



# Clinical Evaluation of an Alumina-Toughened Zirconia Oral Implant: 1-Year Follow-Up

# 943



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## Objective

Alumina-toughened zirconia (ATZ), a ceramic material, possesses the potential for use as oral implant material. No scientific data on the clinical behavior of ATZ implants are available. The objective of this prospective 5-year cohort investigation was to determine the survival rate and bone remodeling of a one-piece ATZ oral implant after one year.

## Materials and Methods

The investigation was approved by the ethic committee of the University Clinics Freiburg, Germany. 20 patients were - after having signed an informed consent - included into the investigation and each one received one ATZ implant (Ziradent, Metoxit, Thayngen, Switzerland, Figure 7) for single tooth reconstruction. Before the initiation of the investigation all patients were asked for their dental and medical history. Subsequently, a dental and periodontal evaluation was performed and a cone-beam computed tomography of the prospective implant site produced. The implant surgeries were performed under local anesthesia with antibiotic coverage. After having raised mucoperiosteal flaps, the implants were placed, an eggshell provisional relined, immediately inserted without proximal and occlusal contacts, and the flaps closed with single sutures or modified everting vertical mattress sutures. Small bone deficiencies around the implants were treated with autogenous bone and bovine bone mineral. The sutures were removed after one week. The definitive single crowns [IPS e.max® CAD LT (Ivoclar Vivadent AG, Schaan, Liechtenstein)] were inserted four to eight months after implant insertion. The implants were evaluated clinically at crown insertion and one year after implant placement. For the evaluation of bone remodeling, standardized radiographs were taken at implant placement and at the 1-year follow-up.



**Figures:** 1. Clinical situation before treatment, 2. Implant inserted and bone deficiency treated with autogenous bone, bovine bone mineral and a porcine membrane, 3. Temporary placed and flaps closed, 4. Standardized radiograph after implant placement, 5. 1-year follow-up: clinical situation, 6. 1-year follow-up: standardized radiograph.

## Results

In 20 patients 20 implants were placed. Two patients lost their implants due to non-integration. One patient reported pain in implant regio 46 four weeks after implant placement. At eight weeks the implant showed mobility and was removed. Another patient presented a mobile implant eight weeks after implant placement. Also this implant was removed. This resulted in an implant survival rate of 90% after one year. All 18 remaining patients could be included in the 1-year follow-up (Table 1) and of all 18 implants standardized radiographs could be analyzed. The average marginal bone loss from implant placement to the 1-year follow-up was 0.88 mm (SD 0.89; n=18 implants). Of these 18 implants only two lost >2 mm of periimplant bone (Table 2).



**Figure 7:** A Ziradent implant

	Implant insertion	Crown placement	1-year follow-up
Patients/Implants	20/20	18/18	18/18
Failures	0	2 prior to crowns	0

**Table 1.** Status of patient evaluation

From implant insertion to 1-year follow-up		
number impl./pat.	18	
Mean	-0.88 mm	
s.d.	0.89 mm	
	n	%
> 0 mm	3	22.2
0 mm	0	0
-0.1- -0.5 mm	1	22.2
-0.6- -1.0 mm	6	11.1
-1.1- -1.5 mm	5	27.7
-1.6- -2.0 mm	1	5.5
-2.1- -2.5 mm	2	11.1

**Table 2.** Bone remodeling/loss

## Discussion and Conclusion

So far, there are only reports on yttria-stabilized zirconia oral implants (Oliva et al. 2010, Kohal et al. 2008, Andreiotelli et al. 2009). This is the first prospective clinical study on ATZ oral implants. Although 10% of the implants were lost at one year, it has to be kept in mind that the cohort with 20 patients has to be regarded as small and could have negatively influenced the survival rate. The initial results regarding the average bone remodeling are comparable to the results obtained from two-piece titanium implants when immediately loaded (Östman et al. 2007) and, therefore, the results are encouraging. However, a larger population needs to be evaluated in order to obtain robust information on the longevity of this implant system.

**Disclosure** This investigation was supported by Metoxit, Thayngen, Switzerland.

## References

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## **Biomechanical and histological behavior of zirconia implants: an experiment in the rat.**

[Kohal RJ](#), [Wolkewitz M](#), [Hinze M](#), [Han JS](#), [Bächle M](#), [Butz E](#).

### **Source**

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### **Abstract**

#### **OBJECTIVE:**

This study aimed at evaluating the integration of zirconia implants in a rat femur model.

#### **MATERIAL AND METHODS:**

Zirconia implants with two distinct surface topographies were compared with titanium implants with similar topographies. Titanium and zirconia implants were placed into the femurs of 42 male Sprague-Dawley rats. Four groups of implants were utilized: machined zirconia implants, zirconia implants with a rough surface, machined titanium implants, and titanium implants with an electrochemically roughened surface. After a healing period of 28 days, the load-bearing capacity between the bone and the implant surface was evaluated by a push-in test. Additionally, after a healing period of 14 and 28 days, respectively, bone tissue specimens containing the implants were processed and histologically analyzed.

#### **RESULTS:**

The mean mineralized bone-to-implant contact showed the highest values after 14 and 28 days for the rough surfaces (titanium: 36%/45%; zirconia: 45%/59%). Also, the push-in test showed higher values for the textured implant surfaces, with no statistical significance between titanium (34 N) and zirconia (45.8 N).

#### **CONCLUSIONS:**

Within the limits of the animal investigation presented, it was concluded that all tested zirconia and titanium implant surfaces were biocompatible and osseointegrative. The presented surface modification of zirconia implants showed no difference regarding the histological and biomechanical results compared with an established electrochemically modified titanium implant surface.

## Immediate and early implant loading protocols: A literature review of clinical studies

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The purpose of this literature review is to present the outcomes of clinical studies on immediate and early loading protocols, identify shortcomings, and suggest a number of questions that still require exploration. English language clinical studies, limited to peer-reviewed journals between 1975 and 2004, were reviewed to identify treatment outcomes with these loading protocols. The data were tabulated from studies reporting on patients treated with fixed and overdenture prostheses. The former included partially edentulous patients treated with single or multi-unit prostheses. Within the limitations of this review, it can be concluded that these treatment protocols are predictable in the anterior mandible, irrespective of implant type, surface topography, and prosthesis design (success rates 90%-100%). Limited evidence for the edentulous maxilla (success rates 90%-100%) and the partially edentulous patient (success rates 93%-100%) are available, underscoring the need for further research. Studies suggest that to achieve predictable results in extraction sites, implant placement should be restricted to sites without a history of periodontal involvement (success rates 61%-100%). A number of questions require further exploration. There is a need to thoroughly investigate clinical outcomes to measure the economic benefit of these protocols and the impact of treatment on a patient's quality of life. Furthermore, more accurate long-term studies reporting on treatment protocols for separate clinical situations are required to allow meaningful comparisons. (*J Prosthet Dent* 2005;94:242-58.)

One requisite for successful osseointegration is an extended submerged healing phase.<sup>1,2</sup> This is based on the initial clinical experience of Branemark et al<sup>3</sup> in treating a group of patients with severe morphological deficits. Eventually, this 3- to 6-month healing phase was described as empirical,<sup>4,5</sup> underscoring the need to test it clinically. Clinical and experimental research on other implant systems directly challenged this notion with convincing outcomes.<sup>6-9</sup> Clinical evidence supports the notion that Branemark implants can be left exposed during the healing phase without jeopardizing the healing response in completely and partially edentulous patients.<sup>10-13</sup> A literature review<sup>14</sup> of the experimental research indicated that early loading itself was not a contraindication to successful osseointegration. The latter was dependent on maintenance of a load that precluded extensive micromotion at the bone-implant interface. A conceptual working definition of these loading protocols was suggested<sup>11,15-17</sup> and comprised immediate loading protocols in which the implants were loaded within 2 days of surgery and early loading protocols wherein a provisional prosthesis was inserted at a subsequent visit prior to osseointegration. Though the implants were not loaded the same day, these protocols directly challenged the healing process by introducing loading during wound healing. The time period suggested for insertion of the prosthesis was between

2 days to 3 months after surgery.<sup>17</sup> This definition of early loading is tenuous, since it includes an extended timeframe during which the bone is allowed to heal. Conventional loading protocols are the original healing periods as envisaged by different implant systems, typically after 12 to 24 weeks. In delayed loading protocols, the healing period was extended due to the compromised host site conditions and, typically, prosthesis connection is later than the conventional healing period.<sup>17</sup> A distinction was made between occlusal and nonocclusal loading, with the former meaning that the immediately or early loaded prosthesis is in contact with the opposing dentition.<sup>16</sup> It should be recognized that in nonocclusal loading, forces on implants could be generated through the oral musculature and food bolus. Surgical protocols that included extraction of residual dentitions and immediate placement of implants in the jawbones were presented.<sup>15</sup> It is acknowledged that the implants can be placed either directly in the extraction sites or in adjacent healed alveolar sites. In certain instances, the surgical preparation of the implant site resulted in the elimination of the extraction sockets. The rationale for the immediate placement of implants in extraction sites was further avoidance of an interim healing phase with a removable prosthesis and a potential reduction in the number of clinical interventions for the patient.

