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Fatigue of biomaterials: a review

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Abstract

Fatigue fracture and wear have been identified as some of the major problems associated with implant failure of medical devices. The actual in vivo mechanisms are complex and involve the hostile body environment. The response of the host tissue to wear debris is a real issue. Fatigue-wear corrosion and environmental stress cracking are common. Although fatigue fracture and wear are frequently reported in orthopaedic applications such as hip joint prostheses, they can be fatal in mechanical heart valves. While it is not possible to avoid failure, recent work has focused on predictive tools to enable more accurate prediction so as to avoid catastrophic failure in vivo. This paper presents an overview of fatigue fracture problems in metallic, polymeric and ceramic implant materials, looks at some recent techniques of testing and discusses the future development of fracture and wear resistant biomaterials.

Keywords: Fatigue; Biomaterials; Wear debris; Host tissue reaction; Fatigue and wear resistant

1. Introduction

Fatigue fracture and wear have been identified as some of the major problems associated with implant loosening, stress-shielding and ultimate implant failure [1]. Although wear is commonly reported in orthopaedic applications such as knee [2] and hip joint [3] prostheses, it is also a serious and often fatal experience in mechanical heart valves [4]. Fig. 1 illustrates some examples of fatigue fracture of implant devices in the hip prosthesis and a mechanical heart valve. It can be seen that fatigue-wear interaction plays a significant role in ultimate failure of these medical devices. The acetabular cup made of ultra-high molecular weight polyethylene (UHMWPE) has been worn so severely that it fractured in a brittle manner. This was in spite of its relatively high initial fracture toughness in the order of 2 MPa$\sqrt{m}$. The cast cobalt chrome femoral stem has fatigue fractured at its lower proximity. The polyacetal occluder of the tilting disk heart valve shows a deep wear groove as a result of the repetitive impact-cum-sliding motion it made with the upper metallic strut.

The selection of biomaterials for wear resistance unfortunately cannot rely only on conventional thinking of using hard ceramics because of their low coefficient of friction and high modulus of elasticity. This is because ceramics are generally prone to brittle fracture (having a fracture toughness typically less than 1 MPa$\sqrt{m}$) and need absolute quality control to avoid fatigue fracture for medical device applications. The development of fatigue fracture and wear resistant biomaterials looks into the biocomposites of two or more different phases such as in interpenetrating network composites. The concept of multiphase biomedical materials has been addressed [5]. The advantage of these composites is that one can incorporate controlled drug release chemicals, friction modifiers, different morphologies to enable better host–implant performance and chemical entities to reduce or aid removal of wear debris. Of equal importance are the tools developed to predict fatigue fracture/wear using new methodologies involving in vitro tests, computational modelling to obtain design stresses and fracture/wear maps to identify mechanisms.

The aim of the present review is to present some phenomenological observations on fatigue failure of biomaterials and methods of evaluation, and to project the future advances in biomaterials engineering in order to develop fracture and wear resistant biomaterials that are more friendly to the host tissue. One way ahead is to

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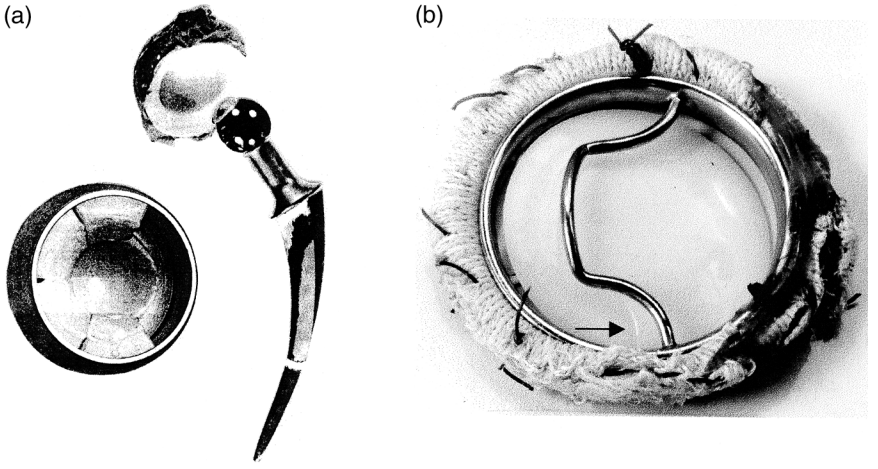

Fig. 1. Some examples of fatigue failure of medical devices: (a) hip prosthesis; (b) explanted Björk–Shiley polyacetal disc mechanical heart valve (arrow indicates fatigue-wear mark).

look at examples of biological systems such as seashells, which have unique microstructural features in nanoscale, to overcome the adverse effect of the wear debris on the environment as well as to be fracture and wear resistant. By no means are the references cited exhaustive, but sufficient to focus on the main issues in fatigue of biomaterials. An important topic of intensive research is on the host-tissue response to the wear debris or fracture fragments and the by-products that are generated during the fatigue process.

1.1. Host-tissue response

One of the main reasons for concern about fatigue of biomaterials, arises from the adverse host-tissue response to wear debris generated by the fatigue process. This appears to be a natural defence mechanism of the body. The wear debris often invokes an inflammatory and immunological response. This in turn causes blood clotting processes, leukocytes, macrophages and, for severe cases, giant cells to move in on the foreign wear particles resulting in interfacial problems between the implant and the host tissue. Numerous biochemical activities occur at this stage. These include a change in the local environment to a highly acidic one (pH less than 3). In general, assuming that the wear debris is non-toxic, there are three scenarios: (i) the cells will try to digest the foreign debris by releasing chemicals and enzymes to dissolve and later absorb them so that the by-products can be eliminated through the blood circulation and lymphatic system into the various organs such as the kidney and liver; if this fails then (ii) the body will try to excrete them out of the body system (in the case of fatigue wear in the oral cavity such as wear products from dental biomaterials during the chewing process, the wear products are easily flushed out through the digestive system and are therefore less of a concern compared to other implant materials); however, if (i) and (ii) cannot be achieved, then (iii) cellular fibrous linings will engulf the foreign bodies so as to keep them away (isolate) from the surrounding host tissue. The last scenario is of great concern as the interfacial strength between the implant and the host tissue will drop drastically giving rise to micro-motion and hence fretting fatigue corrosion failure. The mechanisms of actual in vivo fatigue wear are complex and numerous books have been written on the subject [6,7]. These mechanisms involve the surface chemistry of the biomaterial, the size, shape and surface-to-volume ratio of the wear debris, and the extremely hostile body environment which may contain oxygenated fluid, proteins, enzymes, bacteria, and serum that cause the biomaterial to fail, often under environmental stress cracking. The morphology (size and shape) of the wear particles may have a major effect on the biological response. A unified nomenclature has now been made (ASTM F1877-98) to aid interpretation of biological tests of responses to particles. This will facilitate separation of biological responses associated with shape from those associated with the chemical composition of debris.

