Available online at www.sciencedirect.com
ScienceDirect
Journal of the European Ceramic Society 27 (2007) 1535–1541
www.elsevier.com/locate/jeurceramsoc

Factors influencing the reliability of ceramic femoral components

R. Morrell[a,*], S. Hughes[b,1]

[a] National Physical Laboratory, Teddington TW11 0LW, UK
[b] Morgan Advanced Ceramics Ltd, Rugby CV23 0WE, UK

Available online 5 June 2006

Abstract

The longevity of ceramic components implanted in the human body is controlled by a number of factors associated with their design, manufacture and interfacing with metallic components, as well as factors associated with the surgical implantation and patient use. While the technology can be considered to be mature, it requires maintenance of optimum materials and processes on the part of the ceramic manufacturer, as well as achieving optimum potential performance and failure risk reduction through design, commensurate with achieving practical goals. This paper reviews the issues of performance requirements, and the relevance of standardised tests for both the material and the components compared with *in vivo* loading. Long-term testing to determine resistance to static loading is described. Fractography is shown to be a key element for interpreting failure modes and mechanisms.

Keywords: Biomedical applications; Mechanical properties; Failure analysis

1. Introduction

The use of ceramic femoral components, both heads and acetabular cups is well-established and increasing, primarily because the ceramics chosen, alumina and zirconia, are biologically compatible with the body and very wear resistant, and furthermore, induce less wear in the components against which they are mated[1]. Because some forms of wear debris have been attributed to inducing implant loosening, revision surgery becomes less likely in active patients. However, this is an application which requires continuous attention to detail and improvement as the demands on total hip arthroplasty performance increase, notably on long-term performance. The mechanical stresses applied to a ceramic femoral head as a result of the taper design on the metallic stem are considerable, and typically in a hoop tensile orientation with the maximum at the taper surface. For this reason, requirements have been laid down for type testing of ceramic heads to ensure that the materials and the detailed geometrical design are proved to have certain minimum characteristics, such as those laid down by the US Food and Drugs Administration (FDA)[2]. Such testing is mostly of a short-term nature, whereas it is known that while under stress, ceramics can suffer from a slow degradation of residual strength with time. This paper reviews some of the technical issues facing the component manufacturer in providing this reassurance in the light of the generally unpredictable properties of individual ceramic items.

2. The design process and standards

2.1. Materials

Materials need to conform with ISO 6474/ASTM F603 for high-purity alumina or ISO 13356/ASTM F1873 for zirconia-based ceramics (normally Y-TZP type). The basic requirements are close to theoretical density, fine grain size and high strength. Recently, there has been the proposed introduction of a cyclic flexural fatigue test to evaluate longer-term properties, particularly the tendency of strength under load to degrade with time.

2.2. Design

The detailed dimensional design of both heads and cups using finite element analysis is a key element in determining the viability of a particular concept and its ability to meet the minimum specifications. In order to satisfy surgical demands for flexibility in, for example, femoral stem neck length, the 'safest' design cannot always be used.

* Corresponding author. Tel.: +44 20 8943 6381; fax: +44 20 8943 2989.
E-mail addresses: roger.morrell@npl.co.uk (R. Morrell), steve.hughes@morganplc.com (S. Hughes).
[1] Tel. +44 1788 539 240; fax: +44 1788 578 089.

0955-2219/$ – see front matter.
doi:10.1016/j.jeurceramsoc.2006.04.120

Normally, the analysis is performed simulating axisymmetric loading of the ceramic component onto its supporting structure, which is either a tapered metallic stem for a femoral head or an appropriate mount for an acetabular cup. As well as employing the elastic properties of the respective materials, assumptions have to be made concerning the frictional effects incurred in taper embedment and the elastic/plastic properties of metallic contact surfaces[2,3], which may be deliberately textured. Another variable is the small taper angle mismatch between component and metal support. Although such analyses can reveal the general risk of high tensile stresses being introduced, there is always an element of uncertainty, and therefore corroboration has to be obtained through mechanical testing in order to satisfy minimum short-term performance requirements, such as those provided by the US FDA[2,b].

