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Retrieved total hip prostheses

Part I *The effects of cup thickness, head sizes and fusion defects on wear*

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The effects of polyethylene cup thickness, femoral head sizes (22, 28 and 32 mm) and fusion defects on wear were investigated on retrieved total hip prostheses. When the cup thickness was less than 9 mm, the larger the femoral head, the higher the linear wear rate; however, when the cup thickness was more than 9 mm, the larger the femoral head, the linear wear rate was lower. When the cup thickness was less than 11 mm, the volumetric wear rate increased with increasing size of the femoral head, and when it was more than 11 mm, the volumetric wear rate of the three kinds of the prosthetic cups approached the same values. The wear rate of the cross-linked cups irradiated by 100 Mrad were very low, with no correlation to cup thickness. When the cup thickness was less than 9 mm, the volumetric wear rate tended to increase with increasing number of fusion defects. Large diameter fusion defects diminished the tensile strength.

1. Introduction

It is over 30 y since Charnley's total hip prosthesis was invented [1]. The prosthesis comprises a polyethylene cup and a metal head which substitutes for the hip joint. Since its invention, many researchers have studied total hip arthroplasty and have reported polyethylene cup wear in the body, causing osteolysis around the prosthesis and loosening of the implant [2].

Studies on retrieved prostheses are very important to elucidate the causes of failure of the implants. In general, such studies involve chemical analyses, physical measurement, and microscopic observations of each part of the retrieved prostheses. A necessary consideration in these studies is to compare the results of the retrieved prostheses with those of the same but not yet implanted prostheses. Otherwise, any change observed on the retrieved prostheses could not always be ascribed to the implantation. Unfortunately, such a comparative study is not easy for joint prostheses, because models have frequently been varied, resulting in no stock of the original models after their long-term implantation.

The history of hip replacement has been a long continuation of clinical trial and errors. Consequently, a variety of models have been clinically applied as the hip prosthesis and numerous studies on retrieved prostheses have been published, mostly without comparison with the original, unimplanted prostheses. A representative total hip replacement is composed of a polyethylene cup with or without a metal back, a metal or ceramic head, and a metal stem. In addition, cured bone cement is required to fix the prosthetic materials to bone tissue, unless the hip prosthesis is of the cementless type. During long-term implantation, much debris will be generated as a result of wear.

In addition, undesirable changes in the material properties of the prosthesis during use in the human body are suspected, though there have been few reports so far. Another variable is that the polyethylene's properties and the roundness and surface roughness of the metal head have been improved, over the decades. The decrease in the cup thickness by wear and creep deformity can be measured on radiographs; however, the error in measurement is rather high.

To investigate the above problems, it would be ideal to examine the prosthesis retrieved from patients, who had no complications, after their death. Such opportunities are, however, extremely few. Nonetheless, even prostheses retrieved due to slight loosening or late infections, will help to provide important information.

In the present study we examined the polyethylene cups and femoral heads of total hip prostheses retrieved due to slight loosening or late infections. Several kinds of prostheses were examined, and some prostheses were provided from other hospitals.

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The retrieved prostheses were observed and measured according to the following points:

1. measurement of wear, including creep deformity, of the polyethylene cups;
2. examination of fusion defects in the polyethylene cups;
3. measurement of changes of the mechanical properties of the polyethylene cups by a tensile strength test;
4. observation of surface shape changes, e.g. wear and degradation, etc.

2. The effects of cup thickness and head sizes on wear

2.1. Materials

The prostheses which were used in measurement and observation were as follows:

1. Charnley prostheses consisting of a combination of a 22 mm stainless steel femoral head with a polyethylene cup;
2. Bioceram prostheses consisting of a combination of a 28 mm alumina femoral head with a polyethylene cup;
3. Müller prostheses consisting of a combination of a 32 mm Co–Cr alloy femoral head with a polyethylene cup;
4. SOM prostheses consisting of a combination of a 28 mm COP alloy (stainless steel containing 20% Co) femoral head with a cross-linked polyethylene cup using gamma radiation in heavy high doses, 100 Mrad [3];
5. SOM prostheses without gamma radiation;
6. T-28 prostheses consisting of a combination of a 28 mm stainless steel femoral head with a polyethylene cup (Table I).

