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Primary Hip

Ceramic-on-Ceramic Total Hip Arthroplasty and Noises: A Prospective Blinded Randomized Controlled Trial of Influence of Component Design

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ABSTRACT

Background: Noises have been associated with ceramic-on-ceramic bearings in total hip arthroplasties. The etiology is multifactorial, but a high prevalence of noises was reported in studies using a specific acetabular component system. We examined if specific ceramic component designs are associated with the prevalence of noises in 2 commonly used component systems. We hypothesized that there would be no difference in noises between the 2 systems.

Methods: In this randomized controlled trial, 2 different component designs with ceramic bearings were compared. Inclusion criteria were primary total hip arthroplasties, age between 18 and 65 years, and body mass index less than 35. The primary outcome was prevalence of noises, whereas secondary outcomes consisted of European Quality of Life index, visual analog scale, and University of California and Los Angeles activity scale. Follow-up data were collected at 3 and 12 months postoperatively. Data were available for 91 patients in Group 1 and for 92 patients in Group 2. Preoperative patient characteristics were comparable between groups.

Results: At 12-month follow-up, the prevalence of noises was 19% in Group 1 and 14% in Group 2 ($P = .41$). European Quality of Life index were 0.89 in Group 1 versus 0.90 in Group 2 ($P = .42$). The visual analog scale was 81 in both groups ($P = .88$). When evaluating level of activity, University of California and Los Angeles activity scale scores were 8.2 in both groups ($P = .92$).

Conclusion: At 12-month follow-up, there was no difference in the prevalence of noises between the 2 component designs.

Total hip arthroplasty (THA) is one of the most recognized orthopaedic surgical procedures, with major improvements in pain, quality of life, and disability [1–3]. Different component designs have been investigated, and today's THAs mainly consist of metal-on-polyethylene, ceramic-on-polyethylene, or ceramic-on-ceramic (CoC) bearings [4]. The CoC bearings have been associated with improved tribological properties including extreme hardness, low friction, low wear, and more bioinert debris compared to metal-on-polyethylene and ceramic-on-polyethylene bearings, thus theorized to decrease the risk of aseptic loosening [5].

However, some concerns regarding the CoC bearings have been reported. These concerns include fractures of the ceramic acetabular liner and head, as well as acetabular ceramic insert dislodgment for sandwich designs [6,7]. Another concern is noises, which can be produced from the CoC bearings. Several studies investigated noises from CoC THAs, but the prevalence is variable over time and often differs between studies. A recent systematic review evaluating 7 studies found prevalence ranging from 3%-31% [8]. A new study evaluated 10-year data of CoC THAs and found a noise prevalence of up to 53%, suggesting that noises may be underestimated in previous studies and that the prevalence may be increasing over time [9]. Previous studies have evaluated whether noisy THAs were associated to patient-reported outcomes, but

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overall, the impact on pain, quality of life, and disability is debatable [10,11].

The etiology of noises from the CoC bearings is considered multifactorial. Previous studies reported lubrication deficiency, stripe wear, patient parameters, and component positioning to be associated with noisy THAs [12]. Furthermore, some specific component designs have been reported to be more prone to produce noises [13]. One acetabular component system with an alumina insert was evaluated in a previous study with reports of increased prevalence of noises [14]. However, most previous studies are cohort or register studies producing results that might be influenced by confounding. Also, no randomized controlled trial (RCT) comparing the 2 different component designs in terms of noises exist.

The aim of this RCT was to compare 2 different designed and well-documented component designs with reference to the prevalence of noise. We hypothesized that there would be no difference in noises between the 2 designs.

Methods

This was a single-center RCT with patient blinding and details of this study have previously been published at www.clinicaltrials.gov (NCT01420900). Relevant approvals for conducting the study were obtained from the Regional Ethical Committee (S-201100725). The study was reported according to the Consolidated Standards of Reporting Trials guideline [15].

