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Wear of Novel Ceramic-on-Ceramic Bearings under Adverse and Clinically Relevant Hip Simulator Conditions

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Abstract

Further development of ceramic materials for total hip replacement aim to increase fracture toughness and further reduce the incidence of bearing fracture. Edge loading due to translational mal positioning (microseparation) has replicated stripe wear, wear rates and bimodal wear debris observed on retrievals. This method has replicated the fracture of early zirconia ceramic-on-ceramic bearings. This has shown the necessity of introducing microseparation conditions to the gait cycle when assessing the tribological performance of new hip replacement bearings. Two novel ceramic matrix composite materials, zirconia-toughened-alumina (ZTA) and alumina-toughened-zirconia (ATZ), were developed by Mathys Orthopädie GmbH. In this study, ATZ-on-ATZ and ZTA-on-ZTA bearing combinations were tested and compared to alumina-on-alumina (Al_2O_3-on-Al_2O_3) bearings under adverse microseparation and edge loading conditions using the Leeds II Physiological Anatomical Hip Joint Simulator. The wear rate (±95% confidence limit) of ZTA-on-ZTA was 0.14±0.10mm^3/million cycles and that of ATZ-on-ATZ was 0.06±0.004mm^3/million cycles compared to a wear rate of 0.74±1.73mm^3/million cycles for Al_2O_3-on-Al_2O_3 bearings. Stripe wear was evident on all bearing combinations however, the stripe formed on the ATZ and ZTA femoral heads was thinner and shallower that that formed on the Al_2O_3 heads. Post-test phase composition measurements for both ATZ and ZTA materials showed no significant change in the monoclinic zirconia content. ATZ-on-ATZ and ZTA-on-ZTA showed superior wear resistance properties when compared to Al_2O_3-on-Al_2O_3 under adverse edge loading conditions.

Keywords: Ceramic on ceramic, hip replacement, stripe wear, microseparation, edge loading.

Introduction

Ceramic material for total hip replacement bearings was first introduced by Boutin in the early 1970s[1], when the ceramic material used was alumina oxide (Al_2O_3). Ceramic-on-ceramic bearings have shown superior tribological properties compared to other hip replacement bearings[2-5]. The limited toughness properties of early generations of alumina that made it susceptible to fracture[6,7] have encouraged further developments and improvements to such material.

Ceramic-on-ceramic bearings have become of great interest after the long-term failure of metal-on-polyethylene due to polyethylene debris induced osteolysis[8] and issues with metal debris and metal ions associated with metal-on-metal bearings[9,10]. Ceramic-on-ceramic bearings have lower friction and wear levels than those reported with metal-on-polyethylene and metal-on-metal bearings[3,5]. Retrieval studies have shown extremely low wear compared to other bearing articulations[11-14]. In addition, wear debris produced by such bearings are less biologically active than metal or polyethylene debris[15-18].

Improvements in ceramic materials have extended their design flexibility, resulting in an increase in the sizes available. The greater functionality and range of motion of these increased sizes meets more closely the demands of younger and more active patients. Unlike metal-on-polyethylene bearings, the wear rate of ceramic-on-ceramic does not increase with increasing the head size, thus improving the functionality without having the disadvantages of increased wear. Clinical studies have shown high mid-term survival rates for alumina-on-alumina bearings with some centres reporting survival rates of 95.8% at 9 years[19], 99% at 7 years[20] and even 100% at 11 years[21].

Retrieval studies of ceramic-on-ceramic bearings have shown stripe-like wear on the femoral head, which was associated with increased cup inclination angle and edge loading conditions[12-14]. Increased cup inclination angle may cause edge loading directly due to rotational malposition or by increasing the probability of edge loading due to microseparation of the centres of the femoral head and the acetabular cup or translational malposition. Nevelos *et al* were the first to adapt their *in vitro* hip simulator to replicate stripe wear seen on retrievals[13]. It was shown that increased cup inclination angle alone did not influence the wear of ceramic-on-ceramic bearings[22,23] but the introduction of microseparation, translational malposition of the head and the cup centres, replicated wear rates, wear mechanisms and wear particles seen clinically[13,24]. Edge loading through microseparation has been shown to be the only wear mechanism to generate a bimodal particle distribution of micron size particles as found *in vivo*[13,16,17]. Microseparation was achieved by applying a 0.4-0.5mm lateral displacement of the cup relative to the head during swing phase of the gait cycle allowing edge loading to occur at heel strike. This method was then used to study other bearings such as metal-on-metal bearing combination, which also replicated clinically relevant wear rates and wear mechanisms[25].

