The optimum dose of gamma radiation–heavy doses to low wear polyethylene in total hip prostheses

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Wear volume, surface area and coefficient of friction of UHMWPE cup crosslinked with gamma radiation of 0, 50, 75, 100, 125, 150 and 200 Mrad sliding against an alumina ball were measured using a sphere-on-flat reciprocating type tribology testing machine. The effects of gamma radiation were scarcely observed in coefficient of friction. The coefficient of friction under lubricated (distilled water) and non-lubricated testing conditions was 0.08 to 0.12 and 0.20 to 0.25, respectively. The wear volume of UHMWPE with radiation of 50 Mrad, 75 to 150 Mrad, and 200 Mrad was 70 to 80%, 18 to 25%, and 12 to 15%, respectively, in comparison to non-irradiated specimens. Elongation and tensile strength of UHMWPE with radiation of 100 Mrad decreased to 6%, and 50% of that without radiation, respectively. The hardness increased with increase of the radiation dose. From several kinds of tribological findings, mechanical strength tests, and studies of long-term clinical findings, it is concluded that approximately 200 Mrad is the optimum dose of gamma radiation for clinical use in total hip prostheses.

1. Introduction

In 1960, Charnley chose Teflon with the lowest coefficient of friction for the socket and a 22 mm metal head for the femur of a total hip prosthesis [1]. However, Teflon was found to wear much too quickly. A change was made to high density polyethylene (HDP) in November 1962, which, with various improvements in molecular weight, has been used up to the present time [2]. The RCH 1000 (Ruhr Chemie) versions of ultra-high molecular weight polyethylene (UHMWPE) are quoted to date as having a molecular weight of 2 to 500 million. After the Charnley prosthesis, many surgeons have tried several different prostheses. In 1970, using a cylinder-on-flat wear machine, the authors made wear tests of crosslinked UHMWPE gamma-irradiated with several high doses of Co^{60} of up to 100 Mrad. The results showed that the smallest amount of wear, including creep deformation, was at 100 Mrad (10^8 rad).

We began to use crosslinked UHMWPE irradiated with 100 Mrad (10^8 rad) of gamma radiation clinically in 1971. The prosthesis was named "SOM" after the initials of the developers T. Shikita, H. Oonishi and Mizuho Medical Instruments Corporation [3–8]. The wear rate of the cup with gamma radiation of 100 Mrad was less than 25% of that without gamma radiation. In order to discover the optimum doses of gamma radiation, wear tests using a hip simulator test machine were performed on crosslinked UHMWPE cups irradiated with widely different levels of gamma radiation; 0, 100, 500 and 1000 Mrad. The steady-state wear of the cup with radiation of 100 Mrad was 10% of that without radiation, and that with radiation of 500 or 1000 Mrad was 1% of that without radiation [9]. However, it was supposed that, as the greater the dose of gamma radiation the greater the brittleness, it would be reasonable to find optimum doses of gamma radiation near 100 Mrad.

2. A sphere-on-flat reciprocation type tribology testing apparatus

It is true that the tribological properties of solids are significantly affected by environmental parameters such as lubricants, atmosphere, temperature, humidity and so on. Furthermore, the conditions of contact and frictional movement between the solids are very effective aspects in tribological tests, from the mechanical point of view. In brief, an appropriate tribological testing machine, in which the frictional conditions of the machine are comparable to those of the practical contact elements, should be chosen. Wear testing rigs can be divided into the following three groups, in terms of geometry of the contact at the initial stage of the wear: (1) point contact type; (2) line contact type; and (3) plane contact type. According to the movement of the contacting components, the testing rig can be further subdivided into two categories: (1) rolling contact type; and (2) sliding contact type. In addition, it can be classified into two kinds from the directional point of view: (1) unidirectional friction type; and (2) reciprocating friction type. As a representative example of the unidirectional friction type testing rig, pin (or sphere)-on-disc testing machines can be introduced. This testing machine shows a constant unidirectional frictional velocity. The investigation of the dependence of frictional velocity of a solid can be performed using this testing machine. The value of torque can be easily measured. It is, however, not easy to evaluate the wear volume (volume lost due to wear), as the shape of the worn damage shows a large circular trajectory. On the other hand, using a reciprocation friction type testing rig, it is quite easy to measure the wear volume, because the wear damage corresponds to the reciprocating stroke. In addition, the measurement of coefficient of friction is comparably simple. However, with this type of rig the frictional velocity is not constant at all points on the path of the reciprocating oscillation. This type is, therefore, inadequate to investigate a material in which tribological properties are significantly governed by frictional velocity.

For example, hip joints predominantly show point-contact-type, sliding-contact-type and nonconstant-frictional-velocity-type movements. After taking account of these aspects, an appropriate tribological testing machine should be chosen before the tribological properties of hip prostheses are investigated. The variations of both the coefficient of friction and the wear volume, affected by the combination of materials and the conditions of lubrication, are the most important data in the tests. It can, therefore, be considered that a sliding contact type reciprocating tribology testing machine is the most suitable testing rig in the tribological examinations of hip prostheses.

