# *In vitro* simulation of contact fatigue damage found in ultra-high molecular weight polyethylene components of knee prostheses

**J H Currier**, **J L Duda**, **D K Sperling**, **J P Collier**, **B H Currier** and **F E Kennedy**
Dartmouth Biomedical Engineering Centre, Thayer School of Engineering, Dartmouth College, Hanover, New Hampshire, USA

**Abstract:** An *in vitro* simulation of fatigue loading of ultra-high molecular weight polyethylene (UHMWPE) knee components was carried out on a knee simulator and on a rolling and sliding wear tester. Tibial components for the knee simulator were gamma-sterilized, implantable components taken from manufacturing inventory. The rolling/sliding UHMWPE discs were machined from bar stock and either gamma sterilized in air and accelerated aged, or left as non-sterilized (controls).

Cracking and delamination of samples that had been gamma sterilized in air and aged were observed in both types of tests. Contact fatigue damage was visible in as few as 150 000 cycles using the knee simulator at loads of 122 N (275 lb). The rolling/sliding samples showed signs of damage in as few as 130 000 cycles with an estimated stress of 15 MPa and 25 per cent sliding. However, cracking and delamination were not generated in the never-sterilized or recently sterilized controls. UHMWPE that has been gamma sterilized in air and aged is shown to be susceptible to contact fatigue damage. These results are important to the interpretation of *in vitro* total knee replacement simulations used to assess the performance of tibial bearings.

**Keywords:** polyethylene, wear, delamination, knee prostheses, contact fatigue damage, *in vitro* testing

## NOTATION

| | |
|---|---|
| Hz | hertz |
| lb | pounds force |
| MPa | megapascal |
| N | newtons |
| μm | $10^{-6}$ metre |

## 1 INTRODUCTION

Implantation of total knee replacements (TKR) has reached an estimated 190 000 procedures annually in the US healthcare industry, with significant additional activity in other countries [**1**]. This usage exceeds that of total hip replacements, which represent an earlier, and until the 1990s, more common application of total joint replacement technology. The loading applied to a knee joint replacement is more complex and more severe than those applied to the ball-and-socket hip joint. As the knee flexes, the articulation of the bearing surfaces is a combination of both rolling and sliding. The force applied through the joint can be up to seven times body weight during routine daily activity, such as rising from a chair or climbing and descending stairs.

Most TKR designs in use today incorporate a femoral component which is affixed to the distal end of the femur and serves as a replacement surface for the condyles on the natural bone, which are typically damaged or diseased in the TKR patient. This femoral component is typically a cast cobalt–chrome alloy and is highly polished on its external surface to provide a smooth articulation. The total joint prosthesis also incorporates a replacement bearing surface on the proximal end of the tibia. This tibial component of the prosthesis normally comprises a polyethylene bearing disc which is contoured to match the particular geometry of the metal femoral counterface and often has a metal (cobalt–chrome or Ti–6V–4Al) platform which is affixed to the tibia and serves as a foundation for the bearing disc (Fig. 1). The bearing disc in current generation knee implants is made of medical grade ultra-high molecular weight polyethylene (UHMWPE), a linear polyethylene having a weight-average molecular weight of approximately 4 million and very low levels of impurities [**2**]. This material is chosen

*The MS was received on 17 June 1997 and was accepted for publication on 9 February 1998.*

H02297 © IMechE 1998

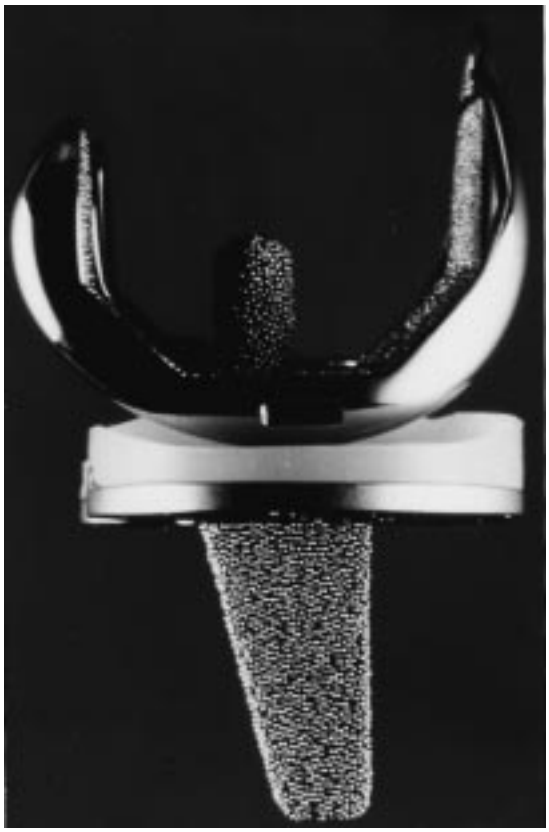


**Fig. 1** Photograph of a typical total knee replacement (TKR) prosthesis. Shown are both the femoral component, for resurfacing the condyles of the femur, and the tibial component, which includes an UHMWPE bearing disc

for its biocompatibility, low coefficient of friction and excellent abrasion resistance.

Much of what is known about the actual performance *in vivo* of joint prostheses is from examination of those devices that have been retrieved from patients, either post mortem or during revision surgery made necessary by clinical indications of unacceptable performance. Studies of such retrieved artificial knee prostheses have shown that the fatigue-related damage modes of cracking and delamination have become a critical mode of failure of UHMWPE tibial components. In early studies of retrieved implants, delamination of tibial components was observed, but was not prevalent in components that had been implanted for a relatively short duration [**3**]. Subsequent investigations have shown increased frequency of delamination. Landy and Walker [**4**] report a 37 per cent frequency of delamination in a series of 90 knee retrievals with an average duration of 5.6 years. Collier *et al.* [**5**] reported cracking or delamination in 40 per cent of 182 retrieved tibial trays of various designs, and of durations ranging from 2 months to over 16 years. In that study, components that had *in vivo* durations of greater than four years showed cracking or delamination in 65 per cent of cases (Fig. 2). Blunn *et al.* [**6**] recently reported wear comparisons for 280 retrieved bearings