This study investigated a consecutive series of patients scheduled for primary uncemented THA between November 1, 2012 and November 15, 2016 at the Department of Orthopaedic Surgery, Lillebaelt Hospital–Vejle, Denmark.

Inclusion criteria were age 18 to 65 years, indication for uncemented THA, and a body mass index less than 35. Exclusion criteria were previous hip surgery, fractures, traumatic hip dislocation, pathology of the hip requiring other component design, contralateral hip surgery, mental disability, or other physical deficiencies affecting patient disability.

Intervention

All patients participating in this study received standardized preoperative care and postoperative hospitalization, but the surgical components were different between the 2 groups:

Group 1 was treated with the Trident hemispheric cup, Biolox Forte ceramic liner with a metal backed metal-metal taper locking mechanism, ABG II stem, and a V40 taper Biolox Forte ceramic head (Stryker, Mahwah, US). This combination was commonly used in our department during multiple years prior to this study.

Group 2 was treated with the Trilogy cup, Biolox Delta ceramic liner with nonmetal backed taper locking mechanism, CLS Spotorno stem, and a 12/14 taper Biolox Delta ceramic head (Zimmer, Warsaw, Indiana, US). This combination was commonly used in Denmark during the period of the study and was chosen as control in Group 2.

All patients were treated by 1 of 4 highly experienced hip surgeons performing at least 130 THAs per year and operated through a postero-lateral approach. Patients were hospitalized 1 to 2 days postoperatively as part of our standard care. Follow-up was made after 3 months by a telephone interview and after 12 months as an outpatient clinical control.

Outcome Measures

Baseline Patient-Related and Surgery-Related Data

Baseline data including age, sex, and body mass index were collected prior to surgery. Surgery-related data include surgery time, blood loss, size of the stem, femoral head, acetabular cup, and liner. The surgeon registered these data postoperatively.

Patient-Reported Outcomes

The primary outcome of this study was the prevalence of noises from the THA after 12 months. Noises were registered after 3 and 12 months and patients were asked to characterize noises in terms of frequency, volume, and type (Table 3). Frequency was registered on a Likert scale as “daily,” “at least once weekly,” “less than once weekly,” or “unknown.”

Volume was registered as “can only be heard by the patient,” “can sometimes be heard by others,” “can always be heard by others,” or “unknown.” Type of noises was registered, as described by Varnum et al [10], as “squeaking,” “creaking,” “grating,” “other,” or “unknown.”

Secondary outcomes consisted of European Quality of Life index (EQ-5D-3L) and visual analog scale (EQ-VAS). Physical activity was evaluated with the University of California and Los Angeles activity scale (UCLA).

The EQ-5D-3L is a standardized generic questionnaire evaluating health-related quality of life on a scale between −0.59 and 1 where 0 equals death and 1 equals perfect health. The EQ-VAS is a linear scale of quality of life ranging from 0 to 100 (perfect health) [16].

The UCLA activity scale is a 10-point scale that evaluates persons’ activity based on 10 descriptive activity levels. These levels range from total inactivity and dependency (level 1) to regular participation in impact sports (level 10) [17].

Radiographic Evaluations

To determine the component positioning of the THA, 2 experienced radiographers measured all radiographs on standardized antero-posterior and axial views. They evaluated cup anteversion, inclination, stem position, and change in leg length. The “version” feature in the software TraumaCad (Brainlab, Munich, Germany) was used to analyze cup anteversion or retroversion [18]. Inclination was determined by measuring the angle of a horizontal line drawn between the 2 teardrops of the pelvis and a line drawn through the long axis of the ellipse on the cup. Stem valgus/varus position was measured as the angle between the longitudinal axis of the stem and the femoral bone. A positive angle signals valgus and a negative value signals varus. The change in leg length on the operated leg was registered from preoperative and postoperative radiographs by measuring the distance from the teardrop sign to the lesser trochanter on the femoral bone.