In this paper, tribological studies of UHMWPE with heavy doses of gamma radiation using a sphere-on-flat reciprocating type testing machine (used in the investigation of the tribological properties of arthroplasty by the authors) is described.

2.1. Design

2.1.1. Sphere-on-flat reciprocating type tribology testing machine

A schematic diagram of a sphere-on-flat reciprocating type tribology testing apparatus is shown in Fig. 1. The specimen contact consists of a sphere-on-flat. The upper spherical specimen is stationary and the lower flat specimen oscillates. A 10 mm diameter sphere is usually used for the upper specimen, and the size of the lower flat specimen can be arranged according to the geometry of the lower specimen holder. As shown in Fig. 1, the normal load is applied to the upper specimen holding arm by the loading weight. The magnitude of the load, from 490 to 5390 mN, can be adjusted by the weight. The normal load corresponds to half of the applied load as the weight holder is located at the centre of the upper specimen holding arm. By this means, a couple of the same weight are usually used as a set. The reciprocating oscillation is produced by the eccentric cam. The frequency of the oscillation can be regulated by a rotating speed controlled servo-motor, from 1 to 10 Hz, linked with a personal computer. The reciprocating stroke, from 2 to 10 mm, can be adjusted using the eccentric cam. Throughout the tests, tangential force, coefficient of friction, temperature, pressure in vacuum and the displacement of the upper specimen at each step can be simultaneously indicated on

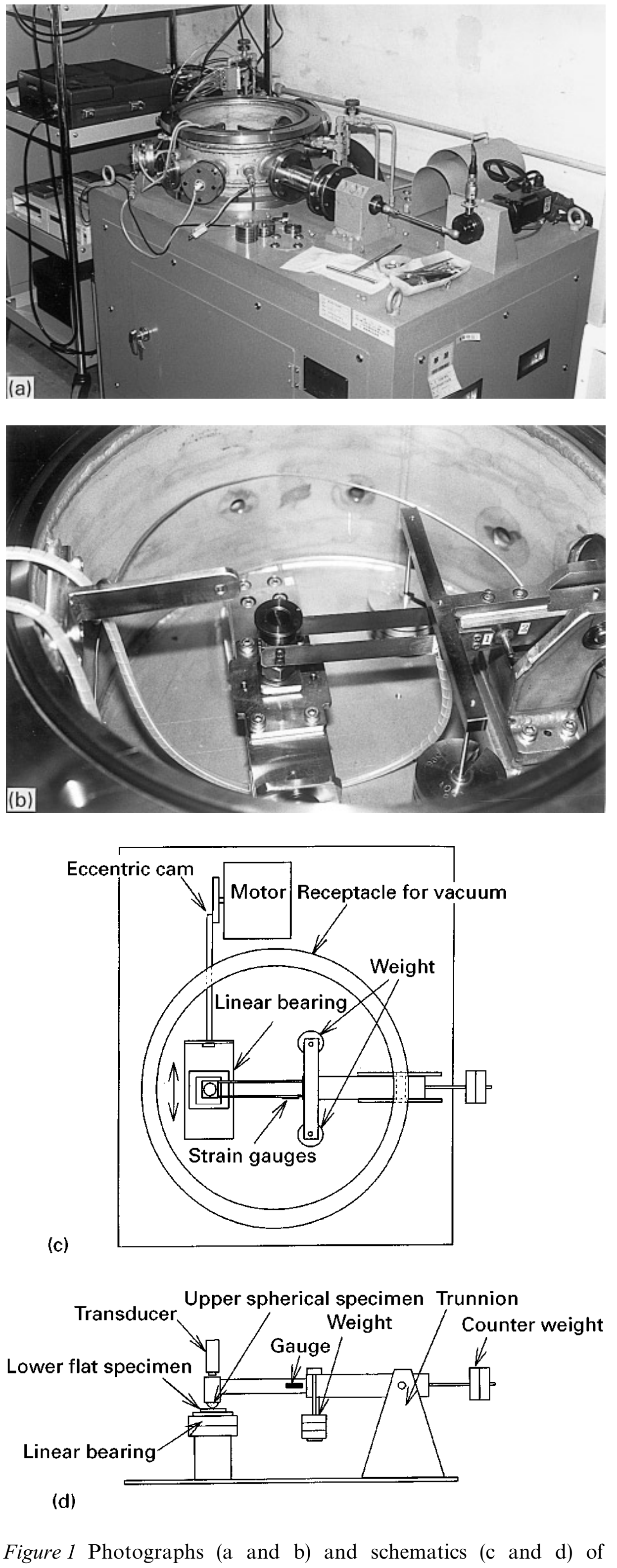

Figure 1 Photographs (a and b) and schematics (c and d) of a sphere-on-flat reciprocating type tribology testing machine.

the computer display. Sampled data are recorded in a computer file.