The observed prostheses were retrieved due to slight loosening of the stem, cup, or both, or due to late infection between bone and components. Prostheses damaged other than by wear by the femoral head were excluded from this study.

2.2. Methods

Generally, the inner surface of the retrieved cup has two spherical surfaces (Fig. 1). Consequently, the distance between the centre O of the spherical surface I and the centre O′ of the spherical surface II was regarded to be the length of the femoral head movement during use, that is, wear including creep deformity of the polyethylene cup. This is named linear wear. The distance between O and O′ was defined as the length of the femoral head movement, *d*. The direction of the movement was defined as the angle from datum plane, β. The volumetric decrement (volumetric wear), *V*, occurring following contact with the head ball was calculated using *d*, β and radius γ using a system developed by Kabo [4] (Fig. 2). The retrieved cups in which the inner surface could be measured are shown in Table I.

Because the number of prostheses of T-28, SOM (cross-linked) and SOM (non-cross-linked) were limited to 4, 2 and 2 cases, respectively, the cups of Charnley, Bioceram and Müller were mainly compared. The wear factors were analysed from the following view points:

1. relationship between head diameter and polyethylene cup wear;
2. relationship between polyethylene cup thickness and polyethylene cup wear;
3. relationship between head diameter, polyethylene cup thickness and polyethylene cup wear;
4. relationship between number and size of fusion defects in the polyethylene cup and polyethylene cup wear;

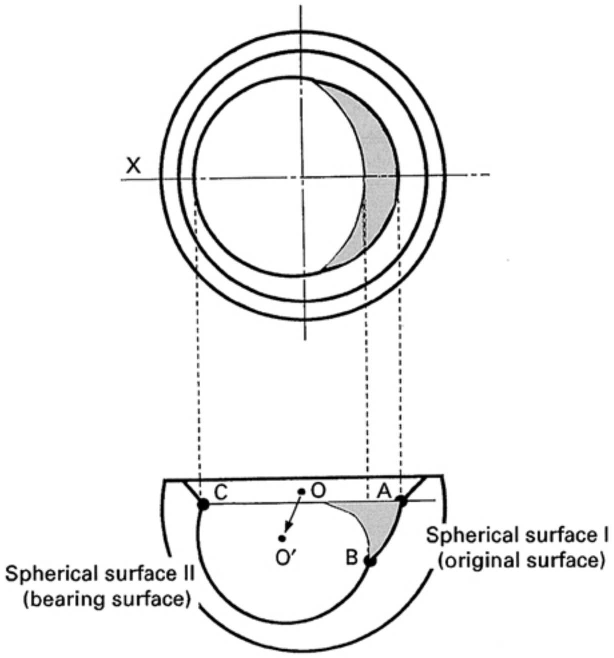


Figure 1 Schematic drawing of the inner surface of the retrieved cup, showing the original surface and the bearing surface after wear.

TABLE I Several kinds of retrieved total hip prostheses used for test

Prostheses	Number of joints	Implanted periods	Average of implanted periods
(1) Charnley (22 mm)	16	5–18 y	13 y 11 mon
(2) Bioceram (28 mm)	17	1 y 9 mon to 13 y 4 mon	8 y 7 mon
(3) Müller (32 mm)	7	7–15 y	11 y 9 mon
(4) SOM-cross-linked (28 mm)	2	9 y 8 mon and 13 y 7 mon	11 y 8 mon
(5) SOM-non-cross-linked (28 mm)	2	12 y and 13 y	12 y 6 mon
(6) T-28 (28 mm)	4	8 y 5 mon to 15 y	12 y 2 mon

