A novel test method for evaluation of the abrasive wear behaviour of total hip stems at the interface between implant surface and bone cement

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Abstract: After total hip replacement, some cemented titanium stems show above-average early loosening rates. Increased release of wear particles and resulting reaction of the peri-prosthetic tissue were considered responsible. The objective was to develop a test method for analysing the abrasive wear behaviour of cemented stems and for generating wear particles at the interface with the bone cement.

By means of the novel test device, cemented hip stems with different designs, surface topographies and material compositions using various bone cements could be investigated. Before testing, the cemented stems were disconnected from the cement mantle to simulate the situation of stem loosening (debonding). Subsequently, constant radial contact pressures were applied on to the stem surface by a force-controlled hydraulic cylinder. Oscillating micromotions of the stem (± 250 μm; 3×10^6cycles; 5 Hz) were carried out at the cement interface initiating the wear process.

The usability of the method was demonstrated by testing geometrically identical Ti–6Al–7Nb and Co–28Cr–6Mo hip stems ($n = 12$) with definite rough and smooth surfaces, combined with commercially available bone cement containing zirconium oxide particles. Under identical frictional conditions with the rough shot-blasted stems, clearly more wear particles were generated than with the smooth stems, whereas the material composition of the hip stems had less impact on the wear behaviour.

Keywords: total hip replacement, test method, wear, interface

NOTATION

AAS	atomic absorption spectrometry
ASTM	American Society for Testing and Materials
F_p	compression force
ISO	International Standardization Organization
PMMA	poly(methyl methacrylate)
PTFE	polytetrafluorethylene
R_z	roughness height
SEM	scanning electron microscopy
THR	total hip replacement
UHMWPE	ultra-high molecular weight polyethylene

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1 INTRODUCTION

After total hip replacement (THR), aseptic loosening is indicated in over 70 per cent of cases as the main reason for subsequent revision surgery, which additionally can be caused by deep infection, dislocation, peri-prosthetic fracture or implant breakage [**1**]. Aseptic loosening of the THR is usually caused by a tissue reaction to wear particles (wear disease) or by changed load conditions at the bone stock after implantation of an endoprosthesis (stress shielding) [**2**–**6**]. Frequently a combination of these factors causes implant loosening. Abrasive wear particles can be generated at the sliding interface between the femoral head and the cup, and at the interface between implant and bone or implant and bone cement [**7**].

In this context, very high early loosening rates were observed with some types of cemented titanium hip stem [**8**–**10**], although better biocompatibility is postulated for titanium and titanium alloys than for cobalt–

chromium (Co–Cr) alloys [**11**]. Until today it is still a matter of discussion whether cemented titanium-based stems should be used clinically. Referring to poor clinical results, Willert *et al.* [**5**] even recommended the general abandonment of cemented hip stems made of titanium alloys. Nevertheless, in individual cases, orthopaedic implants based on nickel and chromium alloys are not recommended in the case of metal sensitivity due to possible allergic reactions of the host and resulting in implant failure [**12**, **13**].

In particular, the disconcerting observation of a mostly blackish discoloured peri-prosthetic tissue during revision of particular cemented titanium hip endoprosthesis [**14**] drew attention to a possible relationship between released metallic wear particles and accompanied inflammatory as well as osteolytic reactions in the peri-prosthetic tissue. The generation of abrasive wear particles caused by relative motions between the titanium stem and the cement mantle is a main reason for early failure of THR. The formation of gaps between the bone cement and the titanium stem may lead to an accelerated corrosion process at the metallic surface [**5**]. This favours wear propagation, which results in increased release of titanium particles. Because of cellular reactions in the peri-prosthetic tissue, titanium particulate debris can cause osteolysis, bone loss and subsequent loosening of the implant [**15**–**17**].

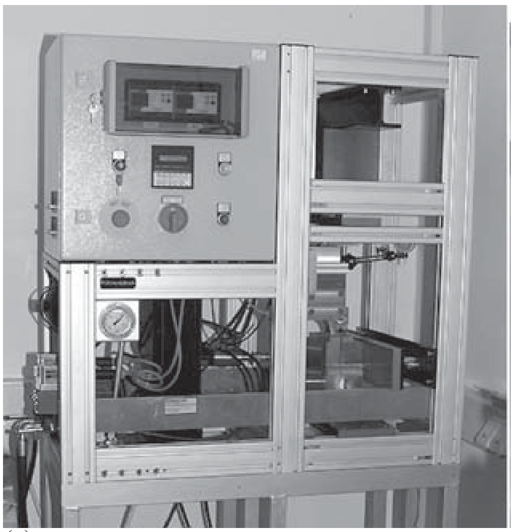
In order to minimize the generation of wear particles at the interface between titanium stem and bone cement, parameters possibly influencing the abrasion behaviour such as surface topography and material composition should be examined in a suitable testing procedure. Moreover, prior to broadening the clinical use of cemented titanium hip stems, the amount and the cellular effects of wear particles should be compared with particles released from Co–Cr stems providing good clinical results.

