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Characterization of Mechanical Properties of Alumina Based Hip Joint Prostheses

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Abstract:
Femoral heads of different designs were prepared with bio-grade alumina. The samples were prepared by isostatic pressing, turning and subsequent sintering for 2 hrs. at 1550°C, 1600° C, 1650° C. Equivalent bar samples were prepared through identical processing steps and their flexural strength were compared to the static fracture load of the alumina based femoral head. These heads were tested for cyclic fatigue under sinusoidal and walking loads and the results are discussed in the light of their microstructure, physical and mechanical properties.

Keywords: Alumina, femoral head, microstructure, fatigue.

Introduction:

The replacement of damaged or diseased synovial joints marks one of the greatest surgical inventions of the present century. It has been found that although replacements are available for hip, knees, shoulder, wrist etc., the first two joints account for most of the surgical intervention mainly due to their frequent vulnerability due to high in-vivo loads. Most of these implants consist of two components: an articulating softer cup / pad (generally made out of polymer: Ultra High Molecular Weight Poly Ethylene) and a harder counter face (Metal or Ceramics).

During last three decades, oxide based ceramics are being increasingly introduced in orthopedic surgery as replacement of metallic parts as the hard, bio-inert component. Generally, in total hip-implants, the ceramic femoral heads are prepared with a tapered bore in which the projected male counter face of the metallic stem are fitted to fix the head with the stem. Nowadays, the diameter of the ball heads used ranges between 22 mm and 56 mm. There are mainly two different cone (with a vertex angle of $5^0$42.5 minutes; i.e. 1:10 cone) used: the larger cone sized 14/16 and the smaller so called Euro-cone, sized 12/14 (1). These ceramic oxides, particularly high purity polycrystalline alumina, with high compressive strength, very low coefficient of friction (2), negligible wear rate (3) and extreme chemical inertness in physiological environment have emerged as the most suitable material of construction for the orthopaedic joints (4). Further, in this case, even after prolonged usage the amount of alumina debris released in the body from the articulating surface is negligible and as a result the associated problems are eliminated. It has been reported (5) that in pure and dense alumina only a very thin [less than 50 Å thickness] hydrated layer of $Al(OH)_3$ is formed on the surface in contact with body fluid which acts as the intermediate lubricating layer between implant components and reduces wear of the polymer in the ceramic-polymer interface.

The present paper deals with the in-vitro characterization techniques of alumina based femoral heads of the bi-modular total hip prosthesis, sintered at three different temperatures and correlate their physical and mechanical properties with the corresponding microstructure. The results of the fracture and fatigue behaviour of these ceramic heads under different dynamic conditions are also discussed and compared with their mechanical properties obtained through the corresponding bar samples.

Materials and methods:

Commercially available fine grained alumina with 99.8 % purity (A-16 SG grade of Alcoa USA) was used for this study. The chemical analysis of the powder is given in Table 1.

Table 1: Chemical composition of alumina powder used for the experiments.

Al_2O_3	99.8 %
Na_2O	0.06 %
Fe_2O_3	0.02 %
MgO	0.03 %
SiO_2	0.03 %
CaO	0.02 %

The powder was pressed isostatically at a pressure of 150 MPa to dense cylindrical shapes by using a Cold Isostatic Press supplied by EPSI N.V., SO 10036, Belgium. The pressed green cylinders were pre-sintered at 800^0C and subsequently turned in CNC (Make: Praga Tools India Ltd., Secunderabad, model no. 342) to get the pre-fixed design of the femoral heads with an accuracy of + 5 micron. The turned items were thereafter sintered for 2 hrs at three different sintering temperatures (1550, 1600 and 1650^oC), ground and polished with diamond paste of progressively reducing grit size to obtain surface finish (R_a) below 0.05 micron as measured by a profilometer (Surtronic 3p, Form Talysurf Plus, Rank Taylor Hobson Ltd, U.K.). A typical ceramic headed hip-implant used in the study along with a schematic elaboration of the fixation system between the ball and the stem is presented in Fig 1. The taper design followed here was standard 12/14 Euro-cone with a taper angle of 5.42^0 in accordance with the German standard specifications DIN 254 and DIN ISO 3040.

