Micro-computed tomography for non-destructive testing of ceramic knee implants

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Abstract

Introduction: There are many reasons for the failure of a total knee endoprosthesis. The most common are infection, loosening, instability, pain and abrasion of the polyethylene. It is therefore necessary to further develop the current models. This study examines a new completely metal-free ceramic total knee endoprosthesis. There are several reports on the clinical results and biomechanical testings. Non-destructive analysis by computed tomography (CT) is a new tool for analysis of a ceramic knee endoprosthesis.

Methods: In this study, 16 samples of a ceramic total knee arthroplasty were scanned including left and right implants (sizes 3 to 6). Each sample was left in its original packaging during scanning in order to preserve its sterile state. During the scanning procedure, two samples of the same size were scanned jointly in order to minimize scanning time. The testing was exclusively non-destructive, which poses a challenge due to the high density of zirconium (6 g/cubic centimeter). We established a non-destructive test protocol especially for ceramic knee implants in which the scanning parameters were optimized and the sample orientation was determined by CT simulations. Additionally, methods for the reduction of beam hardening artifact were applied.

Results: It could be shown that a correct presentation in the micro-computer tomograph is possible despite the high density of the ceramic. In the examined specimens, no internal material defects such as pores or fractures were found. A three-dimensional examination, even of objects with a high density, can be carried out flawlessly using the micro-CT.

Summary: It was shown that no pores or cracks were found in the tested implants. Non-destructive testing in micro CT is a challenging method. The highly compressed material and the complex geometry of the femoral and tibial implants make measurement difficult. Sophisticated corrective tours of the scanning artifacts and a robust scanning protocol are necessary to achieve optimal results. This study provides the prerequisites for further analysis.

Keywords: ceramic, testing, knee, allergy, non-destructive

1 Introduction

The implantation of artificial knee joints is currently the second most successful and one of the most frequent procedures in orthopaedics after the implantation of the artificial hip. Due to the demographic development, the number of operations performed increases every year [1]. Since every total knee endoprosthesis can fail, it is of utmost importance for the surgeon and above all the patient how long the first implant will last [2-4]. The average ten-year revision rate is currently 6.2% (range 4.9% to 7.8%) [5]. One of the most frequent reasons for the change is aseptic loosening, infection but also an intolerance of the metal implants [6]. In order to improve this situation, the further development of total knee endoprostheses is necessary. Here the use of ornamental zirconium ceramics is a suitable option. When using an implant made of zirconium ceramics for the tibia and femur with a polyethylene inlay, it is possible to carry out a completely metal-free treatment of the knee [7, 8]. The use of ceramic on the entire knee joint is relatively new [9]. An important point here is the material testing, which can only be carried out non-destructively in order to enable a later implantation [10]. The ornamental conium ceramic has a very high density (6 g/cubic centimeter) and is difficult to examine in imaging (mic computer tomography, MCT) in connection with the complex geometry of the knee joints [11, 12]. Therefore, the aim of this study was to develop a new test protocol for non-destructive testing of ornamental conical ceramic implants. For this purpose, an XCT simulation with data post-processing was established to achieve an optimal and artifact-free imaging of the implants.
2 Materials and Methods

2.1 Total knee replacement system

The BPK-S Integration (Peter Brehm GmbH, Weisendorf, Germany) is a non-constrained primary total knee replacement system. The bicondylar femoral component and the tibial component are made up of an alumina/zirconia ceramic composite (Biolox®delta; CeramTec AG, Plochingen, Germany). The ultra-high-molecular-weight polyethylene (UHMWPE) insert may be rotating or fixed-bearing. A stump within the inferior part of the insert articulates with the ceramic tibial tray to control its motion.

The metal-free ceramic BPK-S tibia component has undergone in-depth experimental mechanical testing prior to this study, according to standards ISO 14879-1:2000(E) and ASTM F1800-07. Large reserves in mechanical strength have been demonstrated, greatly exceeding the required safety norms (DIN EN ISO 21536:2009) [15]. The geometrical design of the ceramic BPK-S Integration system is identical to the respective cobalt-chromium version from the same producer. Recent short-term studies have shown very comparable clinical and radiological results between these two systems [7, 8].

2.2 Micro-Computed Tomography

The ceramic knee total endoprostheses described above were non-destructively examined for their material structure and any inclusions or cracks by means of XCT. A total of six samples were included in the investigation (left and right implants of sizes 3-6). The implants were left in their original packaging and thus remained sterile. Due to the packaging, examination artefacts could be excluded. Specimens were scanned at an isometric voxel size of 100 μm using a RayScan 250E cone beam micro computed tomography (XCT) system equipped with a Perkin Elmer XRD1620AN14 flat panel detector (2048x2048 pixels with a pixel size 200 µm) and a Viscom 225kV microfocus X-ray tube. The X-ray scanning parameters were set to 180 kV and 480 µA with an integration time of 3000 ms. Additionally, a 1.0 mm thick tin filter-plate was used to reduce beam hardening artefacts. Since X-ray radiation of laboratory XCT systems is polychromatic it becomes “harder” as the beam passes through an object, i.e. its mean energy increases because lower-energy photons are absorbed more rapidly than higher-energy photons. Scanning parameters were determined empirically by test scans prior to the actual scans and special orientation was a part of that test scanning.

