A bicentric approach evaluating the combination of a hemispheric cup with a novel ceramic head in total hip arthroplasty

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Abstract

Medical ceramics are frequently used biomaterials as a liner in total hip arthroplasty. Strong efforts have been made to improve material properties over the last decades. Alumina toughened zirconia ceramics seem to be promising alternatives to further reduce fracture rates and squeaking phenomena. To answer the question if alumina toughened zirconia ceramic liners in combination with a cementless, hemispheric cup are able to reduce squeaking phenomena and fracture rates, we initiated a bicentric, mid-term trial. Noise phenomena will be recorded using MONA Score (Melbourne Orthopaedic Noise Assessment). Functional outcome (Harris Hip Score, University of California-Los Angeles, Forgotten Joint Score, EQ-5D Score, Visual Analogue Scale) and radiographic parameters will serve as secondary parameters. The study has been set up for 5 years, with follow-ups after 6-14 weeks, 12, 24 and 60 months.

Introduction

Since the introduction of total hip arthroplasty (THA) in the middle of the last century, the treatment of patients with hip arthritis has been revolutionized.[1] Yet, in some cases prosthetic failure occurs. Wear debris induced periprosthetic osteolysis remains one of the main causes for aseptic loosening in THA.[2] Based on material specific properties, ceramic-on ceramic (CoC) bearings show the lowest wear rates in tribological studies[3-6] Wear particles of medical ceramics are biologically inert and there are no reports about cancerogenic potential.[7,8] First generation medical ceramics were introduced in the 1970s in orthopaedic surgery and were made of 100% alumina oxide. Unfortunately, first generation medical ceramics have shown low strength and high brittleness.[9] Moreover, these ceramics were characterized by insufficient chemical purity, low density and coarse grain size leading to a suboptimal microstructure and function in articulations.[10] This is due to the fact that first generation alumina ceramics were derived from industrial applied ceramics.[11] There were relevant numbers of ceramic fractures in THA leading to revision surgery with component exchanges and removal of all visible ceramic fragments.[12,13] Due to the high fracture rates of alumina-on-alumina THRs encountered in 1970s the USA Food and Drug Administration (FDA) banned the use of alumina hip prostheses. Considerable progress in the research and development of medical-grade Al_2O_3 was made in Germany in the 1970s.[14-16] The developments have focused on purity, grain size and density since a close correlation exists between the mechanical strength and these parameters. Especially, impurities of the material glassy phases which were located on the grain boundaries of ceramic materials decreased the mechanical strength.[17] In contrast, later generations of alumina ceramics showed a purity of 99.9% and glassy phases were not detected even in transmission electron microscopy (TEM).[18] The grain size is another important parameter in alumina ceramics. With rising grain size, the fracture and wear rates increase.[19] In general, Al_2O_3 implants are manufactured with additions of magnesium oxide (MgO) as dopant to control the grain growth during sintering (ranges 1.8–4.5 µm).[20] The porosity is a further important characteristic of alumina ceramics. Pores, especially intergranular pores, can be sources for cracks leading to increased wear rates or fracture. The old generation of alumina ceramic implants was made by conventional sintering which increased the severity of flaws. Later generations of alumina ceramics are manufactured additional by hot isostatic pressing (HIP) at low temperatures resulting in increased density, defect-free bodies with good homogeneity of compaction and submicrometer grain size. With the improvement of the medical-grade alumina material and better hip design, Sedel *et al.* could show increasing survival rates of alumina-on-alumina THRs.[21] Based on this development, the FDA withdrew the ban on alumina-on-alumina hip prostheses in 2003.[22] However, biomechanical studies revealed high wear rates of HIPed alumina oxide ceramics (BIOLOX® Forte, CeramTec, Germany) with 1.84 mm^3/million cycles under microseparation conditions in hip joint simulators.[23] Zirconia ceramics were introduced in 1985 as an alternative to alumina ceramics for the femoral head. Zirconia is tougher and more resistant to fracture than alumina.[24] Zirconia ceramic is characterized by three phases of physical structure. Especially, the toughness of tetragonal phase is very high whereas the tetragonal phase is very unstable.[25] By the alloying of pure zirconia with oxides such as MgO and Y_2O_3 (yttrium oxide), the tetragonal structure can be stabilized.[26] However, yttrium stabilized zirconia ceramics tend to have risk for late phase transformation and ageing leading to grain pullout, surface cracking and increasing surface roughness.[27] Recent advances in the material research of medical ceramics under the use of zirconia-alumina composites showed promising results with less fracture and low wear rates in biomechanical studies.[28-30] The composites were characterized as scratch-resistant, strong and biocompatible. Even the addition of a small amount of alumina

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oxide (Al_2O_3) reduces significantly the transformation from tetragonal to monoclinic phase in zirconia ceramics.[31] The risk for fractures were demonstrated for femoral heads 0.002% and acetabular liners 0.02%.[32,33] Zirconia toughened alumina oxide ceramics (ZTA; 25% ZrO_2, 75% Al_2O_3; BIOLOX® Delta, Ceramtec, Germany) showed very low wear under adverse microseparation simulator conditions, with wear rates reported below 0.15 mm^3/million cycles.[34] Alumina toughened zirconia (ATZ; 20% Al_2O_3, 80% ZrO_2; ceramys®, Mathys Ltd. Bettlach) showed even less wear rates below 0.10 mm^3/million cycles in biomechanical studies.[35]

Figure 1 illustrates electron microscope photographs of different generations of medical ceramics.