The aim of this literature review is to present these studies under 3 broad categories: patients treated with fixed prostheses (including complete and partially edentulous patients), the single implant-supported prosthesis, and the overdenture approach. This review

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[Int J Oral Maxillofac Implants](#). 2000 May-Jun;15(3):331-44.

## **Suggested guidelines for the topographic evaluation of implant surfaces.**

[Wennerberg A](#), [Albrektsson T](#).

### **Source**

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### **Abstract**

The bone anchorage components of commercially available oral implant systems differ in surface roughness by at least sixfold. Correct reporting of the surface roughness of implant systems is important, since one cannot exclude the possibility that surface roughness will influence clinical results. However, many confusing statements are found in the literature when the surface topography of implants is described. Different measuring instruments and techniques strongly influence the outcome of a topographic characterization. Furthermore, a screw-type design introduces problems for most measuring instruments. Without a standard procedure, it is generally impossible to compare values from one study with another. The aim of the present study was to suggest standards for topographic evaluation of oral implants in terms of measuring equipment, filtering process, and selection of parameters. It is suggested that the measuring instrument be able to measure all parts of a threaded implant if the investigation relates to such a design. Preferably, 3-dimensional measurements should be performed. On screw-type implants, tops, valleys, and flanks should be evaluated. At least 3 samples in a batch should be evaluated, filter size must be specified, and at least one of each height, spatial, and hybrid parameter should be presented.

## **In vitro reaction of human osteoblasts on alumina-toughened zirconia.**

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### **Source**

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### **Abstract**

#### **OBJECTIVES:**

Alumina toughening enhances the mechanical properties of zirconia ceramics but the biocompatibility of this material has rarely been addressed. In this study, we examined the osteoblast response to alumina-toughened zirconia (ATZ) with different surface topographies.

#### **MATERIAL AND METHODS:**

Human osteoblasts isolated from maxillary biopsies of four patients were cultured and seeded onto disks of the following substrates: ATZ with a machined surface, airborne-particle abraded ATZ, airborne-particle abraded and acid etched ATZ. Airborne-particle abraded and acid etched titanium (SLA) and polystyrene disks served as a reference control. The surface topography of the various substrates was characterized by profilometry (R(a), R(p-v)) and scanning electron microscopy (SEM). Cell proliferation, cell-covered surface area, alkaline phosphatase (ALP) and osteocalcin production were determined. The cell morphology was analyzed on SEM images.

#### **RESULTS:**

The surface roughness of ATZ was increased by airborne-particle abrasion, but with the R(a) and R(p-v) values showing significantly lower values compared with SLA titanium (Mann-Whitney U-test  $P < 0.05$ ). The proliferation assay revealed no statistically significant differences between the ATZ substrates, SLA titanium and polystyrene (Kruskal-Wallis test,  $P > 0.05$ ). All substrates were densely covered by osteoblasts. ALP and osteocalcin production was similar on the examined surfaces. Cell morphology analysis revealed flat-spread osteoblasts with cellular extensions on all substrates.

#### **CONCLUSIONS:**

These results indicate that ATZ may be a viable substrate for the growth and differentiation of human osteoblasts. Surface modification of ATZ by airborne-particle abrasion alone or in combination with acid etching seems not to interfere with the growth and differentiation of the osteoblasts.



[Biomaterials](#). 2009 Feb;30(6):979-90. Epub 2008 Nov 22.

## **The gene-expression and phenotypic response of hFOB 1.19 osteoblasts to surface-modified titanium and zirconia.**

[Setzer B](#), [Bächle M](#), [Metzger MC](#), [Kohal RJ](#).

### **Source**

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### **Abstract**

The osteoblastic cell-line hFOB 1.19 with the potential to proliferate and differentiate revealed that cellular differentiation is not affected by material and roughness on newly developed zirconia implant materials. Materials under investigation were surfaces machined titanium (Ti-m), modified titanium (TiUnite, machined zirconia (TZP-A-m),

modified zirconia (ZiUnite), machined alumina-toughened zirconia (ATZ-m) and modified alumina-toughened zirconia (ATZ-mod). After surface description by scanning electron microscopy (SEM) and atomic force microscopy (AFM), cellular proliferation (EZ4U, Casy1) and differentiation were examined after days 1, 3, 7, 14, 21, and 28. Osteogenic differentiation was visualized by alkaline phosphatase staining, mineralization assay (alizarin red) and by expression analysis (RT-PCR) of bone- and extracellular matrix-related genes. Proliferation on rough surfaces was reduced on both titanium and zirconia. Cell-attachment and cytoskeleton organization documented by confocal laser scanning microscopy (CLSM) elucidated attenuated cell attachment within the first 4h to be the reason for impaired proliferation. A specific up-regulation of m-RNAs in an early event (RUNX2, NELL-1, RUNX3, and BMP7) and a late event (Integrin B3) could be observed on TiUnite and ZiUnite. For titanium an up-regulation of IBSP and Integrin B1 could be described at day 21. In total, differentiation was neither affected by material nor by roughness.

## Low-Temperature Aging Behavior of Alumina-Toughened Zirconia

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The corrosion of alumina-toughened zirconia (ATZ) as a consequence of hydrothermal treatment was investigated, especially the transformation kinetics from tetragonal zirconia to the monoclinic phase. For this purpose, polished ATZ specimens ( $R_a < 5$  nm) were aged in water vapor at different temperatures ranging from 70° to 134°C. The fraction of the monoclinic phase was determined using X-ray diffraction and Rietveld refinement. The isothermal transformation curves obtained were fitted to the Mehl–Johnson–Avrami equation by least squares. An Arrhenius plot of the fitted transformation rates was used to determine the activation energy and the pre-exponential factor. Following this procedure, the kinetic parameters of the phase transformation were extrapolated down to body temperature and the formation of the monoclinic phase was simulated. In addition, optical interferometry on well-polished specimens ( $R_a < 2$  nm) was alternatively used to calculate the monoclinic fraction from the histogram dataset. The results agree very well with those of the X-ray measurements. Additionally, the development of surface roughness with increasing aging time is discussed.

### I. Introduction

ALUMINA-toughened zirconia is a material with high potential in total hip arthroplasty because of its excellent mechanical properties. Contemporary to the realm of hip joint endoprosthetics, predominant Cr–Mo alloys and alumina are applied.<sup>1</sup> Alumina exhibits high hardness and wear resistance but has a disadvantage of low fracture toughness. Therefore, in a few cases, fractured hip joint heads occurred *in vivo*.<sup>2</sup>

To avoid these catastrophic failures, partly stabilized zirconia was introduced as a ceramic material for hip joint heads. It exhibits excellent fracture toughness and high bending strength but lower hydrothermal stability.<sup>3</sup> The high fracture toughness is based on a stress-induced phase transformation at the crack tip from the metastable tetragonal phase into the stable monoclinic one. The larger volume of the monoclinic unit cell leads to compressive stress at the crack tip, which overcomes the tensile stress and prevents crack propagation.<sup>4</sup> In addition to mechanical activation, the phase transformation can also be initiated by chemical reactions and temperature increase, e.g. under hydrothermal conditions. This process starts with hydrolysis of the zirconium–oxygen bonds and the formation of stable cracks.<sup>5</sup> Furthermore, yttria is an alkaline oxide and can either be hydrolyzed or leached out of the lattice by water attack, leading to destabilization of the tetragonal phase.<sup>6</sup> Thus, the aging resistance of a yttria-stabilized tetragonal zirconia polycrystal (Y-TZP) depends on both the

amount and the homogenous distribution of yttria in the Y-TZP.<sup>7</sup> The phase transformation starts preferentially at sites where residual tensile stresses exist.<sup>8,9</sup> Therefore, the low-temperature degradation may be considered as a coupled process of chemical attack and stress-induced phase transformation.

In a tribological system, the presence of stresses within the surface area results in tribochemical-activated regions; this is entailed by a reduction of the activation energy and by an acceleration of the phase transformation.<sup>10,11</sup> Thus, monoclinic contents measured on retrieved zirconia femoral heads were higher than the values calculated from aging experiments *in vitro*.<sup>12</sup>

The propagation of phase transformation into the bulk material could be described as subcritical crack propagation.<sup>13</sup> However, this behavior seems to be unfavorable for applications in humid environments, such as inside the human body.<sup>14</sup> Nevertheless, only a few cases of failure of zirconia hip joint heads were reported.<sup>15–17</sup> In,<sup>12,18–20</sup> the monoclinic content of retrieved hip joint heads is reported. An overview is given by Chevalier *et al.*<sup>21</sup> The relevant implants derive from different manufacturers.

There is no significant trend between implantation time and monoclinic fraction of the explants. On this account, it is generally necessary to investigate the aging behavior of each newly developed zirconia-based ceramic.