In addition, since the minimum short-term axial strength requirements are set well above the likely forces that can be applied to the system by human bodyweight, the stress distribution in the performance tests is different from that normally obtained *in vivo* as a consequence of different metal contact area. In fact, in explanted heads, the metallic contact region is often demonstrably asymmetric as a result of off-axis body forces being applied earlier in the implant life. Modelling the latter situation is particularly difficult.

2.3. Implementing the design

The manufacture of femoral heads and acetabular cups has to be made with considerable attention to detail. Not only do the articulating surfaces have to be polished to less than a specified roughness (typically $Ra < 0.02\,\mu m$), but they also have to be accurately spherical, and scratch and pore-free. The shaping operations on the head bore or the cup mating surfaces have also to be carefully controlled. In the case of heads, the maximum tensile hoop stress seen in ultimate axial compression strength tests is generally at the bore surface, although in the so-called 'extended neck' designs it may be at the bore mouth, and thus involve also the bore mouth chamfer region. Minimising machining damage in the bore taper is a critical step. In cups, the crown region of the cup is typically placed in biaxial tension by an axial force, while in the designs intended to lock into an external metallic taper, there is also a near axial tensile stress in the cup wall due to axial drag as the taper fit is developed. Similarly, minimising machining damage in these regions is an important process criterion.

Even if the grinding processes in these critical regions can achieve high strength, there is also a need to ensure that other potential fracture origins are eliminated elsewhere. These include microstructural defects such as pores, agglomerates or inclusions, grinding processes applied to other surfaces, and any marking process to identify uniquely the head type and its serial number. Areas particularly at risk are the junctions of machined surfaces which are the easiest to damage. Careful handling of parts is also required to avoid inadvertent contact damage.

2.4. Quality assurance

Quality assurance (QA) checks on these components is particularly important, but often particularly difficult. While scratches on the bearing surface, pits, pores, blemishes and inclusions which are visually obvious can be a clear basis for rejection, grinding damage is often invisible. Fluorescent dye penetration testing has limited value on machined surfaces, since mechanically significant cracks can be very small and closed at the surface. A proof test is often employed, in which the parts are appropriately loaded, *e.g.* femoral heads can be internally pressurised, cups can be directly loaded, to a predetermined level to simulate loading levels seen *in vivo* for a particular design. This process is the only non-destructive route to ensuring that each item has a minimum strength making it fit for purpose at the point of manufacture, although clearly it does not guard against mishandling thereafter.

3. Fractography

Fractography can be an extremely useful part of the process of destructive testing on femoral components[4]. It allows the manufacturer to identify not just the location of the weakest point in the component, but also the nature of the origin and the stress at the point of failure. The information gleaned can be used to modify designs, dimensional tolerances or elements of the manufacturing processes, particularly during development of new designs or concepts. It is also useful as a routine QA tool to check on the consistency of fracture mode.

Fig. 1 shows an example where simple visual fractography of a strength tested acetabular cup reveals a biaxial fracture pattern in the cup central region. Examination of the fracture surfaces shows that the origin is in the flat, ground exterior surface, and is of an extended nature with the focus of the radiating fracture lines lying outside the surface. This type of origin is known as a 'zipper flaw' and is typical of grinding damage. The strength was subsequently improved by use of a modified grinding technique.The explosive failure in ultimate compression fracture force (UCF) testing of femoral heads can sometimes lead to loss of fractographic information. However, usually the fragments are sufficiently intact to reveal clear fracture origins. Fig. 2a shows a typical fracture pattern for a bore fracture origin. The flat region containing the origin is usually normal to the hoop direction and has no compression curl towards the bearing surface, and is thus readily identified. Once the origin region is identified, the detail of the actual origin can then be identified. In the example shown in Fig. 2b and c, the fracture is initiated from a hoop machining flaw. When this starts propagating its plane rapidly rotates into one normal to the hoop direction, and leaves a tell-tale kink which at higher magnification becomes obvious (Fig. 2c). In this particular case it correlates with a particularly intense band of metal marking in the bore, suggesting that the local contact pressure was higher here than elsewhere.

[b] Typically, a minimum mean ultimate axial compression fracture force of 46 kN, survival in an axial fatigue test to a peak force of 14 kN for 10^7 cycles at $R = 0.1$, a minimum post-fatigue axial compression fracture force of 20 kN, and a minimum pull-off force of 1 kN after applying an axial push-on force of 2 kN.

