Ceramic Macrostructured Acetabular Liner

Integrating directly into Bone: Implant Design, Manufacturing, and In vitro Investigations

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Abstract

The development of new ceramic materials for medical applications enhances the possibilities of implant design. Monolithic acetabular liners based on zirconia-platelet-toughened alumina with a macrostructured backside could increase patient mobility and prosthesis life span. This study developed a ceramic liner with an articulating diameter of 40 mm and a wall thickness of 3 mm. A macroporous coating with an average pore size of 300-400 µm was deposited at the backside of the liner during the manufacturing process. Cytotoxicity testing, microscopic imaging, as well as mechanical examinations (four-point bending test; compressive strength test) were performed to characterize the properties of the implant in vitro. Examinations of the impact resistance and luxation stability were also conducted. The macrostructured backside could be manufactured homogenously. No cytotoxic effects were detected in cell culture experiments. The mechanical examinations were passed without delamination of the coating. No cracks due to impact loading appeared for any of the samples tested. The range of motion of the joint and luxation stability both increased significantly compared to those of an established liner with a 28-mm diameter. The results show that the developed liner has outstanding mechanical and tribological properties.

Keywords: Ceramic acetabular liner, Zirconia-platelet-toughened alumina (ZPTA), Direct osseous integration, Macrostructured ceramic, Implant design

1. Introduction

Ceramic materials are widely used in acetabular liners because of their biocompatibility and low friction [1,2]. However, ceramic joint prostheses are susceptible to spontaneous fracture of both the femoral head and the acetabular component [3-7]. Since the early 1970s, several cementless total hip replacement (THR) systems consisting of alumina ceramics have been implanted with tentative success. Fracture rates of up to 13% have been reported with these systems [8], with massive osteolytic lesions and difficulty in revision procedures because of consecutive wear disease resulting from the presence of ceramic particles in the hip joint. Problems that result from failing ceramic prostheses have been described in detail [9-11]. Most fractures were attributed to large grain size, impurities, poor manufacturing tolerances, inadequate process control, and surgical error [12]. To minimize the cracking risk and ensure sufficient osseous integration, prosthetic systems currently in use include cementless acetabular cups with ceramic bearing press-fit metal-backed components. A ceramic acetabular liner is inserted into the metal back and fixed in place as a result of the conical geometry of both components. The limits of anatomical dimensions in the acetabular region restrict the ball diameter size. Increasing patient mobility and prosthesis life span requires improvements in the range of motion and wear behavior of THR systems. A possible solution is increasing the head size and decreasing the wall thickness of the acetabular liner, facilitating a larger range of motion of the joint [13]. THR systems using metal-on-metal bearings and a combination of large bearing diameter and small liner wall thickness have been developed. Common problems of metal bearings are attributable to wear of the bearing, and include allergic reactions, inflammation, and osteolysis [14-16].

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development of new composite alumina-zirconia ceramic materials with increased resistance to cracking and decreased brittleness [17-20] allow new designs of acetabular liners. Larger range of motion, due to the reduction of the wall diameter resulting in a larger possible articulating head diameter, is a clinically relevant improvement for THR systems. One conceivable concept for future developments in THR systems could be a monolithic ceramic acetabular liner, integrated directly into the bone, with the same dimensions as those of established metal on metal THR systems and a porous macrostructured surface on the back side. Due to the excellent biocompatibility of ceramic materials, the problems associated with metal-on-metal THR systems could be avoided. The present study develops and in vitro tests a monolithic ceramic acetabular liner with a macrostructured backside integrated directly into the bone.

2. Materials and methods

Nano-sized collagen I particles with diameters of 20-30 nm, produced using a high-voltage electrostatic field system as described in detail elsewhere [17,19]. All chemicals used in this study were of reagent grade.

2.1 Implant material, design, and manufacturing process

The liner was based on zirconia-platelet-toughened alumina (ZPTA, Biolox delta, Ceramtec GmbH, Plochingen, Germany). The low wear rate of alumina is combined with the high strength and fracture resistance caused by the transformation toughening of zirconia and crack deflection by platelets. In comparison to medical-grade high-purity alumina (Biolox forte, Ceramtech GmbH, Plochingen, Germany), ZPTA shows two times higher bending stress and crack resistance [17-20]. In addition, in vitro investigations of ceramic liners placed in a metal back have shown that ZPTA liners are more stable against high-energy impact loading than are cups made of alumina [21]. ZPTA has been increasingly used in THR systems with a metal back, with a marginal rate of complications.