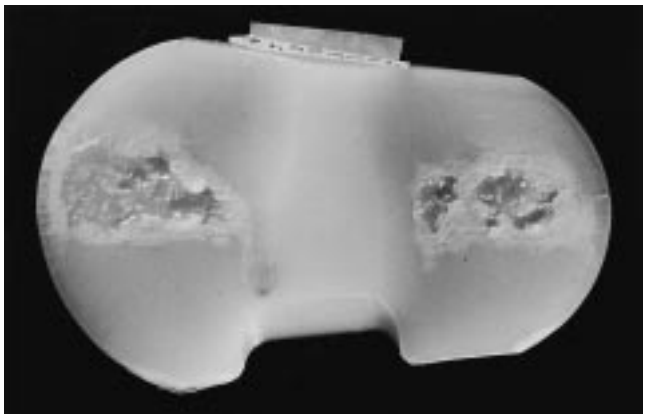


**Fig. 2** Photograph of a retrieved tibial bearing, showing severe cracking and delamination of the polyethylene after 36 months *in vivo*

of eight different designs. Delamination was seen in retrievals of all designs except one, and in the four knee designs for which delamination frequency was reported, 64 per cent of bearings showed delamination.

Ongoing laboratory investigations using *in vitro* tests on knee prostheses have not reflected the same prevalence and severity of fatigue damage with increasing service time that are seen in studies of actual retrievals. Simulator studies of wear phenomena have shown surface modes of wear, and these studies have focused on quantifying the wear and wear rate, and on comparing wear rates for different designs [**7**–**11**]. However, the wear phenomena documented with *in vitro* simulations are predominantly surface wear modes, and do not reproduce the trend towards more frequent subsurface fatigue failure modes seen in clinical retrievals. In their published study of surface damage in polyethylene components, Wright and Bartel [**12**] point out, 'Fatigue has been shown to be the failure mechanism in *in vivo* fracture of polyethylene components, though the conditions for fatigue remain poorly understood. *In vitro* wear testing of polyethylene has focused on the amount of debris generated in total arthroplasties, rather than the mechanisms by which this debris is produced.'

A separate and more recent thrust of research on UHMWPE joint bearings has been the effect of a sterilization technique on the chemical and mechanical properties of the material [**5**, **13**–**15**]. Recent studies have documented significant oxidation and degradation of mechanical properties over time in the subsurface region of polyethylene components that have been sterilized by gamma irradiation in ambient air, which until recently has been the standard technique for sterilization of orthopaedic implants [**5**, **15**]. Specific to load-bearing performance, these studies have shown the tensile strength of the polyethylene reduced by 40 per cent, and ductility and fatigue resistance reduced by more than an order of magnitude. This degradation is an interaction of the gamma irradiation with the material over time; it


H02297 © IMechE 1998

is not related to loading (in fact, it is most pronounced in never-implanted components) and it is not specific to any device design. The impact of these findings is evidenced by the fact that in the past three years, the number of orthopaedic device manufacturers using gamma sterilization in air on polyethylene for the US market has dropped from at least 12—a vast majority—to 0. Accordingly, recent *in vitro* testing programmes have addressed the need to account for the effect of gamma irradiation in air by using test material that is irradiated and artificially aged in a heated, oxygen-rich environment [**16**–**18**].

It is important to bring to bear current understanding of gamma-irradiation-in-air-induced material degradation on the study of device performance using *in vitro* tests. A great deal of information is published on the comparative performance of knee designs, and undoubtedly much additional proprietary testing has guided manufacturers in the development and marketing of improved knee systems. In order to draw the correct conclusions about design-specific performance, the profound effects of bearing material degradation should be understood and accounted for. The hypothesis investigated here is that the use of polyethylene gamma sterilized in air and subsequently aged is critical to reproducing the subsurface fatigue that has become the predominant mode of failure of knee bearings.

## 2 MATERIALS AND METHODS

The current study employed two different wear test machines to assess the fatigue behaviour of UHMWPE. A single-station knee simulator and a rolling/sliding wear tester provided different methods for attempting to replicate the fatigue failures of cracking, pitting and delamination which are observed in retrieved tibial bearings. This study focused on identifying these fatigue-related wear modes. No quantified wear measurements were recorded during any of the tests.

### 2.1 Knee simulator

A single-station knee simulator was used to test the failure modes in the prosthesis. The knee simulator consists of an axial load generator using coil springs and a rotary drive mechanism which provides the articulation. The prostheses are tested in an inverted position, with the femoral component fixed in the base with dental acrylic and the tibial bearing on top facing downwards. A push rod from the rotary drive oscillates the tibial component through a range of flexion. The axial load is activated as the tibial bearing is pushed up over the contour of the femoral component, compressing the linkage containing the springs (Fig. 3). Load, flexion angle and cycle rate are the variables which can be controlled.

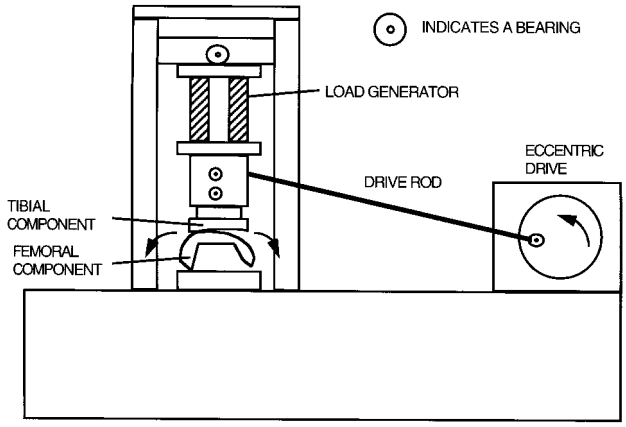



**Fig. 3** Schematic drawing of the single station knee simulator

Loads were changed by using springs with different spring constants and by adjusting the position of the spring reaction framework. Axial loads in this study ranged from 778 to 2000 N (175–450 lb). The range of flexion could be adjusted by changing the initial degree of flexion of the femoral component and the stroke amplitude of the drive rod. All tests were run with a flexion range of 0–35°. Lubrication between the components was provided by a bath of distilled water.