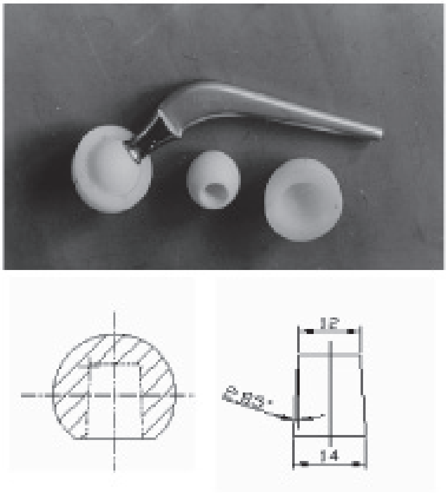

Fig 1: Design of the alumina balls with 12/14 taper (1:10 Euro-cone) used in the study

The spherecity of the balls was measured by a Coordinate Measuring Machine manufactured by Carl Zeiss, GmbH, model no. 850 and the spherecity values were always kept below 10 micron (6). The overall manufacturing process is outlined in Fig. 2. In addition, no. of bar ($45 \times 4.5 \times 3.5\ mm^3$) and plate ($25 \times 25 \times 2\ mm^3$) shaped test samples were also prepared in identical way as adapted for the balls for determination of different typical physical and mechanical properties of the material.

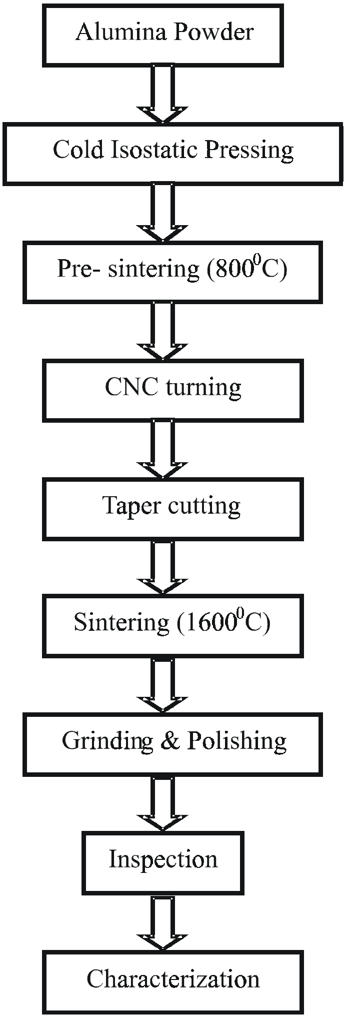

Fig 2: Flow diagram of manufacturing of alumina based femoral head

The X-ray diffraction of the sintered alumina samples were performed by using Philips PW1710 based X-Ray B.V. Diffractometer in flat plate geometry using monochromatic Cu $K_{\text{á}1}$ radiation (wavelength: 1.54056 Å) at 55 mA and 40 KV. The 3-point flexural strength of the bar samples and the static fracture test of the alumina femoral heads were conducted by Instron made Universal Testing Machine, model 5500 R 1185, U.K. For determination of 3-point flexural strength ASTM specifications (7) were followed and accordingly, 10 nos. of alumina bars were tested for generation of single data-point. The strength values (σ) of the samples were calculated from the following relationship:

$$\sigma = 3wl / 2bd^2 \qquad \text{..............................(1)}$$

where w is the braking load, l is the distance between the two support rollers, b and d are the width and thickness of the respective sample.

One mechanical hardness tester, supplied by INSTRON WOLPERT, GmbH (model no. DIA TESTOR 7021) was employed to determine Vicker's hardness and mode-I fracture toughness of the sintered samples. Vicker's hardness (H_v) was determined from the diagonals of the hardness impression (a typical hardness impression is shown in fig. 3) from the following relationship:

$$H_v = 2P \sin 68^o / d^2 \qquad \text{..........................(2)}$$

Where P is the indentation load and d is the size of the diagonal of the impression.