At present, no standardized test methods in accordance with ISO or ASTM standards have been described concerning *in vitro* wear investigations of cemented total hip stems. The available standards only refer to test methods which primarily aim at static and fatigue mechanical tests of the implants strength [**18**] and at tribological investigations of the sliding surface of the artificial hip joint [**19**, **20**].

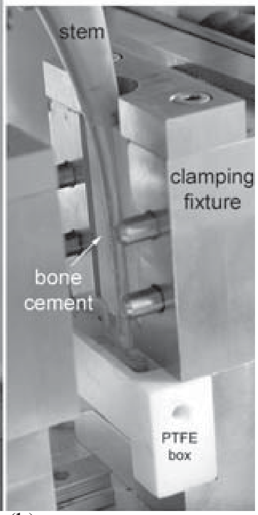
The purpose of the present work was to develop a suitable *in vitro* test method by which the abrasive wear behaviour of cemented total hip stems at the interface between implant surface and bone cement can be evaluated. On the basis of the test device, the influence of material composition (e.g. titanium versus Co–Cr alloys), surface modifications as well as composition of the bone cement should be analysed, with regard to abrasive wear characteristics and particle generation.

2 METHODS

The developed test apparatus is modular built (Fig. 1). Important components are the clamping fixture of the femoral stem and of the cement mantle as well as the adjustable hydraulic elements. Oscillating micromotions at the interface between stem and cement mantle, which induce the abrasive wear process at the interfacial surfaces, are applied by means of a position-controlled hydraulic cylinder (Fig. 2). Clinically relevant oscillating micromotions, which, according to published data, amount to between 100 and 500 μm in the interface



(a)



(b)

Fig. 1 (a) Test apparatus for evaluation of the abrasive wear behaviour of cemented hip stems. (b) Detailed view of the area outlined in white in (a), i.e. of the clamping fixtures, the tested femoral stem and the surrounding bone cement as well as the polytetrafluorethylene (PTFE) box for collection of wear particles

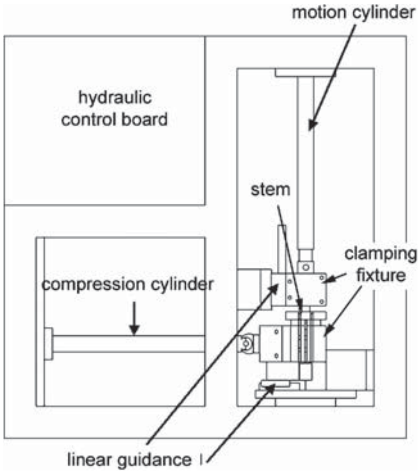


Fig. 2 Sketch of the test apparatus showing some important components

between stem and cement [**21**], can be applied with a frequency of up to 5 cycles/s.

For the cement fixation of the stem, i.e. manufacturing of the cement mantle, both commercial endoprosthetic bone cement and modified bone cement can be used. After mixing and moulding of the bone cement in a special cementing device, each stem has to be disconnected from the cement, i.e. debonding of the interface. Subsequently, the cement mantle is to be cut and separated into three parts (Fig. 3) in order to provide an evenly distributed contact pressure at the stem surface. The cementing of the stem extends to its middle and distal third due to technical reasons.

After insertion of the femoral stem and the three parts of the cement mantle into the test apparatus a definite contact pressure between the implant and bone cement of 2 MPa is adjusted and held constant during the test by means of an assembly equipped with a force-controlled hydraulic cylinder (compression cylinder) (Fig. 2). *In vivo* contact pressures between the stem and the bone cement varying from approximately 2 to 7 MPa are calculated [**21**, **22**]. The application of the contact pressure in the cement mantle is realized by two pivoted clamping jaws. The compressive force of the cylinder is evenly distributed over two components, which are positioned perpendicular to each other (Fig. 3). One part of the clamping fixture for the bone cement is movable, supported in the uniaxial direction by a linear guidance (Figs 1 and 2). This allows compensation movements, which become necessary to maintain constant contact pressure because interfacial wear occurs at the interface between stem surface and bone cement. The opposite side of the clamping fixture is firmly attached to the framework of the test apparatus.