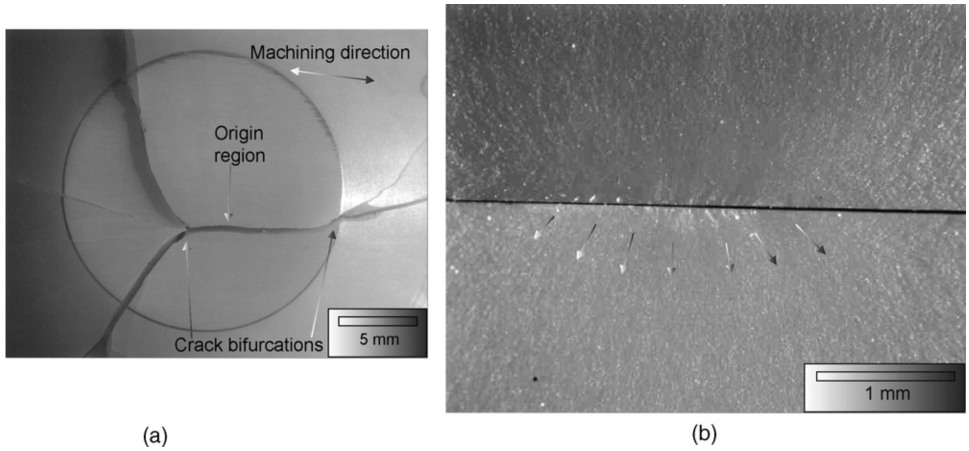

Fig. 1. Ultimate burst test on developmental acetabular cup showing: (a) biaxial fracture pattern in the cup centre viewed from the outside, and (b) external face to face positioned fracture faces showing an extended fracture origin of the 'zipper flaw' type typical of grinding damage.