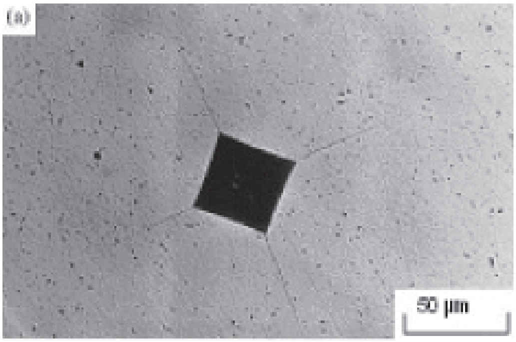

Fig 3: Impression produced by Vicker's Indentation at a load of 100 N showing the cracks originated from the end of the diagonal

The mode-I fracture toughness (K_{1c}) of the samples were calculated from the crack lengths generated from the corners of the impression by using the equation (3) as follows (8 - 9):

$K_{IC} = 0.016\ PC^{-3/2}\ (E/H_v)^{1/2}$..............(3)

Where the indentation load P was kept as 100 N, 2C was the total crack length, H_v was the Vicker's hardness and E was the elastic modulus of alumina which was taken as 380 GPa as determined by adapting ultrasonic pulse-echo technique the details of which has been published else where (9 - 10).

For fracture study under static load, the polished balls (sintered at 1550^{0}C and 1600^{0}C), with two different diameters (28 mm and 32 mm) were press-fitted with a stainless steel tapered counterpart as recommended by ISO 7206-5 (9). Accordingly 20 nos. of balls from each group were subjected to static fracture test and the average values along with the associated scatter were recorded. The fatigue behaviour of the identical alumina balls was studied under dynamic fatigue loading by using an Instron made 'Hip Joint Simulator' (model no. 8511.20). Each of the balls fitted with 316L stainless steel stem were subjected to compression-compression loading cycle against a UHMWPE (Ultra High Molecular Weight Polyethylene) acetabular cup. The cup was programmed to undergo a rocking motion of 10^0 on each side of the center line of the ram to simulate walking load pattern within a human body. The load cycle applied was identical to that experienced by a normal hip of a person with a body weight of 100 kg as shown in Fig 4. In each case, the test was continued up to 10^6 cycles and the progressive change in pattern of the load-time curve was noted. Microstructure of the polished and thermally etched samples were studied by employing one Scanning Electron Microscope (SEM),"LEO 430i STEROSCAN, U.K."

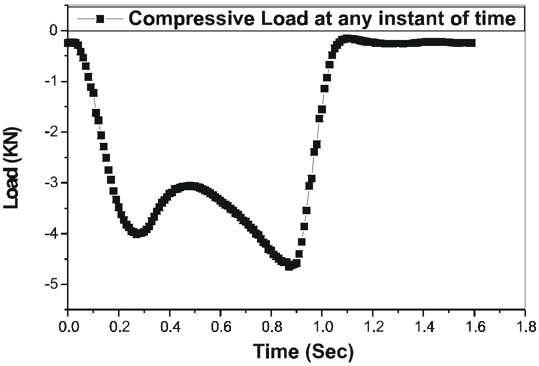

Fig 4: Load cycle applied on the alumina balls during dynamic fatigue testing

Results and discussion:

The XRD pattern obtained from the sintered plate sample sintered at 1550^{o}C is shown in Fig 5. The result revealed that α-alumina (i.e. most stable phase of alumina) is almost the only major phase in all the samples. Presence of any other secondary phases could not be detected in any sample with the facilities available for the present study.

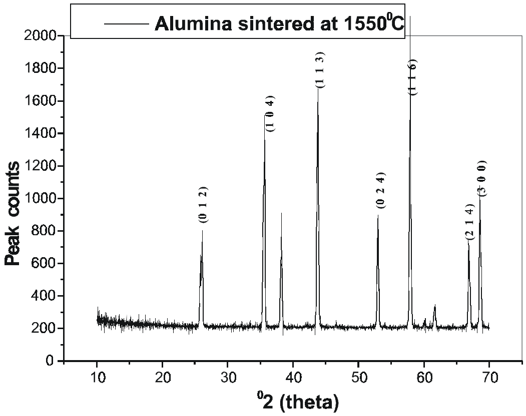

Fig 5: XRD of the sintered alumina used in the experiment

The overall results of the physical and mechanical properties of the material are summarized in Table 2.