Ceramics currently used in hip replacement have undergone substantial improvements. Advanced technologies have allowed precise manufacturing, which has resulted in elevated toughness and hardness properties. The use of a smaller grain size resulted in a smoother surface with improved wear properties[26]. Alumina (Al_2O_3) has excellent tribological and mechanical properties and it is stable and biocompatible. However, as a brittle material, there are concerns regarding the risk of fracture. Zirconia is twice as strong as alumina and has been used previously as a hip replacement bearing but concerns regarding its stability and medium term failure made it an unfavourable material choice[27-29]. In the latest development of ceramic material for hip replacement bearings, alumina and yttria stabilised zirconia (Y-TZP) have been used to form matrix composites without the disadvantages of the pure materials hence producing new materials with high strength and high fracture toughness. Two new materials have been developed; a zirconia matrix mixture also known as alumina toughened zirconia (ATZ) and an alumina matrix mixture also known as zirconia toughened alumina (ZTA)[30-33].

It has become apparent that edge loading caused by lateral microseparation of the head relative to the cup of ceramic-on-ceramic bearings can lead to increased wear rates[12,13,23,24,26,29,34,35]. The clinical environment which may cause microseparation includes head offset deficiency, medialised cup, stem subsidence, soft tissue laxity or neck impingement. In order to better predict the performance of ceramic-on-ceramic bearings *in vivo*, it is necessary to test new bearings under adverse, clinically relevant simulator conditions.

The aim of this study was to test two novel materials for ceramic-on-ceramic bearings in a like-on-like configuration under edge loading condition due to microseparation (translational malposition) of the head and the cup centres, and compare them to the alumina-on-alumina combination under the same conditions.

Materials and Methods

Three different ceramic materials manufactured by Mathys Orthopaedie GmbH (Moersdorf, Germany) were tested in a like-on-like configuration in this study. They were alumina BIONIT® (Al_2O_3-on-Al_2O_3), alumina toughened zirconia (ATZ-on-ATZ) and zirconia toughened alumina (ZTA-on-ZTA). The relative amounts of constituents for each material are detailed in Table 1.

Three couples of each combination (Al_2O_3-on-Al_2O_3, ATZ-on-ATZ and ZTA-on-ZTA) were tested using the Leeds II Physiological Anatomical Hip Joint Simulator. The heads were taper locked onto femoral stems which were mounted in the stem holders using acrylic resin. The liners were fitted into metallic shells which were mounted in the cup holders at an inclination angle equivalent to an *in vivo* cup inclination angle of 55°.

Each test ran for 4 million cycles under edge loading conditions, which included a standard gait cycle with microseparation of the cup and the head. The gait cycle comprised extension/flexion (-15°/+30°), internal external rotation (+/-10°) and a twin peak load of a maximum of 3kN as described in ISO 14242-1 (2002). Microseparation was achieved by lateralising the femoral head relative to the acetabular cup by 0.4-0.5mm during swing phase and edge loading occurred at heel strike according to a standard protocol previously used in several studies[13,23-26,29,34,36].

New-born calf serum (25%) was used as a lubricant which was supplemented with 0.03% of sodium azide to inhibit bacterial growth. The lubricant was changed every third of a million cycles. Wear was assessed gravimetrically; the components were weighed using a Mettler AT201 balance (0.01mg resolution) before and after the test and at every million cycles.

Wear scar analysis including roughness and penetration depth were undertaken using contacting profilometry (Form Talysurf series, Taylor Hobson, UK). For the roughness measurements, a 15mm long trace was taken over the wear scar and analysed by applying a Gaussian filter and the recommended cut-off according to

ISO 4288-1997. The penetration depth was measured by taking three traces 5mm apart across the wear stripe and applying primary analysis and calculating the mean.

The means and 95% confidence limits of wear rates, surface roughness and maximum penetration depth were determined. One way ANOVA was used for statistical analysis and significance levels were taken at $p < 0.05$.

The hip heads were inspected by means of scanning electron microscope to visualise the wear stripes in comparison to unworn regions. Further, the phase composition was measured on the surface of the hip heads with X-ray-diffraction following Rietveld-refinement. During the measurements, the focus of the X-rays was directly within the worn area. For comparison, reference measurements were carried out on the unworn area.

