JOURNAL OF MATERIALS SCIENCE MATERIALS IN MEDICINE 7 (1996) 753–763

Effect of cross-linkage by gamma radiation in heavy doses to low wear polyethylene in total hip prostheses

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Wear, frictional torque and creep deformity of UHMWPE sockets crosslinked by gamma radiation of 100, 500 and 1000 Mrad in combination with 28 mm alumina heads, were measured using a hip simulator (under constant load 250 kgf with lubrication of saline solution). Hardness and hydrophilic increased and creep deformity decreased as a result of gamma radiation. The initial wear (decrement of the thickness) of the socket with radiation of 0, 100, 500 and 1000 Mrad was, 150 μm, 100 μm, 70 μm and 50 μm, respectively. The time to steady-state wear at 0, 100, 5000 and 1000 Mrad was about 0.15 million, 0.15 million, 0.1 million, and 0.05 million cycles, respectively. The steady-state wear (decrement of the thickness) of the socket without and with radiation was 200 μm/million cycles and less than 20 μm/million cycles, respectively. Rotational torque was under 0.65 Nm in every case. Swing frictional torque at radiation levels of 0, 100, 500 and 1000 MRad were 1.60–2.84 Nm, 3.24–9.02 Nm, 5.23–8.78 Nm, and 2.51–6.79 Nm, respectively.

1. Introduction

In 1950, McKee and Watson-Farran introduced a total hip replacement that used a Co-alloy metal cup and femoral head [1]. However, progressive loosening inevitably gave poor results.

In 1960, Charnley's ideas on joint replacement were coloured by studying the natural joint in which extremely low friction was the most striking feature. He chose the material with the lowest coefficient of friction known, poly-tetra-fluoro-ethylene (p.t.f.e.) for the acetabular socket and a metal head 22 mm in diameter for the femur [2, 3].

After a little over a year, it became evident that p.t.f.e. was wearing much too quickly. A change was made to glass-fibre reinforced p.t.f.e. that performed well in the laboratory, but which failed *in vivo* because of chemical reactions and scratching due to the metal head. At the same time, a dark-horse material was being tested in the laboratory that hardly wore at all compared with p.t.f.e. This material was the high density polyethylene, which was switched to in November 1962, and which, with various improvements in molecular weight, has been used up to the present time.

Polyethylene is a polymer of ethylene CH^2. It can be made in many forms according to the molecular weight and degree of crystallinity, with consequent different mechanical properties. Ultrahigh molecular weight of polyethylene (UHMWPE) is defined as having an average molecular weight greater than 1.75 million. All mechanical properties improved with molecular weight up to this value and then remained fairly constant. However, because there is a considerable variation on molecular weight within a given sample, an average molecular weight above 2.25 million is preferred. The RCH 1000 (Ruhr Chemie) versions of UHMWPE are quoted as having a molecular weight of 2 to 5 million.

Since the Charnley prosthesis, surgeons have tried many different prostheses' designs, with a metal (or alumina) head and UHMWPE socket, in different combinations.

In 1970, to increase the wear resistance of UHMWPE, the authors carried out wear tests of UHMWPE irradiated with several high doses of gamma radiation emitted by Co^{60}. As a result, it was found that wear, including creep deformation, was smallest at 10^8 rad (100 Mrad), although there was an increase in the coefficient of friction. We began to use UHMWPE irradiated with 10^8 rad of gamma radiation clinically in 1971 [4–14].

Heads 28 mm in diameter were prepared for these prostheses using a COP alloy; a stainless steel containing 20% cobalt. High density polyethylene (HDP) (Million, followed later by UHMWPE) irradiated with 10^8 rad of gamma radiation was used for the socket. The prosthesis was named "SOM". We have been using SOM prostheses clinically since 1971. Alumina ceramics were also used later by Boutin [14] and Griss *et al.* [15] in Europe.

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There is a limit to how much wear of UHMWPE can be prevented when present UHMWPE is used in total joint prostheses, even if the component sliding on the UHMWPE is made of the best materials and by the best design [16–18]. When wear particles increase, osteolysis increases, causing loosening of the prostheses. In order to solve the problem, the total joint prosthesis needs to be developed using another material, or, the material properties of the present UHMWPE must be improved.

In 1970, in order to improve UHMWPE properties, UHMWPE was irradiated with gamma radiation in doses increasing to a maximum 100 Mrad. In tests using a cylinder-on-flat wear test machine, UHMWPE sockets irradiated with 100 Mrad gamma radiation were observed to be best, and were used clinically for total hip prostheses from 1971. Excellent clinical results were consistently obtained. In order to discover the optimum doses of gamma radiation, hip simulator tests were performed on crosslinked UHMWPE sockets irradiated with different levels of gamma radiation in excess of 100 Mrad. As hardness and brittleness of polyethylene increase with the level of the gamma radiation, good care must be taken in deciding the optimum dose of gamma radiation for use in clinical applications.

For total hip prosthesis combinations other than UHMWPE with metal or aluminum as the sliding parts (i.e. alumina-on-alumina and metal-on-metal combinations) have been highly regarded. In regards to this, we are presently designing an alumina-on-alumina total hip prosthesis. However, the basic design of these combinations of materials must be a simple "ball and socket" shape. In contrast, crosslinked UHMWPE material can be shaped for use in prostheses of every kind such as knee, ankle and so on.

2. Materials and methods

UHMWPE was crosslinked with gamma radiation in doses of 100, 500, and 1000 Mrad. First, soak tests were performed, together with measurements of the socket hardness of total hip prostheses (THP), both with and without gamma radiation. Following this, wear of these sockets in combination with a 28 mm diameter alumina head was measured using an in-house hip simulator. The decrement of thickness and frictional torque of the socket over the stated area were measured over a period of time; creep deformation was also measured via the hip simulator.

2.1. Hip simulator

In the simulator test, the socket was set below and femoral head ball set above. An alumina head was inserted on the taper of a Ti–6Al–4V alloy stem. A load was applied perpendicularly by an automatically controlled hydraulic system. Load was measured by a load cell. Lubrication fluids were pooled in the socket. The head ball was rotated around the longitudinal axis ±10°, and the socket was swung ±20°. Rotation and swing were synchronized. The rotation speed and swing were both 0.44 Hz (0.44 times per second). Both fluctuating and constant loads can be performed with this simulator. In this experiment a constant perpendicular load of 250 kg was used. A circulating saline solution was used as lubricant. The socket was fixed in a metal box with plaster of Paris, and the alumina head was inserted on the Ti–6Al–4V column on the axis of fixation (Fig. 1).