In order to understand the fatigue failure of biomaterials it will be essential to have some understanding of the surface substructure of biomaterials. Fig. 2 shows a schematic picture of the cross-section of a deformed metallic biomaterial surface, surrounded in a physiological environment. Illustrated here are three distinguishable layers, namely (1) the molecular absorbed layer, (2) the passive oxide film, and (3) the deformed layer. How these layers interact with the physiological environment during the fatigue-wear process is of paramount importance to the behaviour of the biomaterial and the long-term fatigue performance of the medical device. Fig. 3 shows schematically the various types of surface and subsurface damage that are exhibited by different materials under a spherical indentor. Type I behaviour is typical of metallic materials having a high fracture

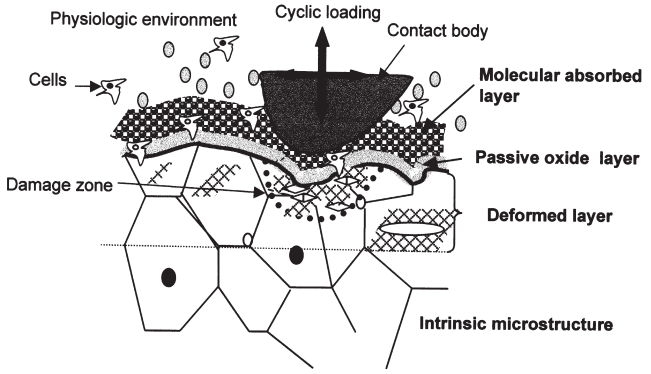

Fig. 2. Schematic illustration of a cross-section of a deformed metallic biomaterial surface showing the complex interactions between the material's surface and the physiologic environment.

toughness and high ductility. A plastic zone with build-up of material around the indentor is obvious. Type II behaviour is typical of brittle material with high yield strength but low fracture toughness (such as in some bioceramics). The damage zone beneath the indentor is basically elastic and a cone crack forms near the perimeter of the indentor. Type III behaviour is quasi-brittle and is typical of materials with moderate toughness and yield strength. Mirco-cracking is often observed in the damage zone. Numerous dental restorative materials exhibit this type of behaviour under repeated impact loading [8].

Though it is beyond the scope of the present review, it is sufficient to mention that the majority of the tissue–implant activities occur in the surface and subsurface layers, which may lead to the formation of an aqueous sandwich layer of biological components to establish a good bond between the host tissue and the biomaterial. It is here that the host tissue interacts with the implant and if it is not biocompatible then an avalanche of biochemical reactions occur. However, the molecular absorbed layer is dependent on the underlying passive oxide layer, which protects the base material from corrosion. If the deformed layer has a high compressive stress field (for instance, in the case of forged stainless steel), the incident of crack initiation is reduced and hence the fatigue strength of the material is increased. One can readily see that the process of removal of these layers (by wear) can greatly affect the fatigue of biomaterials.

1.2. Methods of fatigue evaluation of biomaterials

The current fatigue tests used to evaluate biomaterials can be categorised as follows:

1. Stress/life (S/N) approach,
2. Fracture mechanics approach, and
3. Fatigue-wear approach using simulated physiologic multi-axial loading.

The first two methods are used primarily for the materials screening process and are useful for the initial process of materials selection of implant materials that will be subjected to high cyclic loading conditions (for example, for orthopaedic implant applications). The third method is considered to be an in vitro evaluation to determine the fatigue performance close to a physiologic environment and is normally a precursor to animal experiments. The first two approaches are seen to be less expensive. The third approach is costly as dedicated custom-made simulators need to be used. As simulators vary in design, comparisons of results can be difficult.

The S/N approach is normally done using smooth specimens in a physiologic environment either in (a) cyclic loading (especially for metals) or (b) static loading (especially for polymers). The advantage of this approach is that it represents both initiation and propagation of cracks in the aggressive environment. In the case of metallic implant biomaterials, it allows the electrochemical effects to be considered together with an applied stress–strain field (especially in fretting corrosion fatigue experiments) in the assessment of the durability of the biomaterial. The design stresses rely on the accuracy of the endurance stresses, which need large safety factors and good failure models for prediction.

In the fracture mechanics approach, the fatigue-crack propagation of the biomaterials are studied by (a) long cracks (>3 mm) using compact-tension specimens or (b) small cracks (1–250 μm) using micro indentation

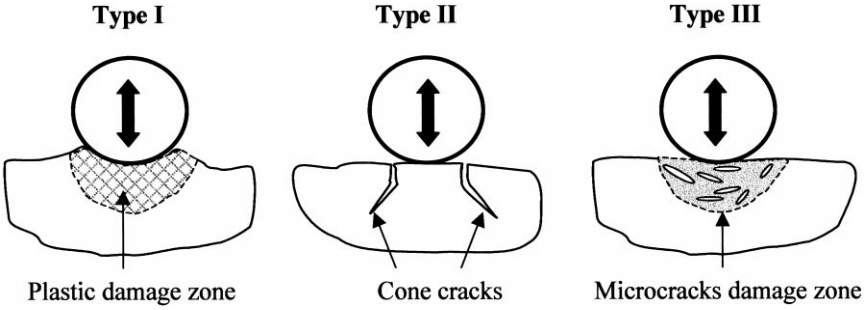

Fig. 3. Schematic illustration of the various types of surface and subsurface damage arising from a spherical indentor.

