Acta Orthop. Belg., 2021, **87 e-SUPPLEMENT** 1, 8-13

ORIGINAL STUDY

The incidence of noise with a new ceramic-on-ceramic bearing in hip replacement : a prospective multicenter analysis of 142 hips

Thomas ILCHMANN, Milan JOVANOVIC, Thomas-Peter RANKE, Martin CLAUSS

From the Kantonsspital Baselland, Switzerland

Ceramic-on-ceramic (CoC) bearings are a promising option in hip replacement to avoid wear and permit the use of larger head sizes. Ceramic fracture and noise are the main points of concern. The aim of this study was to evaluate ceramic-related complications and the incidence of noise of a new alumina-toughened zirconia (ATZ) ceramic.

ATZ ceramic was assessed in a multicentre prospective observational study. It included 135 patients (142 hips) who had received THA using an ATZ CoC bearing. The mean follow-up time was 60.6 months. Clinical data and adverse events were documented, and a noise-specific questionnaire (Melbourne Orthopaedic Noise Assessment [MONA]) was used at final follow-up.

There were no ceramic fractures and no dislocations. Clinical results were satisfactory and comparable to published data. In 19 hips (13.4%), noise was recorded in the MONA questionnaire. In 7 of these 19 hips, the noise was perceived at early follow-up and disappeared later. The most frequent noise was squeaking (9 hips). No patient required revision due to noise.

The use of the new ceramic was safe, but the development of noise remained the main disadvantage. CoC with modern ceramic is an option as a bearing surface for the young and active patient.

Keywords : hip arthroplasty ; ceramic ; noise ; alumina toughened zirconia ; Melbourne Orthopaedic Noise Assessment (MONA).

INTRODUCTION

Wear of the bearing surfaces is most relevant for the young and active patient. It correlates with life-expectancy and function, and it might be the major reason for the increased risk of reoperation in younger patients *(1)*. Furthermore, the risk of revision due to recurrent dislocation might be reduced by using larger femoral-head diameters *(2,3)*.

To address these risks, various bearing surfaces are available, all with specific disadvantages : Ceramic or metal heads on highly crosslinked polyethylene

■ Thomas Ilchmann[1,2],
■ Milan Jovanovic[3],
■ Thomas-Peter Ranke[4],
■ Martin Clauss[1,5].

[1]*Kantonsspital Baselland, Rheinstrasse 26, 4410 Liestal, Switzerland*

[2]*Hirslanden Klinik Birshof, Reinacherstrasse 28, 4142 Münchenstein, Switzerland*

[3]*OZM Orthopädisches Zentrum Münsingen, Krankenhausweg 18a, 3110 Bern, Switzerland*

[4]*Asklepios Orthopädische Klinik Hohwald, Hohwaldstrasse 40, 01844 Neustadt, Germany*

[5]*University Hospital Basel, Spitalstrasse 31, 4031 Basel, Switzerland*

Correspondence : Martin Clauss, M.D., University Hospital Basel, Department for Orthopedics and Traumatology, Spitalstrasse 31, 4031 Basel, Switzerland. Phone : +41 61 328 60 07.

Email : Martin.Clauss@usb.ch

Conflicts of interest: none

still produces particles and the ideal head size is not known *(4)*. Metal on metal (MoM) is known to cause osteolysis and might be carcinogenic, so its use is no longer favoured *(5,6)*. Ceramic on ceramic (CoC) might break and cause noise *(7)*.

Ceramic fracture is of major concern because the removal of all fragments is almost impossible and there are limitations in the selection of the new bearing surface *(8)*. Later generations of ceramic might reduce the fracture risk, but the incidence of noise development is controversial, ranging from 0% to 37% *(9-11)*.