Inspired by an established liner concept (Plasmacup, Aesculap AG, Tuttingen, Germany), the proposed liner has an inner diameter of 40 mm and a wall thickness of 3 mm. For the macrostructured backside, a mean pore size of 300-400 µm and a mean porosity of 45% were specified. Several studies have shown superior bone ingrowth for pore of this size compared to smaller or larger pore sizes [22-25]. To realize the macrostructured back of the liner, during the manufacturing process, axially pressed and green-machined bodies were coated with ceramic slurry (ZPTA) in a spraying process. Spherical organic pore-forming agents were embedded in the slurry layer. For pore-forming agents, paraffine, polyethylene, or polyvinylpyrrolidone can be used. In the first sintering process (temperature > 1400 °C), which eliminates organic particles, the green body was transferred into a solid ceramic part. Porous defects in the dense ceramic substrate were eliminated by hot isotstatic pressing. The parts were then sintered in the final sintering process (temperature > 1400 °C).

A finishing process (sandblasting procedure with dry ice, shaping and polishing with diamond tools) was used to remove unstable parts from the surface. Photographs of the macrostructured liner are shown in Fig. 1.

![Figure 1. Finished liner with macrostructured backside (left) and macrostructured backside and implant rim at 6x magnification.](image)

The topography of the coating was determined using laser scanning microscopy (LSM; 5 PASCAL Exciter, Carl Zeiss, Germany), scanning electron microscopy (SEM; F-4700, Hitachi, Germany) and light optical microscopy (LM). SEM images of the liner surface are shown in Fig. 2.

![Figure 2. As-fired coating (left) and coating after finishing process.](image)

The chemical purity of the material was proved by energy-dispersive X-ray spectroscopy (EDX) at various enlargements. The mechanical and chemical attributes meet the standards given in ISO 13356 (ISO 13356 International Standard 1997).

2.2 Cytotoxicity testing

To ensure that no residues of the manufacturing process, such as cleaning agents or sandblasting agents, which are known to be harmful for osseous integration, remained, cytotoxicity testing was performed. Special testing specimens were manufactured (diameter: 15 mm, height: 5 mm) with 3 types of surface, namely a structured ceramic surface, a smooth ceramic surface, a poly (methyl methacrylate) (PMMA)-well-plate surface. For every surface, seven samples were tested (21 specimens in total, according to the recommendations of the statistical institute of the clinic). The samples were placed in well plates containing Dulbecco’s modified Eagle’s medium (DMEM)/Ham’s F-12 medium (PAA, Marburg, Germany) supplemented with 10% fetal calf serum, 2 mM glutamine, and antibiotics (100 U/ml penicillin and 100 µg/ml streptomycin). Medium and human osteoblastic cells (10^5 cells per specimen) were seeded on the surface. After 24 and 96 h, lactate dehydrogenases (LDH) and adenosine triphosphate (ATP) levels were estimated. For LDH and ATP level detection, an in
vitro toxicity assay kit (Tox 7, Sigma Aldrich, Germany) and an ATP determination kit (Invitrogen, A22066, Germany) were used, respectively. Additionally, cells seeded on the rough surface were incubated 24 h with fluorescein diacetate. The surface adhesion and vitality of the cells were then detected by fluorescence microscopy.

2.3 Mechanical examinations

Investigations concerning the mechanical properties of the substrate and the coating were performed using four-point bending tests (Wolpert TZZ 707, Wolpert, Germany) in accordance to EN-643 (n = 10). For evaluation of the pressure strength, loading of the coated specimen with a hardened steel bolt (diameter: 5 mm) up to 20 kN was also performed (n = 10). For reference, the same investigations were carried out on uncoated fired ZPTA specimens with the same dimensions (n = 10).

2.4 Impact resistance

Resistance against impact was checked using a specially designed impacting machine [21]. Nine pieces were chosen for examination on impact resistance. The principles of the machinery are shown in Fig. 3. Three load cases of the head position were examined, with 3 implants per type used for each case.

Figure 3. Impacting machine. A load is lifted with a stepping motor and a magnetic clutch is opened at a certain height. By means of a liner bearing and a microseparation device, microseparation of the ball can be adjusted before the impact.

Group 1: central impact
Group 2: 0.25 head diameter collateral offset
Group 3: 0.5 head diameter collateral offset

Every group of liners was tested with an impact energy of 15 J 10 times. After every impact, the insert was inspected macroscopically for cracks and chipping. If no damage was detected for the insert after the 10 impacts (15 J), the insert underwent a second cycle of 10 impacts with an impact energy of 20 J. The implants were checked macroscopically after every impact. If no macroscopically detectable damage appeared after the 10 impacts (20 J), the implants were inspected for microscopic damage using a special dye penetration process (Zyglo®, Magnaflux, Basset, England).