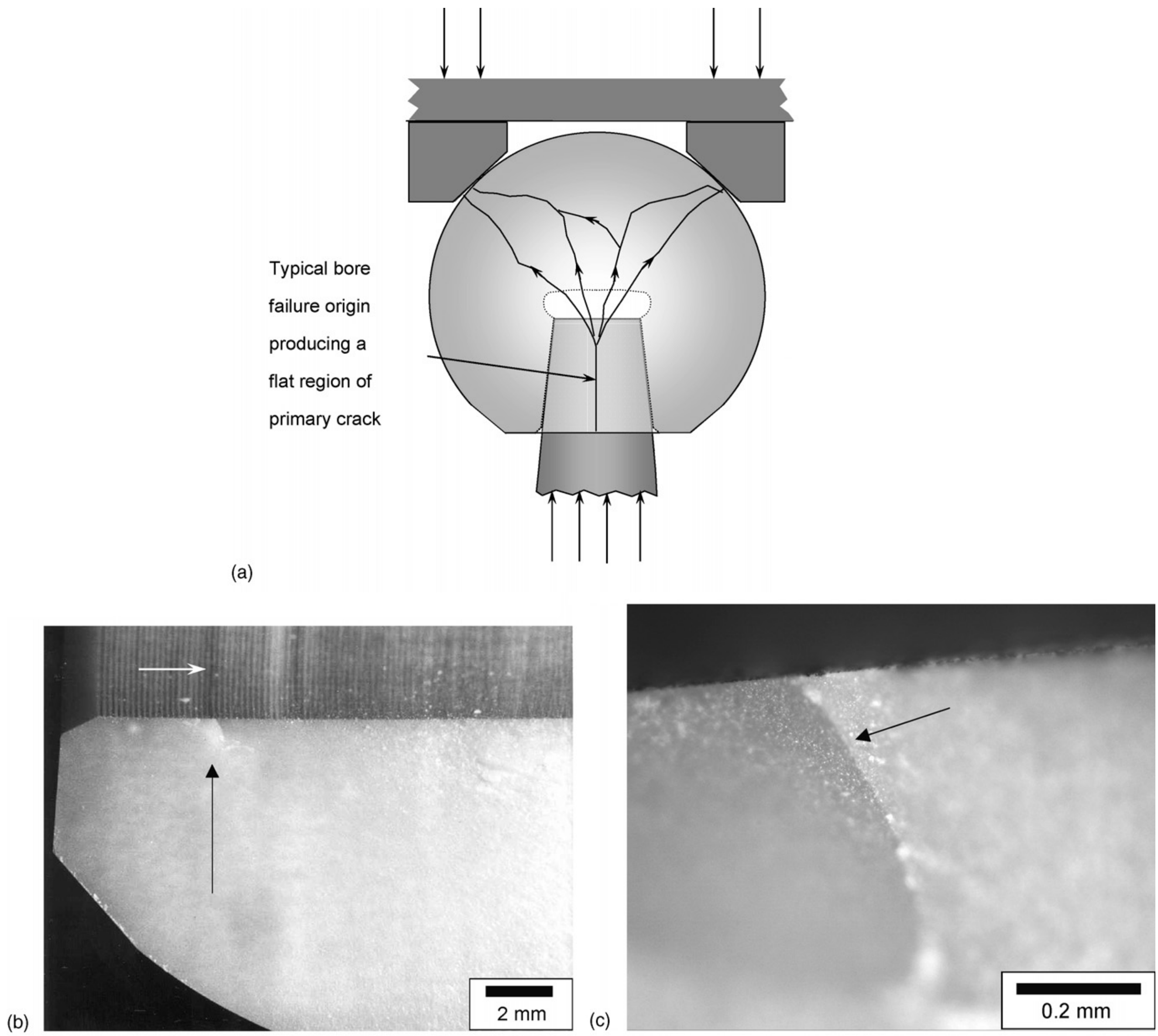

Fig. 2. (a) Typical fracture pattern observed in an ultimate compression strength test (*e.g.* ASTM F2345) on a ceramic femoral head obtained with a bore fracture origin, (b) a fracture origin located in the bore associated with a band of intense metal marking from the metallic stem, and which at higher magnification (c) reveals a hoop ring crack originating from the machining process.

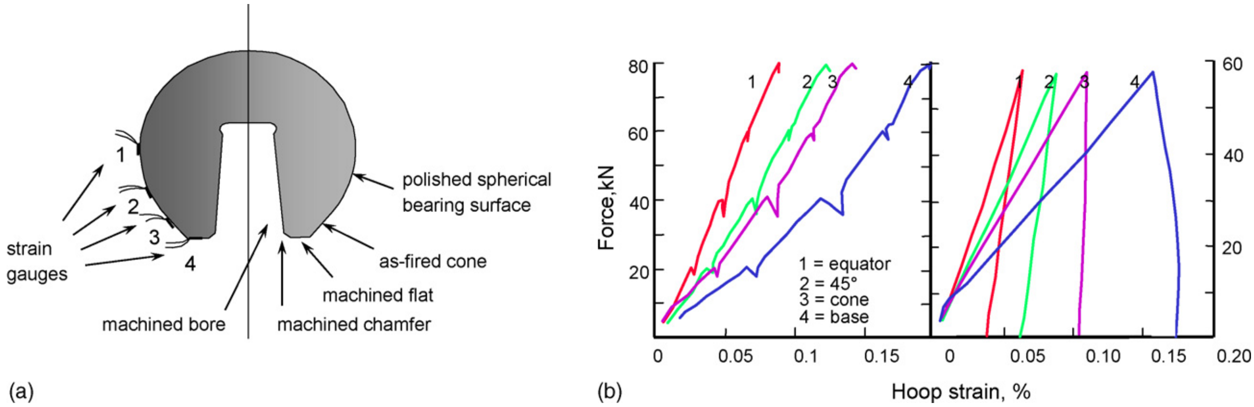

Fig. 3. (a) Strain gauges positioned on the outside of the head; (b, left) load/strain plot for stepwise loading of a head with periods of stress relaxation at each step; (b, right) load/strain plot for a single load/unload cycle to 60 kN.

The fracture stress at the fracture origin σ_f can be estimated from knowledge of the fracture mirror radius r, and the fracture mirror constant A:

$$\sigma_f = \frac{A}{\sqrt{r}}$$

and the ratio of the flaw size a to the mirror size, r, is related to the fracture toughness of the material, K_{Ic}:

$$\frac{a}{r} = \frac{K_{Ic}^2}{A^2 Y^2}$$

where Y is a numerical flaw shape factor typically of the order 1.5. Determination of the fracture mirror constant has to be made using flexural strength test-pieces in which the stress at the origin location can be accurately determined. Once this is known, measurement of fracture mirror size in components can be used to determine whether any apparent poor performance is due to an intrinsic material issue or to an inadequacy in the design (*i.e.* high local stresses with high fracture risk generated by a low applied axial force). An example of such an assessment has been reported elsewhere[4]. In this particular case it was used to demonstrate the weakness of the design, rather than the material being intrinsically weak.