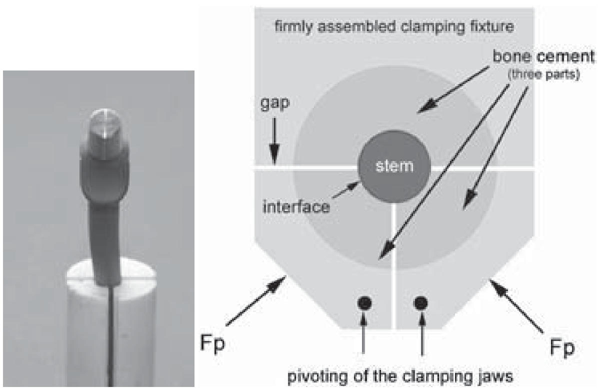


Fig. 3 (a) Separation of the cement mantle into three parts and (b) application of the compression force F_p at the interface between the stem and the cement by two pivoted clamping jaws

The oscillating micromotions of the stem initiate the wear process, by which abrasive wear particles are continuously released at the cement interface. Under dry test conditions the particles, which are present in powder form (mixture of bone cement and metal particles), are collected in a box made of PTFE (Fig. 1). To avoid contamination with foreign particles, the test chamber has an outer cover. During testing in a liquid environment, the abrasive wear particles are suspended in the surrounding solution. This kind of testing is not the subject of the present investigation.

The weight of wear products generated is determined using a precision balance (BP210D; Sartorius AG, Göttingen, Germany). Before and after the test procedure the surface roughness of the stems is measured with a profilometer (Surftest SV 502; Mitutoyo, Neuss, Germany). Moreover, the implant surface is analysed with a scanning electron microscope (CamScan 44, serial number 052; Cambridge Scanning, Cambridge, UK).

Initially, the test procedure was carried out by employing cemented CAP-M total hip stems ($n=12$) made of Ti–6Al–7Nb alloy or a forged Co–28Cr–6Mo alloy (Peter Brehm Chirurgie Mechanik, Weisendorf, Germany) (Fig. 4) with definite surface roughness. All the hip stems were geometrically identical and underwent a shot-blasting treatment prior to testing in order to restore the respective surface roughness. The smooth titanium and Co–Cr stems, which have both been shot blasted, displayed a surface roughness (R_z value) of about 7 μm, and the rough titanium and Co–Cr stems an R_z value of about 20 μm each. For this study, the Ti–6Al–7Nb stems were forged as a custom-made product, since such stems are not available for cemented clinical application. For the manufacturing of the cement mantle, commercial poly(methyl methacrylate) (PMMA) bone cement (Palacos R®; Heraeus Kulzer, Werheim, Germany) was used. This high-viscosity cement contains zirconium oxide (ZrO_2) particles for X-ray contrast of the cement mantle. In the tests performed, constant oscillating micromotions (± 250 μm) of over 3×10^6 cycles with a frequency of 5 Hz were applied under identical frictional conditions [dry environment at room temperature (25 °C) and a contact pressure of 2 MPa at the interface].

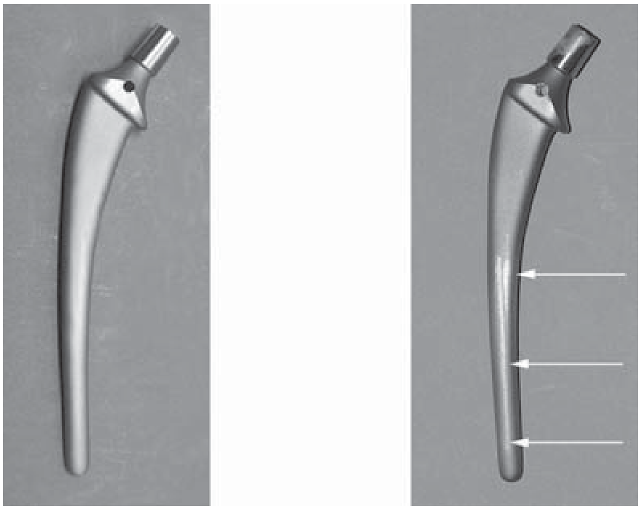


Fig. 4 Anatomical total hip stem made of Ti–6Al–7Nb with rough shot-blasted surface (a) prior to investigation and (b) after the test procedure. After removal of wear particles, polished surface areas (indicated by white arrows) are observable