2.1.2. Temperature control

A furnace is used for elevated temperature tribological tests under non-lubricated conditions only. The maximum temperature is 873 K. The furnace consists of two parts: the upper part can be removed when the test specimens are placed in the holders. Both the upper and lower specimens are located in the uniform heat zone of the furnace, and a thermocouple is used to measure the furnace temperature. A thyristor unit temperature controller is used to keep the temperature constant, control the heating speed, and display the furnace temperature. As shown in Fig. 2, a vessel surrounded with a ceramic band heater is used for the tests in liquid, instead of using the furnace. The vessel is attached to the lower specimen holding device, which is located on the linear bearing. The lower flat specimen and a thermocouple are placed in the vessel. The area in contact between the upper and lower specimens is fully steeped in liquid. The liquid temperature can be raised to 423 K, using the aforementioned thyristor unit temperature controller.

2.1.3. Measurement of displacement of upper specimen

A commercially available transducer is set above the upper specimen holder. The transducer is not in contact with the holder. The sensor head of the transducer can read the distance from the holder with the variation of eddy current. It can be, therefore, used to measure simultaneously the displacement of the upper spherical specimen during the wear tests.

2.1.4. Atmosphere control

Tests in vacuum, up to 1.33 Pa, can be carried out at room temperature under non-lubricated testing conditions. The atmosphere in the chamber may be of various kinds of gas.

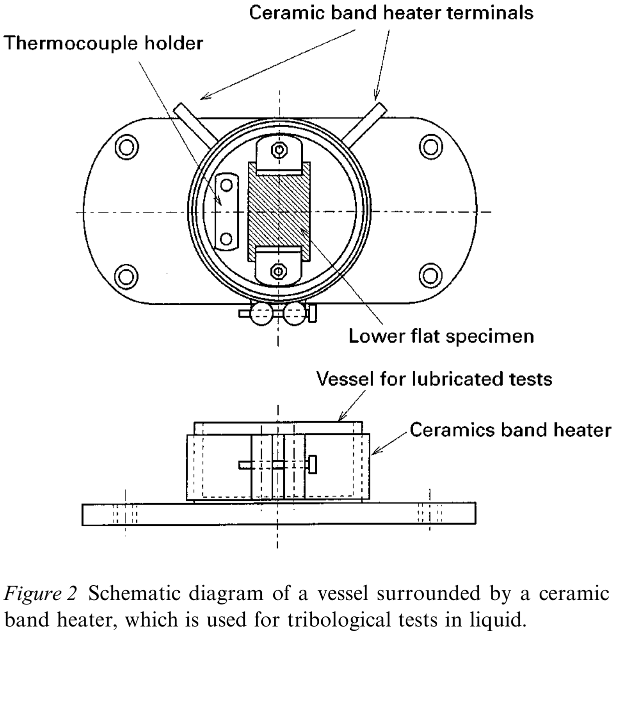

Figure 2 Schematic diagram of a vessel surrounded by a ceramic band heater, which is used for tribological tests in liquid.

2.1.5. Coefficient of friction

A part of the upper specimen holding arm consists of two steel plates, and strain gauges are disposed there. The strain gauges are linked, via an amplifier, to a personal computer to calculate the coefficient of friction. The tangential force is sampled every 5 ms by the computer. According to the direction of the reciprocating oscillation, the tangential force indicates both positive and negative values, as shown in Fig. 3. Initially the turning points of the cyclic trapezium-like-wave (i.e. direction reversals A, B, C, D, E and F in Fig. 3) are found. The middle of the turning points is subsequently defined to be a peak P1, P2, P3, P4, and P5 in Fig. 3. Hence, the peak-to-peak tangential force over a cycle can be obtained by the difference between P1 and P2 or P3 and P4, $2F$. Consequently, the coefficient of friction over a half cycle, μ, can be found from the following equation;

$$\mu = \frac{1}{2} \times \frac{2F}{N}$$

where N is the normal load.

2.1.6. Volume and surface area of wear scar

After the wear tests, the geometry of the wear scars on both the spherical and flat specimens is measured by parallel profilometer traces at specific intervals, such as 100 μm. At each trace, the background is initially defined at both sides of the wear scar, as shown in Fig. 4. The background line is approximated by the method of least squares.

The area of each trace, S, corresponds to the area below the background line. The calculation of the wear volume, V, uses the following equation;

$$V = \sum S \times (n-1) \times \frac{d}{n}$$

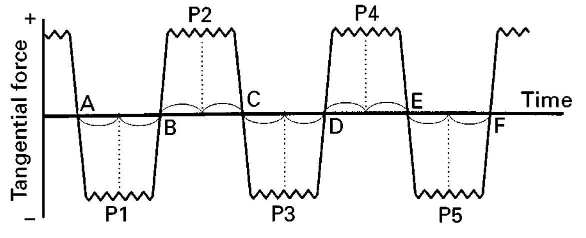

Figure 3 Relationship between sampling time and tangential force.