Table 1 summarizes characteristics of different generations of ceramics.

Squeaking is another frequent complication after THA with CoC bearing. For ceramic acetabular liners, it is reported in up to 21%.[36-40] Noise emanating from CoC-bearing THAs is almost three times more frequent than noises associated with ceramic-on-polyethylene articulations.[41,42] There is neither a uniform definition for postoperative squeaking nor a universal categorization for the sound. The noises range from clicking, grinding, and snapping[43] to popping and clunking.[44] Sound analysis revealed individual frequencies between 400 and 7500 Hz.[45] Various risk factors for post-THA squeaking phenomena have been described. Patients with a high body mass index (BMI) and individuals suffering from rheumatism have an increased risk for the occurrence of post-THA squeaking.[46,47] Extreme limb length shortening and wide ranges of internal and external rotation correlates also with squeaking.[48,49] Implant positioning is another important issue for postoperative squeaking in THA. Walter *et al.* (2014) found that high or low anteversion and inclination of the acetabular component is associated with squeaking.[50] Furthermore, lateralization of the hip center and high prosthetic femoral offset are also associated with hip squeaking.[51] In addition, the type of implant seems to be another crucial factor for the development of post-THA squeaking. In titanium-molybdenum-zirconium-iron alloy stems (18.4%) the risk for post-THA squeaking is seven times higher than in titanium-alumina-vanadium alloy stems.[52] However, in a meta-analysis from Lee *et al* (2014), increased cup abduction angle was the only factor being associated with significant higher rates of squeaking.[53]

It is not fully resolved if ceramic composites will decrease material failure such as brittleness or fatigue fractures and/or show lower rates of squeaking phenomena *in vivo*. For this purpose, the aneXys®-ceramys® study was designed to evaluate squeaking phenomena and complication rates of ATZ acetabular liners in THA.

Materials and Methods

Individuals aged between 18 and 75 years with the indication for a cementless total hip arthroplasty will be included in the study after receiving informed consent. Exclusion criteria were known or suspected non-compliance (*e.g.* drug or alcohol abuse), missing informed consent form (signed by participant and investigator), enrolment of the investigator, his/her family, employees and other dependent persons, age younger than 18 years, revision surgery, presence of sepsis or malignant tumors, ASA (American Society of Anesthesiologists) Classification >3, pregnancy and if patients not able to speak and understand the national language of the study center.

All surgeries will be performed by experienced hip surgeons. The study was approved by the local ethics committee of the University (19-8879-BO) and is conducted according to the common guidelines for clinical trials (Declaration of Helsinki). Informed consent will be obtained for all patients. The study is registered in German Clinical Trials Register (DRKS00021508). The patient enrolment is expected to start soon.

Study design

In 2019 we initiated a prospective, bicentric study (aneXys®-ceramys® study, sponsor: Mathys Ltd., Bettlach, Switzerland, Principal Investigator (PI): senior author) of a CE-marked zirconia-alumina ceramic acetabular liner (ceramys®, Mathys Ltd., Bettlach, Switzerland) in combination with the cementless, microporous titanium coated, hemispheric cup (aneXys®, Mathys Ltd., Bettlach, Switzerland). ceramys® is made of a homogeneous dispersion of ca. 20% alumina (Al_2O_3) and ca. 80% zirconia (ZrO_2) and was first implanted in 2007. The average grain size of ceramys® is 0.4 µm. The liner has a minimum thickness of 5 mm in 45° loading direction. In all patients, the metadiaphyseal anchoring calcar-guided short stem optimys (Mathys Ltd., Bettlach, Switzerland) with a ATZ ceramic head (ceramys®, Mathys Ltd., Bettlach, Switzerland) was implanted. Optimys stem is made of a titanium alloy with a plasma-sprayed surface and a calcium phosphate coating. Two study centers are participating, recruiting 150 patients within a planned recruiting till end of 2021. The study has a planned follow-up period of 5 years, aiming for mid-term results.

Table 1. Properties of the medical ceramics (data provided by Mathys AG, Bettlach, Switzerland).