A new ceramic (alumina-toughened zirconia (ATZ), ceramys®, Mathys Ltd) was introduced in 2007. It has been shown to be more fracture-resistant in mechanical testing *(12,13)* and assumed to cause less noise due to changes in the surface. In a previous report, the corresponding author of the present paper reported no ceramic-related complications at two-year follow-up using the ATZ in combination with a cementless cup (seleXys TH+ [Mathys Ltd, Bettlach, Switzerland]) *(14)*. However, as the cup performance was poor, its use was discontinued. However, a part of the patient population was enrolled in a prospective observational multicentre study. Here, we present the medium-term outcomes to evaluate the incidence of ceramic-related complications alongside the incidence of noise of an ATZ ceramic insert.

Table 1. — Characteristics of the included patients

	N	%
Number of patients (hips)	135 (142)	n.a.
Gender		
Male	76	53.5
Female	66	46.5
Diagnosis		
Osteoarthrosis	122	85.9
Congenital dysplasia	12	8.5
Necrosis	4	2.8
Fracture	2	1.4
Rheumatoid arthritis	2	1.4
Hospital		
Hohwald, Germany	40	28.2
Liestal, Switzerland	83	58.5
Brig, Switzerland	19	13.4
Cup type		
seleXys TH+	123	86.6
seleXys TPS	19	13.4
Stem type (squeeking)		
CBC	82 (8)	57.7 (5.6)
CBH	35 (8)	24.6 (5.6)
twinSys uncemented	17 (3)	12.0 (2.1)
Cemented stem	8	5.6
Head size		
28 mm	6	4.2
32 mm	52	36.6
36 mm	84	59.2
Approach		
Antero-lateral	54	38.0
Transgluteal	88	62.0

MATERIALS AND METHODS

Between December 2007 and December 2008, 175 hips (168 patients) were operated with ATZ CoC bearings in our clinics. Ethics committee approval was obtained prior to study commencement (ethical approval CCVEM 034/07, university of Basel, Switzerland), and all patients provided written informed consent prior to inclusion. Patients with a previous ipsilateral hip replacement or severe general disorders, such as cardiovascular, were excluded, as the articulation should be used in younger and more active patients. The mean age of the patients was 63.9 (range 40 to 76, SD 7.6) years, and the main diagnosis was osteoarthrosis (Table 1).

The ATZ ceramic was used in two types of uncemented shells (seleXys TH® and seleXys TPS®, both Mathys Ltd) and combined with various stems (Table 1). The head sizes were 28, 32 and 36 mm, and the largest fitting head was chosen for each hip. The approaches were antero-lateral and transgluteal, in accordance with the surgeons' preferences.

Postoperatively, clinical and radiological follow-up was performed after 3 months, 1 year, 2 years, and 5 years. At each timepoint, patients were asked whether they experienced any kind of noise at any time and whether this noise was persistent or disappeared. Any kind of reoperation was recorded. Inclination of the cup was measured on plain radiographs be measuring the angle between the interteardrop lins and the longitudinal diameter of the cup and will be presented as mean (SD, range). Additionally, 5 years postoperatively, all patients were given a recently published noise-

specific questionnaire (Melbourne Orthopaedic Noise Assessment [MONA] *(15)*) concerning noise frequency and the quality of noise. Patients were asked if any noise had been heard from their hip joint at any time after surgery.

A modified Harris Hip Score (HHS) *(16)* and the range of motion (ROM, sum of range of motion in flexion – extension, abduction - adduction, and external – internal rotation) were assessed, and ceramic-related adverse events were documented at each follow-up.

Descriptive statistics for clinical and functional outcomes were carried out using mean, standard deviation (SD) and ranges. Outcomes were compared between groups, such as prosthesis components and gender, using non-parametric tests, i.e. Wilcoxon 2-Sample Test and Kruskal-Wallis Test, the latter in cases of more than two groups. Association tests between discrete variables were carried out using Chi2-tests. The paired student's t-test was used to test differences between baseline and follow-up. The level of significance was set at p = 0.05 (two-sided). All statistical analyses were performed with SAS version 9.4 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Of the 168 patients (175 hips), 11 (11 hips) died before the 5 years follow-up. Eleven patients (11 hips) refused to attend the final follow-up ; in a telephone contact, it was affirmed that the prosthesis was still in situ and working well. For 1 patient (1 hip), there were only radiographs available. Two patients (2 hips) were lost to follow-up. Eight patients (8 hips) had a revision in the interim, (5 due to aseptic loosening of the cup, 1 for infection, 1 for periprosthetic fracture and 1 for loosening of the stem). The remaining 142 hips (135 patients) were included for further analysis.

