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Résumé - Une céramique d'alumine à grains fins a été testée pour des applications orthopédiques par mesure des propriétés mécaniques et analyse du comportement à la corrosion. Une nouvelle méthode d'attache des têtes fémorales sur la tige métallique utilisant une fine chemise en polymère est décrite.

Abstract - A fine grained alumina ceramic has been assessed for orthopaedic applications by measurements of mechanical properties and investigations of corrosion behaviour. Anew method of attaching femoral heads to metal stems using a thin polymer liner is described.

I - ALUMINA CERAMIC

The ceramic (VITOX)(1) was prepared from a high-purity fine-particle-sized alumina, with a small addition of magnesia sintering aid, by pressing, and firing at 1600°C. The resulting ceramic is of near theoretical density (3.97 Mg m^{-3}) and of fine grain size (3 µm mean). The microstructure revealed by thermal etching is shown in Fig.1. Samples for mechanical and chemical evaluation were prepared as bars 3.5 x 3.5 x 35 mm, tested in the as-fired condition. Component testing was on full size pieces with the outer surface highly polished to a surface finish of 0.015 µm.

II - MECHANICAL PROPERTIES

The first strength tests were conducted in three point bending on a 26 mm span with a test machine crosshead speed of 1 mm min^{-1}, under ambient conditions and immersed in Ringer's solution (phosphate-bicarbonate). Mean results for 12 specimens, with standard deviations indicated, are

Air	558 ± 70 MPa
Ringer's solution	503 ± 55 MPa

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indicating a small but not highly significant reduction in strength in Ringer's solution. The strength however is well in excess of the minimum value (400 MPa) recommended in the International Standard/1/. It has also been demonstrated that radiation (at a level necessary for sterilisation) does not have a detrimental effect on strength.

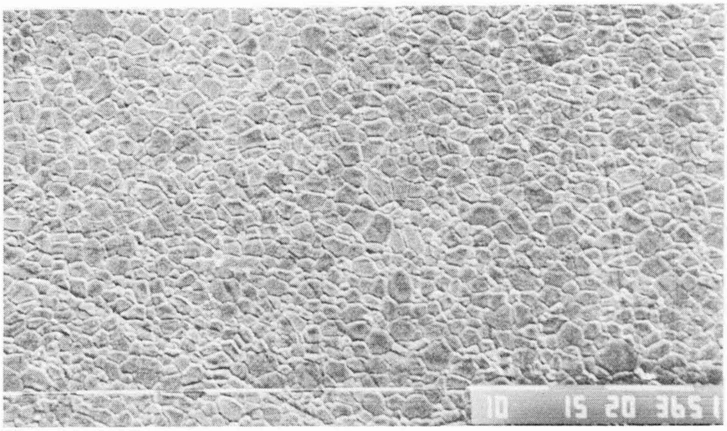

Fig.1 Microstructure of Alumina Ceramic

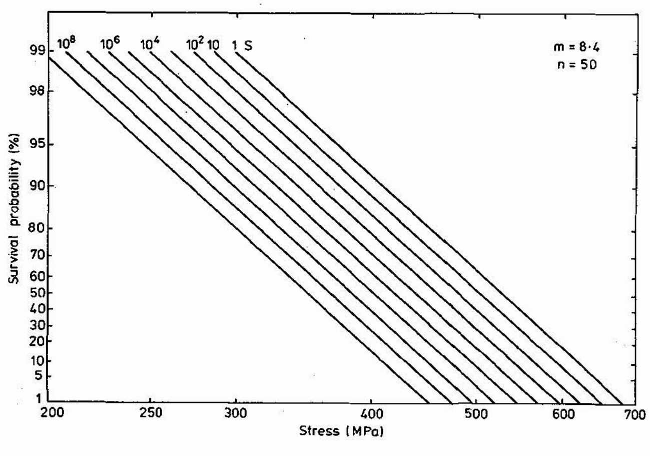

Fig.2 SPT Diagram for the Alumina in Ringer's solution

Similar tests were conducted with single edge notched beams (notch depth 0.5-1.7 mm) to measure the critical stress intensity factor. Results are

Air	6.02 ± 0.68 MN m$^{-3/2}$
Ringer's solution	5.60 ± 0.80 MN m$^{-3/2}$

To predict mechanical performance under operating conditions, further experiments were conducted to give data for the statistical variation in strength and the time dependence in strength. Tests were conducted in Ringer's solution at ambient temperature. Batches of 20 specimens were tested in three point bending at three strain rates with machine crosshead speeds of 0.05, 0.5 and 5 mm min^{-1}. These gave approximate fracture times of 400, 33 and 3 s. A fourth set of specimens was tested under delayed fracture conditions to give more reliability to long term performance prediction. An initial constant stress at 70% of mean strength was applied for up to 30 min, and then at 80% mean strength etc until fracture occurred.