The studied alumina-toughened zirconia (ATZ) ceramic is composed by 80 wt% 3Y-TZP and 20 wt%  $Al_2O_3$ . This material combines the hardness and wear resistance of alumina and the fracture toughness as well as biaxial bending strength of zirconia.<sup>22</sup> The ATZ ceramic that is used for the experiments exhibits optimized mechanical properties, particularly a bending strength of 1160 MPa at a Weibull modulus of 13 and a fracture toughness of 5.2  $MPa \cdot m^{1/2}$ .<sup>23</sup> It is thought that the addition of alumina increases the hydrothermal stability of the tetragonal phase because it could work as a barrier for the propagation of phase transformation into the bulk.<sup>24,25</sup>

The aim of the present work was to determine the long-term aging behavior of an ATZ ceramic in a hydrothermal atmosphere and its prediction at low temperatures compared with 3Y-TZP. The aging process of ATZ was carried out in steam autoclaves in a temperature range from 70° to 134°C. Furthermore, the transformation rate was extrapolated to 37°C body temperature.

Following the aging treatment, the phase composition was determined by Rietveld refinement of X-ray diffraction (XRD) measurements. The Rietveld method is based on the refinement of the structural parameters of all crystalline phases. Therefore, the content of cubic and tetragonal zirconia was obtained separately. The Garvie–Nicholson method is also able to calculate the monoclinic content quite well, but the strong overlapping of reflexes makes it impossible to distinguish between the tetragonal and the cubic phase.<sup>26</sup>

Optical interferometry was used to investigate the modification of the surface topology of ATZ caused by the phase transformation from tetragonal to monoclinic during the aging process.<sup>27–29</sup>

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## **Alumina-reinforced zirconia implants: survival rate and fracture strength in a masticatory simulation trial.**

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### **Abstract**

#### **BACKGROUND:**

Alumina-toughened zirconia (ATZ) is a possible alternative material to titanium for oral implants. No data are available on the fracture strength of ATZ oral implants. Purpose: The purpose of this study was to examine one-piece implants made of ATZ ceramic under artificial loading conditions and to compare the fracture strength of these implants with implants fabricated from tetragonal zirconium dioxide polycrystal (TZP)-A.

#### **MATERIALS AND METHODS:**

A total of 72 implants, 48 ATZ implants (groups A and B) and 24 TZP-A implants (group C), were investigated. A chamfer preparation at the implant heads was performed on all implants of groups B and C. Eight implants of each group underwent 1.2 or five million thermomechanical loading cycles in the chewing simulator (load value: 98 N). Further eight implants of each group were not cyclic loaded. Finally, the fracture strength of all implants was determined using a universal testing machine.

#### **RESULTS:**

No implant fractured during loading in the chewing simulator. All implants were placed in the universal testing machine to evaluate fracture strength. The mean fracture strength values  $\pm$  standard deviations for the implants without artificial loading were 1734  $\pm$  165 N (ATZ, no preparation), 1220  $\pm$  85 N (ATZ, with preparation), and 578  $\pm$  49 N (TZP-A, with preparation); 1489  $\pm$  190 N (ATZ, no preparation), 1064  $\pm$  121 N (ATZ, with preparation), and 607  $\pm$  57 N (TZP-A, with preparation) with 1.2 million loading cycles; and 1358  $\pm$  187 N (ATZ, no preparation), 1098  $\pm$  97 N (ATZ, with preparation), and 516  $\pm$  45 N (TZP-A, with preparation) with five million cycles. The ATZ implants showed significantly higher mean fracture strengths compared with the TZP-A implants. Modification of the implant head using diamond burs and increased loading time also led to a significant decrease in fracture strength.

#### **CONCLUSIONS:**

The ATZ implants showed an increased mechanical stability compared with the TZP-A. Modification of the implant head resulted in a decrease in fracture strength. However, within the limits of this in vitro investigation it can be concluded that ATZ implants will withstand functional loading over an estimated period of 20 years.



## **Are ceramic implants a viable alternative to titanium implants? A systematic literature review.**

[Andreietelli M](#), [Wenz HJ](#), [Kohal RJ](#).

### **Source**

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### **Abstract**

#### **AIM:**

The aim of this systematic review was to screen the literature in order to locate animal and clinical data on bone-implant contact (BIC) and clinical survival/success that would help to answer the question 'Are ceramic implants a viable alternative to titanium implants?'

#### **MATERIAL AND METHODS:**

A literature search was performed in the following databases: (1) the Cochrane Oral Health Group's Trials Register, (2) the Cochrane Central Register of Controlled Trials (CENTRAL), (3) MEDLINE (Ovid), and (4) PubMed. To evaluate biocompatibility, animal investigations were scrutinized regarding the amount of BIC and to assess implant longevity clinical data were evaluated.

#### **RESULTS:**

The PubMed search yielded 349 titles and the Cochrane/MEDLINE search yielded 881 titles. Based upon abstract screening and discarding duplicates from both searches, 100 full-text articles were obtained and subjected to additional evaluation. A further publication was included based on the manual search. The selection process resulted in the final sample of 25 studies. No (randomized) controlled clinical trials regarding the outcome of zirconia and alumina ceramic implants could be found. The systematic review identified histological animal studies showing similar BIC between alumina, zirconia and titanium. Clinical investigations using different alumina oral implants up to 10 years showed survival/success rates in the range of 23 to 98% for different indications. The included zirconia implant studies presented a survival rate from 84% after 21 months to 98% after 1 year.

#### **CONCLUSIONS:**

No difference was found in the rate of osseointegration between the different implant materials in animal experiments. Only cohort investigations were located with questionable scientific value. Alumina implants did not perform satisfactorily and therefore, based on this review, are not a viable alternative to titanium implants. Currently, the scientific clinical data for ceramic implants in general and for zirconia implants in particular are not sufficient to recommend ceramic implants for routine clinical use. Zirconia, however, may have the potential to be a successful implant material, although this is as yet unsupported by clinical investigations.

Thomas Sterner<sup>1</sup>, Norbert Schütze<sup>2</sup>, Guido Saxler<sup>1</sup>, Franz Jakob<sup>2</sup>, Christof P. Rader<sup>2</sup>Auswirkungen von klinisch relevanten Aluminium Keramik-, Zirkonium Keramik- und Titanpartikel unterschiedlicher Größe und Konzentration auf die TNF $\alpha$ -Ausschüttung in einem humanen MakrophagensystemEffects of clinically relevant alumina ceramic particles, zirconia ceramic particles and titanium particles of different sizes and concentrations on TNF $\alpha$  release in a human monocytic cell line<sup>1</sup> Orthopädische Universitätsklinik Essen (Direktor: Prof. Dr. F. Loer)<sup>2</sup> Orthopädische Universitätsklinik Würzburg (Direktor: Prof. Dr. J. Eulert)

Schlüsselwörter: Keramikpartikel, Titanpartikel, TNF, aseptische Lockerung, Makrophage

Key words: ceramic particles, titanium particles, TNF, aseptic loosening, macrophage

**Einleitung:** Als großes Problem der modernen Endoprothetik gilt die aseptische Lockerung von Prothesenkomponenten. Als Initiatorzytokin des Particle Disease wird derzeit der Tumor Nekrose Faktor  $\alpha$  (TNF $\alpha$ ) vermutet. Ziel der Studie war es die TNF $\alpha$ -Ausschüttung von Makrophagen-ähnlichen Zellen (MäZ) zu untersuchen, die durch Partikel, wie sie typischerweise während Revisionsoperationen gefunden werden stimuliert wurden. Hierzu verwendeten wir Aluminiumkeramik- ( $\text{Al}_2\text{O}_3$ ), Zirkoniumoxid- ( $\text{ZrO}_2$ ) und Titanpartikel (Ti) unterschiedlicher Konzentration und Größe wie sie typischerweise bei Revisionsoperationen gefunden werden. Insbesondere sollte die Frage beantwortet werden, ob unterschiedliche Partikelgrößen und Materialgruppen (Titan und Keramik) eine differente TNF $\alpha$ -Ausschüttung bewirken.

**Methode:** Um ein TNF $\alpha$ -Profil der einzelnen Materialien zu erhalten, verwendeten wir ein etabliertes Makrophagenmodell (Rader et al. 1999) mit THP-1 Zellen (humane Leukämiezellen). Die verschiedenen Partikelgrößen wurden in unterschiedlichen Konzentrationen für 6h mit 106 MäZ inkubiert. Der Überstand wurde entnommen und durch ELISA-Technik auf die TNF $\alpha$ -Konzentration untersucht.

**Ergebnis:** die Verwendung von Ti-Partikel löste in beiden verwendeten Größen (0,2  $\mu\text{m}$  und 2  $\mu\text{m}$ ) mit jeweils 8facher und 17facher TNF $\alpha$ -Sekretion gegenüber der Leerprobe den stärksten Anstieg aus. Es waren jedoch deutlich höhere Mengen an Ti-Partikel der Größe 0,2  $\mu\text{m}$  notwendig, um o.g. Werte zu erreichen.  $\text{Al}_2\text{O}_3$ -Partikel zeigten ebenfalls eine signifikante Erhöhung der TNF $\alpha$ -Ausschüttung, lagen jedoch mit einer 4fachen Steigerung gegenüber der Leerprobe deutlich unter den Ti-Werten. In der maximalen TNF $\alpha$ -Sekretion fand sich kein Unterschied beider Partikelgrößen (0,6  $\mu\text{m}$  und 2,5  $\mu\text{m}$ ), jedoch war eine nahezu 1000fach höhere Konzentration an  $\text{Al}_2\text{O}_3$ -Partikel der Größe 0,6  $\mu\text{m}$  notwendig. Beim direkten Vergleich von  $\text{Al}_2\text{O}_3$ - und Ti-Partikeln gleicher Größe und Konzentration stimulierte Ti signifikant höhere TNF $\alpha$ -Ausschüttungen.  $\text{ZrO}_2$  konnte keine signifikante TNF $\alpha$ -Sekretion hervorrufen.