Sample Size, Blinding, and Randomization

A sample size calculation was performed, and to detect a reduction in prevalence of noises from 2% to 15% with a 2-sided type-I error (α) of 5% and a type-II error (β) of 20%, the study population should include 86 patients in each group. Due to an expected drop out of 15% and to the block randomization, 102 patients were included in each group.

Patients were randomized in a 1:1 ratio by 34 balanced blocks of 6 patients to ensure equal distribution of patients between the 2 groups in case the study had to stop prematurely due to any reason. Sealed envelopes containing randomization code were stored safely and opened on the day of surgery by the surgeon to determine the type of components to be used. Patients were blinded regarding the implanted components.

Data Analyses

Categorical baseline patient characteristics were described using counts (percentages) and compared between component groups using *Chi*-squared and Fisher's exact tests as appropriate. Continuous baseline characteristics were described using means (standard deviations) for continuous variables and compared between component groups using 2-sample *t*-tests with unequal variance. The frequency and types of noises were described using counts (percentages) and the frequency was compared between component groups using *Chi*-squared tests for all noises and Fisher's exact tests for the frequency, volume, and type. We used the Danish population norms, when calculating the EQ-5D-3L quality-of-life scores [19]. The distribution of the EQ-5D-3L score, EQ-VAS score, and the UCLA was described using means with 95% confidence intervals and compared between component groups using 2-sample *t*-tests with unequal variance.

Patient Flow and Demographics

During the study period, 204 patients were randomized, but due to various reasons (Figure 1), 11 patients were excluded immediately after surgery and thereby 97 patients were assigned to group 1 and 96 patients to group 2. At 12-month follow-up, 10 patients