2.2. Socket and head ball used for the test

2.2.1. Polyethylene socket

Sockets were made of UHMWPE 340M (Mitsui Petrochemical Co.). First, a socket was prepared by turning, with an inner diameter of 28.3 mm, thickness 5 mm, outer rim thickness 3 mm and outer rim diameter 50 mm (Fig. 2). The second socket, other than

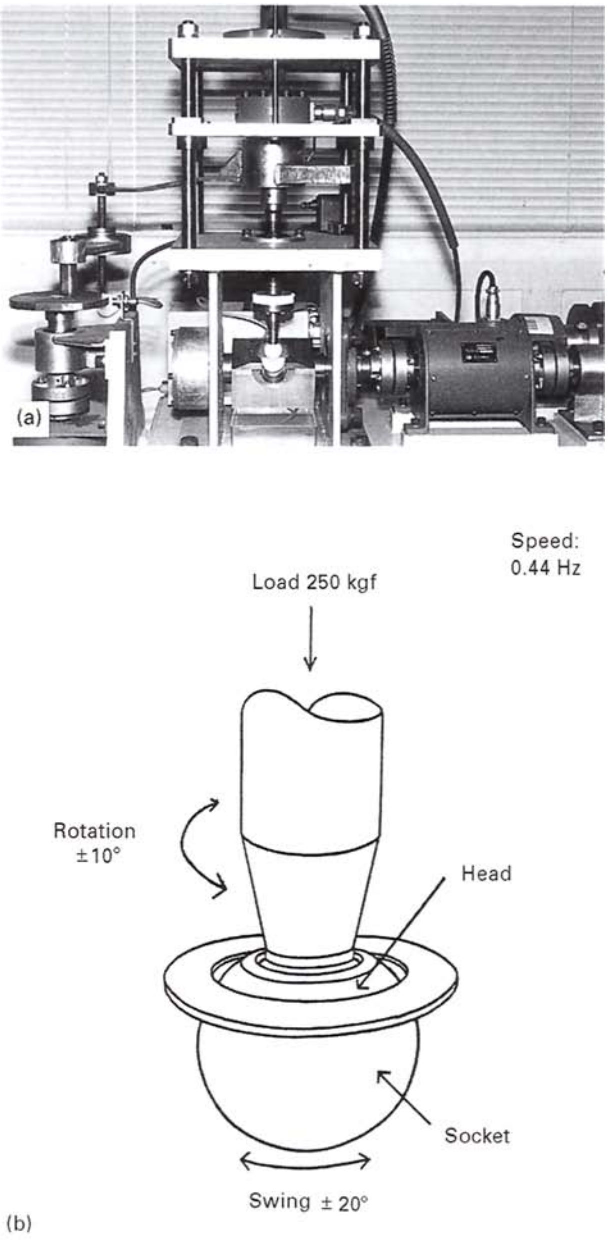

Figure 1 Hip simulator. A socket was set on the bottom and a femoral head ball was set on the upper. The femoral head ball was rotated on the longitudinal axis by ± 20° The speed was 0.44 Hz. A constant 250 kgf was loaded and saline solution was used for lubrication

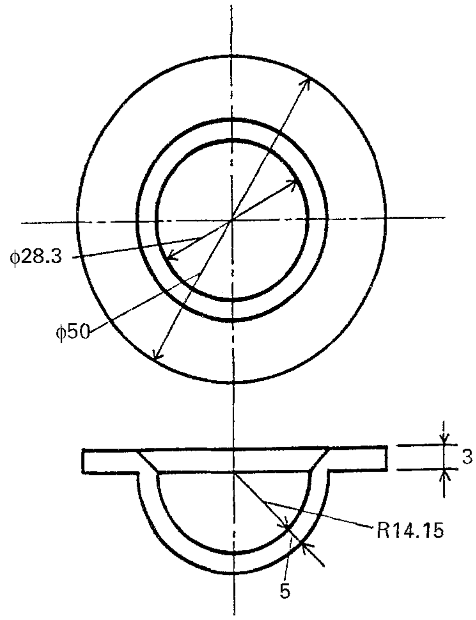

Figure 2 Shape of UHMW polyethylene socket.

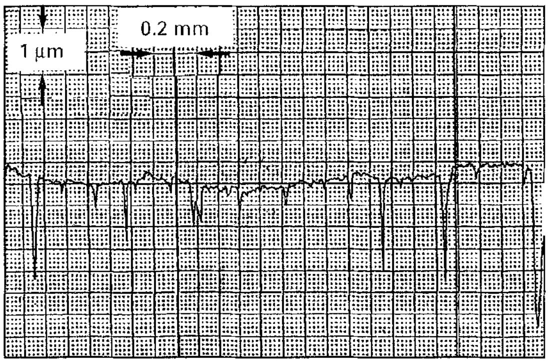

Figure 3 Surface roughness of UHMW polyethylene socket (Ry. 5.15 µm, maximum height).

being treated as turning on the inner surface, was prepared from the first socket. In order to perform mirror treatment to the first socket, a pressing made of the inside surface of the first socket was mirror finished, heated to 220 °C and pressed on to the inner surface of the first socket. The surface roughness was Ry 5.15 µm (maximum height) (Fig. 3). The sockets were irradiated with gamma rays in vacuum. The irradiation rate was 1.5×10^6 R/U$_v$. Radiation was performed from the outer side to the inner side.

In an earlier wear test using the cylinder-on-flat wear test machine mentioned earlier, of UHMWPE irradiated with increasing doses to a maximum of 100 Mrad (10^8 rad), the 100 Mrad dose (the largest dose) was observed to be the most effective [11, 15], and in clinical application of sockets irradiated at 100 Mrad, excellent results were obtained.

In consideration of the above, UHMWPE sockets irradiated with 0 rad, 1×10^8 rad (100 Mrad), 5×10^8 rad (500 Mrad) and 10×10^8 (1000 Mrad) gamma radiation were tested in order to expand the range of results. This irradiation changed the normally white colour of the polyethylene to brown. Decrement of the socket was measured on our hip simulator at the same time as measurements of frictional torque. As well as simulator tests, soak tests, calculations of cross-section hardness and measurements of creep deformation were performed.

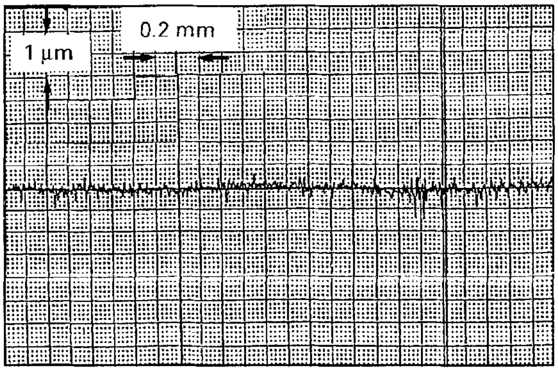

Figure 4 Surface roughness of an alumina femoral head ball (less than 0.5 µm).

2.2.2. Alumina head ball

An alumina head ball of 28.0 mm diameter was used. The surface roughness was Ry 1.05 µm (the maximum height) and the roughness was less than 0.5 µm (Fig. 4). The difference in diameter between the ball and the inner socket (clearance) was 0.3 mm; the inner diameter of the socket was 28.3 mm. The head ball was inserted on a tapered head made of Ti–6Al–4V alloy in the same way that a total hip prosthesis is used clinically.

3. Tests

3.1. Soak test

Soak tests were performed to observe water absorption into polyethylene in relation to level of gamma radiation dose.

3.1.1. Method

As a preliminary experiment, three sockets with mirror surface treatment without gamma radiation and three turned sockets without gamma radiation were soaked in saline solution and the change in weight of the sockets measured over a time period using a Mettler's electronic balance at a room temperature of 37 °C ± 1 °C. Testing procedures were performed in accordance with ASTM (F732-821), and a constant temperature water tank, Tabai PR-2G, was used for soaking. Subsequently, soak tests of the gamma irradiated sockets were performed.