**Schlussfolgerung:** Aufgrund der vorliegenden Ergebnisse empfiehlt sich die Verwendung von Keramikgleitpaarungen, die geringere biologische Potenz aufweisen als Metall- oder PE-Gleitpaarungen. Zu spätige sollten größere Abriebpartikel vermieden werden. Frühzeitige Revisionsoperationen vermeiden große Mengen an Abriebpartikeln, somit könnten ausgedehnte lokale Osteolysen verhindert werden.

**Introduction:** Aseptic loosening is considered to be the main problem of modern endoprosthesis. Tumor necrosis factor  $\alpha$  (TNF $\alpha$ ) seems to be the initiator protein of particle disease. The aim of our study was to investigate the TNF $\alpha$  response of macrophage like cells (MLC) after stimulation with periprosthetic particles, typically found during revision surgery. For this purpose alumina ceramic ( $\text{Al}_2\text{O}_3$ ), zirconia ceramic ( $\text{ZrO}_2$ ) and titanium (Ti) particles of different sizes and concentrations were used. Important was to study the effects of different sizes due to TNF $\alpha$  secretion and the comparison of the biological effects of alumina ceramic and titanium.

**Method:** To obtain an TNF $\alpha$  profile we used an established macrophage model (Rader et al.) with THP-1 cells (human monocytic cell line). Therefore 106 MLC were incubated with different particle concentrations and sizes for 6 h. The supernatant was then investigated for TNF using ELISA assay.

**Results:** Ti-particles provoked in both sizes (0,2  $\mu\text{m}$  and 2,5  $\mu\text{m}$ ) the greatest TNF $\alpha$  response, 8 times and 17 times as high in comparison with control. But substantially more 0,2  $\mu\text{m}$  sized Ti-particles were necessary to get the above mentioned results.  $\text{Al}_2\text{O}_3$ -particles were not as effective as Ti, but they released fourfold more TNF $\alpha$  compared to control. There was no difference in TNF $\alpha$ -secretion comparing  $\text{Al}_2\text{O}_3$ -particles of different sizes (0,6  $\mu\text{m}$  and 2  $\mu\text{m}$ ), but a 1000times greater concentration of the 0,6  $\mu\text{m}$  sized particles were needed. Using  $\text{Al}_2\text{O}_3$ - and Ti-particles of the same size and concentration, Ti provoked a significant higher TNF $\alpha$  response.  $\text{ZrO}_2$  showed no effects on TNF $\alpha$  release.

**Conclusion:** Because of our results we recommend ceramic articulating surfaces, which are superior to metal on metal matings in term of biological reactions. Additionally bigger wear particles should be avoided. Revisionoperation should be done early to avoid huge amount of wear particles and to minimize local osteolysis

## Einleitung

Hauptproblem der modernen Endoprothetik ist die aseptische Lockerung der Prothesenkomponenten. Als wichtigste Ursache werden Abriebpartikel angeschuldigt, die durch Abrasion an den Gelenkpartnern entstehen. Diese werden von Zellen des Monozyten/Makrophagensystems phagozytiert und induzieren die Ausschüttung von osteoresorptiven Zytokinen (TNF $\alpha$ , IL- $\beta$ ). In neueren Untersuchungen kommt dabei TNF $\alpha$  besondere Bedeutung zu.

Als Initialzytokin ist es in der Lage, Osteoklasten zur Knochenresorption zu stimulieren [1, 8, 15]. Ein sich bildendes granulomatöses Gewebe, bestehend aus Fibroblasten, Makrophagen und Fremdkörperriesenzellen ersetzt zunehmend den periprosthetischen Knochen.

Die Reaktion der Monozyten/Makrophagen auf den Reiz der phagozytierten Abriebpartikel hängt entscheidend von der Größe, Komposition und dem Volumen der entstehenden Partikel ab [3, 4]. Die höchste biologische Wirkung von Abriebpartikeln liegt bei einer Partikel-



# CLINICAL ORAL IMPLANTS RESEARCH

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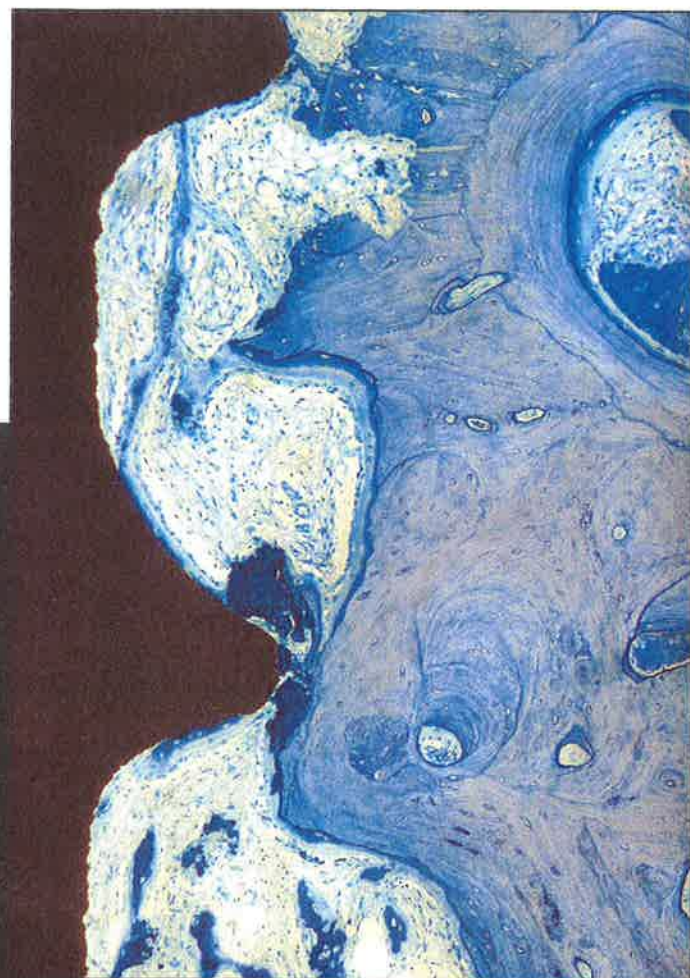
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predictors. These included location of the extracted tooth, number of missing teeth, regular supportive care, bone loss at adjacent teeth, restoration level of adjacent teeth, gender of the clinician and dentists' experience in implant prosthetics. The decision tree identified bone loss at adjacent teeth and number of missing teeth as the most important predictors for single implant treatment.

**Conclusions and clinical implications:** If tooth replacement was deemed necessary at the time of extraction, a single implant was the treatment of choice in only one-fifth of the patients. Mainly oral factors had an impact on the decision-making process in contrast to patients' background and medical factors. Dentists' experience in implant prosthetics also showed a positive association with single implant treatment as opposed to dentists' experience in implant surgery.

#### 072 Short Oral Communications

**Influence of cementation margin position on amount of undetected cement. A prospective clinical study**

**Presenter:** Linkevicius T

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**Co-authors:** Linkevicius T<sup>1,2,3</sup>, Vindasiute E<sup>2,3</sup>, Puisys A<sup>2,3</sup>, Maslova N<sup>2,3</sup>, Linkeviciene L<sup>1</sup>

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**Background:** Current recommendations allow clinicians to place cementation margins of implant-supported restorations up to 2 mm subgingivally. It is known that cement remnants might be associated with development of peri-implant disease, however clinical data on the influence of margin position on amount of undetected cement is lacking.

**Aim:** To perform clinical evaluation the amount of undetected cement after cementation and cleaning of implant-supported restorations.

**Methods:** Eighteen patients were treated with 26 single implant supported cement-retained metal ceramic restorations. The subgingival location of the standard abutment shoulder of each implant was measured with periodontal probe mesially, distally, buccally and lingually. Data was divided into five groups according to the position of the shoulder: 1 mm supragingivally (five cases), at the soft tissue level (30 cases), 1 mm (33), 2 mm (28) and 3 mm (8) subgingivally. Restorations were fabricated with occlusal openings (temporarily closed with composite during cementation) and cemented with resin reinforced glass ionomer. After cleaning, a radiograph was taken to evaluate if all cement had been removed. Then the composite was eliminated to gain the access to the abutment screw and cemented restoration-abutment unit was unscrewed. All quadrants of the specimens were photographed in a special device with standardized distance and analyzed with Adobe Photoshop. Total area of the restoration and the area of cement remnants were measured in each quadrant and proportion calculated. The level of significance was set to 0.05.

