Wear Mechanisms in Ceramic Hip Implants

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ABSTRACT:

The wear in hip implants is one of the main causes for premature hip replacements. The wear affects the potential life of the prosthesis and subsequent removals of *in-vivo* implants. Therefore, the objective of this article is to review various joints that show lower wear rates and consequently higher life. Ceramics are used in hip implants and have been found to produce lower wear rates. This article discusses the advantages and disadvantages of ceramics compared to other implant materials. Different types of ceramics that are being used are reviewed in terms of the wear characteristics, debris released, and their size together with other biological factors. In general, the wear rates in ceramics were lower than that of metal-on-metal and metal-on-polyethylene combinations.

1.0 INTRODUCTION:

With a high demand for hip replacements, especially in younger patients, the need for longer lasting, wear resistant implants is becoming greater. The main reason for failure in hip replacements is due to wear caused by the contact areas on the implants. Using ceramics in total hip arthroplasty appears to be the new direction in total hip replacements. Metal-on-polyethylene is still the most commonly used material in hip replacements, but due to the wear debris issues caused from the polyethylene cup, these materials are now being surpassed by ceramic replacements. Complications due to polyethylene wear debris include that of osteolysis, a disease of the bone that is induced by the debris particles from the polyethylene cup. This has made it necessary to design a new cup that minimizes debris and wear particles. This article presents an overview of the use of ceramics in total hip arthroplasty from a collection of literature /1-111/, and contains specific issues such as wear behavior, ceramic materials, and clinical studies as well as safety issues. Ceramics have been approved by the Food and Drug Administration /111/ in the manufacture of hip implants

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only recently; such prostheses are in the design and development stage in the United States. On the European side, ceramic hip implants are already in use and this article summarizes published data from those registries.

2.0 CERAMICS

Ceramic components have been used for total hip arthroplasty in Europe since the early 1970's, with good results /11,24,26,34,35,36,37,61,64,67,100/. Such components afford a number of theoretical advantages compared with metal alloys. They have been shown to have excellent biocompatibility both in animal studies and clinical investigations in Europe /24,26,35,36,67/. Ceramic can be given a very high, scratch resistant polish. This feature, combined with wettability and corrosion resistance of the material, allows for low friction articulations with excellent wear characteristics /36/. A number of studies have demonstrated that wear rates for ceramic on ultra high molecular weight polyethylene are two to twenty times lower than metal alloy on ultra high molecular weight polyethylene /20,25,29,32,33,36,46/. Ceramics are brittle materials, especially when compared to ductile materials such as metal, and have material properties allowing for it not to be subject to cyclic or fatigue failure /20,58/. The effective strength of ceramic is a function of the strain rate /20,36/. This makes it particularly suitable for the repetitive compressive stress in the hip joint.

The wear rate of ceramics articulating against ceramics is shown to be 4000 times lower than that of metal articulating against polyethylene /37,58/. Because of low wear rate, the amount of debris and wear particles released in blood stream is lower than other materials used in hip arthroplasty. A recent study showed that the concentrations of wear particles in the periprosthetic tissues around alumina-on-alumina bearings were 2 to 22 times lower than those observed around metal-on-polyethylene articulations /20,25, 29,32,33,46,58/. Osteolysis is a major concern and cause of failure in hip replacements when the articulation is made with metal-on-polyethylene and metal-on-metal /83,85,87/. The wear debris on a polyethylene cup can be dissolved in the blood stream and interact with cells that cause inflammatory tissue response and lead to osteolysis and dissolution of bone around the hip replacement parts. This is one advantage that ceramics have over polyethylene /10,12,15,27,62,63,65,66,68,69,72,73,74,75,77,78,79,81,84,88-93,96/.

Another characteristic of ceramics is that they do not form oxidative reactions. Metals, unlike ceramics, react with the oxygen rich environment and form a protective coating that prevents corrosion. If this coating is scratched or removed the implants alloys are susceptible to releasing metal ions and particulates. The presence of the ions and particulates creates third body wear which increases wear rate due to the roughness formed on the outside layers of the alloys /58/. Ceramics do not react with the oxygen rich environment like the metals and add to the biocompatibility over metal on polyethylene and other combinations /58/.