3.1.2. Results and discussion

In the preliminary experiments, the weight changes of sockets without gamma radiation after 427 hours were less than ± 2 mg. There was no weight differences between sockets with a mirror treatment and sockets treated by turning. Weight changes of less than 2 mg were observed after the same period of exposure in every sample. These differences can be assumed to occur as a result of instrument errors. The quantity of water absorbed was extremely small.

The quantity of water absorbed into sockets irradiated with 1000 Mrad and 500 Mrad was about 30 mg after 7000 h, and for 100 Mrad was about 45 mg after

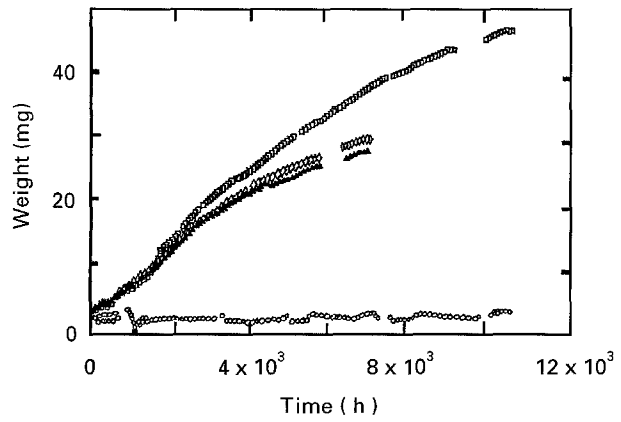

Figure 5 Soak test of UHMW polyethylene socket. No water absorption was found in the socket without gamma radiation, very small amounts of water absorption were found in the sockets with gamma radiation. Radiation dose: ○ zero : ▲ 5×10^8; ◇ 10×10^8, □ 1×10^8

10 000 hours; thereafter the change in the quantity of water absorbed remained constant in all sockets.

No water absorption was observed in sockets without gamma radiation, however, very small amounts of water absorption were observed in sockets with gamma radiation. It is conjectured that as the orientation of the crystal lattice of polyethylene was changed by radiation, molecular crosslinks $\left[\overset{|}{\underset{|}{C}}=O\right]$ and [–C=C–] were produced, the material became hydrophilic, and voids were produced at grain boundaries by H_2 generated in these reactions, and the water absorbability increased (Fig. 5).

3.2. Socket cross-section hardness

The hardness of the cross-section from inner surface to outer surface was measured in order to assess changes in material properties due to gamma radiation as the gamma radiation dose is inversely proportional to square of distance. It can be supposed that if hardness changes correspond with distance from the surface, wear of the socket will also change with time.

3.2.1. Methods

Hardness was measured at 15–30 points from 4–5.5 mm from medial to lateral direction on a central cross-section of the socket (Fig. 6).

Hardness was measured using a J.I.S. B7734 microhardness tester, that is the load divided by the surface area of an impression produced when a diamond square cone is loaded onto a material surface. The load used was 25 g.

3.2.2. Results and discussion

The hardness MHV (25 g) of polyethylene with radiation zero, 100 Mrad, 500 Mrad and 1000 Mrad was 3.59–4.11 (average 3.83), 5.63–6.46 (average 6.07), 6.78–7.91 (average 7.47) and 7.22–8.86 (average 8.14), respectively (Fig. 7).

In comparison with the socket without radiation, the hardness of polyethylene irradiated with 100 Mrad, 500 Mrad and 1000 Mrad treatments increased by about 1.6, 2.0 and 2.1 times, respectively (Fig. 8): hardness increased as radiation dose

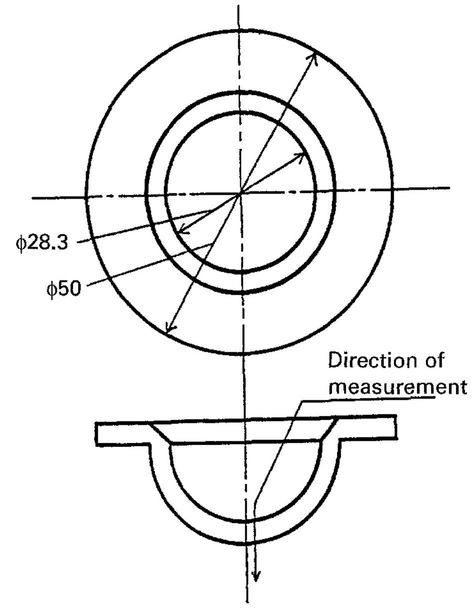

Figure 6 Section of the socket for measuring hardness. Hardness was measured at 15 to 30 points from 4 to 5.5 mm from medial to lateral direction on a central cross-section of the socket.

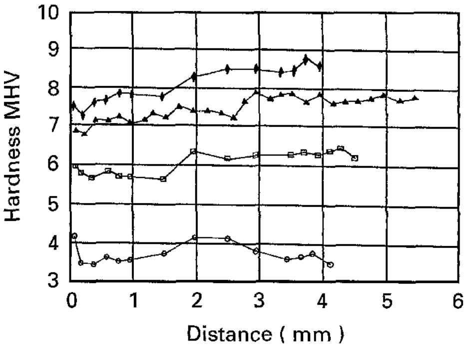

Figure 7 Hardness of UHMWPE socket. The hardness increased as the radiation dose increased. The hardness of the cross-section of polyethylene sockets without radiation did not change, however, those with radiation had increased hardness, increasing slightly at points nearer to the radiation origin. Radiation dose: ○ zero. □ 1×10^8; ▲ 5×10^8; ◆ 10×10^8

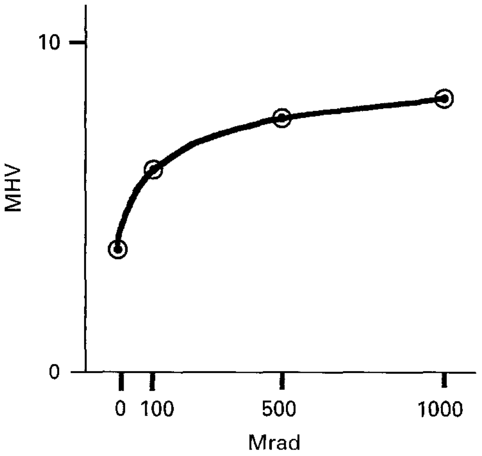

Figure 8 The hardness of polyethylene with radiation 100 Mrad, 500 Mrad and 1000 Mrad increased by about 1.6, 2.0, and 2.1 times, respectively, in comparison with those without radiation.

increased. However, the radiation dose was not directly proportional to hardness as it was observed that hardness increased rapidly until the dose neared 100 Mrad, then increased only slowly after that. The hardness of polyethylene cross-sections from sockets without radiation did not vary over the whole area, however, the hardness of those subjected to radiation increased slightly when the measuring point was near the origin of the radiation (Fig. 7).

However, as shown later, in all cases of gamma radiation, steady-state wear is less than one tenth of that without radiation. Therefore, it is supposed that wear is not dependent upon which side of the socket the radiation is applied.