methods in a servo-hydraulic machine. This approach, often done in a physiologic environment, is good for studying brittle implant materials like ceramics [9,10] and dental composites [8,11], where sensitivity to initial flaw sizes and crack propagation rates determine the lifetime of the implant. The Paris power-law relationship [12]:

$$da/dN = C(\Delta K)^m \quad (1)$$

where C and m are constants and ΔK is the stress intensity range, is normally used for the lifetime prediction. The range of stress intensity factor could be represented by a general equation of the form:

$$\Delta K = Y(\Delta\sigma)(\pi a)^{1/2} \quad (2)$$

where Y is a geometry function and a is the crack length. Combining Eqs. (1) and (2) gives:

$$da/dN = C\{Y(\Delta\sigma)(\pi a)^{1/2}\}^m \quad (3)$$

By integrating Eq. (3) the fatigue lifetime prediction of brittle biomaterials can be written as:

$$\int_0^{N_f} dN = \int_{a_i}^{a_f} \frac{1}{YC(\Delta\sigma)^m \pi^{m/2} a^{m/2}} da \quad (4)$$

where N_f is the total number of cycles for failure, a_i is the initial crack length and a_f is the crack length just before catastrophic failure (this can be estimated by performing conventional fracture toughness tests and using the relationship $K_{IC} = Y\sigma\sqrt{(\pi a_f)}$ to determine the value for a_f for a given value of K_{IC} and applied stress, σ). Since Y is a function of geometry and crack length, the solution to Eq. (4) in the determination of the initial crack length for a given life cycle is best done by numerical solutions. Such a solution will be useful for lifetime prediction of brittle biomaterials. It must be stated that there often is no direct relationship between fatigue resistance and wear performance. However, in some cases, such as dental composites, it has been found that for materials that suffer micro-cracking in the subsurface layer, a high fatigue threshold stress intensity factor and K_{IC} give some correlation to a higher wear resistance [13].

The fatigue-wear approach on smooth specimens is an important contribution as the rate of removal of a passive oxide or molecular absorbed layer between the two articulating surfaces often determines the accuracy of the lifetime prediction and provides cytotoxicity and morphology data of wear debris for evaluating the host-tissue response to the debris. Physiologic loading using a multi-axial load profile is normally applied throughout the fatigue tests. These are more realistic comparative tests than basic wear screening tests, such as pin-on-disk (ASTM F732) or ISO 6474. The frequency and applied pressure need to be considered carefully. Too high a frequency leads to fatigue-wear mechanisms not normally found in vivo. Over the years, numerous dedicated machines such as the hip wear simulator [14] and the accelerated heart valve tester [15], to quote two, have been used. If the actual in vivo wear characteristics can be reproduced in the in vitro experiments in terms of the environment and mode of deformation, then in vitro experiments can prove to be very useful in cost and also in elucidating the actual wear mechanisms.

Apart from the above-mentioned general approaches, over the years numerous specific standard fatigue tests on surgical implant materials and devices have been documented. Some of these are summarised in Table 1. Fatigue testing of porous coatings on metal substrates and spinal instrumentation appear to be a growing demand and challenge. The ISO TC 150 is also compiling other fatigue test methods, especially in coming to a unified approach for hip and knee fatigue-wear testing. It is noteworthy to mention that some brittle materials have microstructural uniqueness, which increases the crack propagation resistance at longer crack lengths giving an R-curve behaviour. R is commonly referred to as the material resistance to crack propagation and gives an indication as to whether a crack is stable or unstable. Variation in the R-curve often indicates that the local material properties varied in position. A material with a rising R-curve cannot be uniquely characterised by a single fracture toughness value and often may be associated with growth and coalescence of microvoids. In this case, the fracture mechanics approach based on K_{IC} will not be useful [8]. For example, Cai et al. [16] found that R-curve and non-R-curve ceramics have strengths that are dependent differently on flaw sizes. The base glass is

Table 1
Specific fatigue testing of surgical implant materials and devices (after ASTM, vol. 13.01: Medical devices, 1999)

Fatigue tests	ASTM ref.
Practice for cyclic fatigue testing of metallic stemmed hip arthroplasty femoral components without torsion	F 1440-92
Test method for bending and shear fatigue testing of calcium phosphate coatings on solid metallic substrates	F 1659-95
Test method for constant amplitude bending fatigue tests of metallic bone staples	F 1539-95
Test methods for static and fatigue for spinal implant constructs in a corpectomy model	F 1717-96
Guide for evaluating the static and fatigue properties of interconnection mechanisms and subassemblies used in spinal artrodesis implants	F 1798-97
Practice for corrosion fatigue testing of metallic implant materials	F 1801-97
Test method for cyclic fatigue testing of metal tibial tray components of total knee joint replacements	F 1800-97
Practice for constant stress amplitude fatigue testing of porous metal-coated metallic materials	F 1160-98

stronger than the glass ceramic if the specimens are polished, but this strength ranking reverses for specimens with a moderately damaged surface. *R*-curve materials generally are less resistant to wear (assuming that wear is predominantly due to short cracks) when compared to damage tolerant materials (a long crack phenomenon) [17]. Another point to note is that fatigue analysis should not just be made on strength data alone, but also on a probabilistic (statistical) approach (over a volume or surface) such as using the Weibull failure model [18]. Such an approach can give insight as to why four-point bend strengths are normally lower than three-point bend tests. The latter configuration concentrates over a very small surface area compared to the former. For the same argument, uniaxial tests generally yield even lower strength values because a larger volume of material and hence a greater probability of encountering larger cracks are involved. Therefore, the laboratory approaches (in vitro experiments) to fatigue evaluation of biomaterials must be studied with care so that appropriate corrective measures can be made when trying to extrapolate to in vivo situations.

2. Fatigue of biomaterials

2.1. Metallic implants

Metal fatigue has been extensively studied [19–21]. The fatigue strengths of common metallic implant alloys used in hip replacements such as stainless steel, cobalt chrome and titanium, and their relationship to their microstructures, surface and corrosion properties have been reported [22]. The fatigue strengths of metallic biomaterials have also been well documented in a recent biomaterials handbook [23]. Fig. 4 shows the fatigue strength (in air) of some common implant alloys using the S/N approach. It is of interest to note the importance of post processing treatment such as forging, which introduces compressive surface stresses. It can be seen that forged 316L stainless steel and forged cobalt–chromium have significant fatigue strengths over the cast components. The use of hot isostatic pressing (HIP) which introduces fine microstructures also has a pronounced improvement [24]. The strength of the leg and arm bones is in the range of 100–200 MPa, the skull is about 97 MPa and that of the vertebral bodies is 1–10 MPa [25]. It can be seen that the majority of these alloys (especially the HIP cobalt–chromium and titanium alloys) have fatigue strengths in excess of 500 MPa (in air) and hence have been deemed to be good for orthopaedic implant applications such as those for the leg and arms.