Ceramic materials have a high elastic modulus and do not plastically deform as metals do; this allows for the susceptibility of fractures /37,98/. Instead of plastic deformation, the formation and propagation of cracks may lead to fracture. The reported prevalence of fracture of the femoral head is low, especially for hip replacements with ceramic on polyethylene articulations. There have only been 11 instances of a fracture of a

Typical Modular Hip Implant

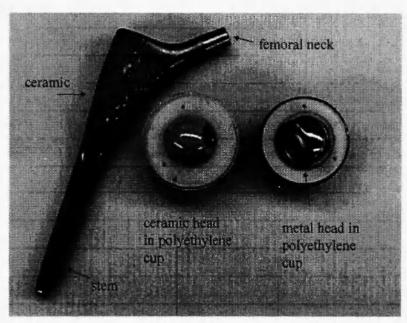


Fig. 1: A typical modular implant with the femoral stem along with a ceramic and a CoCr head, both placed in a polyethylene acetabular cup.

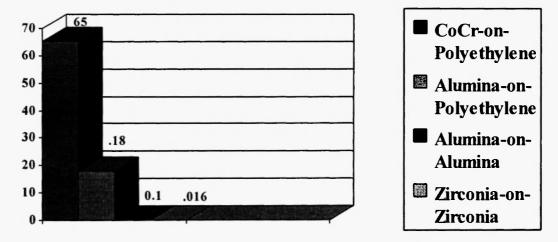


Fig. 2: Wear rate under different bearing conditions, Volume (mm³/Million Cycles)

ceramic femoral head articulating with polyethylene that have been reported in the English language literature from 1970-1997 /21,28,30,31,36/. The prevalence of this fracture has been higher for ceramic on ceramic articulations, especially those in which the ceramic head was manufactured before 1979, when the material was inferior because of its larger grain size which lowered surface finish /2,16,36,67/.

The effective strength of ceramic is a function of the strain rate; several factors may increase the risk of failure of a ceramic femoral head /20,36/. Increased weight and activity of the patient may increase the risk of fracture by increasing the load across the joint; however, in some studies, increased activity has not corresponded with an increased rate of fracture /2,36/. Nizard found that the ceramic components in patients who were less than fifty years old had a better rate of survival than those in older patients /2,21,28,30,31,36/. A history of trauma was associated with only three of the eleven instances of failure of a ceramic polyethylene hip replacement. The trauma involved a minor fall onto the contra lateral hip in two patients and onto the ipsilateral hip in the other. There was no drastic event related to the fracture in the remaining eight patients.

There have been some cases where alumina-on-alumina has been targeted for high wear rates which led to high rates of osteolysis, and most of these are all with the Mittelmeier total hip system /76,94/. The alumina material of this system has a large grain size, low density, and a high porosity, all of which were bad combinations for the solution of minimizing wear rates. In addition, this prosthesis had a poor socket design that was responsible for a rate of failure as high as 27% /2,16,36,61,67,80/.

2.1 Alumina on Alumina Implants

Alumina oxide (Al₂0₃) belongs to the material class of oxide ceramics, which comprises pure and sintered metal oxides. As is well known, metals are arranged in a so-called electrochemical series from noble to base metals. This system can be transferred to metal oxides when turning around the sequence. The noblest metals have oxides of base nature and *vice versa*. The metal aluminum is a typical base metal. Aluminum oxide or alumina is the noblest oxide. It is chemically identical with the well known gem sapphire, and with small additions of chromium it turns out to be a ruby. Sapphire and ruby are monocrystalline. The aluminum oxide Biolox to be described here is polycrystalline.

Biolox alumina is compared to metallic biomaterials with respect to the physical properties in Table 1. The ceramic material has a low specific weight and a high hardness, which is half the weight and 15 times the hardness or steel /58/. The difference in hardness results in a metal abrasion in the ceramic surface where there is contact with a relative motion of both materials. The high hardness requires diamond tools to machine alumina ceramics.

Ceramic materials and metals differ with respect to the mechanical strength properties, whereas the compressive, flexural and tensile strength of metals are about the same range. These properties differ considerably in case of alumina ceramics. The compressive strength is about 10 times the flexural strength and 15 times the tensile strength /1,2,3,4,61,95/. Compared to metals, alumina shows a clearly higher

Property	Unit	Stainless Steel	Co-base Alloys	Titanium Alloys	Biolox
Density	g/cm3	7.8	8	4.5	3.9
Hardness HV	MPa	1500	3000	900	23000
Compressive Strength	MPa	800	1000	600	5000
Flexural Strength	MPa	800	1000	600	500
Tensile Strength	MPa	800	1000	600	300
Youngs' Modulus	MPa	200000	230000	120000	380000
Electrical Resistance	Ω*cm	0.00007	0.00005	0.00005	1.00E+15
Corrosion Resistance in body environment		Fair	good	good	excellent

Table 1

Mechanical behavior of ceramics compared with other biomaterials.

compressive strength and a lower tensile strength shown in Table 1. The flexural strength of Biolox is about the same as Ti-6Al-4V and slightly lower than ferrous metals /16,62,82/.