The knee simulation tests required both a polyethylene tibial insert and a matching metallic femoral component. No patellar components were used. All test specimens were tibial bearings manufactured for implantation and taken from shelf inventory for testing. All were machined from UHMWPE bar stock that had been ram extruded using GUR-415 resin powder as a starting material. The components were gamma irradiation sterilized according to the industry standard protocol of 2.5 megarads from a $Co^{60}$ source, in an ambient air environment before being placed in inventory. Tibial bearing thickness ranged from 8 to 18 mm and shelf age after gamma sterilization in air ranged from 0 to $>8$ years.

One matching metallic femoral component was used for all tests in this series. It was made of cast cobalt–chrome (Haynes 21 alloy), and polished according to the normal protocol by the implant manufacturer. Tests were conducted in the sequence listed in Table 1. Because frictional heat between the components was a concern, a thermocouple was used to monitor the temperature of the lubricating bath. A cooling loop placed in the bath kept the temperature in the range of 21–24 °C.

### 2.2 Rolling/sliding tester

The rolling and sliding wear tester employs two counter-rotating discs to simulate the rolling and sliding in tibio-femoral loading [**19**]. The test discs were machined from UHMWPE bar stock that had been ram extruded using GUR-415 polyethylene resin powder as a starting material. The UHMWPE discs were sterilized by gamma

**Table 1** Test programme for components tested in the knee simulator

| Test number | Thickness (mm) | Time since gamma sterilization (years) | Severity of subsurface oxidation | Load (N/lb) | Duration (number of cycles) |
|---|---|---|---|---|---|
| 1 (control) | 10 | <1 | Non-existent | 2000/450 | 2 500 000 |
| 2 | 18 | 4 | Non-existent | 1223/275 | 500 000 |
| 3 | 10 | 8 | Moderate | 1223/275 | 450 000 |
| 4 | 10 | >8 | Severe | 1223/275 | 150 000 |
| 5 | 8 | >8 | Moderate | 778/175 | 870 000 |

irradiation in air and artificially aged in an attempt to simulate extended time on the shelf. The environment for the accelerated ageing was one atmosphere of oxygen at 80 °C for 17 days, following protocol published previously [**20**]. Control specimens were UHMWPE discs that were not sterilized and not aged. The counterface disc was machined from cobalt–chrome alloy and polished to a finish similar to that of the surface of the manufactured femoral component.

The rolling/sliding cycle in the testing was done at 2 Hz, with 75 per cent rolling/25 per cent sliding. Control testing on a non-sterilized, non-aged specimen was done at 2000 N (450 lb) out to 2 million cycles. Additional benchmark tests using sterilized and aged specimens were run under a maximum load of 1036 N (233 lb) until failures were evident. Testing conditions were then altered to determine the effects of lower load and varying number of cycles on each sample. All tests were conducted in a distilled water bath. A thermocouple used to measure the temperature of the metal counterface disc periodically during testing showed an average temperature of 24 °C on the counterface disc.

Microscopic subsurface cracks are hypothesized as the initial cause in catastrophic failures of tibial components. Therefore, it is essential to analyse both the surface and the subsurface area in each sample to understand further the mechanisms of wear in polyethylene. Analysis of test samples included optical microscopy, sectioning the component to a 200 μm thickness with a microtome, and scanning electron microscopy (SEM). Photographs were taken during each step of analysis to document the wear properties of each sample.

## 3 RESULTS

### 3.1 Knee simulator

Five tibial components were tested using the knee simulator (Table 2). The recently sterilized control was tested to 2.5 million cycles at a load of 2000 N. The only wear that appeared was slight burnishing at the surface of the component. The sterilized and shelf aged components were run for significantly fewer cycles (150 000–870 000), yet exhibited more severe surface wear characteristics than the recently sterilized control. All shelf aged samples revealed flakes of polyethylene peeling from the surface (Fig. 4). In addition, deep wear grooves were worn into the articular surfaces of most of the polyethylene bearings tested.

The components that had oxidized zones rated as moderate showed an intensification of the white band under the area of the condyles loaded during testing. The intensified white band was apparent from examination of post-test thin sections taken through the loaded area of the bearing and corresponding sections taken through an unloaded area between the condyles (Fig. 5). The cracked areas and visible particle boundaries that compose the white band were significantly more numer-

**Table 2** Test results for components tested in the knee simulator

| Test number | Time since gamma sterilization (years) | Severity of subsurface oxidation | Load (N/lb) | Duration (cycles) | Surface wear | Sub-surface cracking |
|---|---|---|---|---|---|---|
| 1 | 0–1 | Non-existent | 2000/450 | 2 500 000 | Slight burnishing of poly | None |
| 2 | 4 | Non-existent | 1223/275 | 500 000 | Wear grooves and surface flaking | None |
| 3 | 8 | Moderate | 1223/275 | 450 000 | Wear grooves and severe flaking | Oxidized zone more pronounced |
| 4 | >8 | Severe | 1223/275 | 150 000 | Mild wear grooves and mild flaking | Severe cracking |
| 5 | >8 | Moderate | 778/175 | 870 000 | Mild wear grooves and mild flaking | Oxidized zone more pronounced |