Results

The mean wear rates of the three bearing combinations are detailed in Table 2 and shown in Figure 1. Over the four million cycles of test under severe microseparation and edge loading conditions, the wear rate of Al_2O_3-on-Al_2O_3 was 0.74mm^3/million cycles. The wear of Al_2O_3-on-Al_2O_3 was split into two distinct phases, an initial bedding in wear rate of 1.54mm^3/million cycles obtained over the first million cycles and a relatively lower steady state phase of 0.55mm^3/million cycles obtained between 1 and 4 million cycles. The ZTA-on-ZTA bearing showed a 5-fold reduction in the overall wear rate compared to the alumina bearing with a steady state wear rate lower than 0.10mm^3/million cycles. The reduction was not statistically significant ($p=0.17$) which could be due to the low number of repeats ($n=3$). ATZ-on-ATZ showed a 12-fold reduction ($p=0.21$) in the wear rate with no distinguishable bedding-in and steady state phases (Figure 1).

The components showed a stripe wear on the lateral/superior position of the head with a corresponding wear area on the lateral edge of the cup (Figure 2). Under microseparation conditions, the acetabular cup translates medially with respect to the femoral head during the swing phase of the gait cycle causing the contact area to migrate from the polished ceramic surfaces to the edge of the acetabular cup. This resulted in two different contact areas; however, wear was only detectable over the contact area under edge loading conditions. There was no detectable surface wear or change in roughness or wear over the contact area between the two polished ceramic surfaces. Over the stripe wear area, the Al_2O_3-on-Al_2O_3 combination showed the highest wear penetration, with a mean penetration of 21µm on the head and 130µm on the cup. ATZ-on-ATZ and ZTA-on-ZTA showed a much lower mean penetration depth of 5µm on the head and 37µm on the cup (Figure 3). The surface of the components over the wear stripe became roughened due to the edge loading conditions. The overall surface roughness (Ra) over the wear stripe on the femoral head of Al_2O_3-on-Al_2O_3 bearings increased by 27 fold to 0.163µm after 4 million cycles of test. However, the Ra values for ATZ-on-ATZ and ZTA-on-ZTA were still below 0.014µm and 0.024µm respectively after 4 million cycles of test under adverse conditions.

The results of the X-ray-analysis in terms of phase content of monoclinic zirconia of the heads with standard deviation (as calculated by the software of the X-ray diffraction machine) are detailed in Table 3. In the original state the phase content of monoclinic zirconia was lower for the ZTA heads since the lower zirconia content in the ZTA ceramic meant there was also less monoclinic zirconia. The measured monoclinic zirconia content in the worn ‘stripe’ regions of ZTA heads was slightly higher following microseparation simulation conditions but the increase was not significant for any of the heads tested. On all measuring points the values were consistent with the International Standard ISO 13356, which specifies a monoclinic zirconia content of less than 20% is required for pure Y-TZP.

The SEM images shown in Figure 4 illustrate the transition area of the 'stripe' wear area. With the ATZ couple the surface of the hip head remained virtually unchanged following the microseparation simulation conditions (Figure 4A). There was no substantial evidence of visible surface change. The surface of ZTA ceramic was more affected by the microseparation process, with some grain break-outs apparent (Figure 4B). The transition zone was indicated by local material fatigue of alumina grains. The 'stripe' region of the alumina heads was characterised by a markedly visual transition zone as can be seen in Figure 4C. In this area considerable material fatigue occurred followed by individual grain pull-outs.

Discussion

Previous studies have shown the necessity of introducing microseparation and edge loading conditions to the gait cycle in *in vitro* hip simulator studies to reproduce clinically relevant wear rates and wear mechanisms[13,16,17,23,24,26,29,34]. Fluoroscopic studies have confirmed that lateral microseparation of the femoral head relative to the acetabular cup can occur during the gait cycle[37]. More importantly microseparation of the centres of the head and the cup does not need physical separation of the head and the cup, it simply needs translational malposition of the centre of the head with respect to the cup[38], a translational displacement which is constrained by loading on the edge of the cup[39]. These microseparation conditions lead to edge loading and the formation of stripe-like wear on the femoral head with a corresponding wear area near the rim of the acetabular cup resulting in elevated wear rates. Microseparation and edge loading conditions can occur due to several clinical reasons including head offset deficiency, medialised cup, soft tissue laxity, stem subsidence or neck impingement. Most importantly, microseparation can occur at displacements as low as 0.5mm and cause edge loading and increased wear, a displacement level which cannot be detected radiographically.