Alumina has excellent corrosion resistance in the body environment. As ion release is always a basic requirement for a chemical reaction, and hence, a reaction between the implant and the bone tissue, it is simultaneously the reason for the superior corrosion resistance and for the biocompatibility of alumina /2-9,61/. It has been clinically observed that the alumina surface is completely covered by protein molecules immediately after the implantation. As a result, the body accepts alumina and does not recognize it as a foreign substance, and the chemical defense mechanisms of the body do not react.

The favorable tribological properties can be attributed to the atomic structure of the alumina crystal, which is characterized by hexagonal stacking of closely packed oxygen layers, with aluminum ions on octahedral sites /58/. Based on this structure, a mechanism has been described to explain the superior wear and friction properties in terms of the absorption behavior of the surface /58/. In a cross sectional view through a sphere model of the surface, the outer ionic layer consists of oxygen ions rather than aluminum ions. Since the bonds are not saturated, a surface layer charge remains /58/. Polarized molecules, such as water are attracted by this charge and become absorbed /58/. This proceeds until a monolayer is formed. This process is known as chemisorption /58/. At higher concentrations of water vapor additional layers are bonded physically /58/. By acting as a lubrication layer, the absorbed molecules reduce friction and wear /58/. In fact, this can be proven in practice under normal loading conditions below 10 MPa /58/.

In the case of ceramic on ceramic sliding combination, this counts only when the articulating faces are sufficiently congruent and smooth. The deviation of roundness should be 1 micron or less and the average

^{*}Hamadouche M, Boutin JD, Bolander ME, Sedel L, Alumina-on-alumina total hip arthroplasty, *Journal of Bone and Joint Surgery*, 2002;84:69-77.

surface roughness should be in the range of 0.01 microns /58/. Alumina ceramic is an attractive material for the articulation in total hip arthroplasty as it can provide an ultra smooth finish /14,17,62,83,86/. Its ionic structure creates a hydrophilic surface with higher wettability than metals, thus facilitating lubrication /62/. It also has low frictional and high wear properties /56,57,62,94/. Additional advantages of alumina are that it shows a high scratch and corrosion resistance along with excellent biocompatibility /25,29,36/. The disadvantage of ceramic is its susceptibility to fracture. Because ceramic has a high elastic modulus, it will not plastically deform as metal does. Instead, the formation and propagation of cracks may lead to fracture; however, the reported prevalence of fracture of the femoral head is low (11 fractures in 7589 femoral heads) /21,28,30,31,36/.

The wear rate of alumina ceramic articulating against alumina ceramic has been shown to be 4000 times lower than that of metal articulating against polyethylene /61/. Because of this wear rate, the amount of debris and wear particles is assumed to be much lower, which decreases the chance of osteolysis. A recent study showed that the concentrations of wear particles in the periprosthetic tissues around alumina-on-alumina bearings were 2 to 22 times lower than those observed around metal-on-polyethylene articulations /37/. The alumina ceramic replacements, which have been used in Europe since 1970, showed a mean wear rate of $0.025 \, \mu m/yr$ /2,61/ Tables 4-5.

Between December 1979 and December 1980 Boutin preformed 118 THR's in 106 patients. The average age of the patients at the time of the index arthroplasty was 62.2 years. The mean body mass index was 25.9. The right hip was operated on in 54 patients, the left hip was operated on in 40, and a bilateral replacement was preformed in 12. The initial diagnoses are shown in Table 2. An alumina on alumina combination was used in all patients. The collared femoral component was made of titanium alloy Ti-6Al-4V and was available in both a cemented and a cementless configuration. The acetabular component and the 32 mm femoral head were made of dense polycrystalline surgical grade alumina Al₂-O₃. The all alumina socket could be either cemented or inserted without cement. Special reamers were available for the implantation of

Table 2
Initial diagnosis and biological effects

Underlying Disease	No. of Hips	Percentage
Primary osteoarthritis	75	64
Congenital hip dyplasia	24	20
Femoral neck fracture	9	8
Avascular necrosis	8	7
Posttraumatic osteoarthritis	1	0.8
Slipped capital femoral epiphysis	1	0.8
Total	118	100

components without cement. The femoral head was secured to the femoral stem with a Morse taper. In all patients, the femoral head and cup were matched to reduce the clearance between the two components to about 50 micrometers. 33 of the 118 acetabular components were cementless, and 85 were cemented. 29 of the 118 femoral stems were cementless, and 89 were cemented. The arthroplasties were preformed with cementing of both components in 85 hips, were hybrid in 4, and were cementless in 29.