3 RESULTS

In the experiments applying Palacos R® cement, both the rough Ti–6Al–7Nb and the rough Co–28Cr–6Mo stems (R_z values approximately 20 μm each) showed a noticeable decrease in the surface roughness of up to 2.5 μm at the loaded areas under dry environmental conditions. Each of the rough stems showed a wide smoothed surface at loaded areas (Fig. 4). In the middle of the stem, i.e. the counterface of the proximal part of the cement mantle, polished zones were detected on the ventral and the dorsal sides. At the tip of the stem, such spots could mainly be observed on its dorsal side. The smooth shot-blasted stems (R_z value approximately 7 μm in each case) did not exhibit considerable roughness differences and macroscopic signs of pronounced wear at the implant surface.

The scanning electron microscopy (SEM) analysis revealed abrasive wear marks on the rough shot-blasted Ti–6Al–7Nb and Co–28Cr–6Mo stems (Fig. 5). Planted areas and wear marks (scratches and grooves) with a width from submicrometre up to approximately 5 μm resulting from third-body wear in the interface were found (Fig. 6). As shown by SEM analysis, marks of abrasive wear were also seen in the frictional loaded areas on the smooth Ti–6Al–7Nb and Co–28Cr–6Mo stems, although macroscopic wear marks were clearly less pronounced.

Regarding the wear particles released, a doubling of the amount of particles (consisting of bone cement and metal) was recorded with the rough Ti–6Al–7Nb and Co–28Cr–6Mo stems compared with the smooth shot-blasted stems under identical frictional conditions. After 3×10^6 cycles the quantity of wear debris was on average 98 mg using the rough titanium stems in comparison with 23 mg with the smooth stem surface. Using the rough Co–Cr stems, particulate debris of 131 mg was generated versus 66 mg with the smooth surface (Table 1). The titanium stems produced less abrasive wear, in particular with the smooth shot-blasted surface, compared with the corresponding Co–Cr stems.

4 DISCUSSION

In the mid-1990s the trade-off of implantation of cemented titanium hip stems came to the fore. Very high

Table 1 Amount of generated wear debris (cement and metal particles) at the interface between the femoral stem and the bone cement after 3×10^6 load cycles. The rough and smooth titanium and Co–Cr stems were rubbed against commercial PMMA bone cement (Palacos R®)

Hip stem	n	Amount of wear debris (mg)
Ti–6Al–7Nb, rough	4	98 ± 28
Ti–6Al–7Nb, smooth	3	23 ± 4
Co–28Cr–6Mo, rough	2	131 ± 29
Co–28Cr–6Mo, smooth	3	66 ± 24

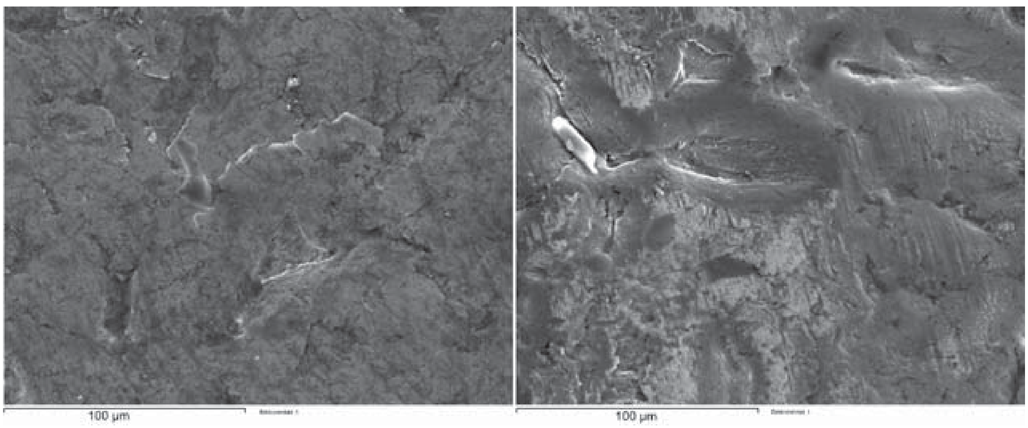
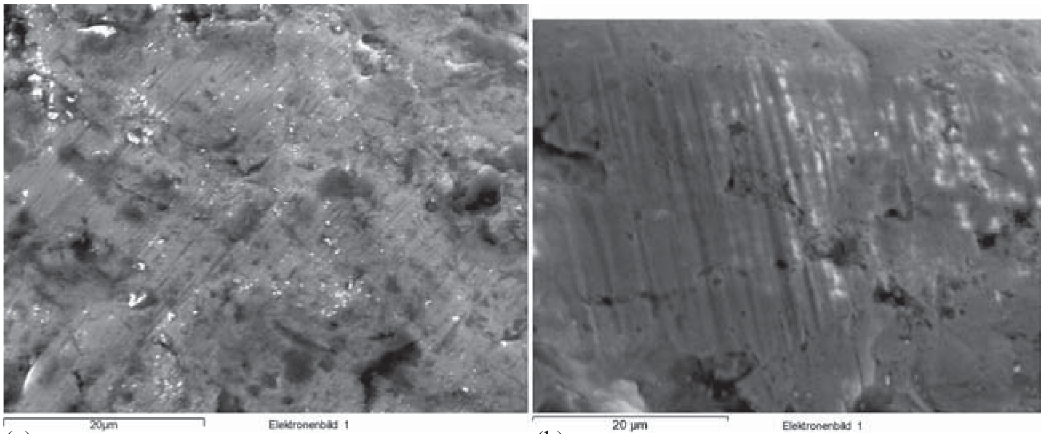