Table 2: Mechanical properties of the alumina samples sintered at different temperatures

Sintering Temperature	Average Flexural Strength (MPa)	Vicker's Hardness (GPa)	Fracture Toughness ($MPa.m^{1/2}$)
1550^0C	400	15.5 ± 0.4	3.80
1600^0C	370	14.7 ± 0.6	3.65
1650^0C	350	13.8 ± 0.6	3.35

Figure 6 a, b and c represent the microstructure of the sintered samples obtained by thermal etching. The photomicrographs clearly indicate that the grain size of the samples progressively increases with increase in sintering temperature. The increase in grain size has inversely affected the strength and other mechanical properties of the material which is in agreement with the findings reported in the literature (12 - 13). The average grain size as measured by the line intercept method (ASTM E112) indicate that the increase of sintering temperature from 1550^o to 1600^oC has only a marginal effect on grain growth within the samples and the average grain size increased from 2 to 4 micron. However, it may be noted in fig. 6b that the samples sintered at 1600^0C, had few large grains surrounded by no. of small grains, whereas in the other ones, the microstructure was more or less homogenous (fig. 6a) and this might have resulted much higher mechanical strength for this set of materials. Increase in sintering temperature to 1650^oC increased the average grain size to about 7 micron and this affected the mechanical properties even further.

The results of the static fracture test (as shown in Table 3) also presented a similar trend. The fracture load went on increasing with decrease in grain size as was evident in the previous case. In case of the heads with 28 mm diameter the strength increased from 20 KN to 25 KN as the average grain size varied from 4 to 2 micron while in the other set of balls the values changed from 40 to 50 KN exhibiting an identical change of 25% in both the cases. In case of flexural strength this change was however much lower and was restricted only to about 10%. As per FDA guidelines (14) the average fracture load of the balls should exceed 46 KN and no ball should fail at less than 20 KN and this has been achieved for femoral heads with 32 mm diameter, sintered at 1550^oC.

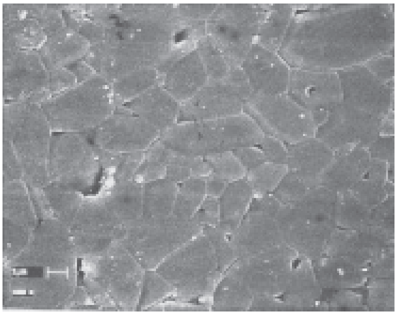

Fig 6a: Microstructure of the alumina sintered at 1550^0C

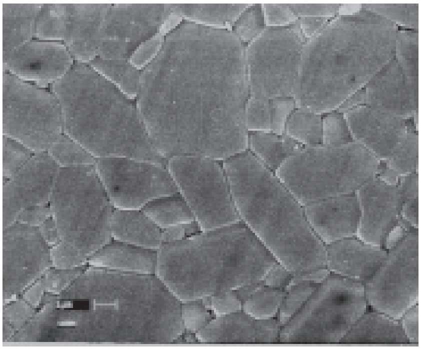

Fig 6b: Microstructure of the alumina sintered at 1600^0C

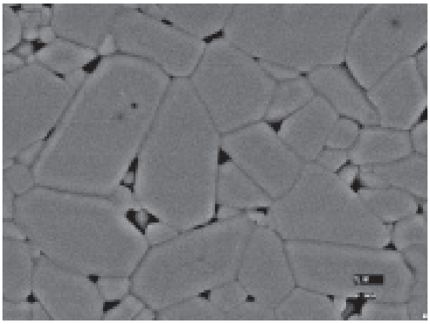

Fig 6c: Microstructure of the alumina sintered at 1650^0C

Under dynamic fatigue loading the progressive displacement of the ball from its initial position under identical stress situation has been reported in Fig 7. It may be noted that the total displacement of the ball was the simultaneous and cumulative effect of (i) the changes in the relative position between the ball and the stainless stem due to deformation/ wear of the metallic component, (ii) the deformation of the polymer cup, and (iii) the wear of the polymer cup due to continuous articulation against the harder alumina surface.