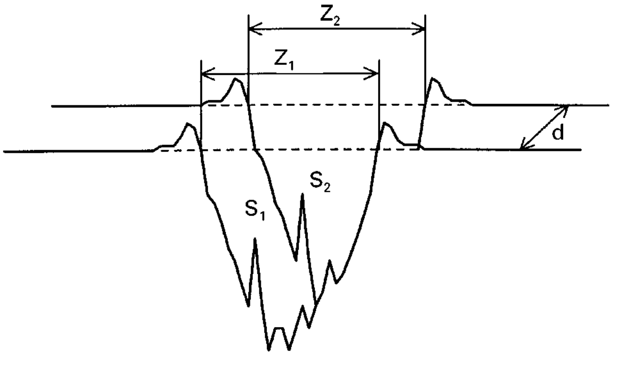

Figure 4 Geometry of wear scar measured by parallel profilometer.

where n is the number of parallel traces, and d is the interval of the traces. The surface area, A, is calculated from each profile of the wear scar by the following equation;

$$A = \sum Z \times \frac{d}{2}$$

Here Z represents the length of the locus in each trace.

2.2. Materials for tribological tests

The original polyethylene material was GUR415 UHMWPE. The process treatments of the material were as follows:

(1) gamma radiation by Co^{60} to UHMWPE rods which diameter was 63.5 mm in atmosphere, which doses were 50, 75, 100, 125, 150 and 200 Mrad respectively;
(2) heat treatment in reduced pressure at 110 °C for 2 h;
(3) machining by cutting from large blocks;
(4) lapping with waterproof abrasive paper #1200 in water.

The test pieces were of size 20 × 20 × 5 mm.

The surface roughness of the centreline average height R_a was 0.23 µm. The maximum value was 0.34 µm and the minimum value was 0.14 µm. This was an average value calculated from four test pieces picked at random. The size of the alumina ball was 10 mm in diameter. The surface roughness R_{max} was 5.1 µm and the roundness was 0.66 µm. For the wear test, an Al_2O_3 ball of 10 mm diameter was used for the upper spherical specimen and the UHMWPE plate specimens were adapted as the lower flat specimens. The UHMWPE plate specimens were made from large blocks without gamma radiation and with gamma radiation of 50, 75, 100, 125, 150 and 200 Mrad (Fig. 5).

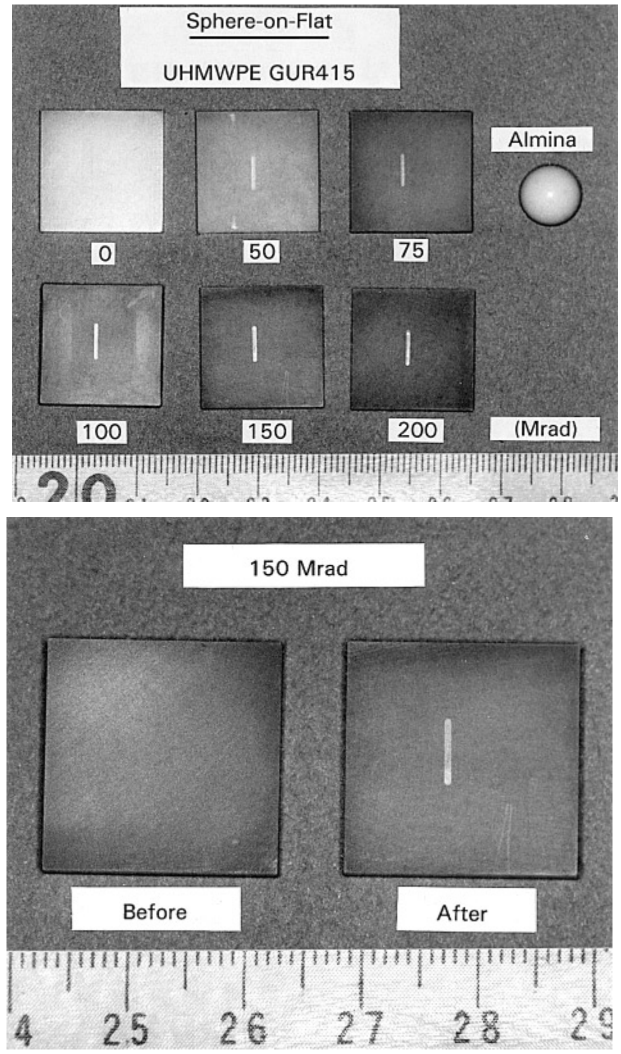

Figure 5 Alumina ball and UHMWPE gamma-irradiated plates used on the sphere-on-flat reciprocating type tribological test machine.

2.3. Experimental methods

2.3.1. Experimental methods for tribological tests

The sphere-on-flat reciprocating type tribology testing apparatus was used at various normal loads, reciprocating strokes, temperatures and atmospheres. For the tribological tests, GUR415 UHMWPE specimens irradiated with various doses of gamma rays were prepared.