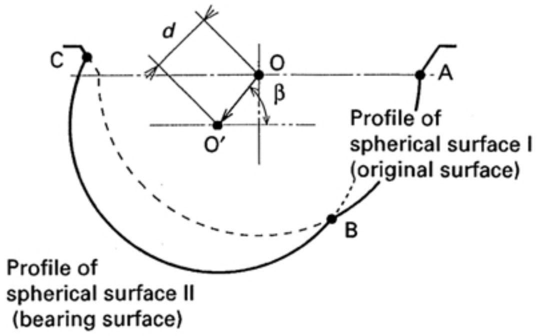


Figure 2 Wear profile diagram. O, centre of spherical surface I; O′ centre of of spherical surface II; d = distance O–O′ (linear wear); β = wear angle, measured from the plane of the mouth of the socket. Volumetric wear equation:

$$V = \pi r^2 d - r^2\left[\pi d \cos^{-1}\left(\frac{d\tan\beta}{r}\right) - \tan^2\beta\left(\frac{r}{\tan^2\beta} - d^2\right)^{1/2}\right]$$
$$-\frac{r^3\tan\beta}{3}\left[\left(1 - \frac{d^2\tan^3\beta}{r}\right)^{3/2} + 2\right]$$

5. relationship between number of fusion defects in the polyethylene cups, polyethylene cup thickness and polyethylene cup wear,

6. relationship between number of fusion defects in the polyethylene cups and implanted age;

7. low wear effects of cross-linked polyethylene cups by gamma-ray irradiation using heavy high doses, 100 Mrad.

2.3. Results

2.3.1. Relationship between head diameter, polyethylene cup thickness and polyethylene cup wear

The head shift per year, that is linear wear and volumetric wear rate, of all examined prostheses, as well as the average for each type, is shown in Fig. 3a–c. In this study, the polyethylene cup thickness of Charnley (22 mm) were 9 and 10.5 mm, those of Bioceram (28 mm) were 7, 8, 9 and 11 mm, those of Müller (32 mm) were 8, 8.5 and 9 mm, and those of SOM with cross-linked polyethylene were 9 and 11 mm. Wear patterns were estimated on graphs, by comparing three kinds of femoral head sizes and several cup thicknesses.

In the case of linear wear, when the cup thickness was less than 9 mm, the larger the femoral head, the higher the linear wear of the polyethylene cup. When the cup thickness was about 9 mm, the linear wear rates of the prosthetic cups of Charnley, Bioceram and Müller were almost the same. In other words, when cup thickness was more than 9 mm, the larger the femoral head, the lower the linear wear rate. The linear wear rate of the cross-linked polyethylene cup was very low, without correlation to cup thickness. In the case of volumetric wear, as seen in the case of linear wear rate, when cup thickness was less than 11 mm, it was estimated using a graph that the larger the femoral head, the higher the volumetric wear rate (Fig. 4).

When cup thickness was around 11 cm, the volumetric wear rate of the polyethylene cups of Charnley (22 mm), Bioceram (28 mm) and Müller (32 mm) was supposed to approach the same wear rate (Fig. 5). However, when the cups become very thick, the greater the cup thickness, the lower the wear reduction rate. The volumetric wear rate of the SOM cross-linked polyethylene cup was very low, without correlation to cup thickness. The linear wear rate of the two measured cups was 0.02 and 0.03 mm y^{-1}. Volumetric wear rate was 9.2 $mm^3\,y^{-1}$ (Fig. 5). For T-28, there was an insufficient number of prostheses for comparison.

In the case of SOM (non-cross-linked) cups without gamma irradiation, the same tendency for wear was seen as in T-28 cups.

2.4. Discussion

2.4.1. The effect of gamma radiation in heavy high doses to produce low wear of cross-linked polyethylene

The volumetric wear rate of polyethylene cross-linked by gamma radiation of 100 Mrad decreased to one-sixth of that without gamma radiation. In comparison to Charnley's prostheses, the linear wear and volumetric wear of the cross-linked polyethylene cups decreased to less than one-sixth and one-third, respectively (Figs 4, 5).