At the time of the follow up, 45 patients were alive and had not had either acetabular or femoral revision. 25 patients had undergone revision of either or both components. 27 patients had died from unrelated causes, and 9 patients had been lost to follow ups; these 42 hips were functioning well. Thus, the status of 106 of the original 118 hips was known at the last follow up examination. Of the 45 patients who were still alive, and had not had a revision, 40 were evaluated both clinically and with use of an anteroposterior radiograph of the pelvis made at a minimum of 18.5 years after the index arthroplasty. With revision of either component for any reason as the end point, the cumulative survival rate at twenty years was 68.3%. With revision for any reason as the end point, the survival rate at twenty years was 85.6%.

In the subject study, of the original 106 patients, no massive osteolysis was reported in the acetabular side of the replacement. In all 106 cases no osteolysis was reported in the femur side of the replacement. Minimal acetabular osteolysis occurred in association with the loose cemented acetabular components, whereas no osteolysis occurred in association with the cementless sockets. This shows that what little bone loss occurred could have been caused by the cement, and not from the alumina debris. Also in the 106 hip replacements studied, there were no fractures of the head or socket after a minimum of 18.5 years; this finding supports the idea that the risk of fracture of alumina is minimal when appropriate material improvements are made. Table 3 shows the different survival rates and the different components.

Alumina ceramic has a Young modulus that is 300 times greater than that of bone and 190 times greater than that of cement /61/. Therefore, the process of loosening of alumina sockets is probably a mechanical phenomenon due to a stiffness mismatch between the alumina cup and either the bone or the cement /61/. The follow up study of 106 hips showed that minimal wear rates along with limited osteolysis can be extrapolated for up to 20 years. provided that sound fixation of the acetabular component is obtained /61/; this is shown in Table 3.

Other studies have focused on how the body reacts to ceramics. Christel preformed one study which found that alumina particles of less than five micrometers have been found within microphages in animal studies /24,41/. Alumina was less reactive than titanium and polyethylene. Alumina particles were inconsistently found in biopsy specimens retrieved from hip capsules during revisions of aseptically loose cups that had been inserted without cement. Christel concluded that the overall foreign body reaction to ceramic particles from loose alumina-alumina prosthesis is less intense that the reaction to other orthopedic biomaterials such as polyethylene, metal, or bone cement /24,41/.

In another study, ceramic on ceramic bearing was inserted without cement, and no evidence was found of acetabular or femoral osteolysis at a mean of nine years after the operation /70/. However, long term results are needed to comment on this issue.

Table 3

Survival of the replacement at twenty years with revision as the end point

Age at index	Number of Hips	Cumulative Survival Rate (%)
more than 50yrs	93	71.1
less than 50yrs	25	61.1
Gender		
Female	79	67.5
Male	39	69.3
Abduction angle of cup		
less than 45 degrees	60	79.3
more than 45 degrees	58	58.6
Size of cup		
less than 48 mm	13	33
more than 48 mm	84	70

2.2 Alumina on Polyethylene

Between 1973 and 1975, Semlitsch extensively tested the wear behavior of the polyethylene/ceramic pairing /56/. The following observations were made.

- The biocompatibility, biostability, and corrosion resistance of Biolox alumina ceramic balls is better than that of metal balls.
- No reduction in strength of Biolox ceramic balls in the body.
- ◆ Hardness and scratch resistance of ceramic are around 6 to 10 times greater than that of metallic materials.
- Surface quality of highly mirror polished Biolox ceramic balls is better than that of metallic balls.
- The wettability of ceramic surfaces with aqueous solutions is better than that of metallic surfaces.
- ◆ The wear of polyethylene cups in combination with Biolox ceramic balls is lower than other combinations.

In order to guarantee good clinical results with ceramic balls paired with polyethylene cups, the purity, density, grain size and the mechanical strength must be subject to minimum requirements /56/. In addition, an optimum fit of cone between the ceramic femoral taper of the ball and the metallic taper shank of the hip prosthesis must be given consideration.