Property	ATZ	ZTA	Alumina
Al_2O_3 (Wt%)	20	75	100
ZrO_2 (Wt%) stabilized with yttria	80	25	0
Theoretical density (g/cm^3)	5.51	4.37	3.99
Medium grain size (µm)	0.4	0.8	2.3
Biaxial bending strength (MPa)	>900	>700	>350
Fracture toughness MPa $m^{1/2}$	>7	>5	>3

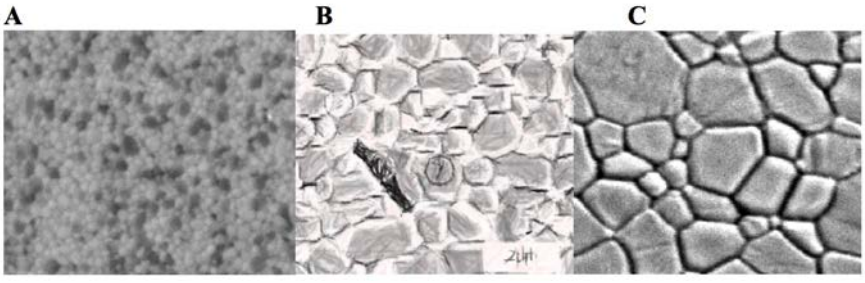

Figure 1. Electron microscope photograph of different generation of medical ceramics. A) ATZ ceramic; B) ZTA ceramic; C) Al_2O_3 ceramic. Photographs provided by Mathys AG, Bettlach, Switzerland.

Table 2. Parameters and methods.

Parameter	Method
Squeaking phenomen	MONA-Score
Implant survivorship	Amount of revisions and complications
Functional Outcome	Harris Hip Score, EQ-5D-Index, Forgotten Joint Score, University of California Score (UCLA)
Pain level	Visual Analogue Scale (VAS)
Radiographic results	Component alignment, leg length discrepancy, radiolucencies, bone hypertrophy, Osteolysis, Implant migration, heterotopic ossifications

Results and Discussion

Follow-up and outcome parameters

aneXys®-ceramys® study has been a designed as a prospective, mid-term analysis of zirconia/alumina ceramics as acetabular liners in combination with a cementless microporous titanium coated, hemispheric cup in THA. The study has been set up for 5 years, with follow-ups after 6-14 weeks, 12, 24 and 60 months. Figure 2 illustrates the timeline of the study.

The study seeks primarily to determine the occurrence of noise phenomena after implantation of a ceramys® acetabular liner in an aneXys® cup. In addition, clinical and radiographic results as well as complication and revision rates will be obtained as further parameters.

Noise phenomena will be recorded using MONA Score (Melbourne Orthopaedic Noise Assessment).[54]

Functional outcome, the well-being of the patient in daily-life activities is measured with the Harris Hip Score (HHS),[55] with the Forgotten Joint Score[56] and with the EQ-5D Score.[57] The activity level is evaluated with UCLA Score (University of California, Los Angeles).[58]

The radiographs will be analyzed for osteolytic changes according to Gruen *et al*.[59] Further radiographic parameters like migration, implant position and ossifications according to Brooker *et al*.[60] will be assessed and documented. Table 2 summarizes different parameters.

Statistical calculations and biometry

The frequency of audible acoustic emission in patients treated with aneXys® cups and ceramys® acetabular liners shall not exceed the benchmark reported for comparable medical devices. Based on a previous unpublished PMCF study (Study ID 0702) an incidence rate of 13.4% was reported for first generation ceramic on ceramic (CoC) articulation. We expect low rates of squeaking for ATZ acetabular liners. Evaluation of endpoints is planned as per-protocol analysis. Statistical tests and presentation will be appropriate to the category and distribution of the respective variables. The test level for statistical significance is defined as P=0.05, two sided, for all tests. Based on an assumed incidence of 13.4%, the 95% confidence interval lies within a range of 8.0 and 19.0%.

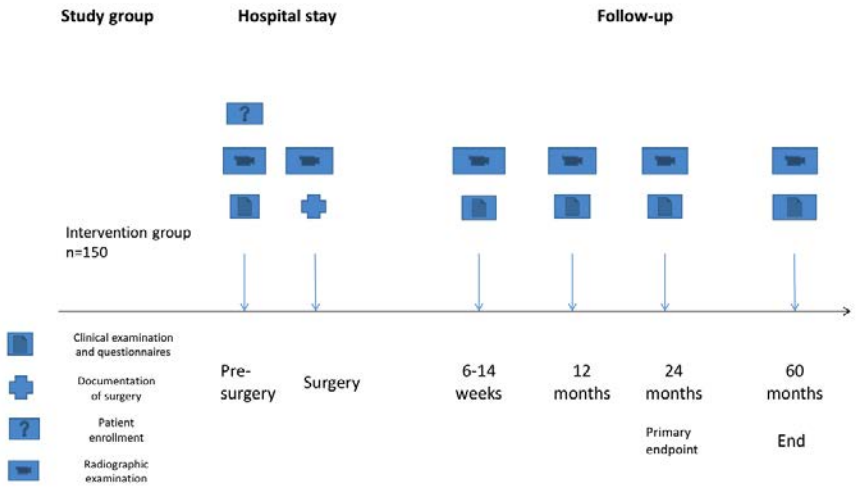

Figure 2. Timeline of the study.

Conclusions

The analysis of MONA Score should grant distinct results for the evaluation of audible acoustic emission of ceramic acetabular liners (ceramys®) in combination with cementless, microporous titanium coated, hemispheric cups (aneXys®). Additional evaluation of radiographic parameters and the functional results as well as the revision and complication rates will allow a mid-term evaluation of the two biomaterials.

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