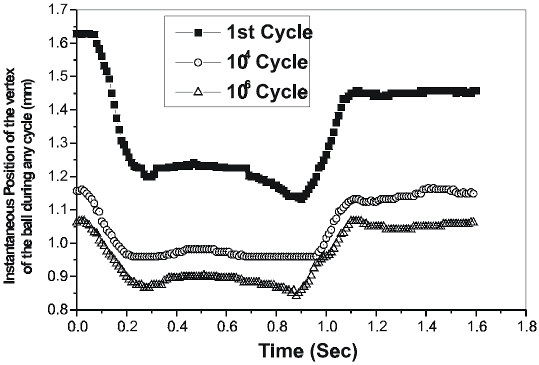

Fig 7: Instantaneous position of the tip of the ball during any cycle when tested with rocking motion due to combined effect of the Polymer cup deformation, Wear of the polymer cup and the deformation of the stainless steel stem

To identify and separate the effect of these different influencing parameters, a polished metallic plate was placed on the acetabular cup and the position of the ceramic head before and after the experiment was noted when it touched the top surface of the plate and from the difference the relative positional shift within the head and stem assembly was measured. In all the cases, this shift was found to be negligible which in turn confirmed the suitability of the fitting arrangement. Further to separate the effect of deformation from the wear of the polymer based accetabular cup, each of the experiments was performed twice: i) once the ceramic head was loaded along with a synchronized rocking motion of the acetabular cup and ii) the loading was without rocking motion. In the first case, the ball displacement represented the combined effect of wear and deformation of the polymer cup, while in the second one, as there was no relative motion between the two components, the displacement of the head only represented the deformation of the polymer cup. The results as summarized in Fig 8, show that a the rate of deformation of the polymer cup decreases with time and after 2 x 10^5 cycles, almost no further deformation was noticed. However, the wear of the polymer- cup continued though the overall wear was negligible, the rate was marginal and decreased with time. During the study none of the ceramic head failed and the post experiment microstructure did not reveal any change in defect concentration.

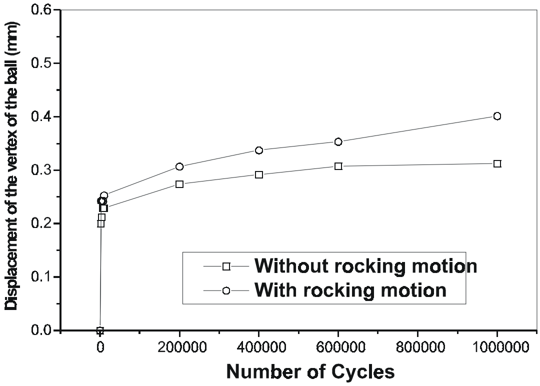

Fig 8: Time dependent displacement of the tip of the ball for both the cases [i.e. i) with rocking motion and ii) without rocking motion]

The fatigued heads were compressed to fracture and the average fracture load was observed to be almost identical with the corresponding values obtained from the fresh samples as reported in Table 3.

Table 3: Static Fracture Load of the alumina based femoral heads

Diameter	Sintering Temperature	Average Static Fracture Load (KN)
28 mm	1600 ^{0}C (2 hr.)	20
	1550 ^{0}C (2 hr.)	25
32 mm	1600 ^{0}C (2 hr.)	40
	1550 ^{0}C (2 hr.)	50

This confirms that the dynamic fatigue loading did not change the existing crack dimensions within the samples which in turn indicate that even for a person with the bodyweight of 100 kg, the stresses experienced were below the threshold fatigue limit of the material and therefore a long and safe performance is expected.

Conclusion:

Alumina based femoral heads with 28 and 32 mm diameter and 12/14 taper and 1: 10 Euro-cone (i.e. with a taper angle of 2.85^0) could be developed as per international standards. The actual components and the identically prepared test samples were mechanically characterized and the results were compared and discussed from the angle of their respective microstructure. The mechanical properties of the material were found to decrease with the increase in sintering temperature and grain-size. The results of the dynamic fatigue study revealed all the femoral heads withstood the cyclic stress parameters experienced by a normal hip of a person of 100 kg body weight without any degradation. The associated creep and wear of the polymer based acetabular cup was also determined and the values were found to be extremely low which in turn indicated that hip-joints developed from this material combination is ideally suitable for clinical application in human patients up to a body weight of 100 kg.

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