The S/N approach has been used in a simulated body fluid environment with electrochemical and fretting devices incorporated. The combined mechanical and chemical processes play a vital role in crack initiation [26]. The inability to repassivate quickly causes the electrochemical breakdown of the surface layers. Fig. 5 shows schematically how the formation of slip planes can break through the protective oxide film during fatigue. This exposes immediately unprotected regions for corrosion. It is interesting to note the work of Taira and Lautenschlager [27] who studied the in vitro corrosion fatigue of 316L cold worked stainless steel and found that the monitoring of corrosion current could give a clear indication of crack initiation which otherwise would have been missed. They have also shown that by applying 200 mV to the surface of the metal so that passivation of the oxide layers is suppressed, a significant drop in fatigue strength, in the order of 150 MPa, is observed (Fig. 6).

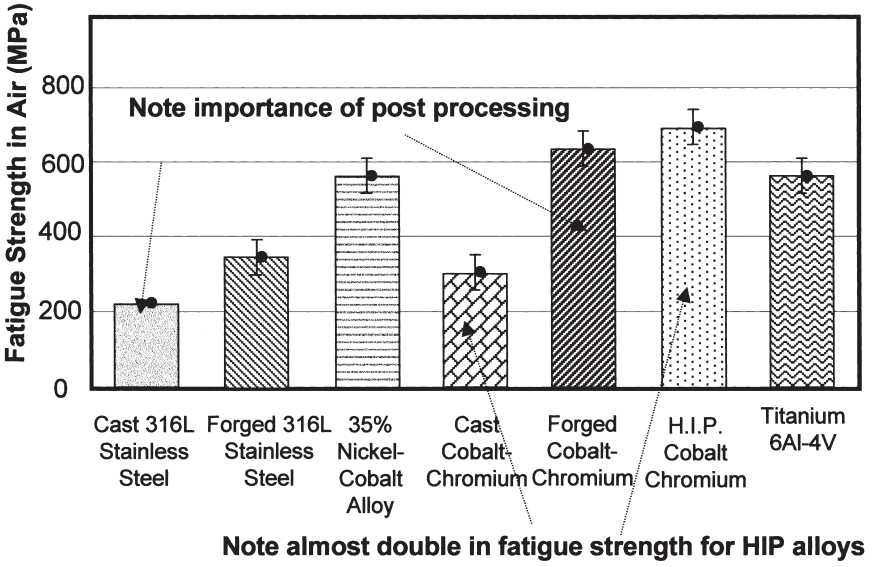

Fig. 4. Fatigue strength of some common implant alloys.

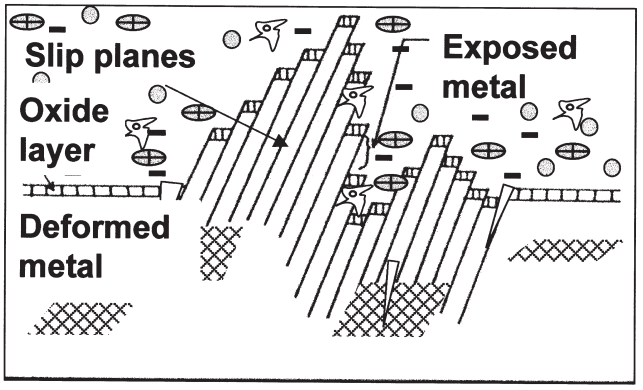

Fig. 5. Schematic illustration of the formation of fresh slip planes in a body fluid environment during fatigue, exposing unprotected regions to electrochemical and biological activities.

Fretting fatigue of implant alloys based on the S/N approach has been studied [28]. In titanium implants, wear debris has given rise to blackening of surrounding tissue. Wear particles also cause implant loosening giving rise to severe 3 body wear. Fretting fatigue is essentially a micromotion phenomenon and often occurs at interfaces such as between the metal and the cement in the case of a hip prosthesis. This can result in a drastic reduction in fatigue strength. The fretting fatigue experiment in simulated body fluid is illustrated in Fig. 7 for Ti6Al4V. The plain fatigue performance in air at 20 Hz and in pseudo-body fluid (PBS) at 2 Hz seems to be the same. This is understood to be due to the ability of the titanium alloy to undergo rapid passivation. However, when fretting is carried out (artificially removing the oxide layer faster than repassivation can occur), a drastic drop of more than 150 MPa in the fatigue endurance stress limit is noted. Referring to Fig. 2, one can then appreciate the value of the oxide protective layer in the fatigue of biomaterials. What is even more critical is the reported cytotoxicity of the debris collected, with concentrations as low as 10 ppb. This will invoke the host–tissue reactions, which further aggravates the biomaterial–tissue interface. It becomes apparent that the need for good fixation of implants, a surgical procedure not related to the material behaviour alone, becomes very important for long-term fatigue performance of medical devices.

2.2. Polymeric implants

In polymers the conventional S/N method using cyclic fatigue machines for determining the endurance stress limit faces two main difficulties. First, because of the low thermal conductivity of polymers, the limits obtained by fatigue experiments is not representative of actual durability of the material as the mechanism of failure is associated with localized thermal fatigue. Long-term failure of polymers is associated with environmental stress cracking and aging mechanisms. Second, the economics of conducting low cycle fatigue

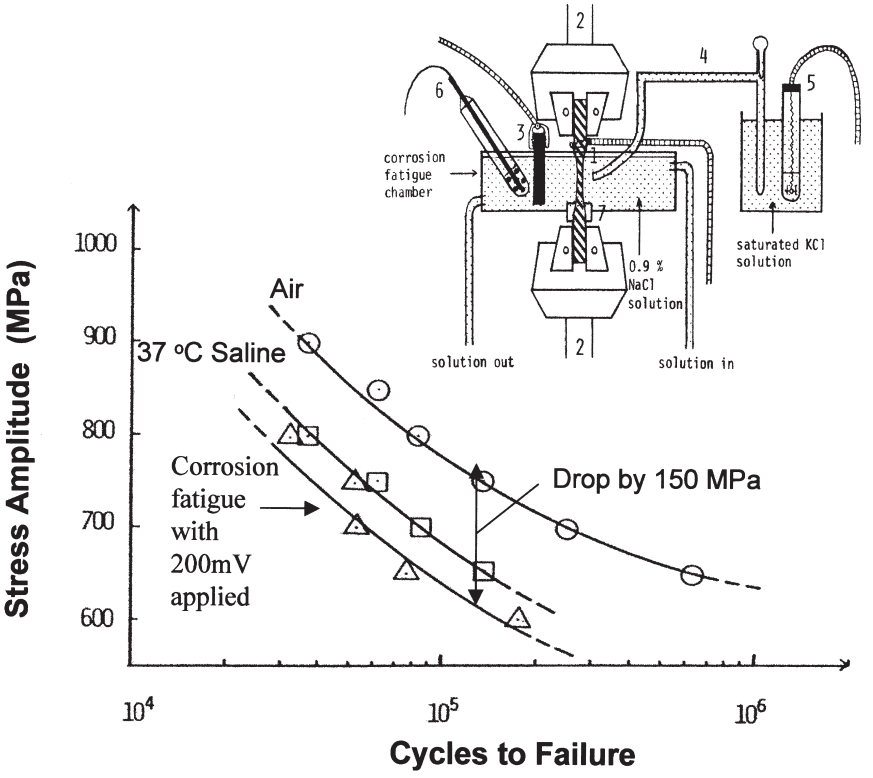

Fig. 6. Corrosion fatigue of 316L cold worked stainless steel (after Taira and Lautenschlager [27]).