4. Understanding long-term reliability

4.1. Introduction

In FE modelling of geometrical design, many assumptions have to be made concerning the contact condition and elastic/plastic effects in the spigot[3,5] and no account is made for long-term behaviour. In order to investigate experimentally the nature of these stresses, their potential levels and the potential lifetimes under stress of various head/spigot geometries, two series of experiments were initiated in 1993[5] on Zyranox®[c]. In the first series, heads were strain gauged on the spherical surface and forced onto titanium spigots, recording the strains during both loading, unloading and cyclically reloading to progressively higher applied forces. In the second series, following from the behaviour in the first series, heads and spigots loaded to various fractions of the mean ultimate failure load have now been immersed for up to 12 years in simulated body fluid (SBF) at 37 °C, and times to failure have been recorded in comparison with dry controls. Supporting experiments concerning crack growth and zirconia phase analysis have also been made. This paper provides an update to the previously published ones[6].

4.2. Strain gauging of heads

It is only possible to strain gauge the external surface of a femoral head loaded onto the test spigot. This means that the maximum stresses within the ceramic are generally not going to be observed. However, such experiments can be used to determine whether the stresses decline or increase with unloading, and whether the pre-stressing of the head by the single loading schedule remains over a long period of time, or declines due to stress relaxation of the metallic spigot.

Fig. 3a shows typical strain gauging positions that were employed on a variety of head designs. The left side of Fig. 3b shows force versus recorded strain for the four strain gauges as the head is loaded at constant displacement rate in a series of stages with a load relaxation of several minutes between each stage. It is clear that as the force is increased, the process is non-linear, which is due to the deformation of the spigot as it conforms to the elastically distorted head bore. It is also noteworthy that the strain increases a little during load relaxation, more so at the mouth that at the equator. This is reinforced by the test on the right side of Fig. 3b, which shows a single loading to 60 kN, followed by unloading completely. In this case permanent strain is recorded by all strain gauges, and the one nearest the mouth of the head shows an increase in strain on unloading. This type of behaviour is predicted.[3]

4.3. Long-term testing of pre-loaded heads

Four designs of femoral head were selected for this study, as shown in Table 1. Ten examples of each type were subjected

[c] Zyranox® is a registered trade name of Morgan Advanced Ceramics Ltd for an yttria partially stabilised zirconia used for femoral components.

Table 1
Ageing programme

Head type		Short-term UCF, kN, for 10 tests	Survival rate, % after approximately 11.5 years (no. of tests)		
Code	Size, neck length		80% of UCF	60% of UCF	40% of UCF
A1	32 mm, S.D.	122 ± 16	–	86 (22)	-
A2	28 mm, S.D.	97 ± 11	43 (30)	90 (30)	90 (30)
A3	28 mm, +5 mm	84 ± 6	0 (29)*	59 (17)	–
A4	28 mm, −3.5 mm	133 ± 13	44 (18)	80 (30)	100 (18)
A2 (dry)	28 mm, S.D.	97 ± 11	–	100 (30)	-

* 20 failures occur during loading or unloading or before placement in the conditioning tank.

to conventional short-term UCF tests using titanium alloy test stems, and the mean fracture force was determined. Types A1 and A2 are considered to be of 'standard neck' length (contact position of stem central in head), Type A3 is an 'extended neck' type (contact position more towards the mouth), and Type A4 is a 'short neck' design (contact position further into the head). The strengths relate to the tendency of the stress field to intensify near the mouth of the head as the neck is extended.