H02297 © IMechE 1998

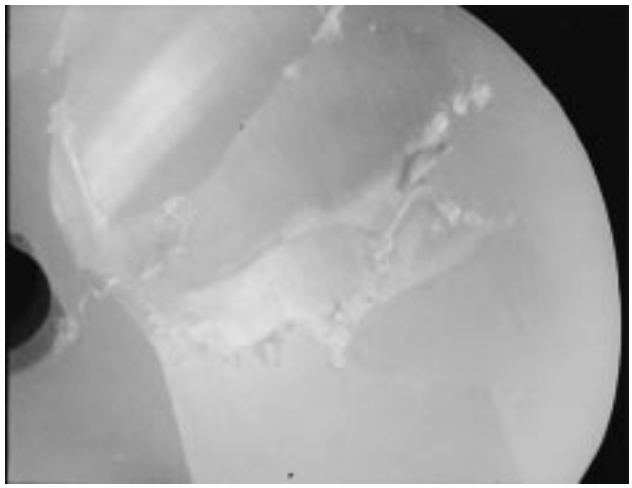


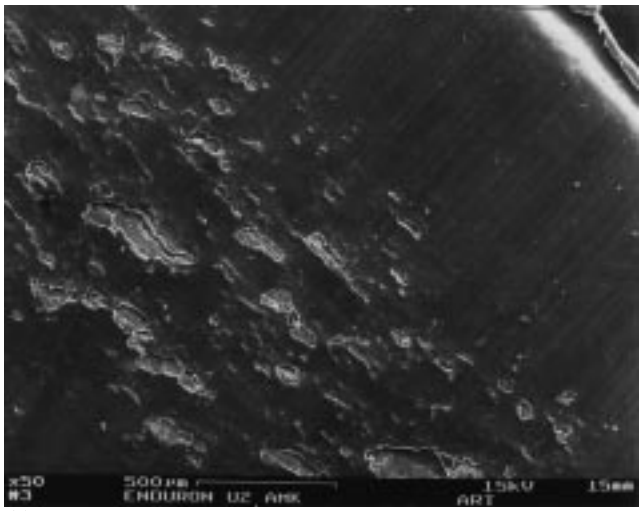
**Fig. 4** Surface flaking and wear grooves on tibial tray after 870 000 cycles at 778 N (175 lb)

ous and more severe under the loaded area of the bearing.

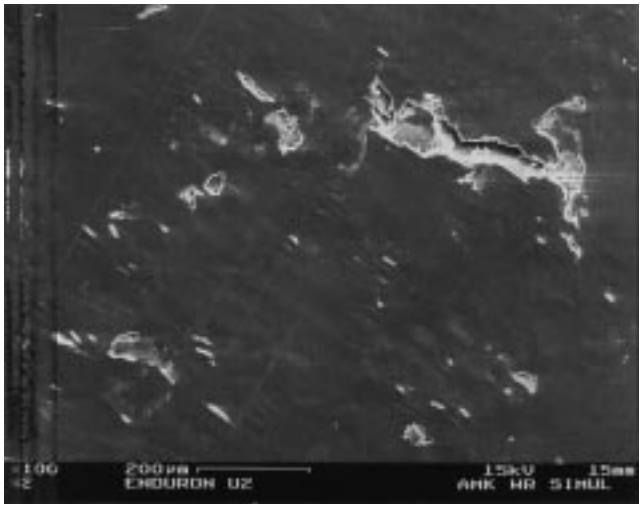
The component that showed the most severe damage during testing was subjected to only 150 000 cycles at a load of 1223 N. This tibial bearing had been gamma sterilized in air and had been shelf aged for more than 8 years. Delamination in the articular area was evident as a white blister-like phenomenon visible through the intact surface layer of the component (Fig. 6). A microtomed cross-section of the sample showed that the cracking had initiated and propagated subsurface, but had not yet propagated to the surface (Fig. 7a). The distinction between the subsurface fatigue cracking and the white band is more clear in an adjacent thin section cut using a diamond impregnated abrasive wheel rather than a microtome (Fig. 7b). The effect of the microtome in producing microcracking which becomes visible as a white band in the oxidized area of the component has been documented previously by Collier *et al.* [**5**].

### 3.2 Rolling/sliding tester

All samples tested on the rolling and sliding simulator reproduced varying degrees of similar wear characteristics: burnishing, surface cracking and surface pitting (Table 3). Specimens tested at the highest loads exhibited significant cracking and pitting (Fig. 8). Evaluation of the wear surfaces with SEM shows that the pitting features and the cracking are surface phenomena (Fig. 9). No subsurface failures were found in the rolling and sliding samples; all tests yielded only surface wear. Post-test analysis of the rolling sliding samples showed that, with the exception of the control sample, all had surface oxidation, rather than the subsurface oxidation normally seen in retrievals. The wear phenomena found on the rolling sliding samples was also restricted to the surface (Fig. 10).




(a)




(b)

**Fig. 5** SEM micrographs of the subsurface white band on thin sections taken from a component tested in the knee simulator for 450 000 cycles at 1223 N (275 lb). (a) Section taken from under the loaded area of the bearing, (b) section taken from under an unloaded area of the bearing

## 4 DISCUSSION

The rolling and sliding tests show the wear modes of burnishing, surface cracking and surface pitting of the polyethylene consistent with the wear modes reported in other *in vitro* studies [**9**–**11**, **21**, **22**]. These surface wear modes were seen in varying degrees over the range of loading, from 133 to 1036 N, and over the range of number of cycles, from about 20 000 to 140 000. From this series of tests the progression of wear modes with increasing load/cycle severity appears to be: burnishing, then surface cracking, then the formation of surface pits.

The samples that were gamma sterilized in air and then oxidized in an accelerated ageing environment showed wear at lower loads, and at fewer cycles than