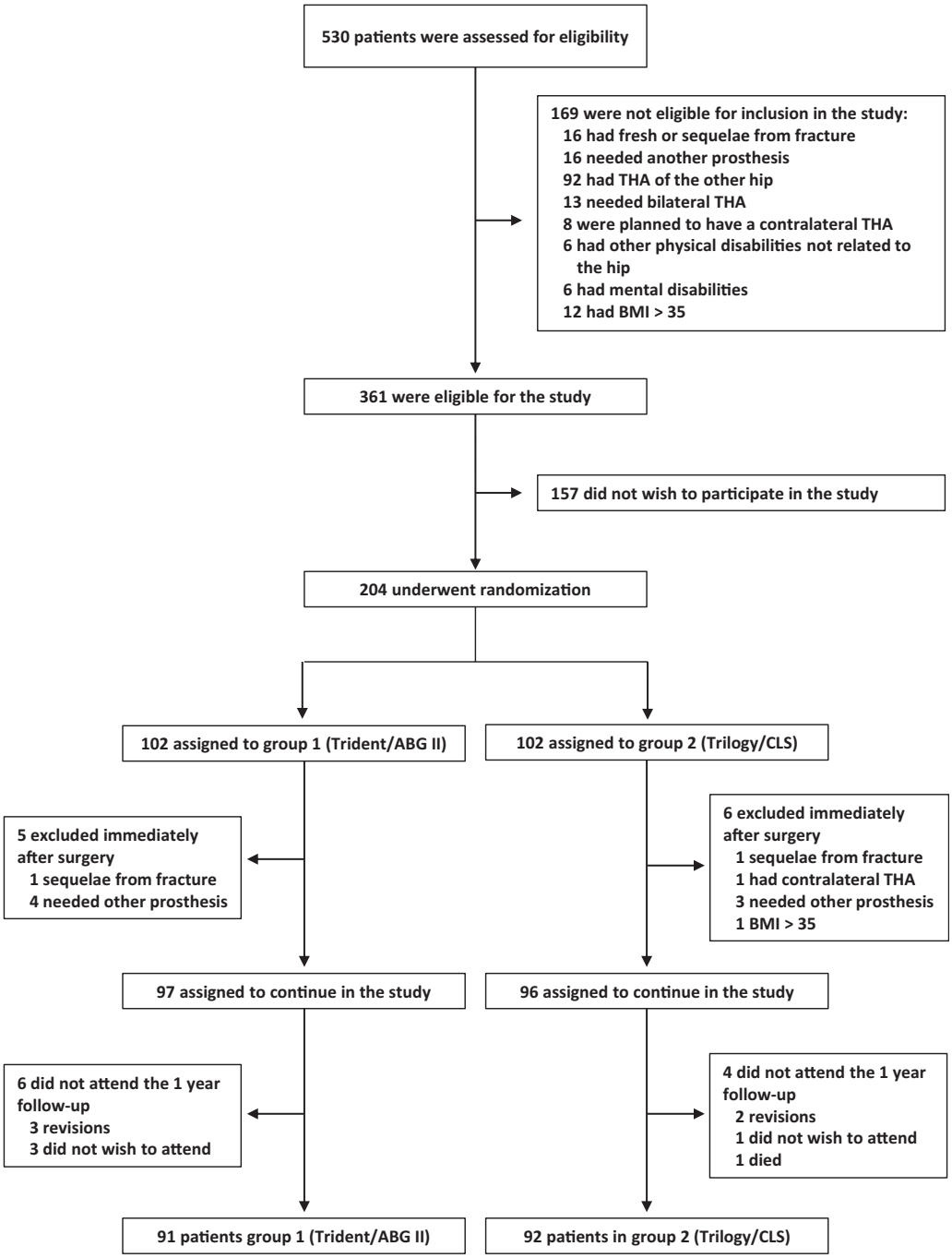

Fig. 1. Flowchart of participants during the study period.

were lost to follow-up and 5 patients had revision surgery (3 infections and 2 periprosthetic fractures), 4 withdrew and 1 patient died. Thereby 90% of the randomized patients responded to our primary outcome of noises after 12 months.

Baseline characteristics are presented in Table 1 and due to the randomization process, equally distributed between groups. There were no differences in surgical time or blood loss between groups. Radiological analyses found group 1 to have a mean 3 degrees more cup anteversion ($P = .005$) compared to group 2, but no differences in terms of cup inclination, stem position, or change in leg length were found (Table 2).

Results

After 12 months, 19% of patients in group 1 and 14% of patients in group 2 experienced noises, but there was no statistically significant difference between the groups (Table 3). Frequency, volume, and type of noises are presented in Table 3, with creaking as the predominant type. After 3 months, 13% in group 1 and 15% in group 2 reported noises.

Quality of life (EQ-5D-3L) and functional status (UCLA) improved significantly in both groups postoperatively, and no differences were found between the groups (Table 4). The EQ-5D-3L improved 0.23 points in group 1 and 0.26 points in group 2 at 12-month follow-up ($P = .35$). The improvement in EQ-VAS was 23 points in group 1 and 19 points in group 2 ($P = .25$). The UCLA scores improved 2.4 points in both groups at 12-month follow-up ($P = .89$).

Discussion

To our knowledge, this is the first RCT to investigate if 1 of 2 CoC component designs were more prone to produce noises 12 months postoperatively. Results showed no statistically significant difference in noise reports after 3-month and 12-month follow-up between the groups.

Overall, 13% of patients reported noises after 3 months, whereas 15% had noises after 12 months. This correlates with reports from previous studies with noise reports between 3% and 36% [8]. This variation may be because presence of noises increases over time after surgery as some studies suggest [9]. In the study from Varnum et al, the median onset of noises was 10 months postoperatively, but a systematic review found that noises typically occur between 14 and 40 months postoperatively [20]. This means that our study might underestimate the proportion of noisy THAs.