The remaining heads were loaded onto similar test stems, but only to 80, 60 or 40% of the mean short-term UCF. These levels are well above the force that would normally be applied by the human body, except possibly under trauma conditions. The pre-loaded heads were transferred to individual transparent polythene bottles filled with full strength SBF and sealed. The bottles were tied to trays which were inserted into a large water tank thermostatted at 37 °C, and kept in darkness. Periodically, the bottles were inspected for head failures, which were removed. Some failures occurred before the bottles were placed in the tank. The statistics of failure are shown in Fig. 4 for each design, based on the total number of heads in each batch, including those failing prematurely. Table 1 updates previously reported data at 8 years[6] to the survival level after approximately 11.5 years. The good survivability of the short neck (−3.5 mm) and standard neck designs is clear. The survivability of the extended neck design is, not surprisingly, the lowest, whilst no dry controls have failed.

4.4. Phase transformation

One of the well-known issues associated with 3Y-TZP is the concern surrounding low-temperature phase transformation in humid conditions. There are a large number of publications on this issue, although most concern ageing at temperatures around 200 °C. In a femoral head operating at 37 °C, the process is much slower, and results in the slow formation of small clusters of monoclinic grains on the articulating surface, leading to a small increase in roughness and a slightly increased wear rate against polymer counterfaces. There have also been reports elsewhere of gross transformation over a relatively short timescale causing severe mechanical weakening, but this appears to have been an isolated incidence caused by inappropriate processing.

The work of Chevalier et al.[7], with other work reviewed by Calès et al.[8], demonstrates that surface nucleation and growth of the monoclinic phase occurs in 3Y-TZP following an incubation period that is temperature dependent, and that the Johnson-Mehl-Avrami growth law can be applied to this phenomenon. The fraction surface monoclinic *f* detected by X-ray diffraction after exposure time *t* was well modelled according to the relationship:

$$f = 1 - \exp[-(bt)^n], \quad \text{where } b = A\exp\left(-\frac{Q}{RT}\right)$$

and where experimentally the exponent *n* has a value of about 3 typical of nucleation and growth kinetics, and the activation energy *Q* is 109 kJ/mol, giving a simple measure of the temperature dependence. The constant *A* has a value of approximately $1.1 \times 10^{13}\ s^{-1}$.

Chevalier's work has since been used in ASTM F2345[9], which now proposes that any tendency of zirconia transformation to cause major weakening can be simulated by subjecting sampled heads to steam autoclaving 134 °C for 5 h (2 bar pressure) or boiling water for 15 h, followed by fatigue testing. Extrapolation of the transformation kinetics would suggest that this is equivalent to 10 years at 37 °C in the human body.

Parallel evaluation of surface changes at 37 °C in simulated body fluid (SBF) using X-ray diffraction has been made as part of the present study[6], but in more detail concerning different surface finishing procedures, as shown in Fig. 5. The percentage monoclinic phase on an as-fired surface develops more quickly than on a machined or polished surface. The machining process develops some initial monoclinic phase, while the polished surface shows none. After 8 years, only 10–15% monoclinic is produced on polished or machined surfaces, a range in line with predictions based on Chevalier's higher temperature data.

In order to compare the data from our femoral head ageing tests with the new ASTM F2345 standard, heads of a similar design and strength to those used for the ageing experiments were pre-loaded onto test stems to 40% (55 kN) of the mean short-term ultimate compression strength. They were then subjected to approximately 4 h steam autoclaving, which is equivalent to about 12 years at 37 °C according to our extrapolations based on Chevalier's raw data. The heads were re-loaded as an ultimate compression strength test at room temperature and were compared with a set of six heads of A2 type, 40% pre-load, taken from the ageing tank. The results are shown in Table 2, which