**Results:** Remnants of the cement were found in all restorations after cleaning: group 1 (0.0036 ± 0.0062); group 2 (0.0117 ± 0.0116); group 3 (0.0268 ± 0.0312); group 4 (0.0409 ± 0.0341)

and group 5 (0.0654 ± 0.0387). There was a significant increase of the relation between 1, 2, 3 and 4 groups ( $P < 0.05$ ), except there was no difference between group 4 and 5 ( $P > 0.05$ ). Dental radiographs did not show cement remnants in 96% of the cases mesially and in 80% of the cases distally.

**Conclusions and clinical implications:** The deeper position of the margin, the greater amount of undetected cement was discovered. The greatest amount of the residual cement was found when the crown margin was 2 or 3 mm below the gingival level. It is impossible to remove all luting agent, if margins are located subgingivally. Clinicians should select supragingival position of the margins for cementation of implant restorations. Dental radiographs should not be considered as a reliable method for evaluation of the residual cement after cementation.

#### 073 Short Oral Communications

**Soft tissue response towards alumina-toughened zirconia oral implants: a 2-year follow-up**

**Presenter:** Sperlich M

*Department of Prosthodontics, University Clinics Freiburg, Freiburg, Germany*

**Co-authors:** Sperlich M, Bernhart J, Kohal R-J

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**Background:** Alumina-toughened zirconia (ATZ) possesses the potential for use as an oral implant material.

**Aim:** The objective of this prospective 5-year cohort investigation was to determine the soft tissue response of a one-piece ATZ oral implant system after 2 years.

**Methods:** The investigation was approved by the Ethics Committee of the University Clinics Freiburg. Twenty patients received one ATZ implant (Ziraldent, Metoxit, Thayngen, Switzerland) for single tooth reconstruction. Implants were immediately temporized after insertion. For the evaluation of the soft tissue response probing depth, gingival recession, clinical attachment level, bleeding index, and plaque index were recorded at prosthetic delivery (baseline), 1-year- and 2-year follow-up. A linear mixed model was fitted with random intercepts for each patient to evaluate effects on response variables. From these models least-square means with 95% confidence intervals were derived with adjustment of  $P$ -values for multiple testing. All calculations were performed with the statistical software SAS 9.1.2 using PROC MIXED.

**Results:** Of the 20 patients, 18 attended the 1-year follow-up and 17 attended the 2-year follow up. Two patients lost their implants due to non-integration after 3 and 4 weeks post implant insertion (implant survival rate: 90% after 2 years). Because of severe medical problems, one patient could not attend the 2-year follow-up. The average probing depth around the implants at the 2-year follow-up was 3.32 mm and increased significantly from baseline ( $P < 0.0001$ ; baseline: 2.19 mm). The probing depth around adjacent teeth increased also, but on a lower level (from 2.1 to 2.5 mm). The gingival recession at implants decreased from baseline (0.36 mm) to the 2-year follow-up (0.11 mm) ( $P = 0.0236$ ), whereas it remained stable around teeth. The plaque index at implant sites increased

# **Ceramics in Orthopedics – 30 Years of Evolution and Experience**

*W. Rieger*

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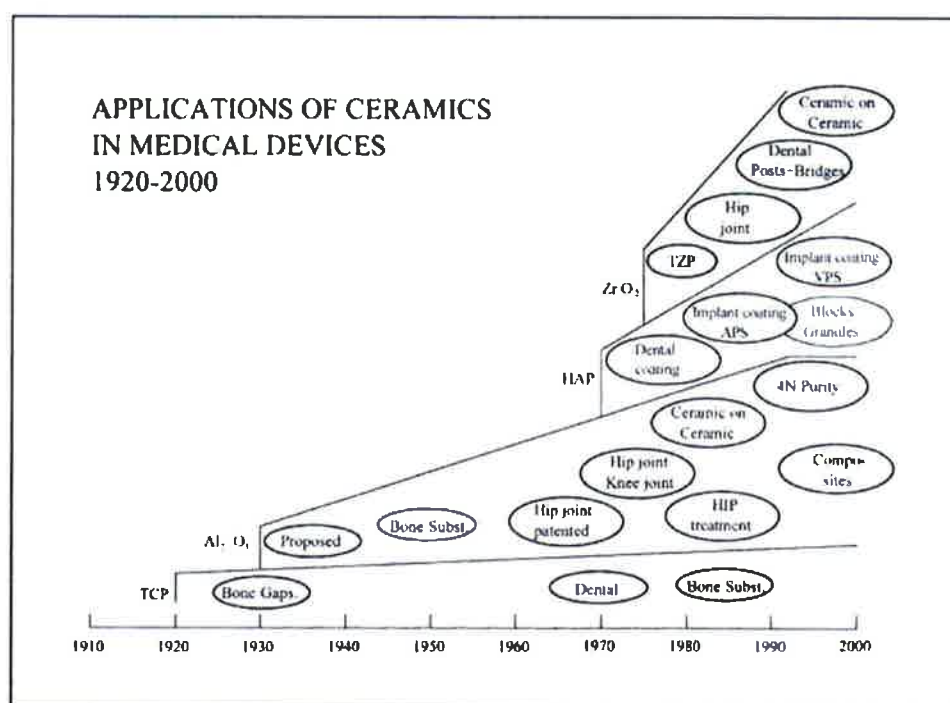
# Ceramics in Orthopedics – 30 Years of Evolution and Experience

W. Rieger

The application of ceramics in orthopedics is going back to the early decades of the past century (Fig. 1). The first to consider the possibility of ceramics as replacement material for joints was Rock, who applied for and received a German Patent for Alumina ceramics in 1930 [1]. Even before, in 1920, TCP (Tricalciumphosphate) which is known as a bioresorbable substance was proposed for bone gaps. However, this material is not capable for load bearing purposes [2].

Due to the relatively low strength, purity and experience connected to the pre-war alumina ceramic, it took more than another 30 years until Sandhaus in 1965 proposed and patented (in England) an Alumina material for hip joints which was known as Degussit AL 23, and can be considered as the great-grandmother of today's high tech ceramics [3].

The next step forward in the application of ceramics in orthopedics came in 1970 with the introduction of Hydroxyapatite which has a



**Figure 1:** Applications of Ceramics in Medical Devices 1920–2000.

bone-like crystal structure and is bio-stable. It's use was originally in coatings for dental implants, applied by plasma-spray, and later on for coatings of metallic hip joints (stems and cups) [4]. Sintered material as blocks or granules is used as filler materials for voids, but is not capable to support loads. Therefore, it's application remains restricted predominantly to coatings [5].

The late seventies brought the invention of a Zirconia material termed TZP (for Tetragonal Zirconia Polycrystals) and opened up a new field [6]. The TZP material, characterized by a structure of high density, fine grain size and high purity, combined with a transformation-toughening mechanism, has twice the strength and toughness of Alumina. It's applications are in orthopedic implants and, more recently, in dental parts of all kinds.

Considering the developments of more than 70 years, the following topics shall be highlighted (Tab. 1).

## Early days and pioneers

(Tab. 2)

Some important names have to be mentioned in the context of the early users of Alumina ceramics. Boutin in France introduced Alumina in 1970 [7], produced by the later Ceraver-Osteal company as ceramic heads as well as, little later, acetabular cups. Langer followed in the same year with Keramed products [8]. Heimke in 1971 with Frialit [9] and Dörre of Feldmühle with Biolox [12], all of them in Germany, were the next.

**Table 1:** Ceramics in Orthopedics: 30 Years of Evolution and Experience.

The early years	1930–1970
The pioneers	1970–1980
The new materials	1980–1990
The new technologies	1990–2000
The producers	1970–2000
The future	

The characteristics of these early days Aluminas were not completely different from today's ceramic. Table 3 compares the properties of the status 1970 to the status 2000 Alumina bioceramics: Progress is made with respect to increased purity (3N or 4N Alumina); close to theoretical density; small grain size; zero porosity; high strength; and excellent fracture mechanical properties.

By the introduction of new ceramic manufacturing processes, advanced raw materials and new machining technologies, the performance and safety, the tribological behaviour and quality aspects of tolerance could be improved. This advancement can be indicated best by the evolution of the ceramic microstructures from 1970 to 2000 (Fig. 2).

From 1970 on, a rapid and broad development of the applications of Alumina in orthopedics started, mainly, but not exclusively for hip joint applications.

The names in Table 2 can only represent some of the pioneers (orthopedic surgeons and materials scientists) who have helped to develop and to introduce ceramic materials into orthopedics. They have proved that ceramic biomaterials could meet the requirements listed in Table 4, which are generally compiled in the form of masterfiles (MAF's).