3.3. Creep deformity

The measurement of creep deformity is very important, because it is premised that if the creep deformity of the polyethylene socket is great, wear of polyethylene socket also increased.

3.3.1. Method

To measure creep deformity a femoral head was inserted into a socket fixed in plaster of Paris and a weight of 300 kgf was loaded perpendicularly. The decrement depth of the socket was measured by means of micrometer over a time period, the test being performed in a constant temperature bath at 37 °C (Fig. 9).

Measurement points were at the centre of the socket (No. 9), and on four points (No. 5, 6, 7, 8) on a circle opened at 20°, and on four points (No. 1, 2, 3, 4) on a circle opened at 50° from a plumb line drawn from the centre of entry of the socket to the centre on the socket (No. 9) (Fig. 10). The decrement of thickness of the socket was also measured at these nine points. The load was sustained until deformation became constant, the load was then removed, and the measurement was finished when the deformation became constant following removal of the load.

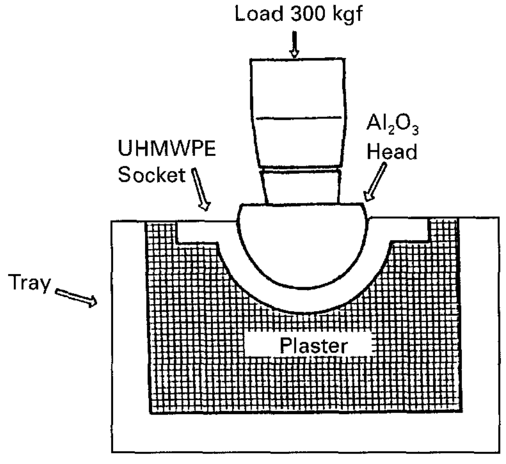

Figure 9 Scheme for measurement of socket creep deformity.

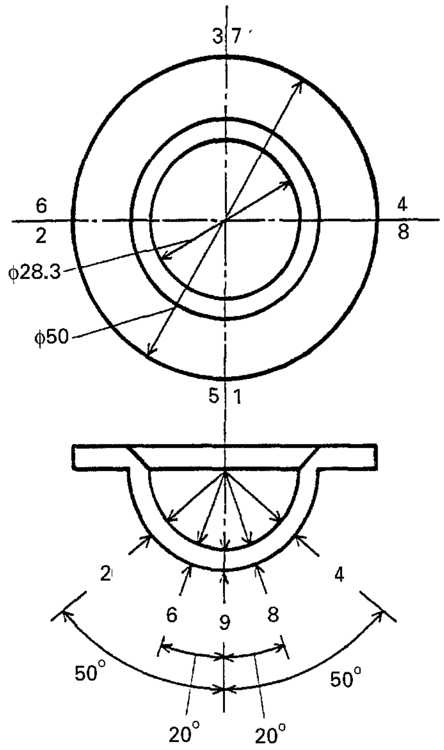

Figure 10 Measurement points for creep deformity and decrease in thickness. Nine points were measured.

3.3.2. Results and discussion

The creep deformity was greatest at the centre (No. 9) where the most load was applied, and was least at distances furthest from the centre in all test pieces.

At the centre (No. 9), the amount of creep deformation increased rapidly over the first 20 h, and thereafter increased, but at a slower rate.

The four sockets were measured at intervals while loaded, and then again after the load was removed. Measurements revealed that the socket without radiation deformed about − 180 μm while the one cross-linked with 100 Mrad gamma radiation deformed about − 65 μm after about 200 h. Sockets crosslinked with 500 Mrad and 1000 Mrad deformed about − 40 μm after about 300 h. Past 300 h, the deformation in all four socket types became constant. Following removal of the load, deformation of the socket without radiation, and those irradiated with of 100 Mrad, 500 Mrad and 1000 Mrad recovered to 53%, 8%, 38% and 38%, respectively, about 70 h later (Fig. 11). The tabulated results show that the amount of deformation exhibited by the socket with 100 Mrad radiation was considerably less than that for the socket without radiation, and further, those irradiated with 500 and 1000 Mrad deformed even less. There was no difference between those cross-linked with 500 Mrad and 1000 Mrad.

We noted in our observation of clinical cases that when a non-metal-backed thin socket is used, the entire shape deforms and wear increases. In contrast, in simulator tests the whole of the shape is protected due to the socket fixation in plaster of Paris. Creep deformation was observed at points other than the centre (No. 9) because these contacted the femoral

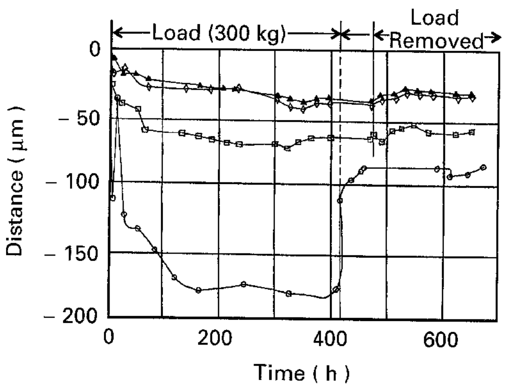

Figure 11 Creep of UHMWPE socket with radiation of 0 (—○—), 100 (—□—), 500 (—▲—), and 1000 Mrad (—◇—) at the maximum loaded points (Point No. 9)

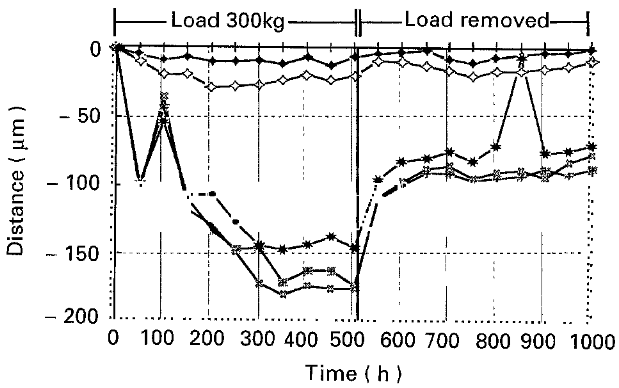

Figure 12 Creep of UHMWPE socket without radiation (radiation of 0 Mrad) at the nine points. Point 1 —◆—; 2 —◇—; 3 —✱—; 4 —+—; 5 – × – ; 6 —□—; 7 —✱—, 8 —⊠—; 9 —+—.

head and were also effected by creep from the centre point. In short, since the total reduction of socket thickness is a measure of wear combined with that of creep deformation, it is very important to measure the creep deformation to predict the wear of a socket.

Creep deformity observed on sockets without radiation was almost the same at the centre (No. 9) as it was at points 20° off-centre (No. 5, 6, 7, 8). At areas measured 50° off-centre (No. 1, 2, 3, 4), creep deformation was extremely small (Fig. 12). Creep deformation of the socket with 100 Mrad radiation at areas other than the centre (No. 9) was extremely small (Fig. 13). On the sockets irradiated with 500 Mrad and 1000 Mrad, as the distance from the centre increased, the amount of creep deformation decreased significantly (Figs 14 and 15).