The tribological tests were performed under the test conditions shown in Table I. An alumina ball of 10 mm diameter was used for the upper spherical specimen. The UHMWPE plate specimens were adapted as the lower flat specimens. Three-dimensional diagrams of the wear scars on the UHMWPE specimens were obtained using the parallel profilometer. Simultaneously, both the volume and the surface area of each wear scar were calculated. For the test, five test pieces from each type of material were used. Wear particles of UHMWPE were observed by scanning electron microscopy.

TABLE I Conditions of the sphere-on-flat reciprocating type tribology test

Test specimens	
UHMWPE GUR415	20 × 20 × 5 mm
Gamma radiation:	0, 50, 75, 100, 125, 150, 200 Mrad
Test conditions	
Upper spherical component	10 mm dia. Al_2O_3 ball
Normal load	4.9 N
Reciprocating stroke	6 mm
Reciprocating frequency	2 Hz
Maximum number of cycles	10 000 cycles
Temperature of unlubricated conditions	20 °C (room temperature)
Temperature of lubricated conditions	37 °C

2.3.2. Measurement of mechanical properties of UHMWPE after heavy gamma radiation of 0 to 500 Mrad

Test pieces were cut from large blocks of UHMWPE irradiated at 0, 100, 200, 300, 400 and 500 Mrad of gamma radiation. Elongation, tensile strength and hardness of these materials were measured.

3. Results

3.1. Coefficient of friction

The influences of gamma radiation were scarcely observed in coefficient of friction measured in sphere-on-flat tests. When distilled water was used as a lubricant, coefficient of friction was 0.08 to 0.12. When lubrication was not used, coefficient of friction was 0.2 to 0.25. The coefficient of friction under dry conditions was higher by 2 to 2.5 times than that under wet conditions.

3.2. The effects on wear volume of gamma radiation

Using the parallel profilometer, three-dimensional diagrams of the wear scars on the UHMWPE specimens were obtained (Figs 6 and 7). The average wear volume (mm^3) is shown in Table II.

The higher the dose of gamma radiation, the lower the volume reduction due to wear (wear volume). The wear volume of 50 Mrad/UHMWPE was 70 to 80% of that without radiation, the wear volume of 75 to 150 Mrad/UHMWPE was 18 to 25% of that without radiation, and the wear volume of 200 Mrad/UHMWPE was 12 to 15% of that without radiation. The wear volume under dry and wet conditions was almost the same (Figs 8 and 9).

TABLE II Average values of volume and surface area of the wear scars on flat specimens of UHMWPE GUR415

Lubrication	Amount of irradiation (Mrad)	Volume ($\times 10^{-3}$ mm^3)	Surface area (mm^2)
Dry	0	17.60	4.69
	50	14.10	5.91
	75	3.54	3.62
	100	3.23	3.66
	125	2.95	3.08
	150	3.87	2.98
	200	2.21	3.21
Wet	0	17.03	5.19
	50	12.28	3.79
	75	3.33	3.78
	100	4.21	3.69
	125	4.15	3.26
	150	3.05	3.16
	200	2.66	3.18

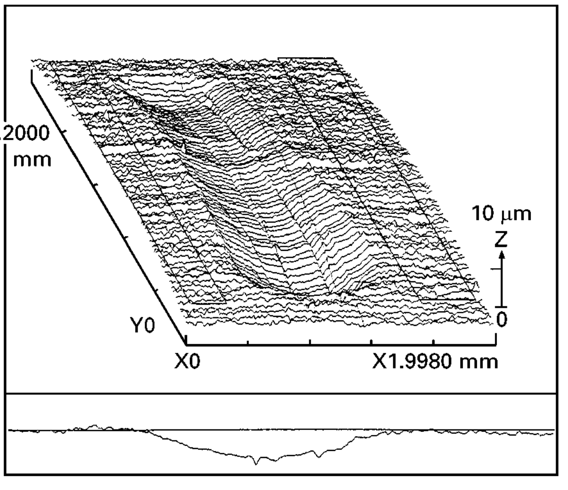

Figure 6 Three-dimensional diagram of wear scars on a UHMWPE specimen without gamma radiation; measured using the parallel profilometer.

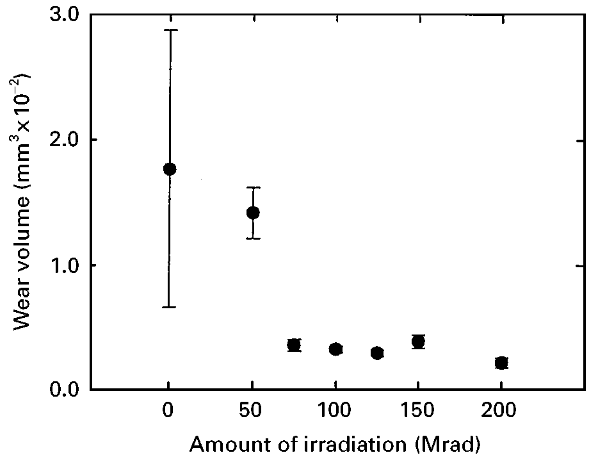

Figure 8 Wear volume of UHMWPE GUR415 plate irradiated with various doses of gamma radiation under non-lubricated conditions: upper component 10 mm diameter Al_2O_3; normal load 4.9 N; stroke 6 mm; frequency 2 Hz, temperature 298 K.