**Table 2:** Ceramics in Orthopedics. The early years and pioneers 1930–1980.

Boutin	1970	AL <sub>2</sub> O <sub>3</sub> , Ceraver	[7]
Langer	1971	AL <sub>2</sub> O <sub>3</sub> , Keramed	[8]
Heimke	1972	AL <sub>2</sub> O <sub>3</sub> , Frialit	[9]
Griess	1973	AL <sub>2</sub> O <sub>3</sub> , biocompatibility	[10, 11]
Dörre	1973	AL <sub>2</sub> O <sub>3</sub> , Feldmühle	[12]
Semlitsch	1977	AL <sub>2</sub> O <sub>3</sub> , 14/16 Cone	[13, 14]
Claussen	1978	Zirconia-TZP	[6]
Willert	1978	AL <sub>2</sub> O <sub>3</sub> , wear reduction	[15]
Mittelmeier	1979	AL <sub>2</sub> O <sub>3</sub> -Al <sub>2</sub> O <sub>3</sub>	[16]
Osborn	1979	HAP-APS coating	[17]
Gruner	1980	HAP-VPS coating	[5]

**Table 3:** Alumina Bioceramics: Status 1980 vs. 2000.

	Status 1970	Status 2000
Purity	99.7 % $\text{Al}_2\text{O}_3$ (2N)	99.95% $\text{Al}_2\text{O}_3$ (3N)
Bulk Density	3.90–3.95 g/cm <sup>3</sup>	3.985 g/cm <sup>3</sup>
Grain Size	< 7 $\mu\text{m}$	< 2.0 $\mu\text{m}$
Porosity	< 1 %	~ 0%
Sphericity	< 5 $\mu\text{m}$	0.1 $\mu\text{m}$
Surface Ra	< 0.05 $\mu\text{m}$	0.002 $\mu\text{m}$
R <sub>max</sub> .	< 0.5 $\mu\text{m}$	< 0.05 $\mu\text{m}$
State	Fired	Hipped
Strength 4Pt	400 MPa	550 MPa
Biax	–	450
Weibull-Modulus m	8	8–10
Crack Growth Exp. n	50	73

### Microstructure of Bioceramics



Zirconia – TZP  
Grain Size 0.4  $\mu\text{m}$



Alumina – BIO-HIP  
Grain Size 1.8  $\mu\text{m}$



Alumina – status 1980  
Grain Size 4.0  $\mu\text{m}$

**Figure 2:** Micro-  
structure of Bioceramics.

**Table 4:** Requirements for Ceramic Biomaterials for Long Term Load Bearing Applications in Joints

Material Properties
Bio compatibility
Chemical and corrosion resistance
Mechanical strength
Fracture toughness
Fatigue strength
Ageing resistance
Surface properties
Laser marking properties

The characteristic properties for bioceramic Alumina for orthopedic applications are represented among others in ISO Standard 6474 [18].

## The new materials and technologies

### New materials

In the late 1970's the new material  $\text{ZrO}_2$ -TZP was introduced into the market of technical ceramics. Though in the beginning only applied

for technical purposes such as machine parts for heavy duty and wear-resistance, it was soon recognized that Zirconia-TZP also showed great potential for application in bioceramics. In 1990, Zirconia-TZP had been proved to be biocompatible and masterfiles were obtained by various companies. Also, an ISO-Standard (13356) was established [19].

Aside from the development of Zirconia-TZP, improved technologies allowed the increase of material purity, surface properties, long-term loading capacity, life expectancy and safety. The introduction of the HIP process by METOXIT in 1986, later followed by other producers, helped to increase the safety of devices [20].

Some recent developments in bioceramic technology are summarized in Table 5.

A comparison of the properties of Alumina and Zirconia ceramics are given in Table 6.

The strength development of Alumina ceramics over the past 30 years is highlighted in Figure 3.

**Table 5:** Some recent developments in bioceramic technology.

AL <sub>2</sub> O <sub>3</sub>	99.9 %	1983	500 MPa
	HIP	1985	–
	Prooftest	1995	–
	99.99 %	1998	550 MPa
ZrO <sub>2</sub>	TZP	1986	800 MPa
	HIP	1988	1000 MPa
	Biocompatibility	1990	Load Bearing
	TZP-A	1990	Aging Resistance
	Dental Bridge	1998	2000 N/3 Seg. Bridge

It shows that by the improvement of the process, the mechanical strength (and, parallel to it, the load bearing capacity) could be increased roughly 2-fold. If compared to Zirconia-TZP, it can be seen that the twofold mechanical strength of Zirconia is accompanied by roughly the double load-bearing capacity or static fracture load (Fig. 4) [21].

## New technologies and processes

New technologies and processes helped to improve the performance and safety of ceramics in orthopedic applications.

### *Manufacturing process, HIP*

The manufacturing process (Tab. 7) which results in the lowest deviations from the required geometry is the one which forms a perfect ball and starts from this shape [22].

After the sintering process, the HIP (Hot Isostatic Postcompaction) step is introduced, which increases the fracture mechanical properties remarkably (Tab. 8). Today, it would not be possible to market a non-hipped material for medical applications [20].

The proof is given in Figure 5, which is difficult to read but easy to understand:

The higher – the better

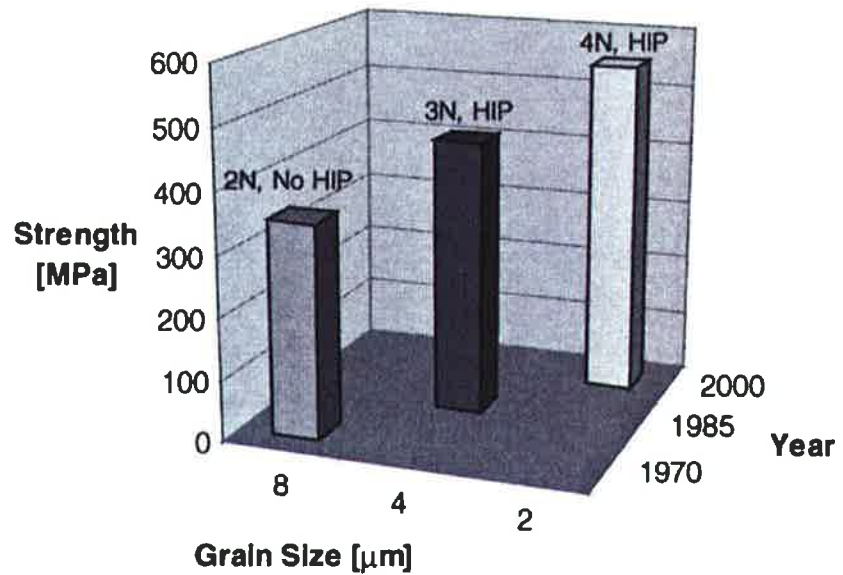
The flatter – the better

The higher relative survival probability for 99.9 % pure Alumina (same applies for Zirconia for a given load) is connected to better life expectancy for pure and hipped material.

**Table 6:** Alumina vs. Zirconia Bioceramics Comparative Assessment.

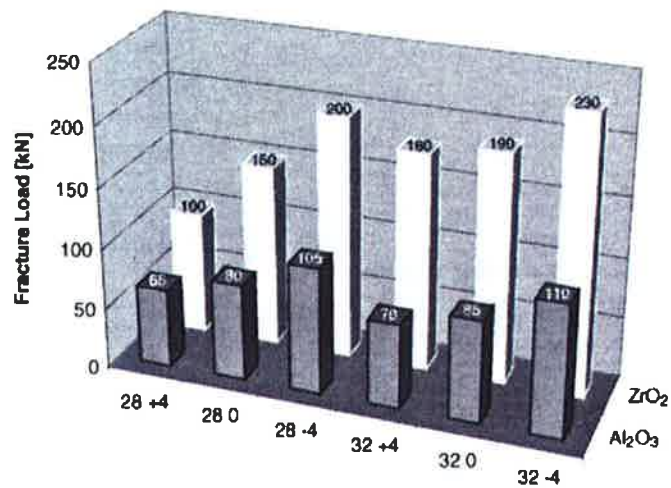
Comparable properties	Advantages ZrO <sub>2</sub>	Advantages Al <sub>2</sub> O <sub>3</sub>
Biocompatibility	Strength	Historical experience
Geometry (surface, sphericity)	Young's modulus	Price
Chemical and corrosion resistance	Burst strength	Hardness
Life expectancy of implant	Fracture toughness	
Hard-hart articulation	Safety	

### Strength Development of Alumina Ceramic



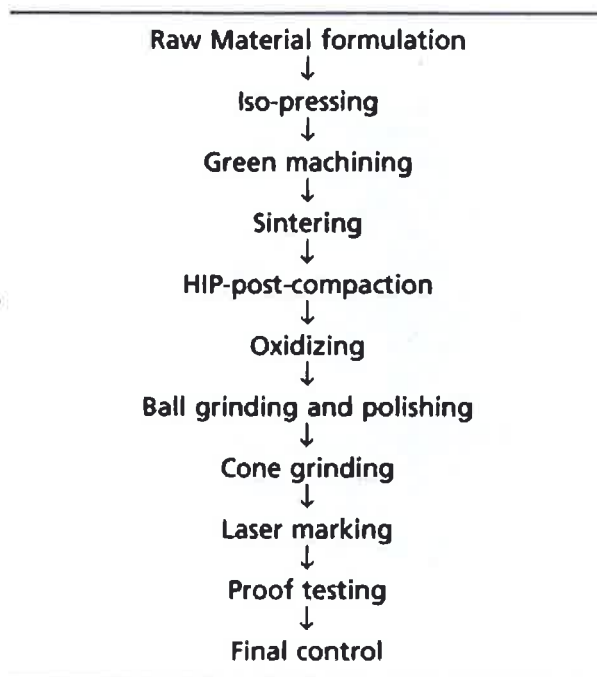
**Figure 3:** Strength Development of Alumina Ceramics.

