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Manufacturing conditioned wear of all-ceramic knee prostheses

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Abstract

To date, bioceramics have not been applied successfully in total knee joint endoprostheses. Sintered bioceramics can be machined only by grinding and polishing processes. Due to high quality requirements, there are significant challenges with regard to these machining technologies. An automated precise economical process chain for the manufacturing of a new all-ceramic knee implant design was developed. It was assumed the geometrical accuracy and the shape of implant contact geometry specified during the manufacturing process has a substantial influence on the wear behavior of the prosthesis. The importance of the surface quality of the ceramic implant surface remains unclear and warrants future examination.

1. Introduction

In 21st century medical engineering is one of the key technologies. In particular, the development of new medical implant technologies that replace or establish failed body or organ functions is of great importance. More than five million patients currently suffer from osteoarthritis in Germany. In 2008, that is the reason why more than 170,000 knee endoprostheses were implanted into patients.

The most common material combination in knee joint replacements is a cobalt-chromium alloy combined with polyethylene as a tribological pairing (denoted as CoCr-PE). The complication rate of such knee implants is approximately 25 % within 20 years. The common reasons for revision surgery are infections, wear and breakaway. However, the major cause of implant failure is implant loosening due to an immune reaction to polyethylene inlay wear particles [1-4].

In hip joint prostheses ceramic materials are currently used due to their wear resistance and biocompatibility properties avoiding the before mentioned reasons for revision surgery. To date, ceramics have not been applied successfully in total knee joint endoprostheses. Such high-toughness, sintered bioceramics can be machined only by grinding and polishing processes. Due to high accuracy and surface quality requirements, there are significant challenges with regard to these machining technologies. The aim of this study was to develop an automated process chain for the manufacturing of a new all-ceramic knee implant design.

v$_f$	feed speed
v$_c$	cutting speed
a$_e$	depth of cut
f$_s$	sideways infeed, tool path distance
d	main tool diameter

r	toric ring radius
d_g	diamond grain size
G,P	indices grinding (G) and polishing (P)
Rxx	workpiece radius
C	counterbody numbering
P	base plate numbering

2. Requirements and Experiences with All-ceramic Implants

During the development of artificial joints, it became apparent that the permanent function of implants depends on the durability of the tribological material pairings and the anchorage in the bone. There are presently no approved all-ceramic knee joint implants on the market. Geometrical and surface-relevant constraints must be used in the development and design of an all-ceramic knee arthroplasty, based on international standards (ISO and ASTM), as well as effects and mechanisms known from conventional metallic CoCr-PE knee joints and ceramic hips.

For the calculation of load-specific geometrical aspects, comprehensive kinematic studies were carried out on conventional metallic knee joint replacements (cobalt-chromium or titanium femoral and tibial components with a polyethylene inlay). The geometrical requirements were deduced from the results of these studies, and the prosthesis concept was patented [5]. Unicompartmental and total knee endoprosthesis systems were implanted into knee joint specimens to evaluate the kinematic behavior [6, 7].

There are several alternatives for metallic implant components. Subsurface modifications of the metal components can reduce the wear of the conventional polyethylene inlay. Current modifications of the femoral metal component include ion implantations (e.g., with oxygen), hardening by oxygen diffusion, diamond-like carbon coating (DLC) and physical vapour deposition coatings with titanium-niobium-nitride (Ti(Nb)N) or manufacturers used a forged zirconium-niobium alloys which was heat treated and enriched with oxygen. However, on explanted knee implants large surface defects were found [5, 8 and 9].

Ceramic materials are biocompatible and also have wear-reducing properties. In the orthopaedic discipline, there have been positive experiences with oxide ceramics in hip arthroplasties for more than 20 years. In combination with polyethylene, wear is reduced by up to 40 % when compared with a standard metallic component, and adverse reactions due to metal allergies are avoided. The use of ceramics in hip implants is unproblematic due to simple ball geometry in a spherical

joint with congruent faces. With this geometry, high loads are transmitted over large surfaces, eliminating the point loadings that can cause fractures of ceramic materials. Clearly, the design of an all-ceramic knee implant must be appropriate for the material properties.