Table 4

Metal level (ppm) produced after 105 cycles in joint simulator against polyethylene

Material	Origin	Fe	Ni	Co	Cr	Ti	Al	Zr
316 SS	Plain	830	190	~	100	~	~	~
	Nitrogen	250	0.5		50			
CoCr	Implanted Plain	250	95	80	25	~	~	~
	Nitrogen							
	Implanted	~	~	130	65	~	~	~
Ti6Al4V	Plain	~	~	~	~	160	30	~
	Nitrogen							
	Implanted	~	~	~	~	185	35	~
A1203	Biolox	~	~	~	~	~	0	~
Zr02	Prozyr	. ~	~	~	2	~	~	0
Zr02	Monoclinic Layer	~	~	~	~	~	~	0

^{*}Cales Bernard, "Zirconia as a sliding material". Clinical Orthopaedics and Related Research. Vol. 379. Pg.94-112

Table 5

Effect of polymethylmethacrylate pin reciprocating abrasion on wear and roughness of bearing surfaces

Material	Surface Hardness	Wear Cycles	Wear Depth (μm)	Increase in Roughness (μm)
316 SS	230	106	48	0.74
Ti6Al4V	330	106	28	4.09
Ti6Al4V'	700	106	31	3.25
CoCr	400	106	1	0.1
ZrO2	1430	107	0	0

^{*}Cales Bernard. " Zirconia as a sliding material", Clinical Orthopaedics and Related Research. Vol: 379. Pg.94-112

Particularly the biocompatibility, but also the corrosion resistance and the stability of the ceramic, in the body are dictated by the purity of the alumina ceramic. Only biostable ceramic possesses such required long-term strength. In every bioceramic, the content of alumina should be at least 99.7% /56,61/. The percentage of silicon oxide plus alkaline oxides may not exceed 0.1% /56,61/. In order to maintain the 4µm mean grain size of the ceramic when annealing the green body, 0.2-0.25% magnesium oxide MgO is added to the ceramic /56,61/. The densities of the ceramics together with its grain size are the factors which determine the long-term strength and resistance to wear of the ceramic material. Therefore, the ceramic should have a minimum density of 3.96 g/cm3 /56,61/. The following mechanical parameters are achieved with the high-quality, MgO stabilized alumina ceramic Biolox.

♦ Vickers Hardness 2,300 HV

♦ Modulus of Elasticity 380,000 N/mm2
 ♦ Resistance to Pressure 5,000 N/mm2

♦ Resistance to Bending 600 N/ mm2

Limits on static compression tests, impact tests, and the subsequent pulsation tests for the two different ball sizes, 28 and 32mm are shown in Table 6. This table shows that the larger femoral heads withstand more compression resistance as well as containing more pulsation resistance.

Figure 3 shows the wear factors in difference in head sizes along with the change from CoCr to zirconia in wear volume. The figure shows that a smaller head size has less volumetric wear. This is due to the reduction in surface area in the smaller head. Reducing the surface area also reduces the area of the material in articulation which will reduce the wear.

In order to avoid failure of ceramic balls, it is highly recommended to order all parts of the total hip prosthesis from only one supplier. The ceramic balls can be sterilized either with gamma rays or steam. The ball is attached intraoperatively to the carefully cleansed metallic cone by performing a rotary motion. The

Table 6
Characteristics of different ball sizes.

Static Compression Resistance	28 mm	> 30,000 N
	32 mm	> 50,000 N
Impact Resistance Capacity	28 mm	> 30 Nm
	32 mm	> 30 Nm
Pulsation Resistance	28 mm	6,000 N
	32 mm	8,000 N

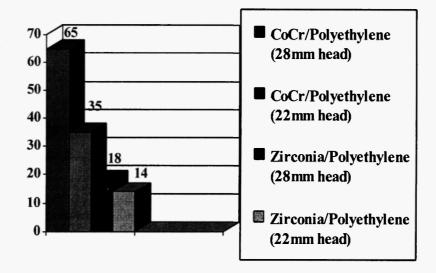


Fig.3: Wear rates with different head sizes, Volume (mm3/Million Cycles)

ceramic ball may break if small bone splinters wedge themselves between the two conical surfaces when mounting the ball. However in the 200,000 Biolox ceramic balls implanted to date this has only happened in about 0.01% of all cases /61/.

In the combination of Biolox ceramic balls with polyethylene cups, polyethylene wear of only 0.05-0.1mm per year is to be expected /61/. For this reason, cups made of polyethylene have twice as long a lifetime as the polyethylene/metal combination /61/.

2.3 Zirconia on Zirconia Implants

Alumina implants have certain limitations that can lead to failure, such as fracture of the femoral head. Zirconia implants have been introduced as an alternate material /97,99,104-110/. Zirconia ceramics are chemically inert materials and are expected to have a high biocompatibility much like the alumina /19.37/. The *in vitro* tests generally concluded that zirconia ceramics have no cytotoxic effect on fibroblasts /37,39,50,52/. In the case of human lymphocytes, a dose dependent cytotoxicity was observed. The same absence of toxicity also was observed on wear particles of alumina and zirconia ceramics /19.37/. *In vitro* genotoxicity and carcinogenicity tests indicated no chromosomic aberration /24,43/.