### Static Fracture Load of Ball Heads



**Figure 4:** Static Fracture Load of Ball Heads.



**Table 7:** Manufacturing Process of BIO-HIP Ceramic Heads.**Table 8:** HIP treatment: Advantages.**HIP: Hot-Isostatic Post-compaction**

Higher Density  
 Higher Purity  
 No Porosity  
 Fewer Defects  
 Smaller Defects  
 Better Surface  
 Higher Strength  
 Better Life Expectancy  
 Less Wear

*Geometrical tolerances and reproducibility*

Some remarks have to be made with respect to the geometrical tolerance and to the reproducibility of production [21].

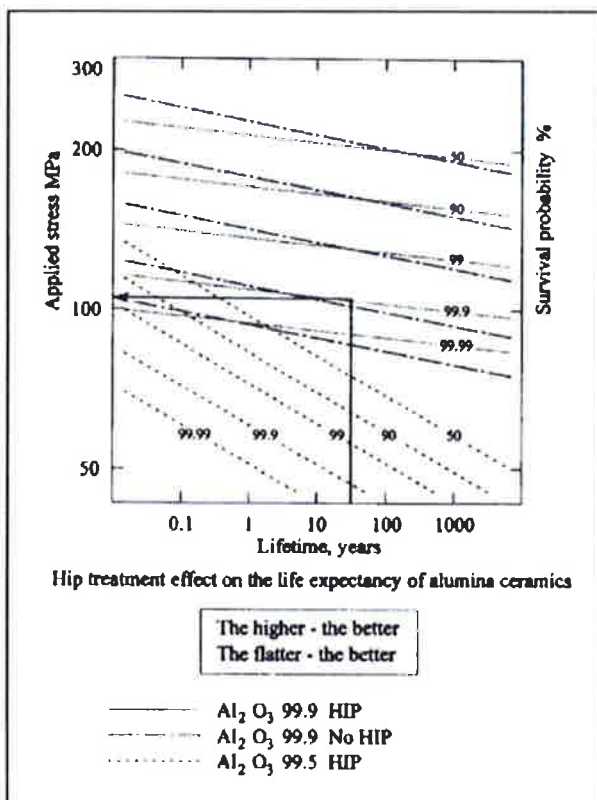
Figure 6 shows the sphericity of ceramic heads with a spherical deviation in every direction (equatorial and inclined) of under  $0.1 \mu\text{m}$  (as compared to the standard of  $5 \mu\text{m}$ ).

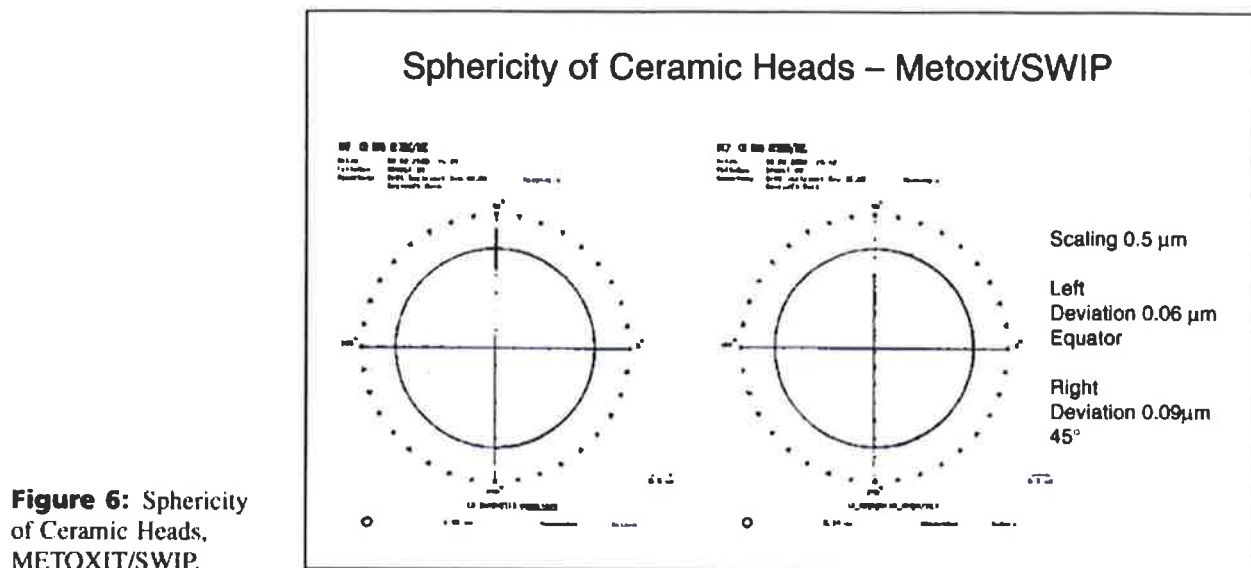
Figure 7 represents the roughness measurement of a surface of a ball head (equivalent values for Alumina and Zirconia) of  $2 \text{ nm}$  or  $0.002 \mu\text{m}$ . This corresponds to a maximum elevation of  $7 \text{ m}$  if a  $32 \text{ mm}$  diameter head would be enlarged to the size of the earth ball, or an average roughness of  $0.7 \text{ m}$ .

Another factor is the reproducibility of the machining processes. Diameter of ball heads can be kept within  $10 \text{ microns}$  for a lot of several hundreds. The typical Gaussian distribution of cone angle measurements of a lot size of  $1000$  pieces is using only  $1/3$  of the tolerance of  $5 \text{ minutes}$ .

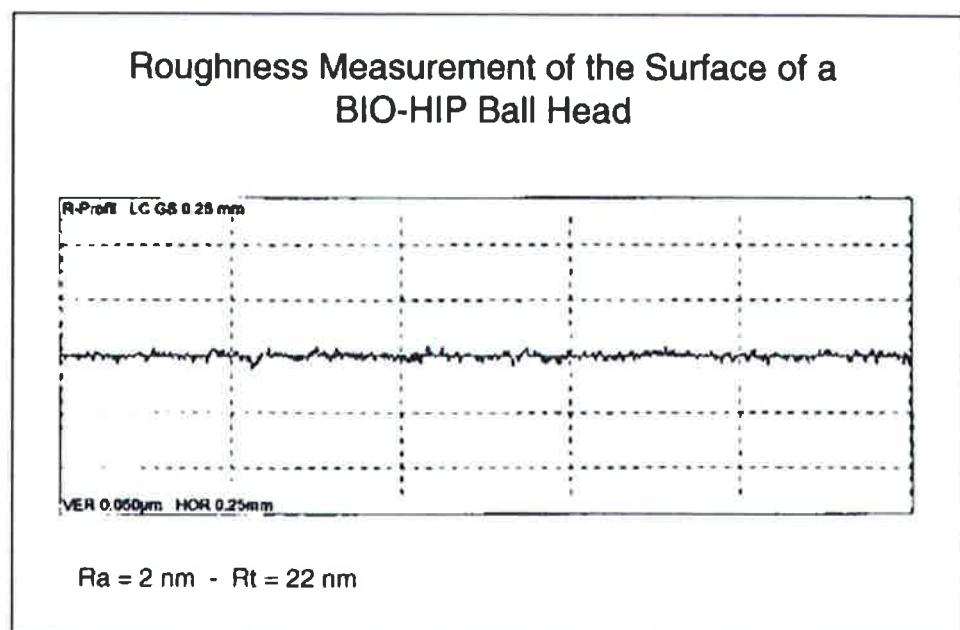
*Identification; proof testing*

Progress has also been made with respect to identification of the products. The mechanical engraving on ceramic heads of status 1980 with a depth of approx.  $300 \mu\text{m}$  and typical edge cracks, is today replaced by a laser mark, of excellent readability and only  $6 \mu\text{m}$  depth. This is of high importance for the safety of the ceramic part. An additional measure to increase safety is

**Figure 5:** HIP Treatment Effect on the Life Expectancy of Alumina Ceramics.



**Figure 6:** Sphericity of Ceramic Heads, METOXIT/SWIP.



**Figure 7:** Roughness Measurement of a Surface of a BIO-HIP Ball Head.

the application of proof testing performed on 100% of the produced parts by applying an internal pressure close to, but under, the load bearing capacity of the ceramic head (or insert). Products with defects are eliminated by rupture under the applied test loads [23].