Data were analysed by well established procedures/2,3/ in terms of an SPT (strength probability time) diagram, shown in Fig.2. The Weibull modulus m is 8.4. The slow crack growth parameter n is 50 (exponent relating crack velocity v and stress intensity factor K as $v \propto K^n$). The data has been extrapolated to a time of 10^9 s (30 y) the anticipated maximum lifetime for the component.

III - CORROSION BEHAVIOUR

A batch of 10 samples were individually wrapped in filter paper and boiled for 2 weeks in a 5wt% sea-salt solution. After exposure the samples were washed in distilled water and dried. This treatment induced a small weight gain equivalent to approximately 0.06 mg cm^{-2}. A very thin deposited surface layer, high in silica was detected, and this is believed to be due to dissolution of silica from the glass reaction flask. No roughening or etching was however detected on polished samples.

Bend strength was measured under ambient conditions for specimens before and after treatment with the following results.

As received	545 $\pm$ 73 MPa
Boiled in salt solution	533 $\pm$ 76 MPa

There is no significant difference.

No penetration of methylene blue dye could be detected and no spalling on heating to 1000°C was observed, suggesting no internal corrosion due to penetration of salt.

Vickers micro-hardness tests (1N force) were conducted on surfaces following a very light polish to give a sufficiently flat surface and to remove the surface deposit left after washing. The results

As received	1891 $\pm$ 78 HV0.1
Boiled in salt solution	1866 $\pm$ 28 HV0.1

show no significant effect. Measurements at higher loads (25N) show little variation of hardness with indentation load. Similar results were obtained for comparable commercially-available aluminas and for sapphire single crystals.

IV - ALTERNATIVE ATTACHMENT METHOD

The conventional method of attaching the ceramic sphere to a metal stem to form the femoral component of a total hip replacement involves the frictional locking of a male taper on the neck of the stem into a matched female taper within the ceramic sphere. The cone angle is often 1 in 10. A disadvantage is that a locked-in hoop stress is produced which can only increase during component lifetime. Furthermore, because the fit of the male and female cones is critical expensive grinding operations are necessary. An alternative method has thus been developed, Fig.3, using parallel-sided components with a thin polymer liner to separate the metal from the ceramic. This system greatly reduces the locked-in stresses and gives a better load distribution through the polymer so that the recess in the ceramic can be in the as-fired state. Potential problems of the polymer extruding from the joint are minimised by having a thin sleeve.

32 mm outside-diameter spheres of alumina with a 16 mm diameter hole were used for tests. The sleeves were 0.5 mm thick ultra high molecular weight polyethylene and

the metal stems were titanium alloy with a sand blasted finish. Tests were also conducted on the conventional taper design of component.