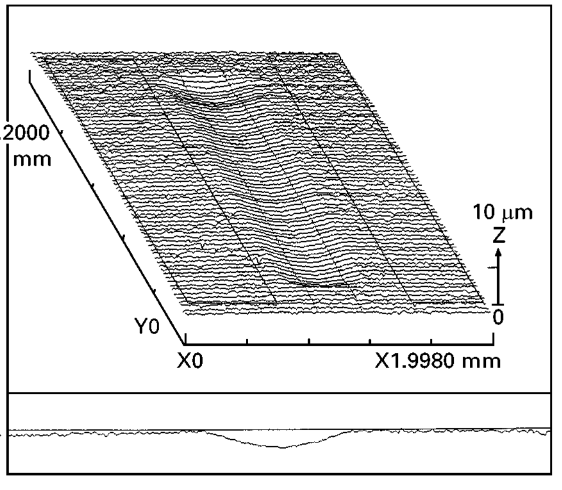

Figure 7 Three-dimensional diagram of wear scars on a UHMWPE specimen with gamma radiation of 200 Mrad (200 Mrad/UHMWPE); measured using the parallel profilometer.

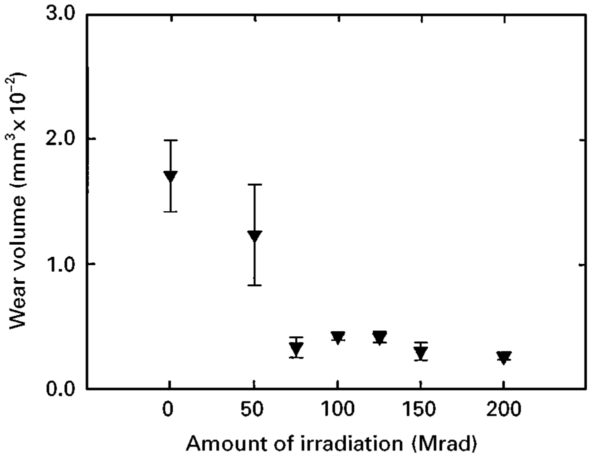

Figure 9 Wear volume of UHMWPE GUR415 plate irradiated with various doses of gamma radiation with distilled water lubrication: upper component 10 mm diameter Al_2O_3; normal load 4.9 N; stroke 6 mm; frequency 2 Hz, temperature 310 K.

3.3. The effects on surface area of different doses of gamma radiation

Generally, the higher the dose of gamma radiation, the smaller the surface area effected. However, the variance in the value of surface area effected in relation to the dose of gamma radiation was much less than that in wear volume. The surface area under dry and wet conditions was almost the same, except for 50 Mrad/UHMWPE (Figs 10 and 11).

3.4. UHMWPE wear particles

The size of UHMWPE wear particles without radiation ranged from 1 to 10 μm, in indeterminate shapes. The shapes were rather flat. The number of large particles was much greater than the number of small particles. The size of 200 Mrad/UHMWPE wear particles was from 1 to 10 μm, similar to the wear particles seen in samples without radiation. However, the number of small-sized particles, i.e. less than 2 μm, was much greater than the number of large particles (Fig. 12).

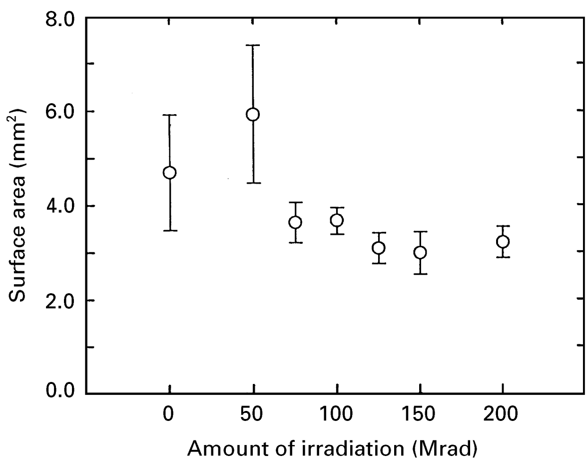

Figure 10 Surface area of UHMWPE GUR415 plate irradiated with various doses of gamma radiation under non-lubricated conditions: upper component 10 mm diameter Al_2O_3; normal load 4.9 N; stroke 6 mm; frequency 2 Hz, temperature 298 K.