In other words, creep deformation of the non-irradiated socket was large, deformation being almost the same at the centre (No. 9) as at areas 20° off-axis (No. 5, 6, 7, 8) because the deformation of the non-irradiated polyethylene socket was large overall. In comparison, the socket irradiated with 100 Mrad radiation had less creep deformation at the centre, consequently, deformation of the off-axis areas was much lower. Moreover, as creep deformation of sockets irradiated with 500 Mrad and 1000 Mrad were much smaller at the centre, the difference between deformation measured at the centre and off-axis was insignificant.

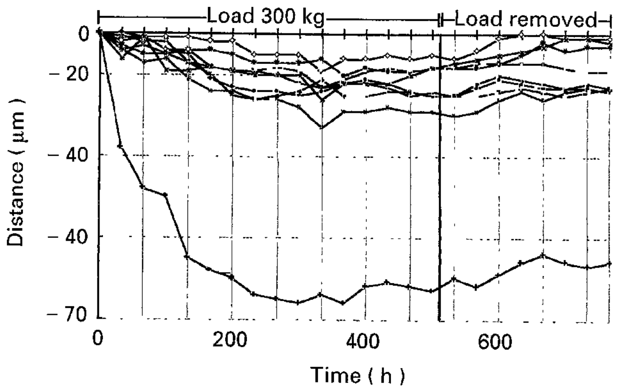

Figure 13 Creep of UHMWPE socket with radiation of 100 Mrad at the nine points: Point 1 —◆—; 2 —◇—; 3 —✱—; 4 —+—; 5 —✱—; 6 —□—; 7 —✱—; 8 —×—; 9 —+—.

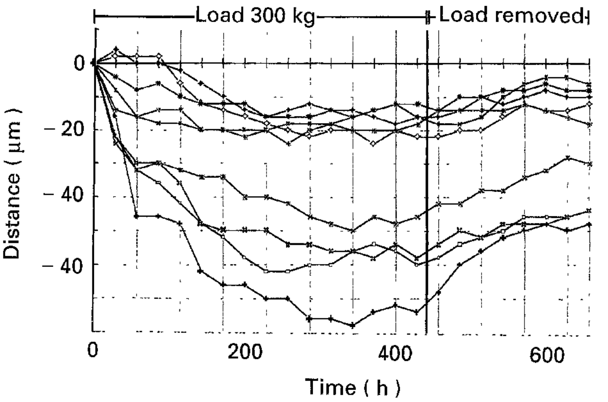

Figure 14 Creep of UHMWPE socket with radiation of 500 Mrad at the nine points: Point 1 —◆—; 2 —◇—; 3 —✱—; 4 —+—; 5 – × – ; 6 —□—; 7 —✱—; 8 —⊠—; 9 —+—.

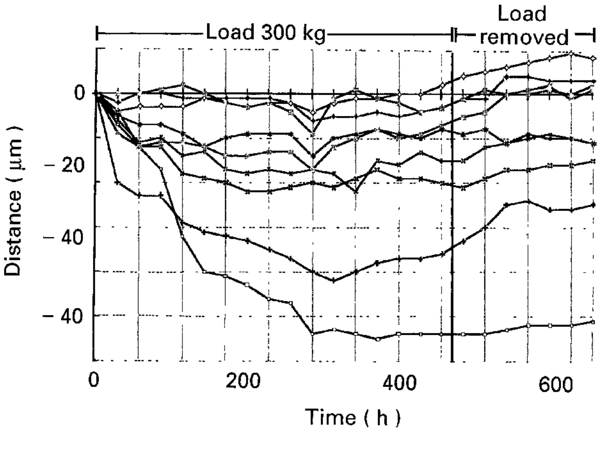

Figure 15 Creep of UHMWPE socket with radiation of 1000 Mrad at the nine points: Point 1 —◆—; 2 —◇—; 3 —✱—; 4 —+—; 5 – × – ; 6 —□—; 7 —✱—; 8 —⊠—; 9 —+—

3.4. Wear test

Pin-on-flat, cylinder-on-flat, ball-on-flat and simulators have all been used to test wear. The simulator test is the best way to approximate real wear.

3.4.1. Methods

The decrement of thickness of sockets (total quantity of both wear and creep deformity) made of

UHMWPE without gamma radiation and with gamma radiation of 100, 500 and 1000 Mrad was measured by means of a hip simulator. Test conditions are noted in the section detailing the hip simulator. The test was performed at a room temperature of 25 ± 3 °C (Fig. 1).

The decrement in thickness of the socket was measured by means of a point micrometer every 10 000 cycles. The test length was 200 000 cycles. This test duration was used as the socket with no radiation, which had the greatest decrement, had attained steady-state wear by 200 000 cycles. The measurement was performed at Points 1–9 (Fig. 10).

3.4.2. Results

In the case of the non-irradiated socket, at the centre (No. 9), initially the thickness of the socket decreased rapidly (initial wear), afterwards, a constant decrease in thickness of the socket continued (steady-state wear) (Fig. 16). Relatively higher decrease in thickness was observed at Points 5, 6, 7 and 8, at 20° off-axis because as the thickness decreased significantly at the centre, off-axis points were strongly affected. These tendencies were similar to those seen in measurements of creep deformity (Fig. 17). Steady-state wear at the centre began at about 130 000 cycles.

In the case of irradiated sockets, initial wear at the centre (No. 9) decreased relative to the magnitude of radiation in comparison to the case without radiation. The initial wear of sockets without radiation and with radiation of 100, 500 and 1000 Mrad was about −150 µm, −100 µm, −70 µm and −50 µm, respectively. The time to attain steady-state wear for the four cases 0, 100, 500 and 1000 Mrad was about 0.15 million cycles, 0.15 million cycles (very similar to the non-irradiated case), 0.1 million cycles (2/3 times of the non-radiation case) and 0.05 million cycles (1/3 times that of the non-radiation case), respectively.

Thus, the time to attain steady-state wear is shorter with increasing doses of radiation (Fig. 16).

A small decrease in thickness was observed at Points 5, 6, 7 and 8. These decreases were similar to those seen off-axis in the creep deformation measurements (Fig. 17). The decrease in thickness of sockets with gamma radiation was smaller than in the socket without radiation at all points, and became smaller with increasing doses of radiation. The decrease in socket thickness at points 20° off-axis (No. 5, 6, 7 and 8) was about 50% of that at the centre (No. 9), and the rate of decrease at points 50° off-axis (No. 1, 2, 3 and 4) was lower with increasing doses of radiation than that at the centre (Figs 18, 19 and 20).