Christel /13,24,37,41/ reported the *in vivo* behavior of an yttria stabilized tetragonal zirconia ceramic after a short (3 months) or midterm (6 months) implantation time in rat paraspinal muscle and rabbit leg bones. In both cases the *in vivo* effect of the zirconia was compared with that of alumina and no difference was detected between the two ceramics /13,24,37,41/. The same zirconia ceramic was used for long term implantation tests in sheep leg bones for as many as 24 months. Even after long term implantation, no

adverse tissue reaction was detected, and the studied zirconia ceramic showed good biocompatibility /13,24,37,41/.

The inflammatory response of zirconia particles, either in the range 1 to 3 μ m or submicron 0 to 1 μ m, was studied using the rat air pouch model and compared with the inflammatory response of alumina particles of the same sizes /37,51/. From a clinical standpoint, one should compare the inflammatory response observed for small zirconia particles (0-1 μ m) with the inflammatory response for large alumina particles (1-3 μ m). The least inflammation was observed with the zirconia particles /37,48,51/.

Recently, the biocompatibility of zirconia surgical grade ceramic was compared with that of alumina using human osteoblast cell cultures. The results indicated that neither material altered cell differentiation or cell growth rate in accordance with the absence of any inducing effect on deoxyribonucleic acid synthesis or cellular proliferation /37,47,48/. Other *in vivo* experiments on magnesia stabilized zirconia or on calcium oxide stabilized zirconia concluded the same absence of tissue reaction.

The radioactivity of zirconia ceramics previously has been a concern because technical grades of zirconia powder were used as pacifiers for bone cement /40/. Contrary to surgical grade zirconia ceramics, such powders were rather impure and contained a low content of uranium and thorium oxides /37,40/. Uranium and thorium radionuclides are present in zirconia raw minerals, but are eliminated during purification processing of surgical grade zirconia powders. Zirconia powders used for surgical products have an extremely low content of radionuclides. As a consequence, the radioactivity of the surgical grade ceramics is lower than the normal ambient radioactivity induced by natural radiations /37,40/.

The primary reason for using zirconia ceramic as a bearing component in orthopedic surgery is its outstanding mechanical properties, which result from the well-known mechanism of phase transformation toughening. The material reinforcement results from the metastability of the tetragonal phase, which can transform into a monoclinic phase under stress. This mechanism is fully active in zirconia ceramic. As a consequence the fracture strength of zirconia ceramic is at least double and currently three or fourfold than that of alumina. Moreover, the fracture toughness of zirconia ceramic is approximately twice that of alumina, making zirconia ceramic not a brittle material, even though fracture occurs in a brittle manner.

In addition to outstanding mechanical properties, zirconia ceramics offer a high corrosion and scratch resistance over metals /25,37,44,45,48,54/. This has been clearly shown by several authors who measured the content of ion release in the lubricant after hip simulator tests of various femoral heads against polyethylene cups. The wear rate and roughness change after pin-on-pin wear test was also measured using polymethylmethacrylate cement pins. The results are summarized in Tables 4 and 5. After 100,000 cycles on the hip simulator test, with polyethylene cups, alumina and zirconia do not show any ion release as observed for metals. Pin-on-disk wear tests with polymethylmethacrylate cement clearly show the scratch resistance of zirconia ceramic. Contrary to metals, after 10 million cycles there are no detectable wear or surface roughness changes shown in Table 5. Figure 2 shows the comparisons and volumetric wear rates between CoCr-on-polyethylene, alumina-on-polyethylene, alumina-on-zirconia.

Several studies have focused on the wear behavior of zirconia ceramics against polyethylene. Zirconia-on-zirconia clearly shows the lowest volumetric wear rates at .016 cubic millimeters per million cycles.

One such study was shown by Derbyshire *et al.*, who compared the polyethylene wear for either stainless steel or zirconia femoral heads with different diameters from 32mm to 22mm. Derbyshire observed a significantly reduced polyethylene wear for zirconia heads and the wear rate of polyethylene decreased with the diameter of the head /46/.

Wear tests done in dilute bovine serum for CoCr and zirconia heads 28mm and 22mm in diameter are shown Figure 3. A decrease of polyethylene wear with zirconia femoral heads was observed. This decrease was two to three times lower for zirconia femoral heads than for CoCr femoral heads /38.42,53/.