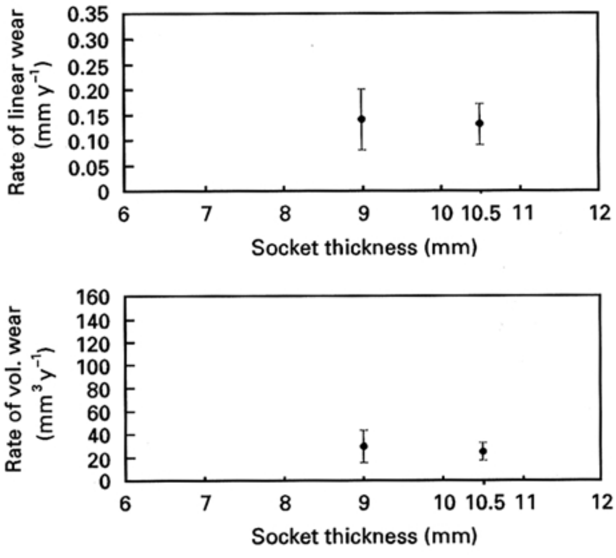
In our clinical results measured on radiographs, linear wear rate of the cross-linked polyethylene with gamma radiation of 100 Mrad was less than one-sixth of that without irradiation. In the case of cross-linked polyethylene, the cup thickness had little effect on cup wear, and cup wear against metal and alumina heads was almost the same (Table II).

The results of the measurements on radiographs and those of retrieved prostheses agreed. Consequently, it was shown that 100 Mrad gamma radiation of polyethylene was remarkably effective in decreasing the wear of the cup. As the creep deformity of the cross-linked cup was much lower than that of non-cross-linked cups, and because the wear of the former was much lower than the latter, we feel that the thickness of the former had little effect on its lower wear rate.

2.4.2. The relationship between the polyethylene cup thickness, femoral head diameter and wear rate of polyethylene cups

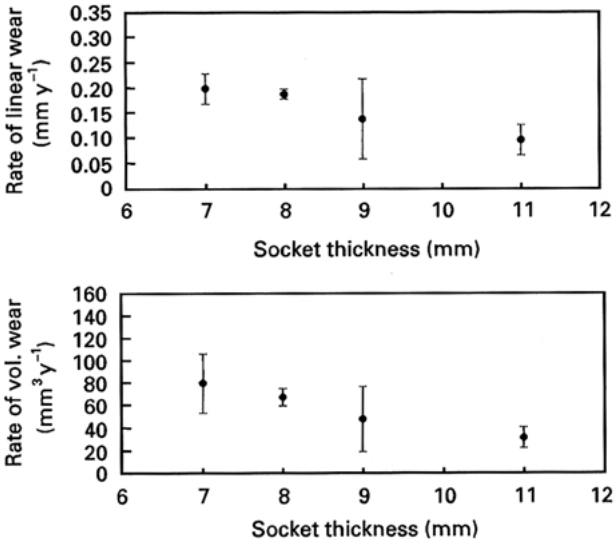
According to the results of our cup wear measurements on radiographs, the linear wear rate of Bioceram cups was 0.1 mm y^{-1} on average. However, this was largely influenced by cup thickness. The linear wear rate of 7, 8, 9, 10 and 11 mm thicknesses was 0.15, 0.13, 0.09 and 0.07 mm y^{-1}, respectively. The thinner the cup, the larger the linear wear rate (Fig. 6).

Other researchers have reported that the linear wear rate is 0.07–0.21 mm y^{-1} for Charnley cups (22 mm) [5, 6] and approximately 0.1 mm y^{-1} for Bioceram cups (28 mm) [7, 8]. The results in our retrieved Charnley prostheses are relatively in accord with those measured on radiographs by other researchers. For the retrieved Bioceram cups, however, our actual



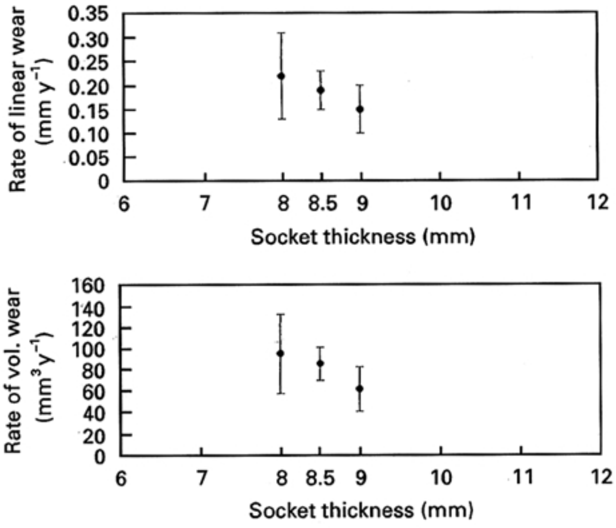
Socket thickness (mm)	Rate of lin.wear (mm y^{-1})	Rate of vol.wear (mm^{3}y^{-1})	No.
9.0	0.14±0.06	30.2±14.0	5
10.5	0.13±0.04	25.8±7.8	11