Fig. 5 SEM images of (a) the unloaded surface area of a rough Co–28Cr–6Mo stem and (b) the rubbed surface area of a rough Co–28Cr–6Mo stem with abrasive wear marks



(a) (b)

Fig. 6 SEM images of the rubbed surface areas of (a) a rough Ti–6Al–7Nb stem showing abrasive wear (scratches and grooves) and residual wear particles and (b) a rough Co–28Cr–6Mo stem, where the grooves with a width (from submicrometre to approximately 5 μm) resulted from third-body wear

early loosening rates were observed with certain types of cemented titanium stem [**9**, **10**, **23**, **24**], e.g. a high failure probability of 28 per cent was reported within only 3 years after stem implantation [**8**]. In contrast, very good clinical experience existed with other types of cemented titanium stem such as Ultima (Johnson & Johnson, Leeds, UK) and Bicontact (Aesculap, Tuttlingen, Germany) [**25**–**27**].

Eingartner *et al.* [**26**] attributed the low revision rate of less than 2 per cent (after 10 years) to certain design characteristics of the femoral stem, which resulted in a small amount of critical micromovements, as well as to the nature of the smooth polished surface of the implanted cemented titanium stems. Using a similar stem design, differences in the revision rates were described by others ranging from 14.1 per cent after 5 years [**23**] to 1.6 per cent after 9 years [**28**]. According to Acklin *et al.* [**28**], a higher risk of revision is mainly caused by rough surfaces, small stem sizes due to decreased implant stiffness, which causes larger micromovements, and increased stress in the cement mantle as well as inadequate operation and cementing technique.

However, current information regarding optimal material selection, morphology and treatment of the surface as well as design of total hip stems based on titanium alloys is still limited. Owing to limited knowledge of the factors influencing early failure of some cemented titanium stems, these days Co–Cr and stainless steel are almost exclusively used as standard materials for cemented hip stems. For stems made of high-alloyed steel or Co–Cr alloys so far no clinical data for such early failures are available [**29**].

An important scientific and clinical goal is to derive principles for the surface finish of cemented hip stems as well as for the composition of the stem (e.g. titanium or Co–Cr alloys) and the bone cement by means of appropriate *in vitro* investigations. For this reason a test method was developed, which allows a comparative analysis of the abrasive wear characteristics at the interface between the implant and bone cement of cemented hip stems. After cementing, the stems were disconnected from the cement mantle to simulate implant loosening. As a result, the stems were rubbed against the cement mantle under the unfavourable conditions that occurred after cracking of the cement [**30**].

Definite micromotions and contact pressures at the interface were applied to preserve constant frictional conditions. Besides the dry environmental conditions (worst case) an additional test setting, i.e. dry lubrication at the interface, can be implemented. For the *in vivo* situation, mixed friction conditions [**31**], i.e. different areas of dry and/or lubricated frictional conditions, might arise at the stem surface. In the current study the tests were carried out under dry conditions. Thereby this procedure avoids dilution and dispersion effects of the particles, which otherwise may occur in liquids in joint simulators in an uncontrolled manner. This can compromise the subsequent particle analysis, since the detected particles should be representative of the entire particle population [**32**].