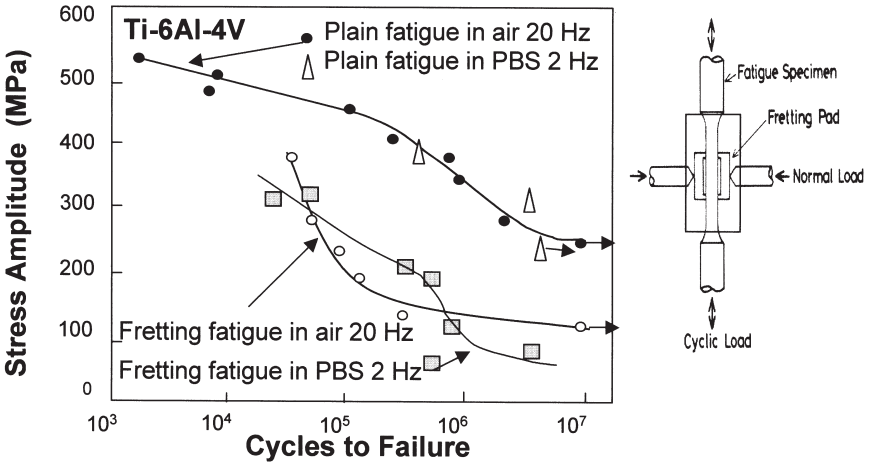

Fig. 7. Fretting fatigue in PBS environment of Ti6Al4V (after Yamamoto et al. [28]).

experiments, especially in a simulated physiological environment (such as in saline and cholesterol lipid solution for medical plastics) is too high. Failure by a creep related fracture process is of primary importance in engineering polymers. In fact, some researchers have termed such tests as static fatigue experiments. Previous work [29–32] has shown that the lower stress limits of many polymers can be obtained by non-linear computational modelling of the creep rupture time using a three-element mechanical model having a rate activated dashpot to simulate plastic flow, in conjunction with a critical elastic energy criterion. The model equation relating to the life span (t_f) of the material, can be written as:

$$\ln t_f = \ln\{1/(C'B)\ \ln(\tanh[B\sigma_{ap}/2]/\tanh[BH/2])\} \quad (5)$$

where C' is the constant related to the activation energy, B is the constant related to the activation volume, $H=\sigma_{ap}-[2E_a(R-\sigma_{ap}^2/E_e)]^{1/2}$, E_a is the anelastic modulus, E_e is the elastic modulus, R is the resilience of the material (defined as the maximum elastic stored energy before failure), and σ_{ap} is the applied stress. It can be seen that when the applied stress reaches $[E_eR]^{1/2}$, immediate fracture occurs and when it approaches $\{R/[1/E_e+1/(2E_a)]\}^{1/2}$, the material sustains the load indefinitely.

Eq. (5), which can best be solved by computational non-linear regression analysis, therefore defines two important limits, the upper stress limit (SX) and the lower stress limit (SN). The SN values at room temperature for a number of polymers such as polyacetal have been shown to correspond to the endurance stress limits obtained by a conventional fatigue tester. Fig. 8 shows some examples of the fit of Eq. (5) to a number of polymers at 37°C in saline solution. Good fits can be observed in all cases. Table 2 shows the results from an earlier work [32] on prediction of the lower stress limits of some medical plastics at 20°C. Results for UHMWPE and polyacetal showed that the lower stress limits were no more than 12 MPa, in saline solution, 37°C. This may well account for the current problems in wear debris formation and failure of the acetabular UHMWPE cup used in many hip joint prostheses where the contact stresses can exceed 30 MPa. Other new potential medical plastics such as polyethyletherkethone (PEEK) and polysulphone have also been modelled giving SN values of 75 and 45 MPa, respectively. These values are much higher than polyethylene and may be more suitable for implant applications where high bearing stresses are concerned. However polysulphone, being amorphous, has been shown [33] to be poor in wear resistance.

Fatigue fracture and wear of polymeric materials used in implants are perhaps the most difficult to understand and over the years numerous reports have resulted. In biomedical applications such as occluders in mechanical heart valves and joint prostheses, fatigue fracture and wear of the polymers have been considered to be an important factor in determining the durability of the prostheses. Factors influencing the wear properties of UHMWPE, which has been used in many hip joint prostheses, were examined by Trainor and Haward [34]. Their results indicated that a significant improvement in wear (using a pin on plate or a rotating shaft on plate system in a medium of distilled water) behaviour was obtained by moulding the UHMWPE between 190 and 200°C. The addition of some antioxidants also appeared to improve the wear resistance. Moulding at higher pressures and increasing the molecular weight were reported to be detrimental. Nonetheless, there is a possibility that there could be an optimum processing condition and molecular weight distribution that could give the best wear characteristics. More recent work [35] has shown that processing conditions play a vital role in the cyclic fatigue of UHMWPE. In particular γ-radiation and oxidative ageing are very detrimental to the fatigue threshold and crack propagation resistance (Table 3). Compression moulding appears to give a better fatigue resistance when compared to extrusion.