The comparison of wear rates observed in joint simulator tests for several bearing pairs shows that zirconia-on-zirconia has the least amount of volumetric wear rates compared with alumina-on-alumina. alumina-on-polyethylene and CoCr-on-polyethylene paired bearings.

The use of zirconia femoral heads in ceramic on ceramic bearing pairs for total hip replacement has also been studied with the main objective for alumina on alumina being to completely eliminate the risk of polyethylene debris. The use of zirconia in ceramic on ceramic total hip prostheses was predicted to be disastrous, both for the zirconia on alumina combination and for the zirconia on zirconia. However, some tests were done with nonrepresentational conditions (ring-on-disk in water under high load) or with inappropriate ceramic material compositions. Joint simulator tests, however, done in bovine serum and, revealed the zirconia on alumina combination to have a very low wear rate, of the same order as the alumina or alumina pair /18,37,49,55/. Such low wear rates were not only observed by Cales /37/, but also by Villermaux /101/. Bovine serum was used in all tests as the lubricant in joint simulators. Therefore, there is a consensus that the zirconia on alumina bearing pair has a low wear rate, as is usually observed for alumina on alumina /37/.

The analysis of the surface of the zirconia femoral heads after wear against an alumina liner confirmed the absence of any significant surface degradation. For instance, an x-ray diffraction study indicated that the monoclinic content at the surface of the zirconia femoral heads after 10 million cycles (sliding against an alumina liner) remains below the detection limit, and is similar to what is currently observed on as-produced zirconia femoral heads. The absence of transformation also is confirmed by fine surface roughness measurements using an optical interferometer on zirconia femoral heads before and after 10 million cycles against alumina inserts /37/. Using dilute bovine serum as the lubricant, the surface roughness changed from .0025µm before the wear test to .0045µm after 10 million cycles /37/. This is attributed to fine and uniform microscratching of the zirconia femoral heads. The wear mechanism is completely different to what is observed for alumina on alumina pairs. In the case of zirconia on alumina combination, because of the lower hardness of zirconia compared with alumina, there is a self-polishing of the zirconia femoral head during sliding against alumina surface /37/. This produces very fine submicron zirconia debris. As reported earlier, such submicron zirconia debris do not induce adverse tissue reaction. In the case of alumina on alumina combination, because of the high hardness of alumina, the wear mode appears to be significantly different.

although the wear rate remains very small. There are fewer scratches than on zirconia femoral heads, but they appear to be deeper and some grain pullout is observed, especially when the two scratches overlap. In addition, the alumina grains are clearly apparent on the worn surface of the alumina femoral head, as if they were etched during sliding against the other alumina surface.

Although they have been used in orthopedic surgery since 1985, few reports exist on the clinical behavior of zirconia femoral heads /37/. Dambreville reported a more detailed study /102/. The author reported on 101 total hip prostheses with 28mm zirconia femoral heads after a follow up of 7 years. In most of the cases the linear wear of polyethylene was detected at zero or below the sensitivity of the measuring technique. The mean polyethylene wear was estimated to be 0.1mm per year /102/. Only two total hip prostheses had high polyethylene wear, of approximately 2mm, but in both cases the high wear was associated with cup loosening caused by a defect in the insert.

The mean penetration rate of the 28mm zirconia femoral head of 0.1 mm per year is similar to the clinical data reported by Jenny who compared the wear rate of different 28mm femoral heads wearing against polyethylene /103/. Jenny reported on 1200 total hip prostheses, including 300 zirconia femoral heads. Jenny concluded that the lowest wear rate was observed for the ceramic on ceramic bearing pair /103/. The wear rate observed for zirconia femoral head after a follow up of 7 years was approximately the same as reported by Dambreville /102/. The two clinical studies above were performed on the same zirconia femoral heads (Prozyr).

3.0 SAFETY ISSUES

Biotechnical investigations show that the ceramic sockets and balls of the Autophor prosthesis regularly stand a static load of about 50,000 N, and also have sufficient fatigue stability of 30,000 N /58,59,60/. It has also been proven that balls and sockets show a high precision of roundness with a deviation in average of only about 0.4µm.

The clinical experience of Mittelmeier shows no visible wear of the ceramic devices, provided there is correct positioning of the components. In remarkable contrast, conventional polyethylene prostheses show severe wear rates. In Mittelmeier's clinical follow up, wear of ceramic components made of Biolox is only visible in primary or in secondary implant, made by wrong positioning. In these cases border impingements of the components with recurrent subluxations and stress concentrations may cause severe wear and even socket fractures by recurrent shattering /58-60/.