By means of the test procedure described, the influence of the bone cement and the hip stem material as well as its surface topography with respect to the abrasive wear behaviour could be demonstrated. However, not only can these parameters be analysed in accordance with other studies [**33**, **34**], but also design features, e.g. rectangle versus cylindrical cross-sectional area and different sizes of cemented hip stems, can be evaluated with the novel test method.

In the present investigation, the rough Ti–6Al–7Nb and Co–28Cr–6Mo stems exhibited an extensive rubbed surface as shown in explanted femoral stems [**2**]. In contrast, using the smooth shot-blasted stems, only minor marks of abrasive alterations were recorded. In the SEM analysis, planted zones and abrasive wear marks were found on the rough shot-blasted stems. However, on the smooth Ti–6Al–7Nb and Co–28Cr–6Mo stems, some microscopic abrasive alterations were also observed in loaded areas.

The signs of pronounced abrasive wear (grooves) suggest third-body wear, most probably caused by ZrO_2 particles added to the bone cement. The ZrO_2 particles are used to contrast the cement mantle in radiological investigations, although the ZrO_2 ceramic particles affect the stem surface strongly by acting as grinding third-body particles at the interface. For instance, Caravia *et al.* [**33**] found clear *in-vitro* damage at metallic surfaces caused by bone cement containing, in particular ZrO_2 particles [**33**].

Regarding the material degradation, more particles were released when rough Ti–6Al–7Nb and Co–28Cr–6Mo stems were used compared with the corresponding behaviour of smooth shot-blasted stems. In additional investigations the amount of metallic particles was detected by means of atomic absorption spectrometry (AAS) in a fluid sample. The concentrations of titanium and cobalt were higher in the wear debris after testing of rough titanium and Co–Cr stems respectively in comparison with identically loaded smooth stems. This emphasizes that the abrasion behaviour at the interface between implant and bone cement is affected considerably by the surface topography of the stem. In fact, clinical studies indicated the advantages of smooth polished cemented stems versus rough shot-blasted stems [**35**, **36**]. Collis and Mohler [**36**] noted a survival rate of 91.9 per cent with the rough surface contrary to 100 per cent with the smooth polished surface after a 7 year follow-up using cemented hip stems, which were based on Co–Cr alloy. The rough and the polished stems had identical geometries and were implanted by the same surgical procedure [**36**].

In the current study, the implant material of the stem is of only secondary importance to the wear behaviour. However, in accordance with the study of Wimmer *et al.* [**34**], using Co–Cr stems a higher amount of wear debris and total content of metallic particles released were detected in comparison with the corresponding values for titanium stems. In particular, the smooth shot-blasted titanium stems caused least wear at the interface. Owing to the hardness of Co–Cr alloy the surface peaks and asperities of the stem are not smoothed by frictional loading [**34**], so that the bone cement counterface can be strongly abraded. The titanium stems exhibit signs of third-body abrasive wear as well as planted areas due to reduced surface hardness, whereas less particulate debris from the PMMA surface may result.

However, in clinical use the lower stiffness of titanium hip stems compared with the Co–Cr stems has to be considered, assuming that the stems have identical designs. The resulting higher micromovements at the interface and the increased stress in the cement mantle caused by rough stem surfaces [**2**, **37**] could affect the wear behaviour. Moreover, the abrasive wear in a liquid environment and the potential corrosion mechanism at the surface of titanium implants have to be considered [**5**]. This will be the subject of subsequent investigations.

In conclusion, the present article characterizes a test method for the evaluation of surface topography and material composition of cemented hip stems with respect to their abrasive wear behaviour. Further studies will address the analysis of the wear debris released in regard to particle size, shape and quantitative composition, e.g. the content of metallic particles, by means of particle analysis using SEM and AAS [**38**]. However, adequate characterization of the pure metallic and ceramic particles (ZrO_2) is only possible after preparation of the wear debris and elimination of the PMMA particles respectively. Subsequent to the characterization the wear particles will be subjected to cell-biological investigations. It is worth mentioning that *in vivo* not only the metallic particles but also the PMMA particulate debris released can activate osteolytic cell reactions within the peri-prosthetic tissue in combination with defects of the cement mantle [**2**]. Additionally, the possible impact of particulate debris on cellular reactions as a result of surface and material modifications should be evaluated, i.e. adverse biological effects on certain modifications, which provide favourable wear behaviour in the test apparatus, have to be identified.

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