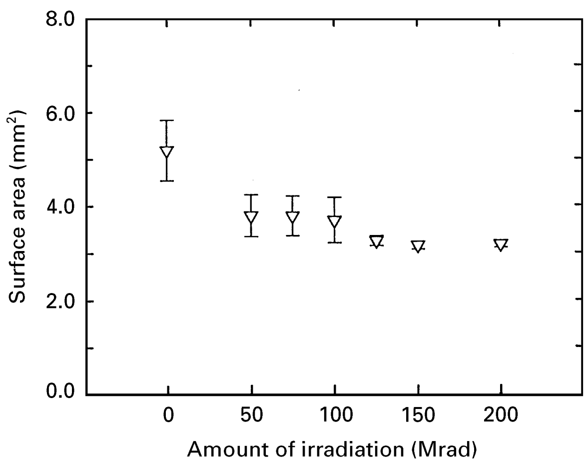

Figure 11 Surface area of UHMWPE GUR415 plate irradiated with various doses of gamma radiation, and with distilled water lubrication: upper component 10 mm diameter Al_2O_3; normal load 4.9 N; stroke 6 mm; frequency 2 Hz, temperature 310 K.

3.5. Mechanical properties of UHMWPE after heavy gamma radiation of 0 to 500 Mrad

Test pieces were cut from large blocks of UHMWPE irradiated at 0, 100, 200, 300, 400 and 500 Mrad with gamma radiation. Comparisons were made with non-irradiated UHMWPE specimens having an elongation of about 400%. The elongation of 100 Mrad/UHMWPE decreased markedly to 6%, and 100 to 500 Mrad/UHMWPE specimens were also constant at 6%. The tensile strength of UHMWPE without radiation was 500 kgf/cm^2. However, tensile strength of 100 Mrad/UHMWPE decreased to 250 kgf/cm^2, that is to half of that without radiation, and those with radiation between 100 and 500 Mrad were constant at 250 kgf/cm^2. Hardness increased correspondingly with increasing level of radiation dose. The hardness of 500 Mrad/UHMWPE was 90 HRR in comparison

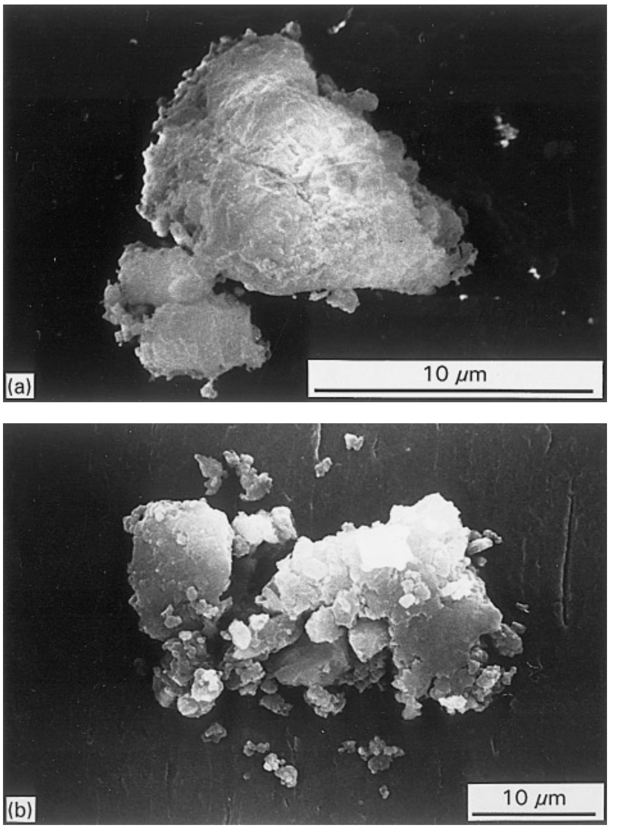

Figure 12 Wear particles after the tribological test, observed by SEM: (a) wear particles of UHMWPE without gamma radiation; (b) wear particles of UHMWPE with 200 Mrad of gamma radiation (200 Mrad/UHMWPE).

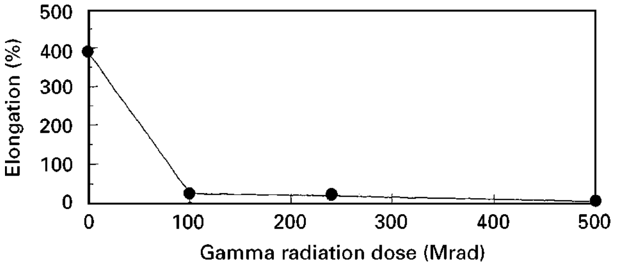

Figure 13 Elongation of UHMWPE GUR 415 irradiated with various doses of gamma radiation.