The first trials of alumina-based knee implant components (femur and tibia) in combination with a polyethylene inlay failed due to early loosening, sinking in tibia bone and component breakage. This material required a high wall thickness, leading to a heavy joint implant. CeramTec and Kyocera currently both offer high-strengthened bioceramics for femoral components which are designed similarly to the commonly used metallic components. Over 200 femoral ceramic components have been used in clinical trials. The first results, after three years, show very low polyethylene wear in the synovial fluid [9-11]. Use of a ceramic inlay component would avoid polyethylene wear altogether. This reduced wear, and the consequential longevity of implants, is the motivation for transferring the benefits of ceramic materials to the challenging geometry of knee prostheses. Progress in ceramic material properties has led to a promising future for ceramics in knee joint replacements.
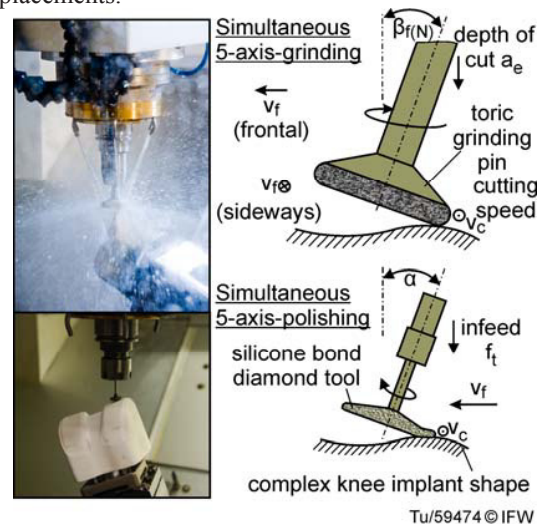

Fig. 1. Principle of 5-axis grinding and polishing of all-ceramic implants

International standards specify the verification and testing of biomedical ceramics (i.e., ISO 6474), the classification and dimensioning of monocondylar and total knee endoprostheses of different materials (i.e., ISO 7207-1), as well as the boundary conditions for knee prostheses regarding their roughness (i.e., ISO 7207-2). However, these specifications are not sufficient and at times irrelevant for the design and testing of all-ceramic implants, especially for knee implants. So, only experience from hip implant industry can be used. A roughness Ra lower than 20 nm and a high shape accuracy (form deviations <2 μm) should be achieved by

manufacturing. Each prosthesis component shall be made of wear-resistant biomedical ceramic. Point loadings and fixed line contacts must be avoided due to the lack of a compensating polyethylene element. Notch and tensile stress concentrations have to be minimized by the geometry of the design, avoiding small radii, sharp edges, steps or cut-ins. As opposed to tensile or bending loads, pressure loading should be the dominant method of force transfer through the prosthesis component.

Furthermore, in the tibiofemoral articulation of the knee, there are six degrees of freedom and a rolling-gliding motion during flexion, that is, the femoral condyles roll and glide over the tibial plateau. In contrast, there is purely gliding motion in a hip joint. Thus, the design and machining technology relating to ceramic hip implants cannot be directly transferred to knee implants.

3. Manufacturing and Testing of All-ceramic Knee Implants

3.1. Manufacturing of All-ceramic Knee Implants

For verification of the functionality of the two-step machining process, implant samples of a ZTA bioceramic were machined with a galvanic tool by means of frontal grinding and their topographies were analyzed. Grinding process parameters and SEM photographs are shown in Fig. 2 (top). A ground surface with a roughness Ra of approximately 100 nm was achieved. Following this, the same surface was polished with resilient silicone bond diamond tools (Fig. 2, bottom). After polishing, the roughness peaks were leveled and the surface had a roughness Ra of 8 nm.