It is therefore important to test ceramic materials for the hip under adverse simulator conditions to better predict their wear performance *in vivo* under a range of clinical conditions. Two novel ceramic materials have been developed for hip replacement bearings and have been tested under adverse and clinically relevant hip simulator conditions in this study.

All bearing combinations tested in this study have shown stripe wear on the femoral head with a corresponding wear area on the acetabular cup. Alumina-on-alumina bearings (Alumina BIONIT®) produced more than 50% lower wear rates when compared to BIOLOX® *forte* bearings (CeramTec, Germany) (wear rate of 1.84 mm^3/million cycles and 95% confidence limit of 1.34 mm^3/million cycles) under similar adverse simulator conditions in the same simulator in the same laboratory[24]. However, the difference was not significant ($p>0.09$), although this could be due to low power in the statistics with three samples in each case. Manaka *et al*[35] reported a lower wear rate of BIOLOX® *forte* (wear rate of 0.4 mm^3/million cycles and 95% confidence limit of 0.07 mm^3/million cycles) than Stewart *et al* [24] under microseparation conditions, although they were tested on different simulators using different techniques. Stewart *et al* achieved edge loading using the technique described in this study, however Manaka *et al* achieved edge loading by applying a negative vertical load during swing phase which resulted in 1mm vertical distraction creating an inferior peripheral wear scar on the head as well as a superior wear scar due to edge loading at heel strike. Also, the peak load used by Stewart *et al* was 3kN compared to only 2kN peak load used by Manaka *et al*.

The ATZ-on-ATZ and ZTA-on-ZTA bearings produced lower wear rates than the alumina-on-alumina bearing combination tested in this study and by other investigators[24,35,40] under adverse microseparation and edge loading conditions. This showed the superior mechanical properties of the two material matrix mixtures compared to pure alumina. The wear rates of ZTA-on-ZTA bearings were similar ($p=0.82$) to those of BIOLOX® *delta* ceramic-on-ceramic bearings (CeramTec, Germany) (wear rate of 0.13 mm^3/million cycles and 95% confidence limit of 0.08 mm^3/million cycles) tested under the same adverse simulator conditions[23]. ATZ-on-ATZ showed even lower wear rates compared to ZTA-on-ZTA bearings under the same adverse conditions.

The alumina BIONIT® femoral heads and liners had the highest wear penetration depth and overall surface roughness value over the wear stripe. The mean penetration depths of ATZ and ZTA femoral heads were lower than 5 microns after four million cycles of test compared to 21µm for alumina. Previous studies have reported 90µm penetration over the wear stripe on alumina BIOLOX® *forte* bearings tested under similar simulator conditions[34]. The overall surface roughness of the femoral head only increased to approximately 0.02µm for both the ATZ and ZTA materials, compared to 0.16µm for alumina heads. This reiterated the high resistance of the new bearings to adverse simulator conditions.

Although microseparation conditions caused stripe wear and increased wear rate of ceramic on ceramic bearings, the wear rates measured for ATZ-on-ATZ and ZTA-on-ZTA under adverse microseparation conditions were still extremely low (< 0.14

mm^3/million cycles) when compared to metal-on-metal and metal-on-polyethylene bearings. To put these wear rates into context, the wear rate of metal-on-metal bearings has been reported to be in the range of 4 - 9 mm^3/million cycles under microseparation conditions[25,36], and the wear rate of metal on cross linked polyethylene could be 100 times higher than ceramic-on-ceramic bearings[41].

In order to meet the demands of younger and more active patients, continual innovations and improvements in hip bearing materials and design are required in order to reduce the wear and the body's biological activities towards the wear debris, and to increase functionality such as the range of motion. Hip replacement bearings have to endure many daily life activities and have to be resistant to any adverse conditions they may come under. Current preclinical testing focuses on replicating the standard walking gait cycle, but this will not represent the adverse *in vivo* conditions and surgical implantation variables that could lead to prosthesis failure. Thus more clinically relevant adverse conditions have been developed and validated against retrievals to better predict the performance of new hip replacement bearings.

The latest developments in ceramic materials, which have involved mixing alumina and zirconia to produce two new material composites (ATZ and ZTA), have been shown to be more wear resistant under clinically relevant adverse simulator conditions than pure alumina. Finally, the wear performance of Alumina–on-Alumina, ATZ-on-ATZ and ZTA-on-ZTA bearings have been shown to be superior to other hip replacement bearing materials.