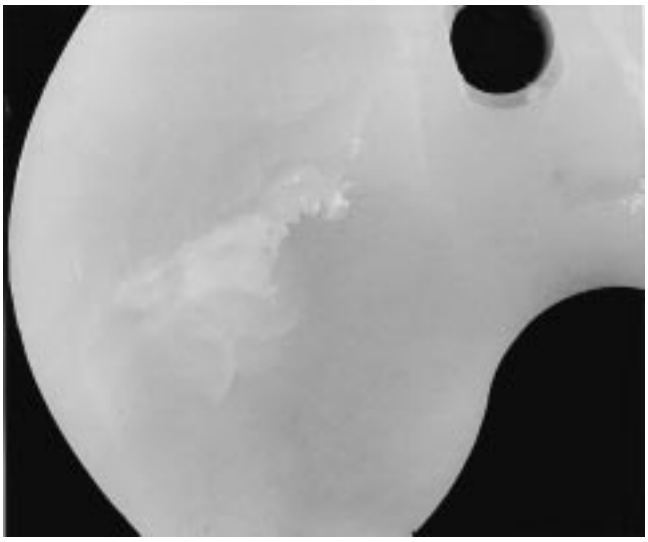
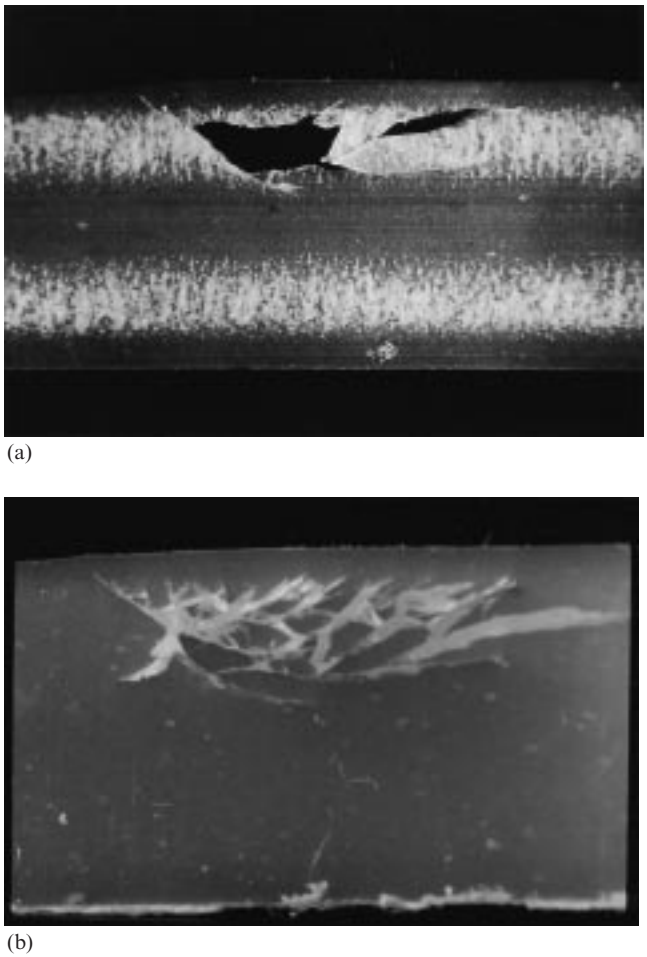


**Fig. 6** Plan view (× 10) of the delaminated area of the component tested in the knee simulator for 150 000 cycles at 1223 N (275 lb)

the control test, indicating that oxidation of the polyethylene has a negative impact on resistance to these common wear modes. This relatively rapid appearance of surface wear in the accelerated aged material is more notable in light of previous tests performed on this same test apparatus with the same sample geometry and loading regime [**10**, **19**]. In Lee's [**10**] tests of unsterilized material, 22 tests were run at loads up to 1334 N, and for durations of 1 million cycles, with one test extended to 5 million cycles. In all of these tests, the most severe wear modes seen were surface cracks and the beginning of pit formation or 'pock marks' [**10**]. The artificially aged polyethylene samples for the rolling/sliding tester showed a white band at the surface, rather than subsurface as is seen in shelf aged material. This represents a limitation of the artificial ageing protocol used. However, the wear damage seen was also at the surface, corresponding to the location of the white, oxidized band.

The knee simulator tests give a comparison of wear modes seen for a series of components of the same design, and same gamma sterilization method, but with differing severity of subsurface oxidation which has developed with shelf time. The extent of subsurface damage during testing appears to increase with severity of the subsurface oxidation. The two components with no white band or a faint white band showed no subsurface damage. The components with a moderate white band showed evidence of cracking and localized, inter-granular failure, but these components did not develop macroscopic cracking and delamination during testing.

The only components that showed wear modes similar to those seen in retrieved tibial components were the components with pronounced subsurface white bands.



(a)

(b)

**Fig. 7** Thin sections of the delaminated area of the component tested in the knee simulator for 150 000 cycles at 1223 N (275 lb). (a) Microtomed thin section showing whiteness of the subsurface oxidized zone, enhanced by microtoming (× 10). (b) Adjacent thin section, cut with a diamond saw, in which white band is not visible (× 10). Sections cut by both methods clearly show that the fatigue crack failure has initiated subsurface, distinct from the cracking that produced the 'white band', but at the same location

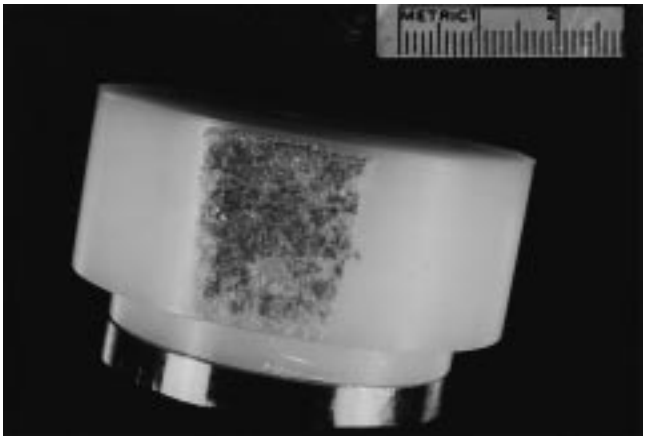
One such component developed macroscopic damage which had a subsurface initiation site (Fig. 7). The subsurface nature of the fatigue cracking cannot be attributed to component thickness, since its thickness, 10 mm, was greater than the recommended minimum thickness of tibial bearings to avoid bearing stress increases (8 mm) [**23**, **24**].