In order to consider all of the aspects of material, design and geometric-kinematic boundary conditions, it is necessary to develop an economical, automated and precise manufacturing chain. Knee implant components have complex, partly free-form surfaces. Free-form surfaces are industrially milled by machines with five or more axes [12]. Such a milling process can only be carried out on ceramic components in a green or white-body state. Then, the components are ground and polished after sintering and high-isostatic pressing (HIP). For the finishing of complex ceramic knee implants, a two-step machining process was developed. Both steps can be performed using the same multiple-axis machining center. The 5-axis grinding process generates macro geometry with the best possible surface topography, resulting in a reduced polishing effort. Toric diamond grinding pins are used for this procedure (Figure 1, top) [13, 14]. Enclosing, the polishing process employs resilient silicone or polyurethane bond diamond tools which only level the roughness peaks (Figure 1, bottom). The material removal produced during

polishing step is below 1 μm. The combination of the grinding and polishing steps ensures the requirements regarding shape accuracy and surface quality of the articulating surfaces are met [15].
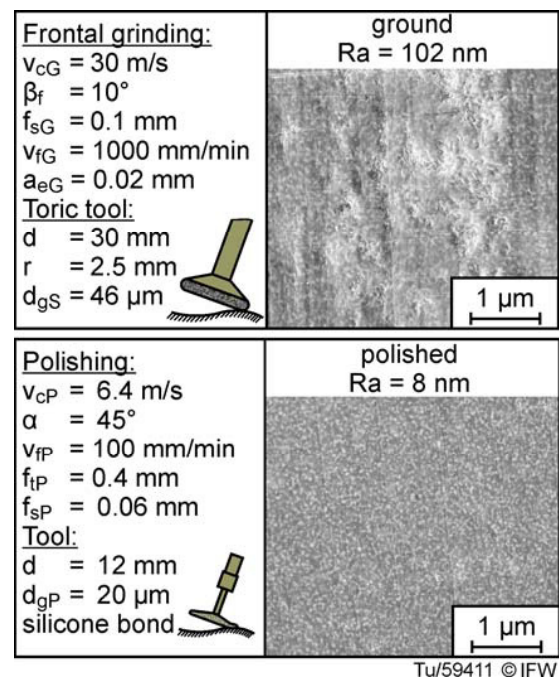

Fig. 2. Surfaces of 5-axis ground and polished all-ceramic implant components

3.2. Testing Procedure of All-ceramic Components

In order to analyze the wear behavior of ceramic implant components, a wear simulator was used which was developed by Richter et al. [5]. The three articulation mechanisms of the tibiofemoral joint – pure rolling, rolling-slipping and gliding – are accounted for by the wear simulator. Essentially, a base plate moves in the horizontal direction, rolling and gliding against a semicylindrical counterbody under axial loading [Fig. 3].
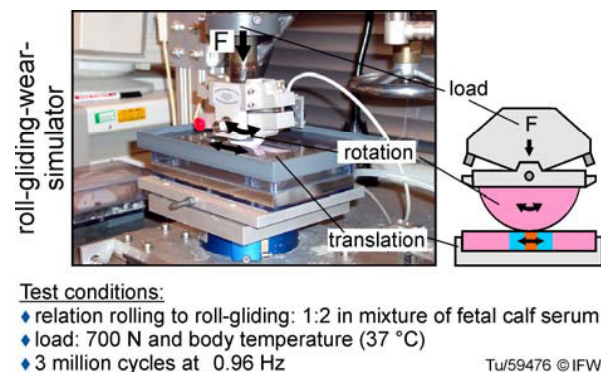
Test conditions:
♦ relation rolling to roll-gliding: 1:2 in mixture of fetal calf serum
♦ load: 700 N and body temperature (37 °C)
♦ 3 million cycles at 0.96 Hz

Fig. 3. Principle of wear testing of all-ceramic components

The base plate represents the inlay of a knee endoprosthesis, while the counterbody represents one of the two articulating surfaces of an endoprosthesis' femoral component. The wear of the specimens was measured gravimetrically according to ASTM standards F2025 and F1715. The specimens were cleaned and dried prior to weighing. After wear testing, these processes were repeated under the same conditions and wear was calculated from the change of mass. Wear measurement was carried out after 100,000, 500,000, 1 million, 2 million and 3 million cycles.

4. Experimental Design of Wear Investigation

To determine the influence of surface machining on the wear behavior of ceramic components, simplified implant samples were machined as previously described. The authors are interested in the influence of machining quality and the roughness and shape deviations on the wear behavior of the samples.