2.5 Push out testing of cup

For characterization of the primary integration stability of the liner, push out testing was performed. Prototypes of the proposed cup with an outer diameter of 46 mm and an established liner system, based on a metal back with a macrostructured surface (Plasmacup, Aesculap AG Tuttlingen, Germany), with the same outer diameter were tested on push out resistance due to a press fit. In standardized bone-like Polyurethane blocks, recommended for biomechanical testing (Sawbones 30 PCF, Malmö, Sweden), first a hole with diameter of 10 mm was drilled, and then for the liners, a press fit was milled with Operation milling instruments according to the manufacturer’s instructions. Two conditions were tested for the two implants:

Best fit: diameter of milling instruments 2 mm smaller than that of liner
Normal fit: diameter of milling instruments 1 mm smaller than that of liner

After milling, the inserts were pressed into the testing material by a universal testing machine (Wolpert TZZ 707, Wolpert GmbH, Darmstadt, Germany) until the collar of the insert was parallel to the surface. A 10-mm steel bolt was then used to push the insert out of the bone substitute material from the cranial side with a velocity of 10 mm/min. The maximum push out force was recorded. Three inserts were tested for every press fit condition.

2.6 Range of motion and luxation stability

The range of motion and stability of the proposed liner against spontaneous dislocation of the ball were examined using the method described by Bader et al. [26]. Three implants were tested in 90° flexion and 0° adduction/abduction position. The liners were placed at 60° inclination and -15, 0, and 30° anteversion. The testing velocity was 2°/s. A standard 12/14 cemented hip stem (Exica®, Aesculap AG, Tuttlingen, Germany) and a ZPTA head (Ceramtec Delta®) with a diameter of 40 mm were used. For reference, a standard ceramic insert with a 28-mm articulating diameter (Ceramtec Biolox Forte®) was used. Therefore, the same stem was utilized with a new ball with 28 mm diameter. The bearings were lubricated using ringers solution. The range of motion until impingement and dislocation and the maximum torque level before dislocation were recorded during the trials. Three trials were conducted for each condition.

3. Results

3.1 Manufacturing process surface characterisation

After the finishing process, no unstable parts remained on the insert backside. The distribution of the porous cavities appeared smooth all over the backside of the insert. The
average height was 0.3 to 0.4 mm and the surface porosity was on average 47%, as determined from LM and LSM images. The diameter of almost 80% of the porous cavities was between 280 and 400 µm, as determined from LSM images.

3.2 Cytotoxicity testing

After 24 and 96 h, no significant difference between the LDH and the ATP levels of the control group (24 h, 48 h: LDH 100%, ATP 100%) and the group with the smooth surface (24 h: LDH 98% ± 3%, ATP 96% ± 4%; 48 h: LDH 102% ± 6%, ATP 97% ± 5%) and the group with the structured surface (24 h: LDH 105% ± 6%, ATP 96% ± 8%; 48 h: LDH 96% ± 5%, ATP 98% ± 3%) could be detected. Results are shown in Fig. 4. The samples with the structured surface, examined by fluorescence microscopy, showed groups of vital osteoblasts predominant at the edges of the pores, as shown in Fig. 5. No signs of apoptosis could be detected in microscopic examinations in any of the groups. Proliferation of the cells took place with no significant difference between groups (student’s t test, p > 0.05, significance level 0.05).

3.3 Mechanical examinations

In four-point bending tests, coated samples reached up to 75% (average: 884 MPa ± 163 MPa) of the four-point bending strength of the uncoated reference samples (average: 1150 ± 123 MPa). Axial loading with the hardened steel bolt up to 20 kN did not influence the integrity of the coating in any case. No delamination of the coating could be detected in any case. An example of the coated structure after loading is shown in Fig. 6.

3.4 Push out testing

There was no significant difference in the results of the push out testing between the proposed monolithic ceramic insert and the established insert with a rough-structured metal back. Higher press fit remained consecutive in higher push out values. With a press fit whose diameter was 2 mm less than that of the insert, the main push out values (MPVs) for the Plasmacup and proposed insert were 1.6 kN ± 0.15 and 1.64 kN ± 0.14 kN, respectively. For a press fit whose diameter was 1 mm less than that of the insert, the MPVs for the Plasmacup and proposed insert were 1.2 kN ± 0.12 kN and 1.35 kN ± 0.16 kN, respectively.