The geometry and size of the component that showed the most severe subsurface wear was identical to the recently sterilized control sample. The only difference was the shelf time following gamma irradiation in air, and the associated development of a subsurface oxidized zone. The recently sterilized component showed minimal wear out to 2.5 million cycles, which is performance typically seen in laboratory wear tests on knees. When tested on the same machine, the older, oxidized component


H02297 © IMechE 1998

**Table 3** Test programme and results for samples tested in the rolling/sliding tester

| Test variable | Load (N/lb) | Number of cycles | Surface wear observations |
|---|---|---|---|
| Non-sterilized control | 2000/450 | 2 000 000 | Slight cracks, burnishing of poly |
| Base test with sterilized samples | 1036/233 | 140 000 | Deep cracks forming surface pits |
| 80% load reduction | 133/30 | 140 000 | Slight burnishing of the poly |
| 86% reduction (number of cycles) | 1036/233 | 19 600 | Slight burnishing of the poly |
| 40% load reduction | 632/142 | 130 000 | Cracking, small surface pits |
| 85% reduction (number of cycles) | 632/142 | 110 000 | Cracking, small surface pits |
| 50% reduction (number of cycles) | 632/142 | 65 000 | Little cracking, no surface pits |
| 35% reduction (number of cycles) | 632/142 | 85 000 | Few cracks, no surface pits |



(a)

(b)

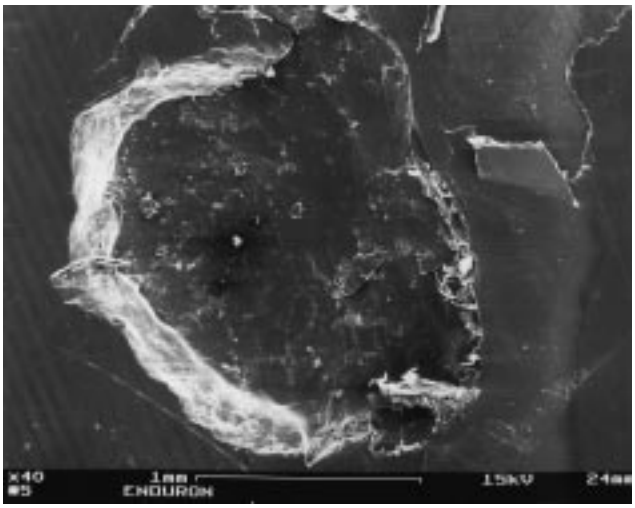
**Fig. 8** (a) Photograph of a rolling sliding test specimen after 140 000 cycles at 1036 N. (b) Magnified (×10) view of surface shows significant pitting and cracking at the wear surface

(Fig. 7) developed marked subsurface fatigue damage, like that seen in clinical retrievals. Most notably, it did so at 60 per cent of the control load and only 6 per cent of the number of cycles.

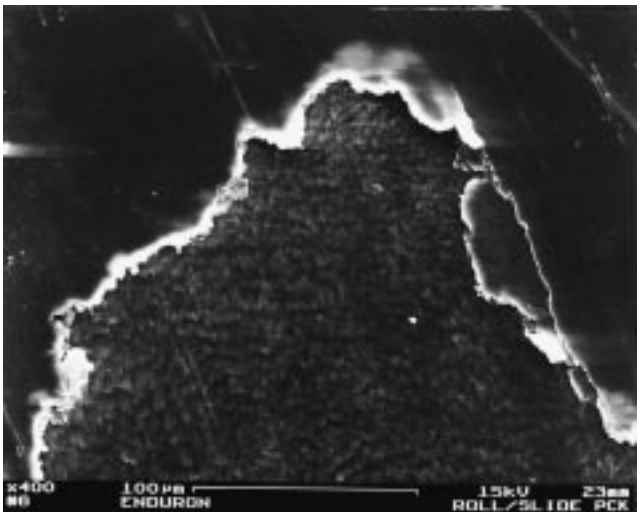
The differences in radii of curvature between the contacting surfaces of the femoral and tibial components of a knee prosthesis result in a contact zone which is elliptical in shape. The contact area and associated contact pressure under bearing loads have been extensively documented for a wide range of prosthesis designs [**8**, **12**, **22**, **24**, **25**]. The stress distribution which results from this contact pressure has been studied for the case of homogeneous tibial components using finite element techniques [**23**, **24**]. The results, which are consistent with contact mechanics theory [**26**], predict the occurrence of cyclic compressive-to-tensile stresses at the surface of the tibial component under the rolling/sliding articulation of the knee; they also predict a von Mises equivalent stress which reaches a maximum in the subsurface region. These studies, along with fracture mechanics analysis [**27**], point out the correspondence between predicted subsurface stress peaks and the clinical observations of subsurface fatigue cracking. However, the studies have not explained the apparent paradox of why subsurface failure has not previously been reproduced in the laboratory. Satisfactory explanation of the failure location requires consideration of the properties of the UHMWPE material and of the stresses seen by that material in service.

Recently published results have shown significantly altered properties in the subsurface layers of UHMWPE bearings that have been gamma irradiated in air and aged in a natural environment containing oxygen [**5**, **15**]. Those studies show that the ultimate tensile strength of the UHMWPE in the subsurface oxidized zone of tibial components is typically reduced by 40 per cent. Ductility of the oxidized zone is decreased by an order of magnitude compared to adjacent zones; i.e. a reduction in elongation from 200 per cent to less than 20 per cent.

Other studies have indicated that Young's modulus of oxidized polyethylene, such as that in the subsurface layer of tibial components gamma irradiated in air, is significantly higher than Young's modulus in adjacent,




(a)




(b)

**Fig. 9** (a) SEM micrograph showing a pit on the wear surface of a rolling sliding specimen after 110 000 cycles at 632 N. (b) SEM micrograph showing cracking and subsequent flaking of a very thin layer at the wear surface of a rolling sliding specimen after 110 000 cycles at 632 N

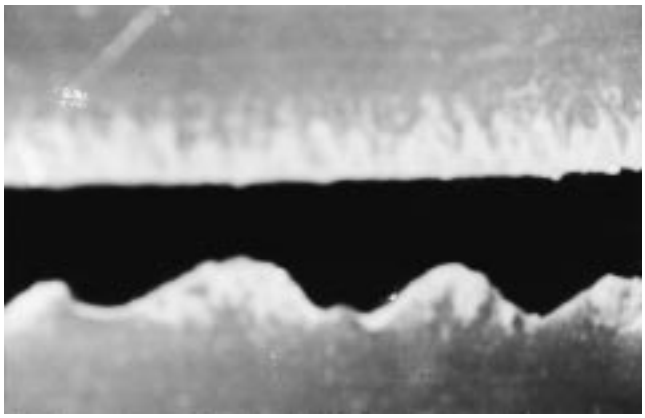


**Fig. 10** Photograph of thin cross-sections of a rolling/sliding specimen. Top cross-section (inverted) shows the oxidized white band to the surface of the specimen. Bottom section shows a similar cross-section after testing, with wear features at the surface coinciding with the location of the oxidized zone

less oxidized layers [**14**, **28**, **29**]. Data from Kurtz *et al.* [**30**] indicate that the density increase typical of the oxidized subsurface zone corresponds to a local increase in Young's modulus of approximately 30 per cent.