In order to answer these, samples of ZTA bioceramics were machined by grinding and polishing (Fig. 1 and 2). For grinding an electroplated toric tool and for polishing a silicone bond tool were used. The parameter settings are described in Table 1.

Table 1. Parameter settings for grinding and polishing processes

Parameter settings	Grinding	Polishing
Tool type	Electroplated, Toric Tool	Silicone bonding
Grain size d_g	46 μm	20 μm
Cutting speed v_c	30 m/s	6.4 m/s
Feed speed v_f	400 mm/min	100 mm/min
Sideways infeed f_s	0.1 mm	0.06 mm
Depth of cut a_e	0.02 mm	-
Infeed f_t	-	0.4 mm

The simplified femoral components had a sagittal plane radius of 32 mm, and the simplified inlays (base plates) were firstly planar (pairs C1.X and P1.X, Fig. 4), secondly curved (pairs C4.X and P4.X, Fig. 5). The same machining process was applied to of three component pairs each and the roughness parameters Sa, Ra, Sz and Rz were measured with a white-light microscope.

5. Results of Wear Investigation

The gravimetric wear measurements wear reasonably consistent. The average volumetric wear of the first three samples 1.1-1.3 was approximately 0.96 mm³. No systematically influence of the roughness deviations could be measured in the wear behavior. In comparison

to a conventional implant pairing (CoCr to PE) tested using the same wear simulator and protocol, the ceramic-ceramic pairing showed a reduction of wear behavior by 88.5 % (wear of PE component: 7.62 mm³ after 3e[6*] cycles, calculated using the known density of 0.943 g/cm³).
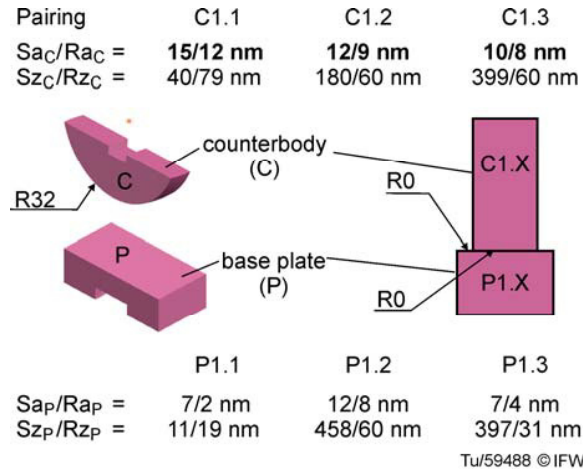
Fig. 4. Geometry and roughness of sample pairs C1.X and P1.X

The inspection of wear behavior (Fig. 6) of the samples at multiple points throughout 3 million wear cycles did not reveal additional findings. Here was roughly linear wear, mostly after a brief "running-in" period, for all samples except the counterbody C1.3, which had some chipping of the edge (not the articulating surface).
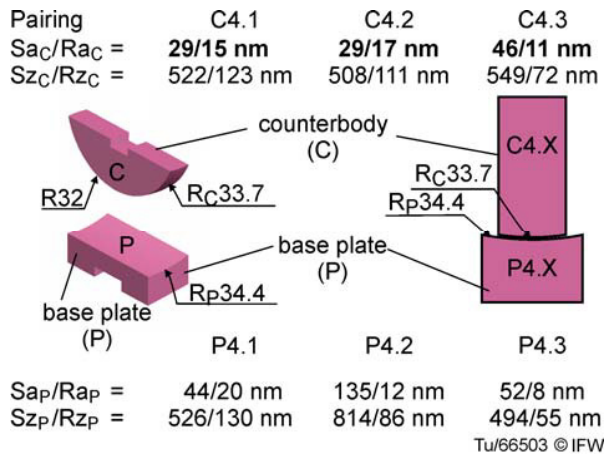
Fig. 5. Geometry and roughness of sample pairs C4.X and P4.X

The wear behavior of the samples 4.1-4.3 shows a similar, almost linear, stronger increasing wear (Fig. 7). This correlates with increased surface point loadings due to second curvature of these samples compared to the pairs of Fig. 4. The average volumetric wear of this three pairs was 2.6 mm³ with very low standard deviation of 0.14 mm³. Compared to the single curved samples 1.1.-