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Tables

Table 1: Constituents of the three ceramic materials used in this study.

	Alumina oxide (Al_2O_3)	Zirconia (ZrO_2)
Alumina BIONIT®	100%	-
ATZ	20%	80%
ZTA	75%	25%

Table 2: Mean wear rate (mm^3/million cycles) and 95% confidence limits for the three bearing combinations tested.

	Al_2O_3-on-Al_2O_3	ZTA-on-ZTA	ATZ-on-ATZ
Bedding in (0-1 million cycles)	1.54 ± 3.80	0.24 ± 0.18	0.03 ± 0.03
Steady state (1-4 million cycles)	0.55 ± 1.24	0.10 ± 0.08	0.07 ± 0.01
Overall (0-4 million cycles)	0.74 ± 1.73	0.14 ± 0.10	0.06 ± 0.004

Table 3: Mean phase content of monoclinic zirconia (wt%) with standard deviation on the femoral head following microseparation conditions.

	ATZ-on-ATZ		ZTA-on-ZTA	
	Unworn	Worn	Unworn	Worn
Monoclinic zirconia (wt%)	4.0±1.4	3.7±1.6	1.0±0.9	1.3±0.9

Figures

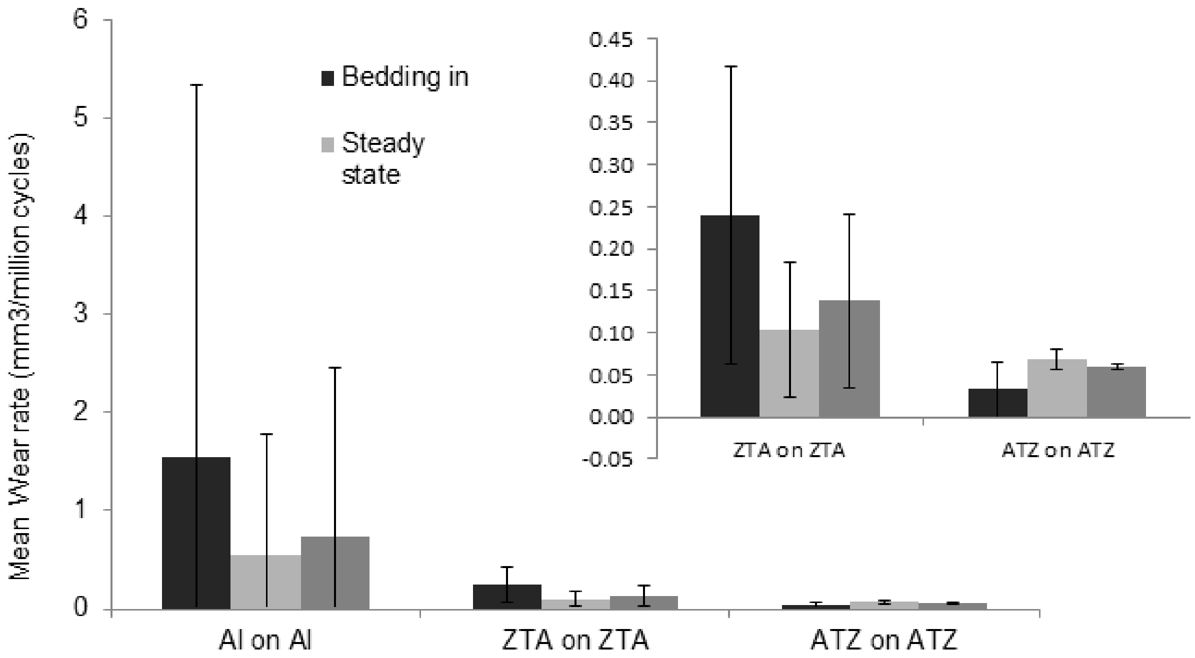
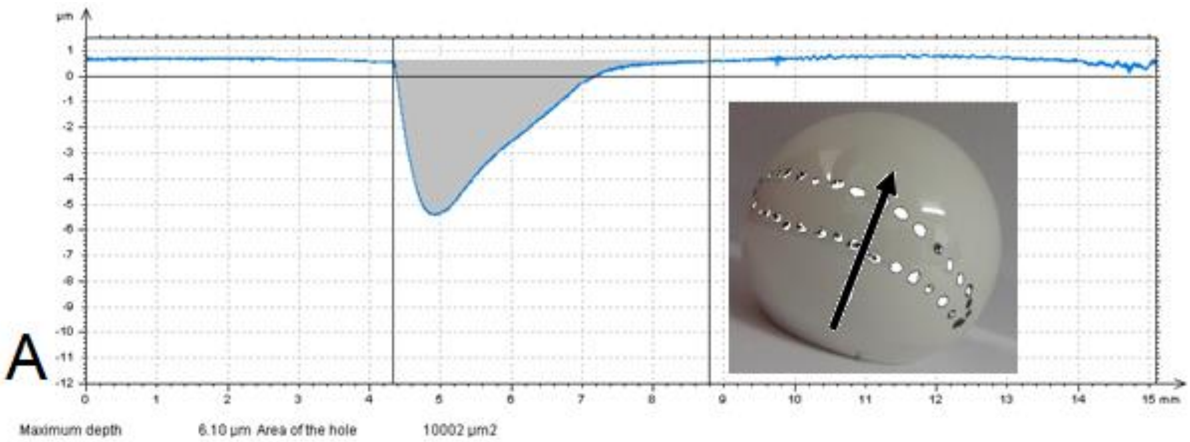