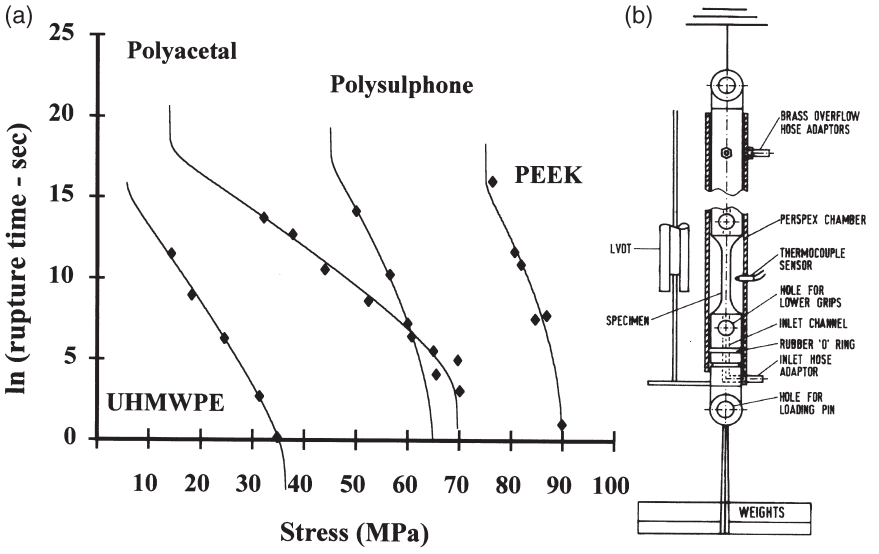

Fig. 8. (a) Creep rupture modelling of some medical plastics; (b) experimental set-up for creep rupture testing in a saline solution environment.

Table 2
Lower stress limits at 20°C of some medical plastics as estimated by Eq. (5) (after Teoh [32])

Plastics	Lower stress limit (MPa)
Polyacetal	30
Polycarbonate	47
Polyethylene	8
Polymethylmetacrylate	34
Polypropylene	10
Polysulphone	42
Polyvinyl chloride	35

Table 3
Effect of processing condition on the fatigue threshold (ΔK_{th}) of UHMWPE (after Pruitt and Bailey [35])

Condition	ΔK_{th}
Compression molded	1.8
Compression molded γ-air	1.2
Extruded 90°	1.7
Extruded 0° non-sterilised	1.3
Extruded 0° γ-air	1.0
Extruded 0° γ-peroxide	1.1

Extensive work has been carried out to study the wear and degradation of retrieved polymeric implants [36]. This interesting piece of work examined 30 implants ranging from UHMWPE to silicone occluders. Wear mechanisms related to abrasive wear and environmental stress cracking of the incompletely sintered UHMWPE powder were reported. For polymeric valve occluders, abrasive wear was predominant. Such conclusions were also reported for polyacetal [37]. In an examination of an explanted valve (Björk–Shiley polyacetal disc mechanical heart valve) which had been in a patient for more than 17 years, abrasive and static wear marks, arising from plastic deformation and surface material flow and polymer debris adhesion on the metallic struts, were observed. The work by Clarke and McKellop [38] should also be mentioned. They compared the wear of polyacetal with UHMWPE, polyester and Teflon (PTFE). A pin (polymer)-on-disc (316 stainless steel) in bovine serum solution was used. Their results indicated that polyacetal, polyester and PTFE wear 60, 2576 and 4986 times more than UHMWPE, respectively. In recent studies on total knee joint prostheses, it has been shown that UHMWPE debris can contribute to implant loosening [1,2]. The UHMWPE debris can migrate down from the bulk component to the bone–cement or bone–implant interface and provoke a host response resulting in bone resorption.

It has been noted that many accelerated fatigue testers could not reproduce the in vivo performance and caution needs to be exercised when interpreting the results, especially for heart valves. In the case of mechanical heart valves with a single tilting disc design, Teoh et al. [33] have noted that the in vivo loading consists of an impact-cum-sliding action and proposed a new impact-cum-sliding accelerated wear test to evaluate polyacetal, UHMWPE, polysuphone and PEEK as materials for the occluder. This is a much simpler and more cost-effective method. Their results are summarised in Figs. 9 and 10. On the basis of wear depth and debris morphology, polyacetal was concluded to be better than UHMWPE because the debris size of UHMWPE was large (>100 μm) compared to that of polyacetal (about 30 μm), even though polyacetal was ranked second after UHMWPE in wear depth penetration. The large debris morphology was deemed unacceptable in cardiovascular applications.

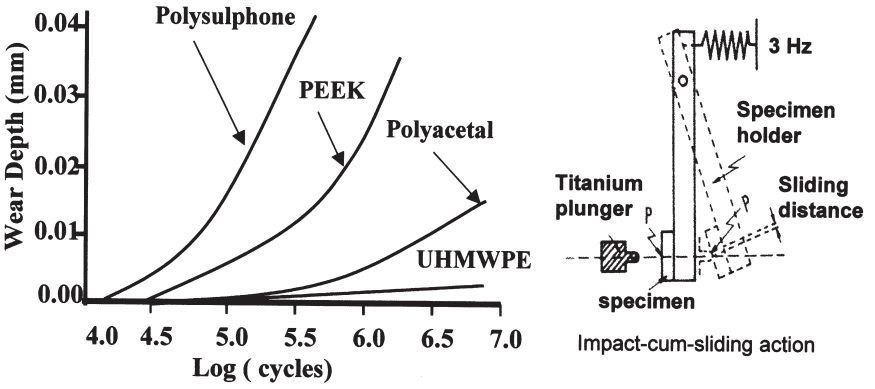

Fig. 9. Wear depth of polyacetal, UHMWPE, polysuphone and PEEK subjected to an impact-cum-sliding action (after Teoh et al. [33]).

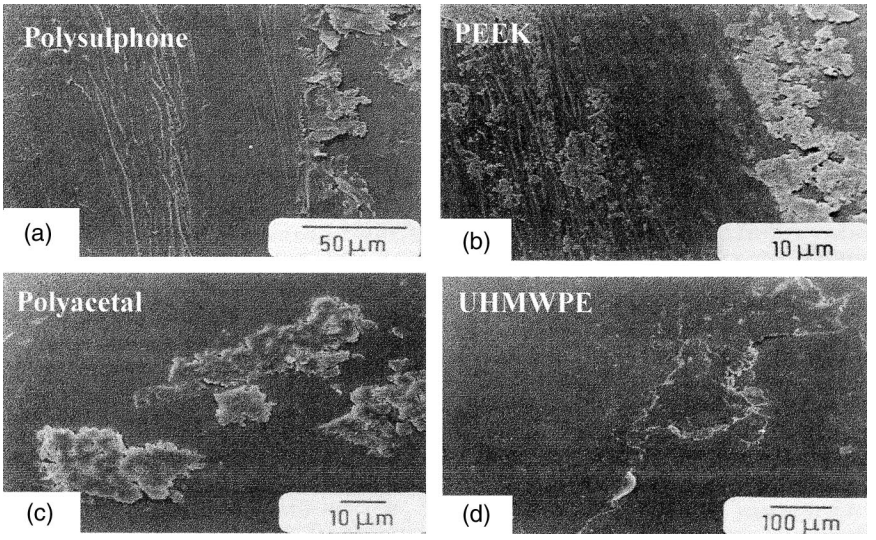

Fig. 10. Scanning electron micrographs of (a) polysuphone, (b) PEEK, (c) polyacetal, and (d) UHMWPE subjected to an impact-cum-sliding action (after Teoh et al. [33]).