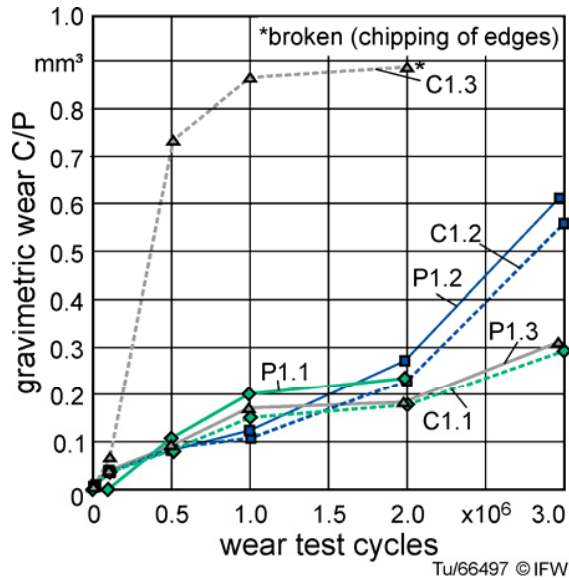1.3 the wear is 2.5 time higher, but even less to conventional pairings.

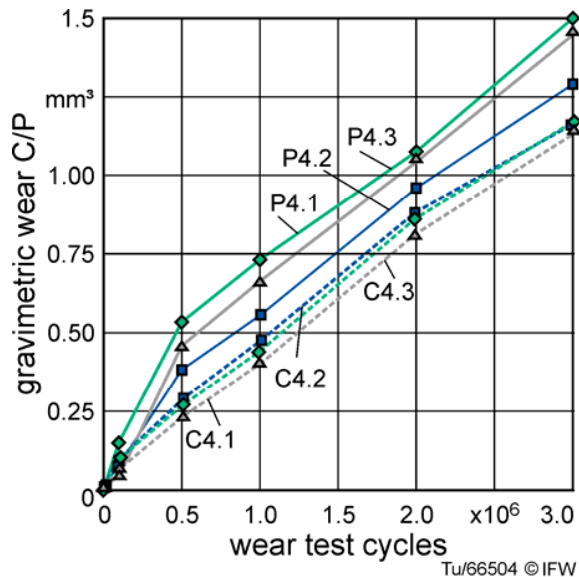Fig. 6. Wear behavior of sample pairs C1.X and P1.X

Fig. 7. Wear behavior of sample pairs C4.X and P4.X

6. Conclusion and Outlook

The analysis of tribological implant pairings under "human"-appropriate loading and kinematic conditions is of great importance for the production of low-wear knee endoprostheses. The present study focused the influence of the manufacturing tolerance of ceramic components on wear and the wear reduction to conventional implant pairings (CoCr-PE). The study found that the influence of machining is not significant despite the presented range of quality. The geometrical shape influences the congruency of the tibia and femur

components and therefore the type of loading. The first three sample mainly worn due to line-contact under loading of 700 N. Under the same loading samples with a different geometry causing mainly point loadings have a 2.5 times higher wear. So small differences in shape due to manufacturing tolerance did not influence the wear considerably, but wear increases with increasing congruency of the sample pairs.

The average wear rate of ceramic single-curved samples with almost identical surface topography was 0.32 mm³ per 1 million cycles. Previous experiments show that a geometrically identical specimen of the conventional knee implant material combination (CoCr-PE) displayed wear of the PE-component of 2.54 mm³ per 1 million wear cycles. Thus, the wear of a conventional paring using this simulator was more than eight times the wear of a ceramic pairing.

Due to the limited number of sample pairs tested, further investigations are needed for a more completed understanding of the influence of frontal-plane radius on wear behavior and to verify the wear results presented here. This and the results of the influence of the roughness of the samples are being prepared for the next paper. As this research uses simplified components and simplified rolling-gliding kinematics, the data cannot be directly compared with the wear test results from a total knee endoprosthesis simulator. Nevertheless, the results of the simplified samples of CoCr-PE showed a similar behavior to total knee prostheses [16].

Acknowledgements

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