Figure 1: Mean bedding in, steady state and overall wear rates of Al-on-Al, ATZ-on-ATZ, and ZTA-on-ZTA bearing combinations under microseparation conditions. Error bars represent 95% confidence limits.



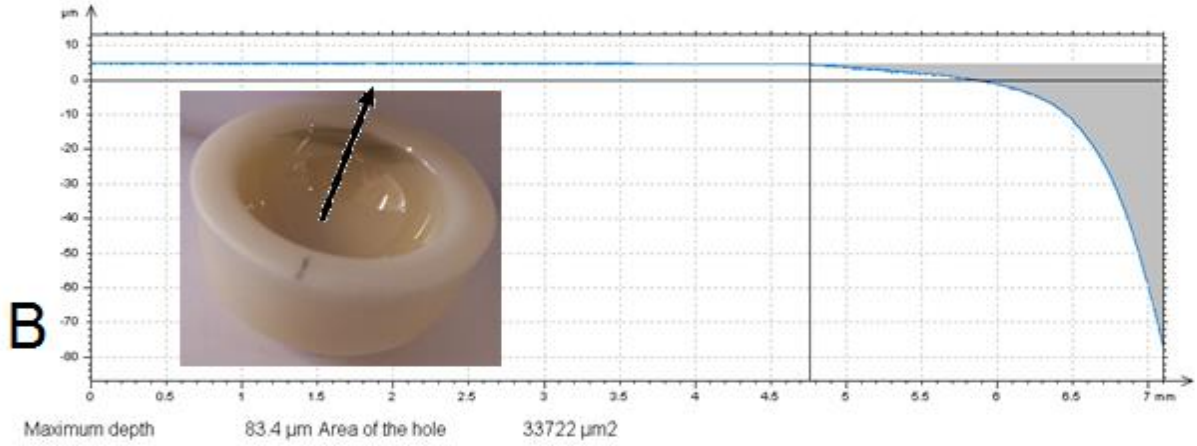


Figure 2: Examples of contact profilometry traces across the wear scar on the ATZ head (A) and Alumina cup (B). A dotted line is drawn around the wear stripe on the head and pencil was rubbed over the wear area on the acetabular cup for clarity.