To ascertain the stress magnitude at the stress concentration areas, Teoh et al. [39] also carried out in vitro strain measurements on a St Vincent's mechanical heart valve in a pulse simulator. Results were combined with a finite element (FEM) stress analysis of the titanium valve housing. The imposed stress on the occluder by the upper strut was less than 2 MPa. This is below the lower stress limit of polyacetal (5 MPa [29]) and may explain why no fracture of the polyacetal disk occluder has been reported. (It needs to be emphasised that the mechanical polishing of the polyacetal occluder introduces compressive surfaces stresses, which further enhances the fatigue and wear resistance of the occluder.) This may explain why polyacetal used in the artificial hip joint prostheses [40] where the contact stresses exceed this limit was known to wear severely and failed by fatigue.

2.3. Ceramic implants

Ceramic materials for implants fall under two main categories, namely, (a) bioactive (such as calcium phosphate, glass-ceramic (Cerabone®) and hydroxyapatite, and (b) bioinert (such as pyrolytic carbon, alumina and zirconia). The bioactive materials are extensively used as coatings on metallic implants as they promote rapid bone growth (osseointegration). These are normally not used directly as load bearing elements and have low fracture toughness of about 0.5–1 MPa$\sqrt{m}$. However, the glass-ceramic implants like Cerabone® and Ilmaplant® can have higher fracture toughness of 2–2.5 MPa$\sqrt{m}$ [41,42]; in these cases the fatigue problems are therefore usually related to fatigue at interfaces. The bioinert ceramics have a higher fracture toughness. For example, alumina has a fracture toughness of about 4–5 MPa$\sqrt{m}$

and zirconia about 6–15 MPa√m [43]. Because of the low fracture toughness, alumina hip balls are restricted in size to greater than 28 mm. Zirconia, on the other hand has a higher fracture toughness, but suffers from potential biodegradation and radiation. Table 4 summarises the fracture toughness of some common bioceramics.

One of the most studied bioinert ceramic implants is the pyrolytic carbon used in mechanical heart valves. Many pyrocarbon heart valves have been successfully implanted. However, more than 40 recent structural failures due to cyclic fatigue have been reported [4]. The human heart beats about 40 million times per year and prosthetic heart valves must endure at least a fatigue lifetime of 10^9 cycles. Because of the safety-critical nature, the Food and Drug Administration (FDA) requirements demand that mechanical valves be evaluated using the fracture mechanics approach based on damage-tolerant design analyses [44]. Life prediction is defined in terms of the time or the number of loading cycles required for the largest crack to grow to a critical size, usually measured by the material's fracture toughness K_{IC}. Typical K_{IC} values are usually less than 2.5 MPa√m. However, Ritchie et al. [45] have shown that pyrolytic carbon–graphite composites display true cyclic fatigue failure in air and in simulated body fluid. Failure can occur at lower delta K_I values of 0.7–1.2 MPa√m (50% lower). This is contrary to previous scepticism over fatigue of brittle materials [46]. Little difference was observed for the results performed in air as well as in saline solution. Dauskardt et al. [47], using small indentation cracks (100–600 μm), showed that the crack growth rates exceeded those for long cracks at the same applied stress intensity and the results showed extensive scatter. Ritchie [10] extensively studied the subcritical crack growth by cyclic fatigue of pyrolytic carbon in the mechanical heart valve and using a similar approach to Eq. (4) predicts that the critical crack size for failure is between 80 and 128 μm. For safety purposes, non-destructive testing methods should detect cracks (especially edge cracks) at least 45 μm in length before passing for service. The effect of repetitive impact on the strength of pyrolytic carbon has been studied by Kepner and Cao [48] who found that pyrolytic carbon exhibits the cone cracks damage mode (Type II in Fig. 3).

Table 4
Fracture toughness of some common bioceramics (compiled from Ref. [43])

Bioceramics	Fracture toughness (MPa√m)
Zirconia	6.0–15.0
Alumina	4.0–5.0
Ilmaplant®	2.5
Cerabone®	2.0
Sintered hydroxyapatite	1.0
Bioverit®	0.5–1.0

3. Future advances in the development of fatigue fracture wear resistant biomaterials

The forgoing has highlighted the numerous problems related to fatigue fracture and wear of biomaterials. Wear is considered more of a system problem and improvement of wear performance has been made from various approaches ranging from ion implantation, cushion bearing to elastohydrodynamic lubrication. The poor tribological properties of titanium alloys as compared to cobalt chromium alloys articulating against UHMWPE acetabular cups has prompted the use of surface treatments such as plasma vapour deposition coating of TiN and TiC, thermal treatments (nitriding, surface hardening), and ion implantation (N+) [49]. Cushion bearing materials, though improving the lubrication of joints, have been shown to have poor fatigue behaviour both in vitro and in vivo [50,51]. New materials are constantly being developed. Researchers recognised that wear debris will always be generated when two surfaces are in sliding contact. The challenge is developing engineering solutions to take care of wear debris rather than eliminating wear debris, a seemingly impossible task. Increasing hardness and fatigue resistance may only be a partial solution. Future advances may take one or more of the following routes:

1. Interpenetrating network composites: nanolaminate layer of interpenetrating network composites such as those found in nature have unique fracture resistance. Examples are seashells which have been shown to give improved fracture resistance with unique wear characteristics [52]. The microstructure is made of a nano brick type arrangement of a ceramic phase sandwiched by an ultra-thin polymeric protein layer. Presumably, the small brick like ceramic components (often biodegradable) allow easy removal/dissolution, a concept which needs to be mimicked in engineering a biomaterial that has wear debris which is eco-compatible. By using a laminates concept, fracture toughness values as high as 16 MPa√m can be achieved, for instance for boron carbide/aluminium laminates (Fig. 11). These laminates also have high flexural strength. Interpenetrating network composites such as those by bi-axial stretching of one crystalline phase (UHMWPE) and infiltrating with elastomeric polyurethane (PU) [53] to produce microlaminates has shown significant improvement in the strength and fracture toughness of an elastomeric composite membrane (less than 40 μm) for biomedical applications (Fig. 12).
2. A triplex phase composite consisting of a ductile