The presence of stiffer subsurface layers can have a substantial influence on stresses within the tibial bearings. Past studies of contact stress distribution in layered elastic or elasto-plastic solids have shown that increase in modulus of elasticity of near surface layers can cause a decrease in contact area, and increase in contact pressure, and an increase in the maximum von Mises stress [**31**–**34**]. These changes can be especially significant if the thickness of the layers is smaller than the contact size and if the change in modulus of elasticity is significant, and both of these conditions are satisfied in the oxidized tibial bearing. Plumet and Dubourg [**35**] have recently undertaken numerical analysis of stresses in a layered medium with layer thicknesses and properties similar to those found in an oxidized tibial bearing. They have confirmed that the higher modulus of the subsurface oxidized layer results in a smaller contact zone with increased contact pressure. They have also shown that, for a typical prosthesis geometry and for the measured layer thicknesses and properties the peak von Mises stress is found within the stiff oxidized layer.

The magnitude and location of the stress peaks in the oxidized UHMWPE material are particularly important because of the reduced strength and ductility which are seen in the oxidized layer. The reduced tensile strength of the oxidized polyethylene [**5**] promotes crack initiation at sites within the oxidized layer, as opposed to the stronger surface layer. Furthermore, the substantially reduced ductility of the oxidized layer [**5**] and its reduced toughness lead to much easier crack propagation within the subsurface layer. The result is considerably reduced contact fatigue life for tibial bearings which have become oxidized as a result of gamma irradiation and ageing in air.

The key to reproducing delamination failure in knee simulation may lie not in refinements to the load function and test conditions during laboratory testing, but rather in using bearing material that is actually representative of those retrieved tibial components that exhibit the delamination failure *in vivo*. Implanted polyethylene components are sterilized and undergo subsequent ageing—for some *in vivo* duration, at least—before delamination occurs. Previous studies associate the process of gamma irradiation in air and subsequent ageing with the development of the brittle subsurface white band [**5**, **15**]. The knee simulation tests presented here support the perspective that the ageing history of the


H02297 © IMechE 1998

polyethylene is an important factor in the results of knee simulation studies.

This study indicates that a reduced incidence of fatigue damage may be expected as components which have undergone gamma sterilization in air are phased out of clinical use. These results may help explain findings such as those of Blunn *et al.* [**6**], wherein substantial delamination damage was found in clinical retrievals of components from manufacturers known to use gamma irradiation sterilization, but no delamination was observed in components from a particular manufacturer known historically to have used a different sterilization method.

The knee simulator used in this study is limited in that it does not allow for internal/external rotation or adduction/abduction. While it does model a walking gait in the sense that maximum normal loading occurs at low angles of flexion and lower loads occur at higher angles of flexion, the relationship between normal load and knee flexion is not as complex as that in a normal knee. Work is currently in progress to confirm these results in a simulator that more closely recreates a physiological gait cycle, and with bovine serum as a lubricant to model more closely *in vivo* conditions. The current series of tests have established, however, that with only water as a lubricant, recently sterilized components showed no evidence of fatigue or significant wear at relatively high cycles, while aged gamma irradiated components did.

## 5 CONCLUSION

The findings presented here are notable because of the marked departure of the results of the knee simulator test on irradiated and aged material compared with other published results for non-aged material. It is useful to put these results in the context of other research on the properties of UHMWPE in orthopaedic implant bearings.

The knee simulations shown here provide a comparison of wear modes seen for a series of components of the same design, with increasing severity of subsurface oxidation which has developed with increasing time on the shelf. The extent of damage during testing appears to increase with severity of the subsurface oxidation, from minimal surface wear, to significant surface wear, to the subsurface cracking typical of fatigue failures in clinical retrievals. The differences in shelf life after gamma sterilization in air, and hence the presence or absence of a highly oxidized subsurface zone in the tibial bearings tested, can explain the differences seen in the wear modes of the tests in the current study. The absence of a highly oxidized subsurface zone in test specimens may explain why previous *in vitro* testing has failed to model *in vivo* subsurface delamination and cracking.

## ACKNOWLEDGEMENTS

The authors gratefully acknowledge the support of DePuy Incorporated, DePuy DuPont Orthopaedics, and the Veterans Administration Research and Rehabilitation Service through grant A-473–3DA.