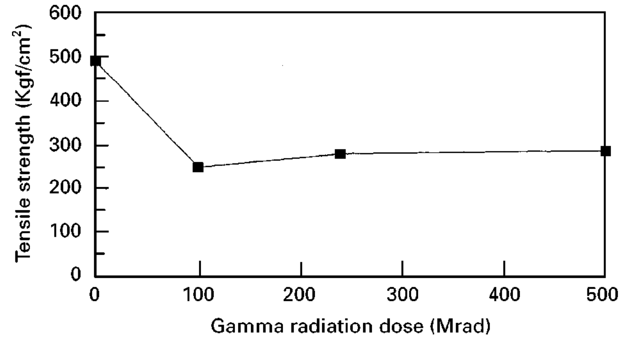

Figure 14 Tensile strength of UHMWPE GUR 415 irradiated with various doses of gamma radiation.

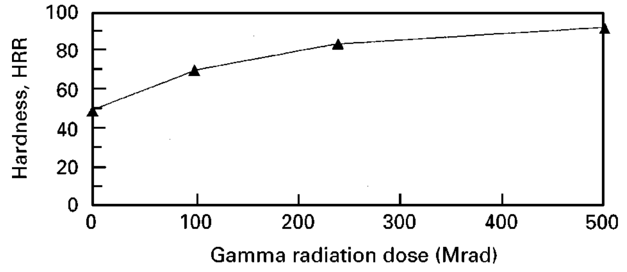

Figure 15 Hardness of UHMWPE GUR 415 irradiated with various doses of gamma radiation.

with non-irradiated samples that had a hardness of 50 HRR (Figs 13, 14 and 15) [10].

4. Discussion

The gamma-irradiated test pieces were cut from larger blocks, thus preventing oxidation, a cause of increasing wear. The sphere-on-flat reciprocating type tribology testing machine is considered one of the simplest and a suitable test rig for tribological tests of total hip prostheses.

We began to use crosslinked 100 Mrad/UHMWPE clinically in 1971. The wear rate of the cup with radiation was less than 25% of that without radiation. The long-term clinical results were excellent. In order to discover the optimum dose of gamma radiation, wear tests using a hip simulator test machine were performed on crosslinked UHMWPE cups irradiated with widely different levels of gamma radiation: 0, 100, 500 and 1000 Mrad. The steady-state wear of the cup with radiation of 100 Mrad was 10% of that without radiation, and that with radiation of 500 or 1000 Mrad was 1% of that without radiation. However, it was supposed that as the greater the dose of gamma radiation, the greater the brittleness, it would be reasonable to find an optimum dose of gamma radiation near 100 Mrad. A sphere-on-flat reciprocating type tribology testing machine was used for this purpose.

The results were as follows: (1) the wear volume of 50 Mrad/UHMWPE was 70 to 80% of that without radiation; (2) the wear volume of 75 to 150 Mrad/UHMWPE was 18 to 25% of that without radiation; and (3) the wear volume of 200 Mrad/UHMWPE was 12 to 15% of that without radiation. The production rate of smaller particles of gamma-irradiated UHMWPE was higher than that without radiation. However, although the production rate of smaller particles was greater in gamma-irradiated UHMWPE, the total number of small particles was not large and there were no ill effects in any long-term clinical cases.

From these results we suggest that the optimal dose was around 200 Mrad. After several kinds of tribological studies, mechanical strength tests and long-term clinical findings [3–9], it is concluded that the optimum dose of gamma radiation is around 200 Mrad.

5. Conclusions

The testing process used to find the ideal level of gamma irradiation for use with crosslinked UHMWPE total prostheses made use of the simple and thorough sphere-on-flat reciprocating type tribology testing rig. A sphere-on-flat reciprocating type tribology testing apparatus is designed to produce wear damage over the range of reciprocating stroke from 2 to 10 mm, at frequencies of up to 10 Hz, and with applied normal loads from 490 to 5390 mN. Tests can be carried out over a specimen temperature range of 293–873 K under non-lubricated conditions. Additionally, tests in liquid can be performed with the liquid temperature adjustable to 423 K. Tests can also be performed in vacuum, up to 1.33 Pa, at room temperature under non-lubricated testing conditions. The atmosphere in the chamber is replaceable by a number of different gases. The displacement of the upper spherical specimen during the test is measured, and the coefficient of friction is continuously monitored. After testing, the geometry of wear scars of both spherical and flat specimens can be observed using a parallel profilometer.

As one of a number of presently available low wear total hip prostheses, the combination of 200 Mrad/UHMWPE cup with alumina or zirconia femoral head may be the most wear resistant at present. Moreover, these combinations can be expected to be widely applicable in other kinds of total joint prostheses.

In wear tests using the sphere-on-flat reciprocating type tribology testing rig, the wear volume of gamma-irradiated UHMWPE in comparison to non-irradiated UHMWPE was as follows: 50 Mrad/UHMWPE → 70%–80%; 75 to 100 Mrad/UHMWPE → 18%–25%; 200 Mrad/UHMWPE → 12%–15%.

In addition, from several kinds of tribological studies, mechanical strength tests and studies of long-term clinical findings, it is concluded that the optimum dose of gamma radiation is around 200 Mrad.

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