Selecting suitable positions for the specimens in the X-ray beam is essential to minimize beam hardening and cone beam (reconstruction) artefacts. XCT simulation has been used to facilitate the selection.

2.3 XCT Simulation

Corresponding positions in the MCT were found out in preliminary tests and then determined for the scanning protocol. The goal of the simulation was to develop a scanning protocol for the optimal scanning position. Numerical simulations were carried out beforehand using the SimCT software [16]. This tool can calculate a realistic projection of the CT images for the RayScan 250 E. The femoral and tibial components were homogeneously represented by surface models using triangulated meshes and were overlaid with the defined density of the ceramic composition. The positions determined in this way enabled the representation shown in the results.

2.4 Artefact correction

Due to the complex geometry of the knee joints with many corners and jumps in caliber in combination with the high density of the ceramic war war artifacts can occur. These effects are known as cupping artifacts or the appearance of dark or light bands and circles. These effects reduce the image quality and should therefore be avoided in non-destructive imaging. The IAR module in the software package VolumePlayerPlus (EZRT, Fraunhofer Development Center for X-Ray Technology) was used to achieve a hardening correction [17]. This correction method is based on a linearization technique.

Figure 1: XCT imaging of a ceramic tibia plateau (left: from the top, middle: frontale, right: coronal)
3 Results

It could be shown that a correct presentation in the micro-computer tomograph is possible despite the high density of the ceramic. In the examined specimens, no internal material defects such as pores or fractures were found. A three-dimensional examination, even of objects with a high density, can be carried out flawlessly using the micro-CT. After the optimal positioning of the tibial and femoral ceramic implants had been determined, the material testing of the ceramic parts could be performed. The cone beam and beam hardening artefacts were eliminated as far as possible. The complex geometry of the knee joints, where there are cuts in all planes through the ceramic, favors artifacts. Overall, it could be shown that all tested implants showed no inclusions, no chipping and no fracture inclusions of pores were found (Figs. 1 and 2).

![XCT imaging of a ceramic femoral implant (left: sagital, right: frontal)](image)

4 Discussion

Cobalt chrome alloy is standard for artificial knee joints. A cemented or cementless implantation can be performed. In any case, complications can occur during the service life, the most common ones being infection, loosening, instability, pain and polypropylene abrasion [18]. However, intolerance reactions and other allergic or pseudoallergic reactions also occur time and again. And to prevent these, new materials should be used. Especially models with a chrome content of more than 10 % can cause problems. The release of metal ions can trigger an immunological reaction, which can also be the case with materials containing aluminium. The advantage of the knee system presented here is that it is completely free of metal, so there is no secondary release of metal ions with secondary stimulation of the immune system by the metals (cobalt, chrome, nickel) in patients with suspected metal hypersensitivity. The role of metal implant allergy in TKA is still not fully understood. Cutaneous and systemic hypersensitivity reactions pose an increasing concern because of their still uncertain nature. The prevalence of metal-sensitivity among the general population has been estimated as high as 10% - 15%, with nickel sensitivity averaging 13% and sensitivity to cobalt/chromium being 3% [19, 20]. Especially in patients with knee arthroplasty, noncutaneous complications such as unexplained pain, recurrent effusions, reduced range of motion and aseptic loosening can be associated with metal hypersensitivity/metal sensitization [21]. Corrosion or metal debris may lead to secondary sensitization and possibly to failure of the TKA. However, still few studies have examined corrosion and release of metal wear products (metal ions and debris) in TKA [22].

The clinical application of ceramics has shown good medium-term results. Literature on long-term outcomes of ceramic TKAs is scarce, especially concerning partly metal-free systems. Bergschmidt et al. [23] published a 96% Kaplan-Meier’s survivorship of ceramic femoral components in 109 TKAs at 60 months follow-up. The only adverse event was a posttraumatic crack within the femoral component, no other implant migration or loosening was seen. Nakamura et al. demonstrated excellent results with a survival rate of 99.1% (69/70 patients) at 10-year follow-up of their alumina medial pivot prosthesis with ceramic femoral component [24]. One patient required revision surgery after a traumatic fracture of the tibial plateau. To our knowledge, the first completely metal-free TKA system was analyzed by Meier et al., showing significantly increased clinical scores at 12 months follow-up of the BPK-S knee system with tibial and femoral components made of an alumina/zirconia composite [8]. There were no osteolysis or implant loosening, and no induction or exacerbation of previous allergies. Another study was previously able to demonstrate similar clinical and radiological outcomes of the BPK-S metal-free knee system in comparison to its identical metal counterpart at the 1-year follow-up [7]. Within the current 4-year follow-up, we were able to record a high level of patient satisfaction without any occurrence of revisions, implant failure, or allergic exacerbation.
In conclusion, this ceramic knee system a suitable option for patients with known metal hypersensitivity/metal intolerance reactions. Long-term studies will be required to demonstrate the overall efficiency of this TKR to potentially expand its medical indication.

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