The mean follow-up with the MONA questionnaire was 61.3 (50 to 74.8, SD 3.7) months. In 26 hips (18.3%), noise was noted at any postoperative visit or in the MONA questionnaire. At three months follow-up, there was noise in 3 hips, and the noise disappeared later. At 1 year follow-up, noise was noticed in 4 additional hips, which disappeared in 2 hips. At 2 years follow-up, noise was noticed in 6 additional hips, which disappeared in 3 hips.

At 5-year follow-up, self-reported noise at any postoperative point in time, as documented in the MONA questionnaire, was reported in 19 hips (13.4%), and there was no noise perception in 123 hips (86.6%). In 18 hips (12.7%), noise was both detected during the follow-up visit and self-reported in the MONA questionnaire. In 1 hip (0.7%), noise was reported in the MONA questionnaire only.

In 7 of the 19 hips with noise reported in the MONA questionnaire, the noise was perceived at early follow-up and disappeared later. Therefore, the prevalence of noise at the 5 year follow-up was 8.4%. Furthermore, in 7 of the 19 hips, the noise was reported to be reproducible by the patient.

For the hips with noise, there was no difference between sex (p=0.117), used cup (p=0.695), used femoral component (p=0.298) or ROM (p=0.582) as compared to the hips without noise.

None of the 6 hips with 28 mm head developed noise, but 7 of 52 (13.5%) with 32 mm and 12 of 84 (14.3%) with 36 mm had detectable noise (p=0.325). The thickness of the ceramic inlays did not correlate with the incidence of noise. The inclination angle of the squeaking cups was 40.8 (7.7, 28-58) degrees and did not correlate with the incidence of noise.

The most frequent noise was squeaking (9 hips), followed by grinding (5 hips), popping (3 hips) and clicking (2 hips). There was no correlation between the nature of the noise and ROM or head size (p=0.255). Multiple qualities of noise were noted in none of the hips.

In 5 hips, the noise could be heard by others. No patient was that disturbed that a reoperation was taken into consideration.

The mean clinical follow-up was 60.6 (range 39 to 107, SD 5.0) months. The ROM improved from a mean of 152.7° (30 to 240, SD 34.8) preoperatively to 222.5° (125 to 290, SD 26.6) at final follow-up (p<0.0001). The mean ROM was similar for all head sizes (28 mm : 220.0° (150 to 270, SD 42.0), 32 mm : 225.8° (125 to 290°, SD 26.5), 36 mm : 220.7° (150 to 280, SD 25.6), p=0.447).

The HHS improved from a mean of 58 (25 to 90, SD 15) preoperatively to 93 (32 to 100, SD 12) at final follow-up (p<0.0001). There was no difference

in the HHS concerning the stem used (p=0.155). At final follow-up there was no difference in the HHS for the 19 hips with noise (mean 93, 32 to 100, SD 12) as compared to patients without noise (mean 94, 74 to 100, SD 8, p=0.754). There was no dislocation and no ceramic breakage observed.

DISCUSSION

The use of the new ceramic is safe, and we found no ceramic-related adverse events that led to reoperation. In the present study, any kind of noise was reported by 13.4% of all patients at mid-term follow-up. The mechanism of noise, including squeaking, is not yet fully understood but well-known to potentially occur after CoC THA. Generally, noise may be related to stripe wear, edge loading, ceramic fracture, prosthesis components, patient-specific factors, and surgery-specific factors *(17)*.

An incidence of noise perception in CoC bearings up to 37% is reported *(9-11)*. We assessed noises in the scheduled follow-up and, additionally, with the MONA questionnaire, which has a high sensitivity for the detection of noises *(15)*. Any kind of noise was documented occurring at any postoperative time point, even if it appeared occasionally and was not disturbing. Thus, it has to be considered that no hips with noise were missed and that the observed incidence of any noise was within the range reported in the literature *(9-11,18)*. Additionally, it has to be taken into consideration that all bearing surfaces can produce some kind of noise ; even in the use of ceramic on polyethylene, a noise incidence of 12.7% is reported *(11)*.