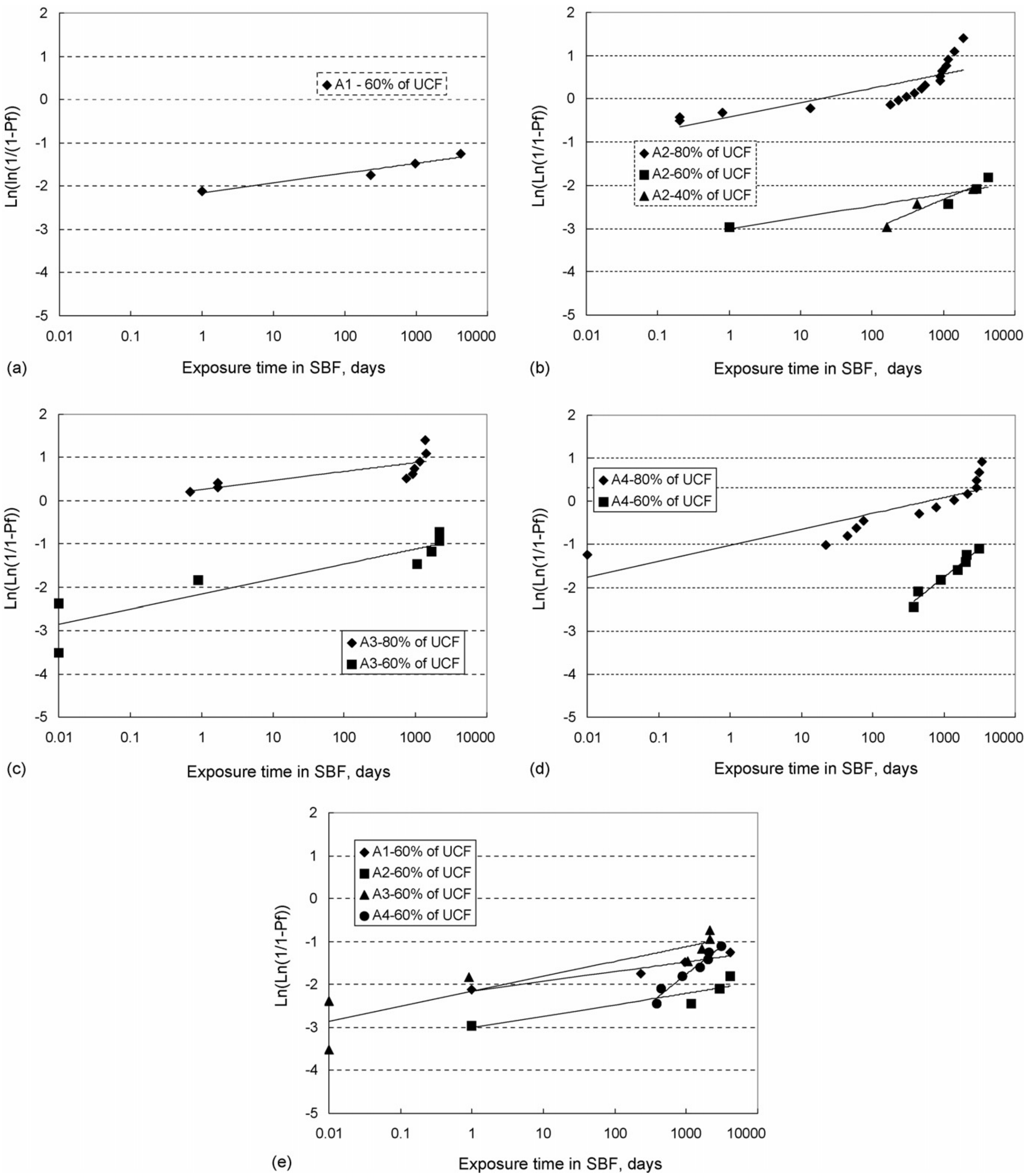

Fig. 4. Failure statistics of pre-loaded heads over 11.5 years exposure in SBF at 37 °C.

demonstrates that there was no diminution of short-term strength as a result of the accelerated ageing under applied stress. Inspection of the reloading force/displacement curves for discontinuity in slope when further plastic deformation of the test stem occurs revealed that the pre-loading had not relaxed significantly either in autoclaving or over 12 years ageing. Furthermore, none of the fractures originated from obvious phase transformation causes. More importantly, it indicates that if a head is inadvertently pre-loaded in implantation, the residual stress will last the life of the implant.

Table 2
Strength after 12 years ageing

	Autoclaved heads, 40% pre-load	Tank-exposed heads, A2 design, 40% pre-load
UCF, as manufactured, kN	138	97 ± 11
Pre-load, kN	55.2	39
Number of tests	7[a]	6
Mean fracture load after ageing, kN	138 ± 25	109 ± 15
Re-loading discontinuity, kN	∼50	∼35

[a] One head failed in autoclaving, fracture origin was a near-bore agglomerate.

