decreased capsular compliance, which increases intracapsular fluid pressure. Periprosthetic osteolysis develops in association with repeated hip-loading causing hydrodynamic pumping of fluid through the screw holes [2].

Acetabular components without screw holes therefore provide the theoretical advantage of reduced acetabular osteolysis. There are, however, disadvantages associated with these. The main concern is that of inadequate early stability with cup loosening and disengagement [4]. Screws have been shown to augment the initial stability of the press-fit cup [5–7].

Early designs of uncemented acetabular components had deficient locking mechanisms allowing micromotion between the liner and the shell. Poorly articulating inner surfaces of the liner with the rough metal shell further compounded the problem, resulting in increased generation of wear debris ("back side wear") [8].

Implant design has improved markedly since then with greater conformity of the polyethylene liner with the metal shell of the acetabular component, polished inner surfaces and improved locking mechanisms [9]. Improved polyethylene sterilization techniques and packaging have also lead to reduced generation of wear debris [10]. The introduction of highly cross-linked ultra-high-molecular-weight polyethylene (UHMWPE) has had a huge effect on reducing the occurrence of osteolysis. Numerous clinical trials of cross-linked polyethylene have shown significant reduction in wear of acetabular liners in comparison with conventional polyethylene liners [11,12].

With the advent of newer generation implants and improved polyethylene resulting in decreased wear debris, there may no longer be a detriment to using cluster-hole cups instead of solid cups in all hips. This would then give the surgeon the option to use screws for stability as required.

This prospective trial randomized patients undergoing total hip arthroplasty to either a solid-backed or a cluster-hole acetabular component. Patients were then assessed until 5 years post-operatively for evidence of osteolysis, cup migration or reoperation.

Materials and Methods

Ethics approval was granted by the Hospital Human Research and Ethics Committee. The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12609000958280). The study

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design and reporting were based on the CONSORT (Consolidated Standards of Reporting Trials) principles.

Eligibility Criteria

Any patient requiring total hip arthroplasty for osteoarthritis or rheumatoid arthritis was eligible for inclusion. Exclusion criteria were: post-traumatic arthritis, hip dysplasia, Paget's disease or presence of large lytic lesions in the acetabulum.

Setting and Location

The trial was conducted at one metropolitan tertiary hospital. All eligible patients presenting to the trial surgeon's clinic were consented for trial enrolment.

Interventions

One experienced hip arthroplasty surgeon performed all surgery (R.J.K.K.). The procedures were standardized by the use of the same posterior approach and same prostheses. The acetabulum was under-reamed by 1 mm. A Reflection uncemented cup and Spectron cemented stem (Smith & Nephew, Memphis, Tennessee) were used. The cup used was either cluster-hole (with no central hole cover) or solid (with central hole cover) depending on patient randomization. The cluster-hole cups have 3 holes for screws and a central hole for cup introduction.

A cross-linked polyethylene liner (XLPE, Smith & Nephew, Memphis, Tennessee) was used with a cobalt chromium femoral head.

The Reflection cup has an interference fit of matching scalloped rims and splines, between the rim of the titanium metal shell and the polyethylene liner. The XLPE liner is made with cross-linked polyethylene that is irradiated with 10 Mrad of gamma radiation, remelted post-irradiation and sterilized with ethylene oxide [10].

At the time of surgery, if the press-fit was not stable and the surgeon thought that screws were necessary for primary stability, a cluster hole cup was used with screw augmentation, regardless of randomization group. These patients were separated into a third group (Screws Group) for the per-protocol analysis. However, they were still analyzed in their randomization group for the intention to treat analysis.

Outcomes

Osteolysis (primary endpoint)

Annual radiographs were taken and assessed for presence and location of osteolysis in the 3 acetabular zones described by DeLee and Charnley [13]. Computed tomography (CT) scan was taken at 5-year follow-up. The scan region was from 5 cm above the acetabulum to mid femur, covering 5 cm above and below the prosthesis-bone interface. Osteolytic lesions were defined as any region devoid of bone communicating with the joint space, which were not present on the immediate post-operative radiograph. Presence, location and number of osteolytic lesions were recorded. An experienced musculoskeletal radiologist measured osteolytic defect volumes. Regions of osteolysis were identified on each slice and the volume of acetabular osteolysis was computed using a validated imaging program (GE Medical Systems Advantage Workstation 4.4, Fairfield, Connecticut). Location of osteolytic lesions identified on sequential radiographs and CT was noted using the 3 acetabular zones, described by DeLee and Charnley [13].

Revision

Revision due to aseptic loosening and due to all causes was recorded.

Cup Migration

Evidence of acetabular component migration was assessed by measurements taken on serial radiographs. A linear change of greater than 3 mm was considered indicative of migration. All measurements were taken by two independent observers.

The vertical position of the cup was assessed using the distance between the center of the cup and the teardrop line. The horizontal position of the cup was assessed using the distance between the center of the cup and the vertical line through the teardrop [14].

Functional Assessment

Functional assessment was performed pre-operatively, at 2 years and 5 years post-operatively. Patients were evaluated using Oxford Hip Scores (OHS) and the SF-12.

Randomization

Patients had an equal probability of being randomly assigned to each of the two arms (cluster hole group or solid cup group). Randomization was carried out with use of a computer-generated list. The randomization sequence was concealed prior to enrolment and was not made available until the morning of the surgery.

Blinding

Both the patients and the investigators measuring the final outcomes were blinded with regard to which trial arm the patient had been assigned. Although arguably the radiologist would be able to see the type of cup used, they were blinded to the specifics or purpose of the trial.

Statistical Analysis

An intention to treat analysis was conducted based on the two initial randomization groups. A per protocol analysis was conducted based on the actual acetabular component used, with a third group created for those requiring screws. Binary logistic regression was used to investigate the relationships between presence of acetabular osteolysis and intervention group. Linear regression was used to investigate the relationships between volume of osteolysis and intervention group. Due to the repeated nature of the data, with measurements taken at multiple time points on each individual, linear mixed models using the 'nlme' R package were used with a random person effect to investigate the relationship between functional assessment and intervention group. Where appropriate, a variance stabilizing log transformation was carried out on the response variable. All analyses were adjusted for pre-operative demographics using the R environment for statistical computing [15].

Results

One hundred patients were enrolled in the study: 48 in the cluster hole arm and 52 in the solid cup arm. Two patients in the cluster hole arm were excluded from the analysis: one developed Paget's disease with extensive lytic lesions around the pelvis and one had an intra-operative fracture requiring plate fixation. At the time of surgery, the surgeon decided to use a cluster hole cup with screw augmentation in 12 patients (10 in the solid group and 2 in the cluster group). In the per protocol analysis, the number of patients was therefore 44 in the cluster group, 42 in the solid group and 12 in the screws group. Thirty patients were deceased and four patients were lost to follow-up, prior to the 5-year review. Patient flow is presented in Fig. 1. Demographics were similar between the two randomization groups (see Table 1).

Osteolytic lesions were present in 34.4% of all patients on the 5-year CT scan. There was no difference in the incidence of osteolysis between the two randomization groups on the ITT analysis: 11 of 30 (36.7%) in the cluster randomization group and 11 of 34 (32.4%) in the solid randomization group. In the per protocol analysis, osteolysis was present in 10 of 28 patients (35.7%) who received cluster hole cup without screws,