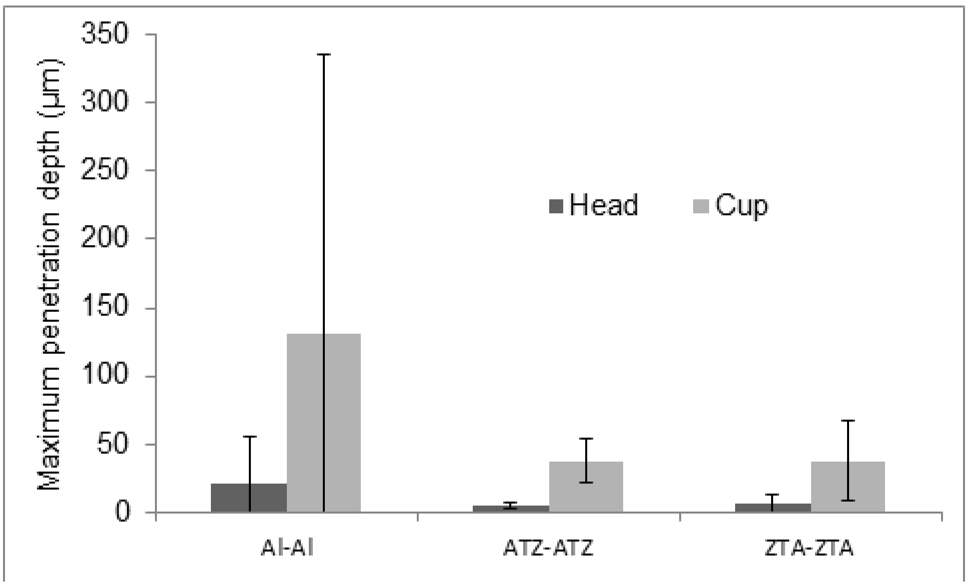


Figure 3: The mean maximum penetration depth over the wear stripe of heads and cups. Error bars represent 95% confidence limits.

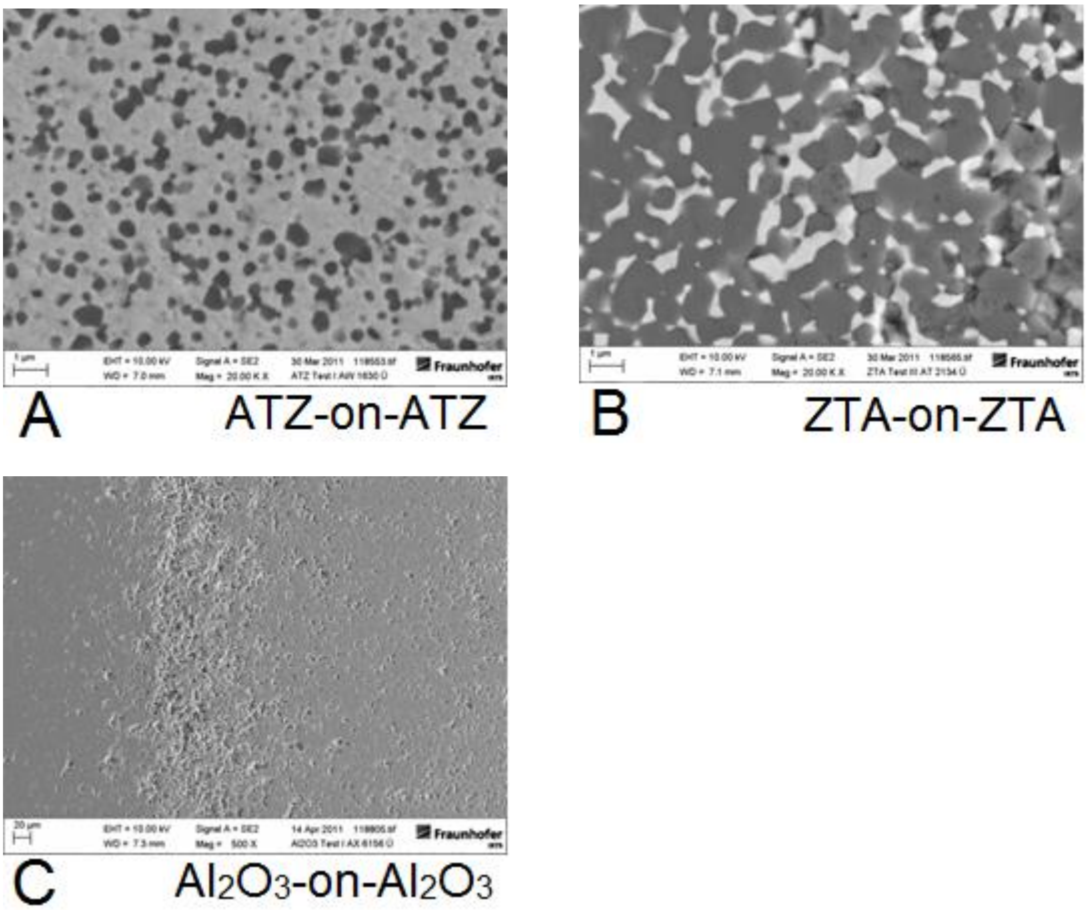


Figure 4: SEM images of the surface of the femoral heads after microseparation simulation conditions.