It was described that smaller heads might show a higher incidence of noise development *(10)*. We found no noise in the 6 hips being operated with 28 mm heads, but the number was low, and the difference as compared to the larger heads was not statistically significant.

No patient was so disturbed by noise that a reoperation had to be taken into consideration. The clinical outcome (HHS) was not inferior for patients with noise perception, and these patients did not seem to be particularly disturbed ; this was found in other studies too *(15)*. But in many series, patients with noise perception had inferior results, even leading to reoperations *(10,11)*, and thus a low incidence of noise would be targetted in any case. Fortunately, if reoperation due to squeaking is indicated, the liner exchange is a relatively benign procedure which hardly impairs the clinical outcome *(9,19)*.

No fracture of a liner or a head was observed. The follow-up time was 5 years with a minimal follow-up after 39 months, and most ceramic fractures seem to occur within the first 2 postoperative years *(20)*. Lee et al *(20)* found a risk for fractures of modern ceramic heads of about 0.02%, and the risk of fracture in the present series seems to be very low as well.

There was an improvement in ROM as compared to preoperatively, and the clinical results correspond with published results after CoC THA *(8,19)*. We found no correlation between head size and ROM, and it is questionable that the use of larger heads improves ROM *(2,21)*. The use of larger heads might reduce the rate of dislocation *(2,22)*. We observed no dislocation ; thus, the risk of dislocation was low, and the use of head sizes above 36 mm might further reduce it *(2,3)*. However, the maximum available head size for ceramic inlays is 36 mm, which corresponds to the recommended *(23)* and most-used *(24)* head sizes.

The studied population was younger (63.0 vs 68.0 years), there were more male patients (53.5 vs 48.0%) and the mix of diagnosis was similar (85.9% vs 84.8% primary osteoarthritis) as compared to the average Swiss THA population (SIRIS 2016) *(25)*. This reflects the selection of more young and active patients, as intended for the used bearing surface.

There are several limitations : The study was performed on three different hospitals. As this study was purely observational, different surgical approaches, acetabular shells and femoral stems were used, and postoperative care might have differed as well. This can affect the clinical outcome and ROM. But as there were no differences in patient parameters and in the clinical outcome between the hospitals, we do not think that this has affected the studied questions and represents the daily practice of the participating surgeons.

Restrepo et al *(26)* assumed that the type of stem might affect the incidence and quality of

noise. Almost all of the investigated stems were uncemented, having the same shape of neck and trunnion but differing slightly in material (Ti6AL7Nb and Ti6AL4V) ; thus, we believe that this did not affect our results. Shell design seems to affect the incidence of noise *(10)*, the two different shell designs that were used were identical in terms of material and thickness and only differed in the outer macro- and micro-structure ; the ceramic liner was the same, so the shell should not have affected the incidence of noise.

There was no group for comparison ; thus, the results could only be interpreted in relation to published data, but there are large case series available to make such a comparison possible. The studied population was too small for analysis of subgroups, and more patients being observed over a longer period of time would be needed to detect specific risk factors for noise development. Component position and orientation might affect the incidence of these noises *(15,27)*, but these parameters were not assessed in this study. A strength of the study is the almost complete follow-up including the detailed MONA questionnaire concerning noises.

CONCLUSIONS

The use of the new ceramic was safe, and no fracture was observed, but the development of noise remained the main disadvantage of the CoC bearing. There was rarely squeaking, and patients were relatively undisturbed. No reoperation was taken into consideration due to the use of CoC. CoC with modern ceramic is an option as a bearing surface for the young and active patient.

ACKNOWLEDGEMENT

Mathys Ltd Bettlach partially funded this study. We thank Dr. Dominik Pfluger (numerics data GmbH) for the statistical support.

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