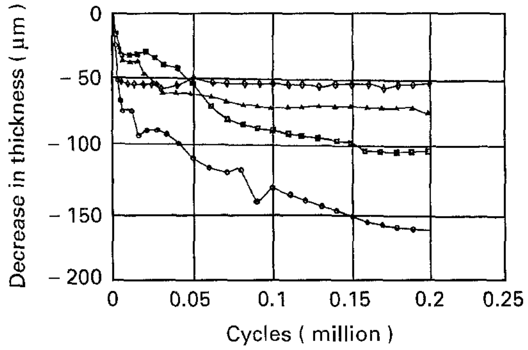

Figure 16 Decrease in thickness of UHMWPE sockets with radiation 0 (—○—), 100 (—□—), 500 (—▲—), and 1000 Mrad (—◇—) at the maximum loaded points (Point No. 9)

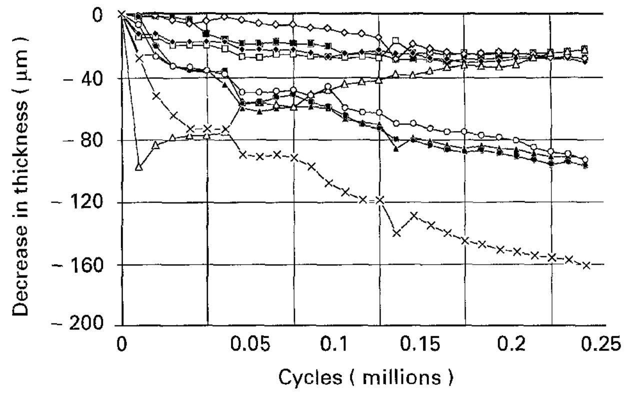

Figure 17 Decrease in thickness of UHMWPE sockets without radiation (radiation of 0 Mrad) at the nine points· —■— Point 1; —□— 2, —◆— 3; —◇— 4, —▲— 5, —△— 6; —●— 7; —○— 8; —×— 9

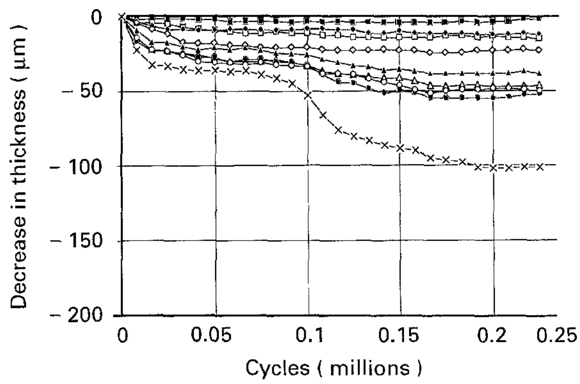

Figure 18 Decrease in thickness of UHMWPE sockets with radiation of 100 Mrad at the nine points: —■— Point 1; —□— 2; —◆— 3; —◇— 4, —▲— 5, —△— 6; —●— 7; —○— 8; —×— 9.

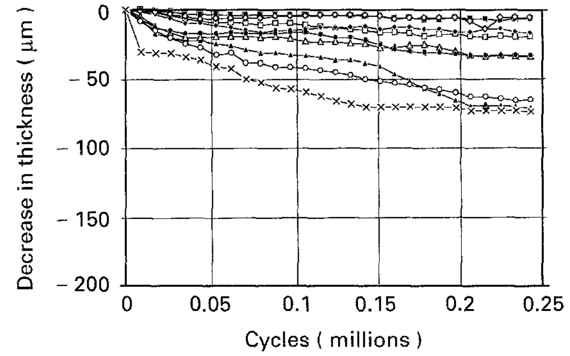

Figure 19 Decrease in thickness of UHMWPE sockets with radiation 500 Mrad at the nine points: —■— Point 1, —□— 2; —◆— 3, —◇— 4, —▲— 5, —△— 6; —●— 7; —○— 8; —×— 9.

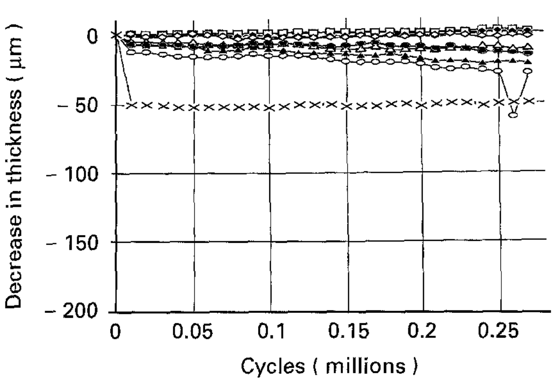

Figure 20 Decrease in thickness of UHMWPE sockets with radiation of 1000 Mrad at the nine points: —■— Point 1; —□— 2; —◆— 3; —◇— 4, —▲— 5, —△— 6; —●— 7; —○— 8; —×— 9.

Under steady-state wear at the centre (No. 9), the decrease in thickness of the socket without radiation after 5000 cycles was about 1 μm (200 μm/million cycles), while that with radiation of 100, 500 and 1000 Mrad was less than 0.1 μm (20 μm/million cycles); i.e. the decrease in thickness in the case of radiated sockets was 10 times less than that of non-radiated sockets.

The surface of sockets loaded during the hip simulator test were observed by SEM. The non-irradiated sockets showed scratches and peeling-off of the surface polyethylene, while irradiated sockets showed much less evidence of scratches, and peeling-off decreased as the radiation dose increased (Fig. 21).

3.4.3. Discussion

It is supposed that the initial decrease in thickness (initial wear) is affected by creep deformity rather than by the surface condition of a socket.

Reviewing the results, initial wear of the socket without radiation was −150 μm, and the initial wear of sockets with radiation of 100, 500 and 1000 Mrad were, −80 to −100 μm (60% of that without radiation), −60 to −70 μm (43% of that without radiation) and −50 μm (33% of that without radiation), respectively. The creep deformity of the socket without radiation and those with radiation of 100, 500 and 1000 Mrad was −120 μm, −40 μm, −20 μm and −20 μm, respectively, over the initial 5 h. Considering these results, the characteristic of the socket's initial thickness decrement was in accordance with the trend of creep deformity.

Even polyethylene socket surfaces irradiated in vacuum oxidized (due to residual oxygen) in extremely small quantities, and the initial wear increased. The increase in initial wear is due to the fact that the hardness of non-irradiated-polyethylene is not always enough to bear both load and sliding present under normal weight bearing circumstances. Most likely, the surface of the polyethylene peels off and wear increases as a direct consequence.

In summary, the tests showed that as the hardness of polyethylene increases with irradiation, peeling-off of the surface is very much reduced, the occurrence of creep deformation decreases, and further, decreases in socket thickness reduces. However, although the initial decrease in thickness of an irradiated socket (initial wear) is reduced with higher doses of radiation, steady-state wear of all three irradiated sockets was extremely small, with scarcely any differences in some cases. The toughness of the polyethylene decreased when radiation was increased further.

Therefore, the optimum radiation dose is slightly higher than 100 Mrad. This increases the toughness of the polyethylene and reduces the initial wear. The exact optimum dose is being sought at present.

3.5. Frictional torque

Frictional torque acts on a joint when a joint moves. If the frictional torque increases, the shearing strength and stress due to vibration increase at the interface between bone and component, which sometimes is the cause of component loosening.

Frictional torque of conventional total hip prostheses in combination with a non-gamma-irradiated-UHMWPE socket and metal or alumina femoral head is relatively low, and there is no problem clinically, based on 30 years of clinical evidence.

Moreover, based on clinical experiences of over 20 years, there have been no problems with total hip prostheses comprised of a combination of UHMWPE socket with radiation up to 100 Mrad and metal head. However, torque must not greatly exceed the maximum manageable by the 100 Mrad socket.