Whether noisy THAs have an influence on patient-reported outcomes is still debated. Chatelet et al found little to negligible impact on quality of life when evaluating 100 ceramic THAs 10 years after surgery [11]. Varnum et al found significantly worse patient-reported outcome scores (Hip dysfunction and Osteoarthritis and Outcome Score, EQ-5D-3L, EQ-VAS, and UCLA) for patients experiencing noisy THAs [10]. Taniguchi et al investigated the results of CoC THAs after a median of 14 years in 62 patients and found no difference in patient satisfaction or Hip dysfunction and Osteoarthritis and Outcome Score between noisy and silent hips [9]. In their study, however, a surprisingly high prevalence of noisy hips was discovered (53%). In the same study, possible causes of noisy THAs were investigated, but no correlation was found despite that. One cup-stem combination has been associated with a high prevalence of noisy THAs of up to 35% possible due to a high rim and short femoral neck [20]. Stripe wear due to edge loading was investigated in a laboratory setting by Tayler et al and they found that this wear has the potential of producing noises [21]. An *in vitro* study from Chevillotte et al found fluid lubrication of the ceramic joint to be the most important contributor to noises and their theory is that film fluid between the 2 layers of the ceramic surfaces is disrupted, potentially due to transfer of third body metal particles [12].

Our study evaluated if there were any radiological differences in component positioning between the 2 groups. Group 1 had slightly more anteversion (3 degrees) of the acetabular component, but we assume no clinical relevance of this. Previous studies evaluated if component positioning influences the prevalence of noises. Walter et al suggested that acetabular cups positioned outside the range of

Table 1
Baseline Characteristics.

Baseline Variables	Group 1	Group 2	*P* Value
	n = 91	n = 92	
Men, n (%)	42 (46)	52 (57)	.16
Age, mean y (range)	57.0 (30.0-64.9)	55.6 (34.6-65.3)	.20
BMI, mean (range)	27.0 (18.8-40.7)	27.8 (19.5-50.1)	.21
Diagnosis, n (%)			
Primary arthrosis	85 (93)	88 (96)	.23
Osteonecrosis	3 (3)	1 (1)	
Arthritis	0 (0)	1 (1)	
Perthes	2 (2)	0 (0)	
Epiphysiolysis	1 (1)	0 (0)	
Acetabular dysplasia	0 (0)	2 (2)	
Caput size n (%)			
28	2 (2)	0 (0)	.58
32	75 (82)	4 (4)	
36	14 (15)	88 (96)	
Neck length n (%)			
< 0	28 (31)	10 (11)	.52
0	49 (54)	50 (54)	
> 0	14 (15)	32 (35)	
Surgery time, mean min (range)	54 (30-95)	56 (30-110)	.22
Blood loss, mean mL (range)	220 (50-500)	231 (50-510)	.46

Chi-squared and Fisher's exact tests were used to compare categorical outcomes. Two-sample *t*-tests were used to compare continuous outcomes.

Table 2
Radiographic Assessments.

Radiographic Measures	Group 1	Group 2	*P* Value
Cup anteversion, mean (SD)	20.5 (6.8)	17.5 (7.4)	.005
Cup inclination, mean (SD)	41.5 (5.9)	42.3 (7.2)	.39
Stem position, mean (SD)	−1.8 (1.9)	−1.8 (1.6)	.96
Change in leg length, mean mm (SD)	4 (7)	3 (7)	.35

Two-sample *t*-tests were used to compare continuous outcomes.

Table 3
Noises.