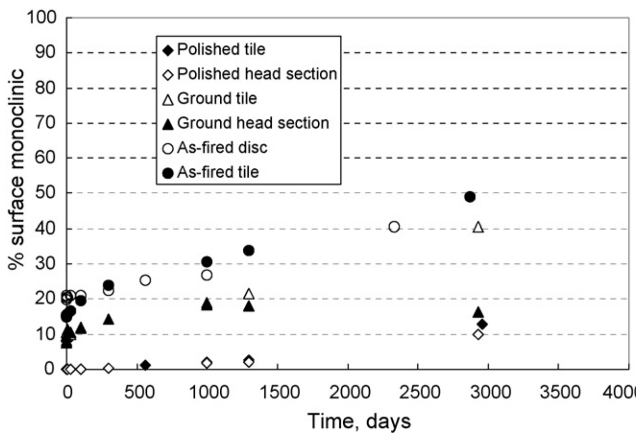

Fig. 5. Surface monoclinic content as a function of exposure time to SBF solution at 37 °C for various surface finishes applied to Zyranox® material.

5. Conclusions

The testing and quality assurance processes involved in the design and production of ceramic femoral head systems have been reviewed. The basic short-term ultimate compression and fatigue testing are minimum requirements to meet design acceptance criteria imposed by regulatory authorities, especially those of the FDA, and combined with fractographic assessment can be used to identify design limits and material and process quality issues.

To support the development of zirconia femoral head systems and to provide better understanding of the risks associated with phase transformation of the tetragonal phase to the monoclinic phase, long-term ageing tests have been undertaken with two aims:

1. To understand the role of surface preparation on the nucleation and growth of surface monoclinic phase.
2. To demonstrate the statistical reliability of heads pre-loaded to well above the axial force levels normally applied by the surgeon or the human body.

These tests, which are now in their 12th year, continue to show that zirconia provides excellent mechanical survivability even though some surface transformation occurs.

Acknowledgements

The authors would like to thank a number of former and current NPL and Morgan staff for their contributions to this work, including Liam Byrne, Jerry Lord and Andrew Gant (NPL), Andrew Pryce, Mark Newman, Michael Murray and Janet Stuart (Morgan).

References

1. Saikko, V., A simulator study of friction in total replacement hip joints. *Proc. I. Mech. E. Part H (J. Engineering in Medicine)*, 1992, **206**(H4), 201–211.
2. US Food and Drugs Administration, 510(k) Guidance Document for the Preparation of Pre-market Notifications For Ceramic Ball HIP Systems. [Website: http://www.fda.gov/cdrh/ode/355.html].
3. Andrisano, A., Dragoni, E. and Strozzi, A., Axisymmetric mechanical analysis of ceramic heads for total hip replacement. *Proc. I. Mech. E. Part H (J. Engineering in Medicine)*, 1990, **204**(H3), 157–167.
4. Morrell, R., Byrne, W. P. and Murray, M., Fractography of ceramic femoral heads. In *Fractography of Ceramics and Glasses, IV; Ceramic Transactions*, *122*, ed. J. R. Varner and G. D. Quinn. America Ceramic Society, Westerville, Ohio, USA, 2001, pp. 253–266.
5. Dragoni, E., Andrisano, A. and Bertuzzi, F., In *Experimental Mechanics*, Clinical aspects of biomedicine, Vol 3., ed. G. E. Little. Elsevier Science Publ. BV, Amsterdam, Netherlands, 1992, pp. 23–34, ISBN 0444905809.
6. Murray, M., Stuart, J. and Morrell, R., Performance evaluation of zirconia femoral heads. Proc. Conf. ‘Engineers and Surgeons – Joined at the Hip’, April 2001. *I. Mech. E.*, 2001.
7. Chevalier, J., Drouin, J. M. and Calès, B., Low-temperature ageing behaviour of zirconia hip joint heads. Bioceramics. *Vol 10*. In *Proc. 10th. Int. Symposium on Ceramics in Medicine, Paris, France, October 1997*, 1997, pp. 9–11.
8. Calès, B., Blaise, L. and Villermaux, F., Improved bearing systems for THP using zirconia ceramic. In *Biomaterials and Bioengineering Handbook*, ed. D. L. Wise. Marcel Dekker Inc., 2000, Chapter 21, pp. 483–508.
9. ASTM F2345-03, Standard test methods for determination of static and cyclic strength or fatigue of ceramic modular femoral heads.