3.5.1. Methods

The frictional torque of rotation and swing in joints was measured during the wear tests by means of the hip simulator (Fig. 1). A torque meter (strain gauge system) was set between the swing axis, with an electric motor used as power source. The functional torque was detected continuously and recorded on a chart recorder (Fig. 22). The frictional torque of all test pieces was measured over the period from 0–2 × 10^4 cycles.

3.5.2. Results and discussion

Rotational torque was extremely small in every socket, however, rotation torque is present at all times while moving. Swing torque is zero at the central axis. Frictional torque, both rotation and swing, was high at the start of movement. These phenomena can be explained as follows: frictional torque increases at the time of changing from static friction to dynamic friction. Moreover, no lubrication film of saline solution exists in a joint at rest, lubricant entering into the joint again only after movement.

Rotational torque was 0.65 to 0.00 Nm in every test pieces except at the beginning of the movement. Gamma radiation had no influence. The maximum and minimum of a swing frictional torque of a socket without radiation and with radiation of 100, 500 and 1000 Mrad were 1.60–2.84 N m, 3.24–9.02 N m, 5.23–8.78 N m and 2.51–6.79 N m, respectively (Figs 23, 24, 25, 26).

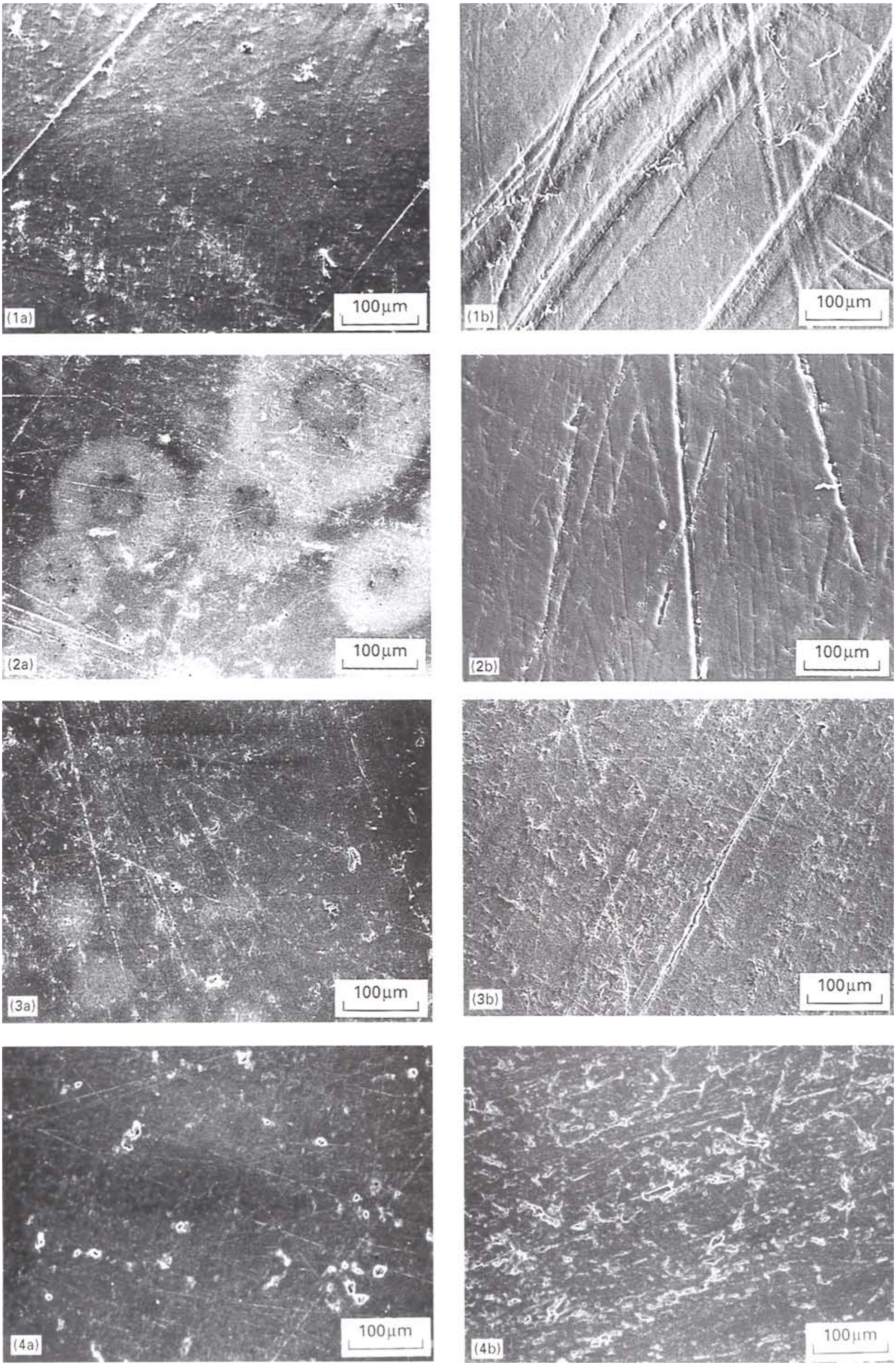

Figure 21 Surfaces of the sockets observed by SEM (a) before and (b) after simulator tests: (1) without radiation; (2) radiation of 100 Mrad; (3) radiation of 500 Mrad; (4) radiation of 1000 Mrad.

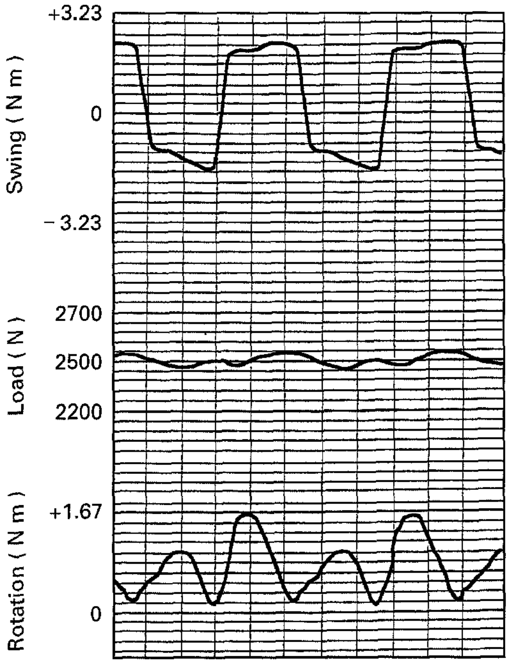

Figure 22 Frictional torque of rotation and swing, and load detected continuously and recorded on the chart recorder.

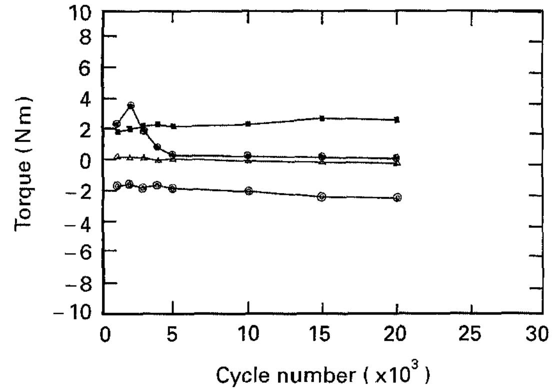

Figure 23 Frictional torque of the socket without radiation. —■— swing of the socket to the right; —⊙— swing of the socket to the left; —⊙— rotation of the head to the right (cw); —△— rotation of the head to the left (ccw).