Noise Variables	3 Mo			12 Mo		
	Group 1	Group 2	*P* Value	Group 1	Group 2	*P* Value
Noise complaints, n (%)	12 (13)	14 (15)	.67	17 (19)	13 (14)	.41
Frequency, n (%)						
Daily	3 (25)	5 (36)	.68	3 (18)	4 (31)	.66
At least one time weekly	4 (33)	2 (14)		3 (18)	1 (8)	
Less than one time weekly	5 (42)	7 (50)		11 (65)	8 (62)	
Unknown	0 (0)	0 (0)		0 (0)	0 (0)	
Noise Volume, n (%)						
Can only be heard by the patient	9 (75)	12 (86)	.38	9 (53)	9 (69)	.21
Can sometimes be heard by others	1 (8)	2 (14)		4 (24)	4 (31)	
Can always by others	2 (17)	0 (0)		4 (24)	0 (0)	
Unknown	0 (0)	0 (0)		0 (0)	0 (0)	
Type of noise, n (%)						
Squeaking	0 (0)	0 (0)	.15	3 (19)	0 (0)	.12
Creaking	0 (0)	4 (29)		3 (19)	7 (54)	
Grating	3 (25)	2 (14)		1 (6)	1 (8)	
Other	9 (75)	8 (57)		9 (56)	5 (38)	
Unknown	0 (0)	0 (0)		1 (6)	0 (0)	

Chi-squared test was used to compare categorical outcomes.

Table 4
Patient-Reported Outcomes.

Outcome Measures	Group 1	Group 2	Difference Between Groups	*P* Value
EQ-5D-3L, mean (CI)				
Baseline	0.65 (0.62-0.69)	0.64 (0.61-0.68)		
3 m	0.87 (0.84-0.89)	0.86 (0.84-0.89)	−0.01 (−0.04 to 0.04)	.95
12 m	0.89 (0.86-0.91)	0.90 (0.88-0.93)	0.01 (−0.02 to 0.05)	.42
Difference 3m-baseline	0.21 (0.17-0.25)	0.22 (0.19-0.26)	0.01 (−0.04 to 0.06)	.71
Difference 12m-baseline	0.23 (0.19-0.27)	0.26 (0.22-0.30)	0.03 (−0.03 to 0.08)	.35
EQ-VAS, mean (CI)				
Baseline	58 (54-62)	62 (58-66)		
3 m	79 (76-82)	80 (77-84)	1 (-3 to 6)	.62
12 m	81 (78-85)	81 (77-85)	0 (-5 to 5)	.88
Difference 3m-baseline	21 (16-25)	18 (14-23)	−3 (-9 to 4)	.44
Difference 12m-baseline	23 (18-27)	19 (14-24)	−4 (-11 to 3)	.25
UCLA, mean (CI)				
Baseline	5.8 (5.4-6.1)	5.8 (5.4-6.1)		
3 m	7.8 (7.4-8.1)	7.5 (7.2-7.8)	−0.3 (−0.8 to 0.2)	.21
12 m	8.2 (7.9-8.5)	8.2 (7.8-8.5)	−0.0 (−0.5 to 0.5)	.92
Difference 3m-baseline	2.0 (1.6-2.4)	1.7 (1.3-2.1)	−0.3 (−0.8 to 0.2)	.28
Difference 12m-baseline	2.4 (2.1-2.8)	2.4 (2.0-2.9)	−0.0 (−0.6 to 0.5)	.89

Two sample *t*-tests were used to compare continuous outcomes.

35 to 45 degrees inclination and 15 to 35 degrees anteversion were more likely to produce noises [22].

Methodological strengths of this study include the randomized design, patient blinding, and a high follow-up rate of 90% after 12 months. However, one weakness is that we only evaluated short-term data after 12 months postoperative. Our study was not powered to perform multivariate analyses of associations between preoperative variables and the risk of noisy THAs and thereby we did not perform any analysis of etiology in this study, which is a weakness. There were 11 patients excluded immediately after surgery due to various reasons (Figure 1) and these patients could potentially increase the risk of selection bias, as some of them needed other components despite being randomized. Another limitation is that no data were collected on the patients who declined to participate in the study, representing another risk of selection bias.

Conclusions

This RCT did not find any differences in terms of noise, disability, or quality of life between 2 different component designs with CoC bearings after 3 and 12 months. Both groups experienced good clinical results with an overall noise prevalence of 15% after 12 months. Future studies should focus on the etiology by including large sample sizes and correlate suspected preoperative and perioperative factors to the presence of noises postoperatively.

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