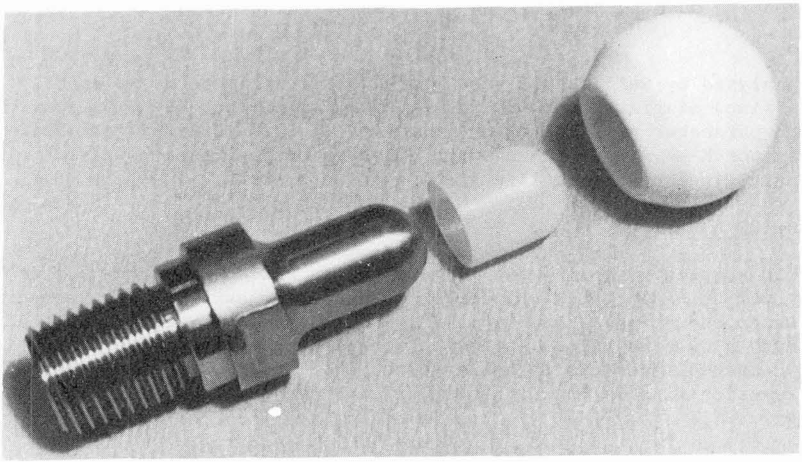

Fig.3 Alternative Design for Femoral Head Assembly

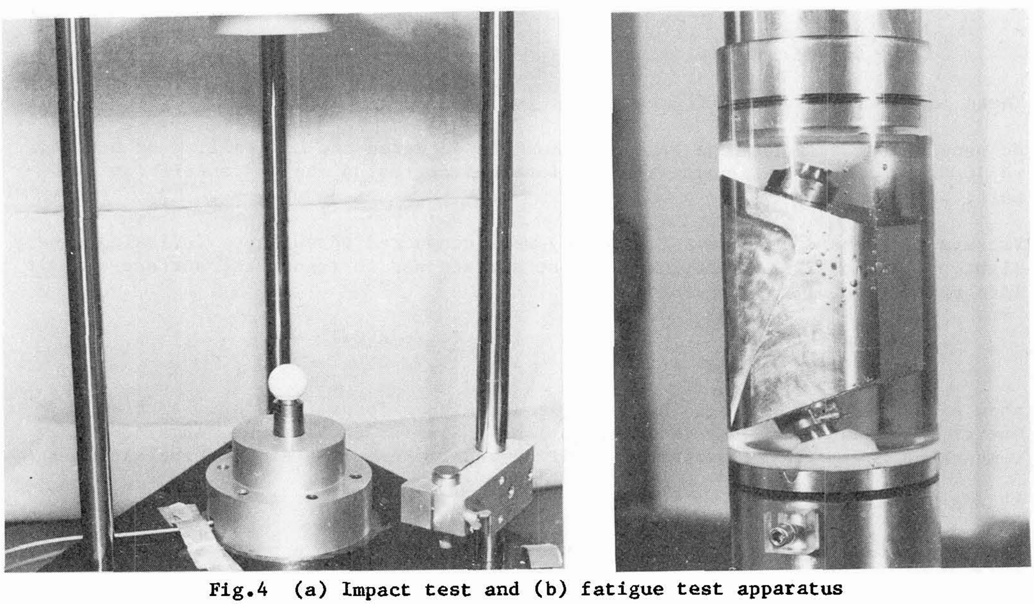

Fig.4 (a) Impact test and (b) fatigue test apparatus

A drop tower apparatus was used for impact testing of simulated prostheses, Fig.4(a). The drop mass was 50 kg and the height was 0.7 m. Taper components failed at loads between 54 and 93 kN (mean 74 kN) for batch of 17 components. Six straight sided components failed at peak forces between 90 and 106 kN (mean 100 kN). 22 other straight sided components did not fail, even after 5 impacts each with mean peak forces of 100 kN.

Fixation strength tests were conducted with dry components at ambient temperature to determine the relationship between the degree of sleeve interference and rotational fixation strength. Other tests studied the effect on rotational fixation strength of long term soaking in Ringer's solution at 37°C. The torques to rotate the heads relative to the spigots were measured under an axial force of 1 kN. Rotational strength increased from 10 to 15 Nm as the sleeve interference increased from 12 to 50 μm. The soaking tests were conducted for times of 1 day,

1, 2 and 3 months. Unlike the previous tests, these components were assembled under a force of 10 kN. Rotational torques in the range 40-50 Nm were obtained relatively independent of the soaking time.

Fatigue tests, Fig.4(b), were conducted on a double headed rig with a servo controlled hydraulic test machine. Data are summarised below

Design	Condition	Cycles	Load	Comment
Taper	Air RT	10^7	2-18 kN)	No deterioration or
			)	reduction in impact
	Ringer's 37°C	10^7	2-18 kN)	strength.
Sleeve	Air RT	10^7	1-9 kN	No thinning of sleeves.
"	" "	10^7	2-18 kN	Both 9% thinning.
"	Ringer's 37°C	10^7	2-18 kN	10% and 30% thinning

Two samples were tested under each condition. The observed thinning, measured in an axial direction at the internal crown, results from the polymer being pressurised further into the surface roughness of the other components, or into any free space from a small imperfect fit of the components. Most of the thinning occurs in the initial stages of testing (1M cycles). For the last series of tests the torques to produce rotation of the heads relative to the spigots were 55 and 58 Nm which is higher than one day after assembly. Further components are undergoing simulator testing, and if successful, clinical trials will follow.

V - DISCUSSION

The mechanical and chemical tests on the new ceramic material show that it is well within the ISO standard for implants for surgery and could thus be used reliably with the conventional taper head design. The average impact strength on the taper design components of 70 kN is equivalent to a hoop stress on the alumina sphere of 320 MPa/4/. This is equivalent to approximately 70 x bodyweight. For a reasonable requirement of 12 x bodyweight (12 kN) the hoop stress is 70 MPa/5/. The SPT data show that the material can withstand this stress to a very high degree of reliability. Any potentially defective components could be readily eliminated by a proof test procedure/5/.

An alternative straight sided hole design has been evaluated. This eliminates some of the disadvantages of the taper design and is cheaper to produce. Test evaluations are promising and more detailed studies are in progress.

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