Laboratory measurements of 52 ceramic retrieved prostheses showed only an extremely small wear. This was an average wear on the heads of $9.4\mu m$ and on the sockets of $4.5 \mu m$, which corresponds to an annual wear on the heads of $5.56 \mu m$ and on the sockets of $2.66 \mu m$, being only about 1/40 to 1/80 of polyethylene wear of the conventional prosthesis /22,23/. Higher wear was seen only in steep socket positionings with more than 55° inclination of the entrance plane against the horizontal and in cases of ceramic fractures where

the wear increased rapidly after the fracture. Therefore with respect to the safety of ceramic implants, a socket inclination with only 40° and an anteversion of 15° is recommended by Mittelmeier /58-60,76.94/. The tolerance reaches up to about 55° but, if at the final X-ray a steep implantation is found, it needs to be corrected immediately.

After analyzing the fractures of ceramic components in Mittelmeier's study of 2356 cases, the overall number of ceramic breaks, 0.59%, included fractures of cemented Xenophor sockets (4 isolated and 3 in combination with head fractures), 5 isolated Autophor socket fractures and finally 2 isolated head fractures. (The head fractures concerned only the older designs with ceramic neck components, no round ball).

The analysis of the ceramic breaks revealed in 6 cases a remarkable trauma and in 8 cases fatigue shattering fractures in primary wrong positioning (2 cases), impingement of returned neck (2 cases) and a socket tilting after loosening (4 cases). Ceramic is not fully resistant against severe trauma shocks, but the break incidence is very rare and certainly does not exceed the danger of traumatic fracture of the acrylic cement in conventional prostheses. Correct implantation and change of the head-design (without ceramic neck) might avoid fractures due to primary wrong implant positioning with recurrent neck-socket impingement in future /76,94/. Even decrease of aseptic loosening of the components in cementless fixation may contribute to the safety of ceramic implants in the future. Furthermore, in the conventional prosthesis steep position of the polyethylene sockets causes a stronger and earlier wear; also in polyethylene sockets fatigue fractures do occur, as Mittelmeier has shown in his evaluation of his revisions of conventional prostheses /76,94/.

The real traumatic fractures of ceramic components may be caused, of course, by the relative low shock absorption of the ceramic and its high elasticity modulus. Mittelmeier did not observe fractures of the ceramic balls in combination with polyethylene sockets or metal sockets with polyethylene inlays. However, it may not be interpreted that combinations of ceramic balls with polyethylene sockets or metallic sockets with polyethylene inlay are better. On one hand they showed more favorable shock absorption characteristics, on the other hand much higher wear /58-60/. Zichner showed that polyethylene wear, even in combination with Biolox ceramic, is much higher than simulator investigations /17/. Clinically it is only about ½ of the conventional prosthesis and therefore much more than the ceramic on ceramic pairing.

With respect to the safety of arthroplasties and based upon Mittelmeier's long lasting clinical experience, polyethylene may be useful only in older patients with short life expectancy /76,94/. However, in younger patients with longer life expectancies, ceramic on ceramic pairing may be favored because of the much lower wear rates and debris involved. The ceramic on ceramic pairing does not provide absolute security concerning severe traumatic shock. But this is more than compensated by proved low wear behavior, superior to all other sliding combinations known to date /76,94/.

4.0 SUMMARY

With the growing need for a longer lasting hip implant, materials which reduce wear and osteolysis are in great demand. From this study ceramics have been found to be a superior alternative to metals. Ceramics are biocompatible and produce smaller wear debris particles at a much lower rate than metals. Ceramics are also corrosion resistant, while metals do oxidize, which can lead to the release of metal ions in the body. Ceramics are also much harder and much more scratch resistant than any other type of implant material used today. The surface of ceramic heads can be polished to a smoother finish than metals. This means when in articulation ceramics have lower wear in the joint. Ceramics also have great wettability properties and work well in a wet environment, unlike metals which can corrode and pit. This moisture that ceramics keep in the joint through their wettability properties help keep the joint lubricated which reduces wear. Throughout this article, it has been documented that wear is the main cause for premature replacements. The wear affects the potential life of the prosthesis and subsequent removals of implants. By reducing wear and eliminating the risk of osteolysis, longer life spans of the components may be achieved. Ceramics meet most of the requirements in order to extend the life of the implants, as long as compressive stresses develop in the bearing.

There are two main types of ceramics that are used today, alumina and zirconia. These materials are both good choices, especially when in comparison to metal and polyethylene components. However, zirconia does have a higher tensile strength and a harder and more scratch resistant surface which can also be polished down slightly smoother than the surface of alumina.

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