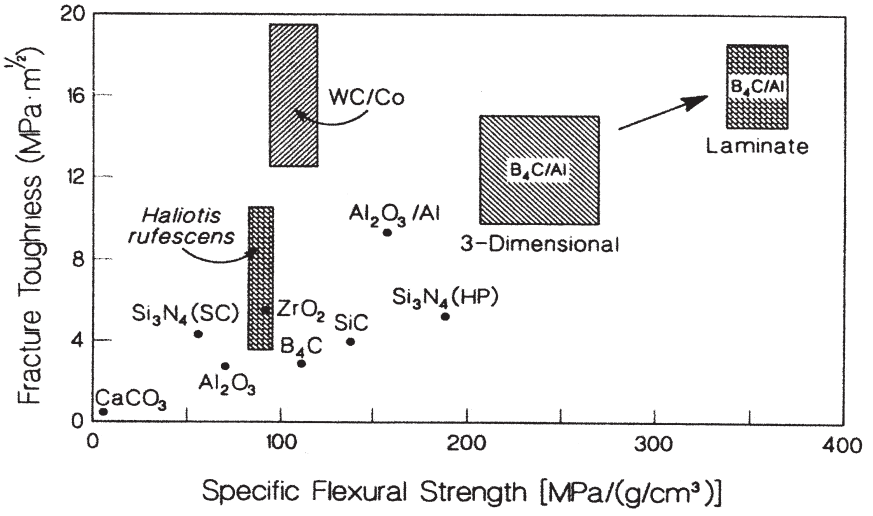

Fig. 11. Fracture toughness versus specific flexural strength of some bioceramics and nanolaminates of metal matrix ceramic composites. Note the effect of laminates in improving both fracture toughness and flexural strength (after Saikaya and Aksay [52], courtesy of Springer-Verlag).

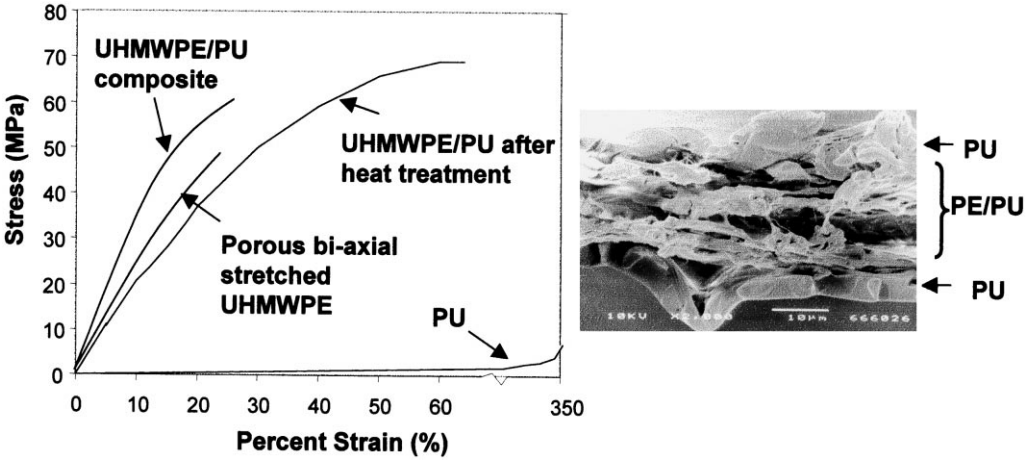

Fig. 12. (a) Stress–strain behaviour of interpenetrating network composites of porous bi-axial UHMWPE and infiltrating with elastomeric PU to produce microlaminates with significantly improved mechanical properties; (b) shows the cross-section view of the internal microstructures (after Teoh et al. [53]).

phase, a hard phase and a lubricating phase that protects both articulating surfaces (e.g. Ti–TiC–graphite [54], which was designed with pure titanium providing the ductile damage resistant phase, titanium carbide the hard wearing phase, and the graphite the lubricating phase (Fig. 13));

3. Engineered biomaterial surfaces and tribosystems that are able to trap/isolate wear debris and promote easy removal of such wear debris.

4. Conclusions

Materials used in medical devices are subjected to high stresses and high cycle loading. This very demanding condition coupled with the aggressive body environment leads to fatigue failure of metallic, polymeric and ceramic implants. A fatigue wear process involving fretting causes the generation of wear debris which invokes acute host–tissue reactions which tend to aggravate the fatigue problems of the biomaterial by producing enzymes and chemicals that are highly corrosive. The methods of fatigue evaluation for biomaterials must include wear debris morphology characterisation so as to understand the host–tissue reaction to wear debris and simulate as close as possible the imposed stress–strain and environmental conditions in vivo. The development of fatigue fracture and wear resistant biomaterials is still in its infancy. Research geared towards biocomposite systems with different phases to cope with the conflicting properties of fatigue fracture resistance and hard, but brittle, phases required for wear resistance and a good lubrication phase, seems to provide some future direc-

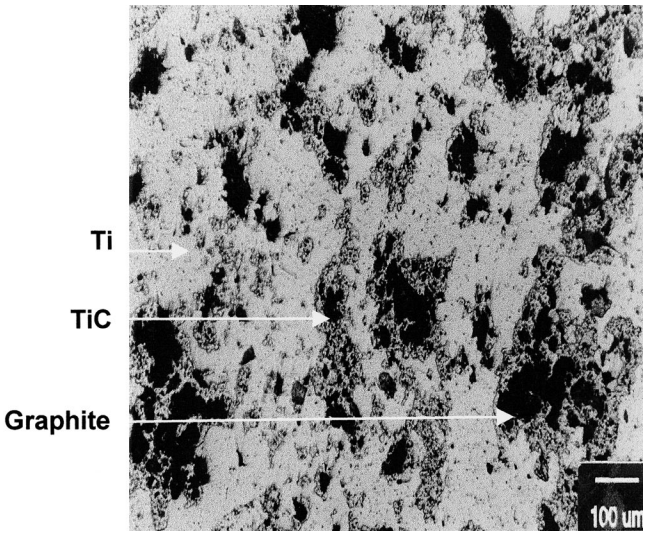

Fig. 13. Microstructure of a Ti–TiC–graphite composite with improved wear resistant characteristics (after Teoh et al. [54]).

tion. An example towards this end is the development of Ti–TiC–graphite and UHMWPE/PU interpenetrating network composites. Fatigue fracture research could take the form of nanolaminates such as those found in seashells. The morphology of wear debris that forms must be readily acceptable by the body. The ability to engineer biomaterials that have the capability to trap/isolate wear debris and promote easy removal of such wear debris remains a challenge.

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