(a)



Socket thickness (mm)	Rate of lin.wear (mm y^{-1})	Rate of vol.wear (mm^{3}y^{-1})	No.
7	0.20±0.03	79.8±26.7	4
8	0.19±0.01	67.2±7.7	3
9	0.14±0.08	47.9±28.7	5
11	0.10±0.03	31.7±9.0	2

(b)



Socket thickness (mm)	Rate of lin.wear (mm y^{-1})	Rate of vol.wear (mm^{3}y^{-1})	No.
8.0	0.22±0.09	94.8±37.8	3
8.5	0.19±0.04	85.1±15.7	2
9.0	0.15±0.05	60.9±20.8	2

(c)

Figure 3 Relationships between linear and volumetric wear rates and cup thickness: (a) Charnley, (b) Bioceram, (c) Müller.

measurements were larger by 50% than the values obtained by our measurements on radiographs. The difference might be explained as follows.

1. In the case measured on the retrieved cups, the initial wear, which was relatively high, was included in the wear rate. However, in the case measured on the radiographs, it was not included in the wear rate.
2. As the retrieved prostheses were not obtained by autopsy, but due to complications such as loosening of the components or late infections, the retrieved prostheses had some damage.
3. Polyethylene may have been produced by different methods, depending on the decade in which it was produced, and that may have caused differences in wear rate.
4. The indications for disease and age may have been different, depending on the decade of the operation.

In retrieved prostheses, when the cup thickness increased to some extent, the decreasing rate of wear was found to become gradually lower. Consequently, an optimum size for the femoral head and thickness of the cup for clinical use can be sought to minimize the rate of wear.

In clinical cases, when a large femoral head is used, a thin cup might be used, but wear will increase. Consequently, when a large femoral head is used, a cup with a thickness of over 11 mm must be used even if bone grafting on the margin of the acetabulum becomes necessary.

When a cup thickness of 11 mm is used, for femoral head diameters of 22, 26, 28 and 32 mm, cup outer diameters of 44, 48, 50 and 54 mm, respectively, are needed.

3. The effects of fusion defects in polyethylene cups on wear and mechanical properties

3.1. Fusion defects and wear

There are reports of polyethylene cups with fusion defects, which were taken to be one of the causes of wear of the polyethylene. Fusion defects are produced when some polyethylene powder does not completely fuse with the surrounding powder. Spaces form in the boundary between the powders that are fused incompletely (Fig. 7). Some defects are large enough to be easily visible. ASTM F 648 provides that, by visual test, the number of fusion defects less than 300 μm in diameter must be less than 10, and that defects of more than 300 μm must not be present. These observations are made by light stereo-microscopy.

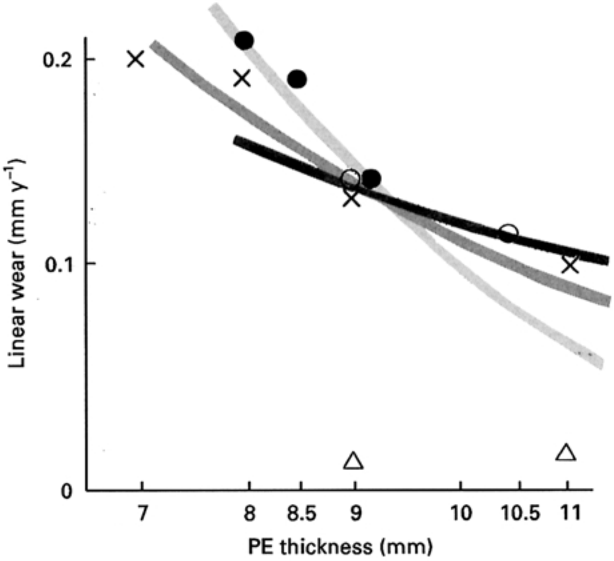


Figure 4 Relationship between linear wear, polyethylene cup thickness and femoral head size. (○) Charnley 22 mm, (×) Bioceram 28 mm, (●) Müller 32 mm, (△) cross-linked 28 mm.