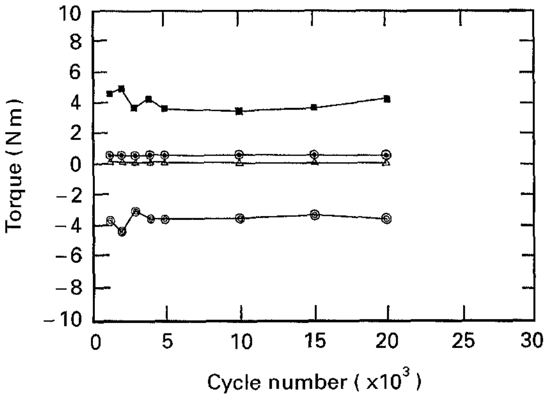

Figure 24 Frictional torque of the socket with radiation of 100 Mrad. —■— swing of the socket to the right; —⊙— swing of the socket to the left; —⊙— rotation of the head to the right (cw); —△— rotation of the head to the left (ccw).

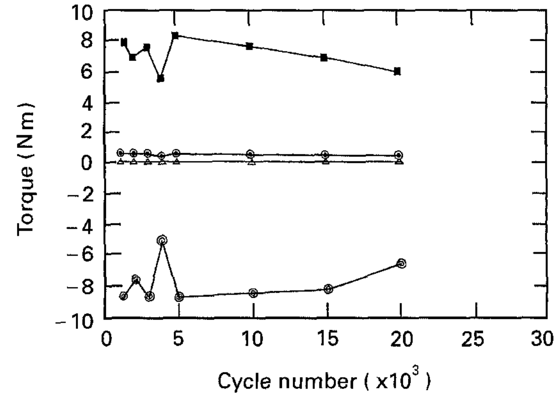

Figure 25 Frictional torque of the socket with radiation of 500 Mrad. —■— swing of the socket to the right; —⊙— swing of the socket to the left; —⊙— rotation of the head to the right (cw); —△— rotation of the head to the left (ccw).

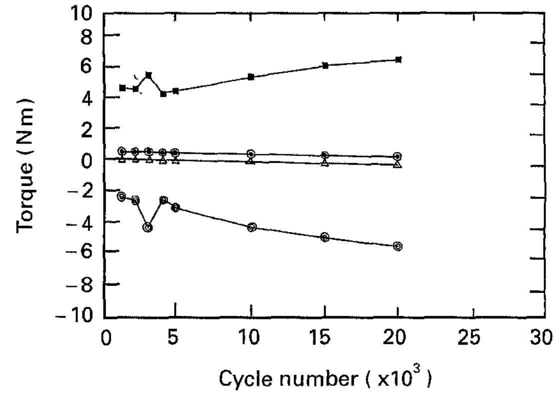

Figure 26 Frictional torque of the socket with radiation of 1000 Mrad. —■— swing of the socket to the right; —⊙— swing of the socket to the left; —⊙— rotation of the head to the right (cw); —△— rotation of the head to the left (ccw).

Swing frictional torque is strongly affected by gamma radiation. Swing frictional torque increased with increasing levels of radiation. Thus, it is supposed that the hardness of the polyethylene increased in relation to the increase of radiation dose.

The changes in loading were 230.3 to 280.0 kg while hip simulator testing. These changes were about 10% of the 250 kg load.

Swing frictional torque increased by two to three times due to gamma radiation, but there was almost no difference in swing frictional torque in the 100–1000 Mrad range of radiation. It is supposed that as the hardness of the increased due to radiation, swing torque also increased.

In over 20 years of clinical experience with polyethylene sockets subjected to 100 Mrad gamma irradiation and a metal head, an increase of frictional torque has not influenced the interface between bone and implant. Therefore, clinically there will be no problems due to frictional torque with a socket irradiated with 100–1000 Mrad.

3.6. Conclusions

As the hardness of polyethylene increases and creep deformity decreases, brittleness increases, with increasing radiation doses. The creep deformity of the UHMWPE socket with a radiation dose of 100 Mrad is relatively greater than that for 500 and 1000 Mrad, however, the decrease in socket thickness (wear including creep deformity) was very small and almost the same at steady-state wear in sockets subjected to the three different radiation dose levels.

The decrease in the thickness of a socket is small at the initial stage of wear with increasing doses of radiation, and is extremely small when steady-state wear is reached; there is scarcely any difference in the wear of the three irradiated sockets tested. Synthetically, judging from hardness, creep deformity, initial wear and steady-state wear, a gamma radiation dose a little higher than 100 Mrad is supposed to be the optimum. The optimum dose is now being sought.

In conclusion, as a low-wear total hip prosthesis, the combination of a UHMWPE socket with gamma radiation dose a little higher than 100 Mrad and an alumina or zirconia femoral head is supposed to be the best at present. Moreover, these combinations can be expected to be widely applicable to other kinds of total joint prostheses.

4. Summary

Wear, frictional torque and creep deformity of UHMWPE sockets crosslinked by gamma radiation in high doses of 100, 500 and 1000 Mrad, in combination with 28 mm alumina heads were measured using a hip simulator under a constant load of 250 kg with lubrication by saline solution. Soak tests and measurements of hardness were performed. UHMWPE was changed to a slightly hydrophilic form after gamma radiation and hardness increased with increasing radiation dose. Creep deformity of UHMWPE was decreased by gamma radiation. Decrease in thickness of a socket is small at the initial stage of wear with increasing doses of radiation, and is extremely small when wear reaches steady-state in all sockets.

At the maximum loading area, the initial wear (decrease in thickness) of sockets with radiation of 0, 100, 500 and 1000 Mrad was $-150\ \mu\text{m}$, $-100\ \mu\text{m}$, $-70\ \mu\text{m}$ and $-50\ \mu\text{m}$, respectively. The time needed to attain steady-state wear was about 0.15×10^6, 0.15×10^6 (nearly equal to that without radiation), about 0.1×10^6 and about 0.05×10^6 cycles, respectively.

At steady-state wear, decrease in the thickness of the socket without radiation was about $200\ \mu\text{m}/1 \times 10^6$ cycles, and that with radiation of 100, 500 and 1000 Mrad was less than $20\ \mu\text{m}/1 \times 10^6$ cycles. By SEM observation, scratches and peeling-off of polyethylene on the surface was shown to be decreased as the radiation dose was increased. Rotational torque was 0.65 to 0.00 Nm in every case. The maximum and minimum swing frictional torque of sockets with radiation of 0, 100, 500 and 1000 Mrad were 1.60–2.84 Nm, 3.24–9.02 Nm, 5.23–8.78 Nm and 2.51–6.79 Nm, respectively. Swing frictional torque increased 2–3 times as a result of gamma radiation. A total hip prostheses having a UHMWPE socket subjected to a gamma radiation dose of a little higher than 100 Mrad combined with an alumina or zirconia femoral head is suggested to be the best.

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Received 1 May
and accepted 30 May 1995