## REFERENCES

1 *In Vivo.* Business and medicine report, April 1995, p. 3.
2 ASTM Designation F-648-84 *Standard Specification for Ultra-high-molecular-weight Polyethylene Powder and Fabricated Form for Surgical Implants.* Annual Book of ASTM Standards, 1994 (American Society of Testing and Materials, Philadelphia, Pennsylvania).
3 **Hood, R. W., Wright, T. M.** and **Burstein, A. H.** Retrieval analysis of total knee prostheses: a method and its application to 48 total condylar prostheses. *J. Biomed. Mater. Res.*, 1983, **17**, 829.
4 **Landy, M. M.** and **Walker, P. S.** Wear of ultra-high-molecular-weight polyethylene components of 90 retrieved knee prostheses. *J. Arthroplasty*, 1988, **5**(Suppl.), S73.
5 **Collier, J. P., Sperling, D. K., Currier, J. H.**, *et al.* Impact of gamma sterilization of clinical performance of polyethylene in the knee. *J. Arthroplasty*, 1996, **11**, 377.
6 **Blunn, G. W., Joshi, A. B., Minns, R. J.**, *et al.* Wear in retrieved condylar knee arthroplasties. *J. Arthroplasty*, 1997, **12**, 281.
7 **Walker, P. S.** and **Hseih, H. H.** Conformity in condylar replacement knee prostheses. *J. Bone Jt Surg.*, 1977, **59B**, 222.
8 **Treharne, R. W., Young, R. W.** and **Young, S. R.** Wear of artificial joint materials III: simulation of the knee joint using a computer controlled system. *Engng Medicine*, 1981, **10**, 137.
9 **Feehan, J. P.** A multi-axis knee wear tester: design and preliminary results. MS thesis, Thayer School of Engineering, Dartmouth College, 1990.
10 **Lee, P. H.** Failure of UHMWPE surfaces in rolling/sliding contact with metals. MS thesis, Thayer School of Engineering, Dartmouth College, 1992.
11 **Walker, P. S., Blunn, G. W.** and **Lilley, P. A.** Wear testing of materials and surfaces for total knee replacement. *J. Biomed. Mater. Res.*, 1996, **33**, 159.
12 **Wright, T. M.** and **Bartel, D. L.** The problem of surface damage in polyethylene total knee components. *Clin. Orthop.*, 1986, **205**, 67.
13 **Wright, T. M., Rimnac, C. M., Stulberg, D. S.**, *et al.* Wear of polyethylene in total joint replacements. *Clin. Orthop.*, 1992, **276**, 126.
14 **Kurtz, S. M., Rimnac, C. M., Li, S.**, *et al.* A bilinear material model for UHMWPE in total joint replacements. *Trans. ORS*, 1994, **19**, 289.
15 **Sutula, L. C.**, *et al.* Impact of gamma sterilization on clinical performance of polyethylene in the hip. *Clin. Orthop.*, 1995, **319**, 28.
16 **Fisher, J., Chan, K. L., Hailey, J. L.**, *et al.* Brief Communication: Preliminary study of the effect of aging following irradiation on the wear of ultrahigh-molecular-weight polyethylene. *J. Arthroplasty*, 1995, **10**, 689.

17 **Bell, C. J., Simmons, J., King, P.**, *et al.* Is oxidation of ultra high molecular weight polyethylene the main cause of delamination wear in total knee replacement? *Trans. ORS*, 1997, **22**, 96.

18 **Perry, J., Walker, P. S., Blunn, G. W.**, *et al.* Long-term durability testing of total knee replacements in a simulating machine. *Trans. European ORS*, 1997, **7**, 244.

19 **Kennedy, F. E., Lee, P. H., Feehan, J. P.** and **Collier, J. P.** Failure of UHMWPE polymer surfaces of knee prostheses: a rolling sliding contact. In *Advances in Engineering Tribology* (Eds Y. W. Chung and H. S. Cheng), 1991, pp. 100–109 (Society of Tribology Lubrication Engineering, Park Ridge, Illinois).

20 **Collier, J. P., Sutula, L. C., Currier, B. H.**, *et al.* Overview of polyethylene as a bearing material. *Clin. Orthop.*, 1996, **333**, 76.

21 **Rostoker, W., Chao, E. Y. S.** and **Galante, J. O.** The appearance of wear on polyethylene—a comparison of *in vivo* and *in vitro* wear surfaces. *J. Biomed. Mater. Res.*, 1978, **12**, 317.

22 **Walker, P. S., Ben-Dov, M., Askew, M. J.**, *et al.* The deformation and wear of plastic components in artificial knee joints—an experimental study. *Engng Medicine*, 1981, **10**, 33.

23 **Bartel, D. L., Bicknell, M. S.** and **Wright, T. M.** The effect of conformity, thickness, and material on stresses in ultra-high molecular weight components for total joint replacement. *J. Bone Jt Surg.*, 1986, **68A**, 1041.

24 **Collier, J. P., Mayor, M. B., McNamara, J.L.**, *et al.* Analysis of the failure of 122 polyethylene inserts from uncemented tibial knee components. *Clin. Orthop.*, 1991, **273**, 232.

25 **McNamara, J. L., Collier, J. P., Mayor, M. B.**, *et al.* A comparison of contact pressures in tibial and patellar total knee components before and after service *in vivo*. *Clin. Orthop.*, 1994, **299**, 104.

26 **Johnson, K. L.** *Contact Mechanics*, 1987 (Cambridge University Press, Cambridge).

27 **Connelly, G. M., Rimnac, C. M., Wright, T. M.**, *et al.* Fatigue crack propagation behavior of ultrahigh molecular weight polyethylene. *J. Orthop. Res.*, 1984, **2**, 119.

28 **Rimnac, C. M., Klein, R. W., Foster, B.** and **Wright, T. M.** Post-irradiation aging of ultra-high molecular weight polyethylene. *J. Bone Jt Surg.*, 1994, **76A**, 1052.

29 **Rimnac, C. M., Baldini, T. H., Wright, T. M., Saum, K. A.** and **Sanford, W. M.** *In vitro* chemical and mechanical degradation of Hylamer ® ultra high molecular weight polyethylene. *Trans. ORS*, 1996, **21**, 481.

30 **Kurtz, S. M., Rimnac, C. M.** and **Bartel, D.L.** The degradation rate of UHMWPE components. *Trans. ORS*, 1996, **21**, 492.

31 **Kennedy, F. E.** and **Ling, F. F.** Elasto-plastic indentation of a layered medium. *ASME J. Engng Mater. Technol.*, 1974, **96,** 97.

32 **Komvopoulos, K.** Finite element analysis of a layered elastic solid in normal contact with a rigid surface. *Trans. ASME, J. Tribology*, 1988, **110**, 477.

33 **O'Sullivan, T. C.** and **King, R. B.** Sliding contact stress field due to a spherical indenter on a layered elastic half-space. *Trans. ASME, J. Tribology*, 1988, **110**, 235.

34 **Kral, E. R., Komvopoulos, K.** and **Bogy, D. B.** Finite element analysis of repeated indentation of an elastic-plastic layered medium by a rigid sphere, Part II: subsurface results. *Trans. ASME, J. Appl. Mechanics*, 1995, **62**, 29.

35 **Plumet, S.** and **Dubourg, M. C.** Analysis of a sterilized tibial insert to understand gamma sterilization effects in knee prostheses. Internal Report, Laboratoire de Mécanique des Contacts, INSA, Lyon, France, 1997.




H02297 © IMechE 1998