3.5 Impact resistance

No mechanical failure of the liner and no microscopic damage in the dye penetration test could be detected for any tested samples. All of the samples passed the loading protocol (10 impacts with 15 J, 10 impacts with 20 J) without any failure for all positions of the impacting head (central impact, quarter head diameter offset, half head diameter offset). Even impacting with maximal energy (20 J) and a half head diameter offset directly on the rim of the insert with 20 repetitions caused no cracks or other damage.

3.6 Range of motion and displacement

For 60/0 position in inner rotation, both types of implant remained stable until 90°. For outer rotation, impingement occurred after 56° and the head dislocated from the insert after 76°. For the reference insert with a 28-mm diameter,
impingement occurred after 21°, and luxation took place after 45°. For 60/30 position in outer rotation, impingement occurred after 87° (reference insert: 82°), but no dislocation occurred until 90° for both types of insert. For internal rotation, impingement occurred after 67° (28-mm reference insert: 48°) and the head dislocated after 83° (28-mm reference insert: 71°). In 60/-15 position, dislocation occurred spontaneously after application of physiological joint loads for both systems.

4. Discussion

The concept of ceramic acetabular liners integrated directly into bone has been around for several decades, with some success achieved. Concepts for osseos integration based on macrostructured metallic surfaces such as Spongiosa Metal® are in widespread use [27]. A direct integration concept based on alumina ceramic was invented by Mittelmeier in the 1970s, with a monolithic liner integrated with a truculent thread at the backside of the liner in the acetabulum. However, this concept failed due to a lack of osseos integration and a high revision rate based on implant failures. Implant failures were related to the material, aluminium oxide, which can take pressure but is prone to fracture at lower levels when exposed to tension, bending, and torsion [28,29].

With the introduction of improved manufacturing processes over the last 20 years with 100% proof testing concepts and the introduction of ZPTA ceramic, material weakness has been solved. The bending strength of ZPTA (> 1100 MPa) is more than double that of alumina ceramic (> 500 MPa) [17-20].

The maximum impact force of about 20 J is clinically relevant, as it is the energy required to induce a proximal femur fracture [21]. This can be regarded as an worst case scenario concerning the mechanical requirements of the liner. The forces that act on the liner when it is impacted into the socket are about ten times lower. The insert was able to withstand more than 10 impacts at 20 J without any detectable damage.

The proposed liners can be manufactured with a wall thickness of 3 mm, significantly increasing the range of motion with a head diameter of 40 mm, compared to that obtained with common inserts with a 28-mm inner diameter. For younger active patients, this enhances the mobility of the joint and prevents spontaneous luxation (a larger angle is required for impingement). However, dislocation can occur in instable positions such as 60/-15°.

Various investigations concerning ceramic dental implants integrated directly into bone have been conducted. The quality of osseos integration has been clearly shown to be related to surface roughness [30,31]. The transfer of clinically established macroporous structures of metal backs to the backside of a monolithic ceramic liner is a promising concept. No cytotoxic effects due to the material itself, morphological structure, or remaining cleaning and sandblasting agents on the backside of the liner could be detected in the biological examinations. The manufacturing and cleaning process can be regarded as biologically safe. The mechanical integrity of the rough-structured surface was tested by standardized examinations. No delamination or cracking of the rough-structured surface could be provoked in any of the trials.

For osseous integration and stable liner position, primary stability is a critical aspect in implant development. Therefore, push out tests were performed on the proposed and clinically established liners, whose dimensions were the same as those of a reference insert. Typically, lever out tests are performed to check interconnection stability. In this case, this was not possible because attempts to get a lever fixed to the ceramic liner failed. The authors tried to glue the lever into the liner or glue the ball into the liner, and adapt the lever to the ball. In all cases, the adhesion surface area failed before the liner. In our opinion with the push out test, the characterization of the primary stability is also warranted. We have seen a clear dependency of the pushout resistance of the liner, depending on the matter of pressfit. In the mechanical examination, the primary stability of the liner was comparable or superior to that of the established liner.

The very high stiffness of the ceramic liner may cause some problems over the long term. The stiffness of the material could cause some kind of stress shielding with aseptic loosening of the cup. Further investigations using animal experiments are necessary regarding the osseous integration of the cup. Therefore, short-term and long-term investigations have to be performed. Most of the liners with a macroporous structured backside that are in clinical use at the moment show poor long-term investigations. This may cause big problems for a monolithic ceramic liner with a smooth articulating surface. Suitable tools and techniques must be developed for revision surgery. The development of new biocompatible ceramic materials with outstanding mechanical and tribological properties allows for large implant improvement. For young patients with a high amount of physical activity, an acetabular liner could be a possible solution.

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References