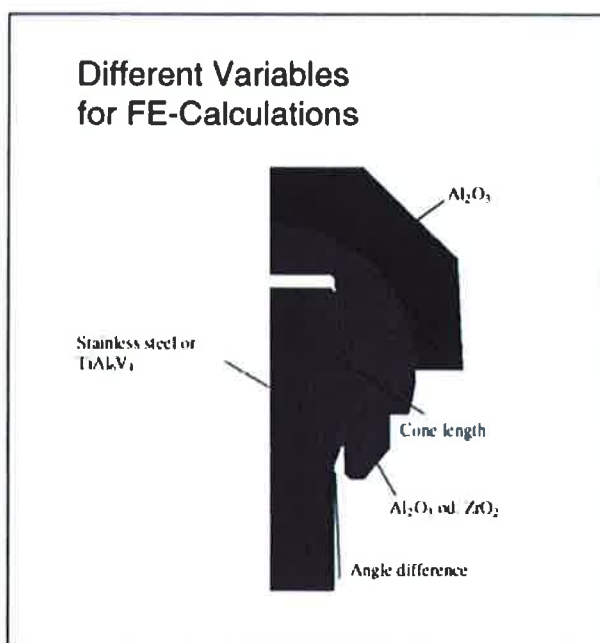
#### *Finite element calculation*

The use of finite element calculation to determine the stresses inside a ceramic head or insert under load has been used already very early for the optimisation of design [24].

Today, more refined calculations are applied for the estimation of stress states and values.

Figure 8 describes the variables used for FE calculation, including load cases, cone lengths, materials of the head, materials of the trunnion, and tolerances for the conical fit. Different load cases for the combination of ceramic heads with ceramic inserts or metal cones used for test purposes are calculated [25].

Table 9 describes the influences of load cases and/or angle differences on the stress development in Ceramic heads under load, compiling the results obtained for the combination of variables.



**Figure 8:** Different Variables for FE-Calculations.

**Table 9:** Ceramic-Ceramic Articulation  
FE-calculations: Summary of Results.

Influence on the stress in the head	
Cone angle difference (ceramic/metall)	very high
Load case, direction	very high
Cone length (s, m, l)	high
Material of metal trunnion	high
Surface structure, friction	medium
Material of head ( $\text{Al}_2\text{O}_3$ or $\text{ZrO}_2$ )	small

### *Tribology, ceramic-ceramic*

Another important development in ceramics for orthopedics is the combination of ceramic heads with ceramic inserts. The object is clearly, as in metal-on-metal combinations such as Metasul, to eliminate PE wear. As has been shown, this idea has received prime interest from the beginning of the ceramic age in orthopedics. Early hard-hard couplings were used already in the 1970's, for example the systems known under the names of Boutin [7], Griss [11], Mittelmeier [16], Salzer [26], and others. Figure 9 shows the various shapes of the ceramic inserts for total hip replacements, including those for bone in-growth, combination with PE, or combination with Titanium sockets.

Whereas the preferred combination of ceramic hard-hard couplings still seems to be the one pairing Alumina against Alumina, recent developments have shown that Zirconia against Alumina appears to be another option. This combination is already offered on the market. A comparison of wear characteristics under identical test conditions performed, for example, with a Boston hip simulator, shows even a slightly better performance of Zirconia ball heads as compared to an Alumina ball head, both paired against Alumina inserts [27].

The most accurate method to determine the wear of a ceramic-on-ceramic articulation is the measurement of the change in spherical shape, as seen in table 10 for equatorial and polar direction. The values obtained after 5 Mio. cycles are equally small and well under  $0.1 \mu\text{m}$ , corresponding to a wear-determined loss of less than  $3 \times 10^{-4}$  percent over the test period.

## The future

These advances have been made possible by the improvement in material technology, processing technique, machining capability, and quality control, which are well under command with the leading producers of bioceramics today (Tab. 11).



**Figure 9:** Various Shapes of Ceramic Inserts.

**Table 10:** Ceramic-Ceramic Articulation

Sphericity Measurement of BIO-HIP ball heads after hip-simulator test.

Material	AL 1	AL 2	AL 3	ZR 1	ZR 2	ZR 3
Sphericity, initial [micron]	0.11	0.06	0.1	0.14	0.06	0.04
Sphericity, after 5 million cycles [micron]	0.18	0.17	0.2	0.18	0.14	0.09
Difference [micron]	-0.07	-0.11	-0.1	-0.04	-0.08	-0.05
Average [micron]		-0.09			-0.06	

Measuring incertainty = 0.04 micron

An estimation of the orthopedic replacement surgeries performed world-wide shows figures of 1 300 000 per year. In terms of population figures, this is between 0.2 and over 1 per 1000 inhabitants per year for various countries (Tab. 12).

The use of ceramics in hip arthroplasty is evidently not equal for Europe and the US. Whereas Central Europe has approx. 50 % of all hip arthroplasties performed using ceramic heads, and increasing number of inserts, the US is using less than 10 %. Equally different is the

preferred ceramic material: Alumina in Europe with the exception of France, Zirconia in the US (Tab. 13).

## Summary and outlook

What lies ahead?

A summary and perspective of the future use of ceramic is given in Table 14 (technology/ceramic-on-ceramic bearings) and Table 15 (safety/applications).

**Table 11:** Ceramics in Orthopedics: The producers.

Country	Company	Year	Material
France	Ceraver-Osteal	1970–present	Al <sub>2</sub> O <sub>3</sub>
	Saint-Gobin/Desmarquest	1980–present	ZrO <sub>2</sub> , Al <sub>2</sub> O <sub>3</sub>
	SCT	1985–present	Al <sub>2</sub> O <sub>3</sub>
Germany	Keramed	1971–present	Al <sub>2</sub> O <sub>3</sub>
	Friedrichsfeld	1971–1990	Al <sub>2</sub> O <sub>3</sub>
	Feldmühle/Ceramtec	1972–present	Al <sub>2</sub> O <sub>3</sub>
	Rosenthal	1972–1978	Al <sub>2</sub> O <sub>3</sub>
Switzerland	Metoxit/Saphirwerk	1983–present	Al <sub>2</sub> O <sub>3</sub> , ZrO <sub>2</sub>
UK	Morgan-Matroc	1985–present	Al <sub>2</sub> O <sub>3</sub> , ZrO <sub>2</sub>
Japan	Kyocera	1985–present	Al <sub>2</sub> O <sub>3</sub> , ZrO <sub>2</sub>
USA	Bio-Pro	1988–present	ZrO <sub>2</sub>
<b>Leading producers</b>			

**Table 12:** Orthopedic replacement surgical treatments.

Country		per 1000 inhabitants/year	total
THR	CH	>1	> 10.000
	D	1	80.000
	US	0.7	200.000
	JAP	0.2	20.000
TKR	CH	0.7	5.000
	D	0.7	56.000
	US	1	300.000
	JAP	N.I.	N.I.

THR = Total Hip Replacement

TKR = Total Knee Replacement

**Table 13:** Use of ceramics in hip arthroplasty (ceramics vs. PE).

		Al <sub>2</sub> O <sub>3</sub>	ZrO <sub>2</sub>
CH	60%	90	10
D	40%	95	5
A	80%	95	5
F	50%	50	50
USA	< 10%	10	90
JAPAN	< 10%	20	80

**Table 14:** Summary and Perspective.**Improved Ceramic Technology (1970–2000)**

- HIP Process
- High Material Purity (99.9 + %)
- Improved Strength
- Improved Precision
- Al<sub>2</sub>O<sub>3</sub> 999 and ZrO<sub>2</sub>-TZP

**Ceramic-Ceramic Bearings**

- Technically Solved
- Close-Tolerances → Wear close to zero
- FE Calculations for Design Refinement
- Al<sub>2</sub>O<sub>3</sub>/Al<sub>2</sub>O<sub>3</sub> and ZrO<sub>2</sub>/Al<sub>2</sub>O<sub>3</sub> possible

**Table 15:** Summary and Perspective.**Safety Improved**

- Proof Test (100 %)
- Risk remains with incorrect positioning

**Application of ceramic-on-polyethylene and ceramic-on-ceramic**

- Young patients
- High mobility patients

**Applications in dentistry**

- Posts, Abutments, Crowns, Bridges in Zirconia-TZP



**Table 16:** Ceramic Implants at Sulzer Orthopedics 30 Years of Evolution and Experience.

1970	Modular alumina femoral head
1974	First implants, head size diam. 32
1986	Head size diam. 28, 14/16 cone
1988	Head size diam. 28 + 32, 12/14 cone
1994	Sulox ceramic femoral head, HIP Processed, laser marked
1998	Cerasul ceramic-on-ceramic coupling

By the improved material and process technology we command today over two high quality, high strength, high performance and high precision products: Alumina and Zirconia.

By these improvements, ceramic-on-ceramic bearings of both types ( $\text{Al}_2\text{O}_3\text{-Al}_2\text{O}_3$  and  $\text{ZrO}_2\text{-Al}_2\text{O}_3$ ) are technically solved. By making use of advanced machining methods, proof testing and process control, wear can be reduced to almost zero.

Application of ceramics is possible in combination with PE, cross-linked PE, and against ceramics. Application will be preferably for young and high mobility patients [28]. Applications in dentistry are an example for interesting new aspects in other fields of medical devices [29, 30].

The evolution of ceramic applications in orthopedics can best be demonstrated by the contributions which Sulzer Orthopedics has made over the past 30 years (1970–1998), as seen in Table 16.

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