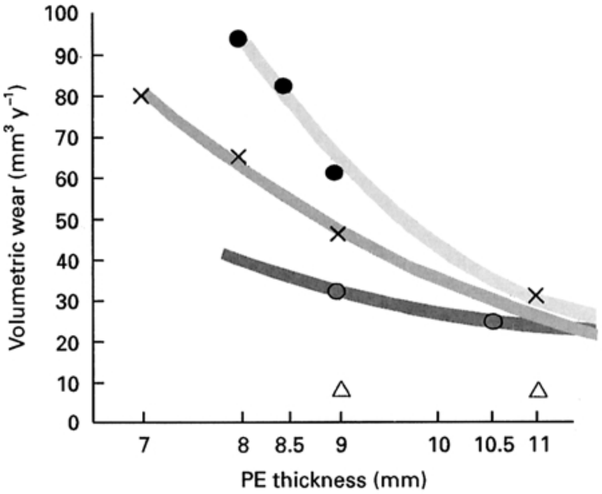


Figure 5 Supposed relationship between volumetric wear, polyethylene cup thickness and femoral head sizes. (○) Charnley 22 mm, (×) Bioceram 28 mm, (●) Müller 32 mm, (△) cross-linked 28 mm.

3.1.1. Materials

The prostheses available for observation are shown in Table III.

3.1.2. Methods

Retrieved polyethylene cups were sliced with a cutter to about 30 μm thickness. These sliced specimens were observed by means of a stereo-microscope and the number of defects per square centimetre was calculated by dividing by the square and the thickness.

The relationship between number of fusion defects and implanted age, the relationship between the maximum size of fusion defects and implanted age, and the relationship between the wear and fusion defects, were investigated.

3.1.3. Results and discussion

3.1.3.1. Relationship between number of fusion defects and implanted age. In Charnley prosthetic cups, from 1970–1990, scatter in the number of fusion defects was very wide, and there was no difference in the number of fusion defects through this period. However, in almost all the cases, the number of defects was less

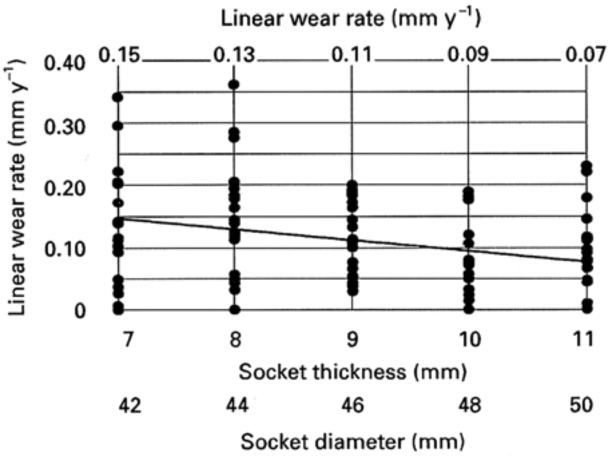


Figure 6 Relationship between linear wear rate and polyethylene cup thickness measured from radiographs on Bioceram consisting of 28 mm alumina head and polyethylene cup.

TABLE II

Cup thickness (mm)	COP metal head with non-cross-linked cup		COP metal head with cross-linked cup		Alumina head with cross-linked cup	
	Linear wear rate (mm y^{-1})	Number of joints	Linear wear rate (mm y^{-1})	Number of joints	Linear wear rate (mm y^{-1})	Number of joints
7	0.32 ± 0.04	5	0.04 ± 0.02	8	0.04 ± 0.02	3
8	0.29 ± 0.05	4	0.04 ± 0.02	8	0.03 ± 0.01	5
9	0.21 ± 0.07	2	0.03 ± 0.02	4	0.03 ± 0.01	2

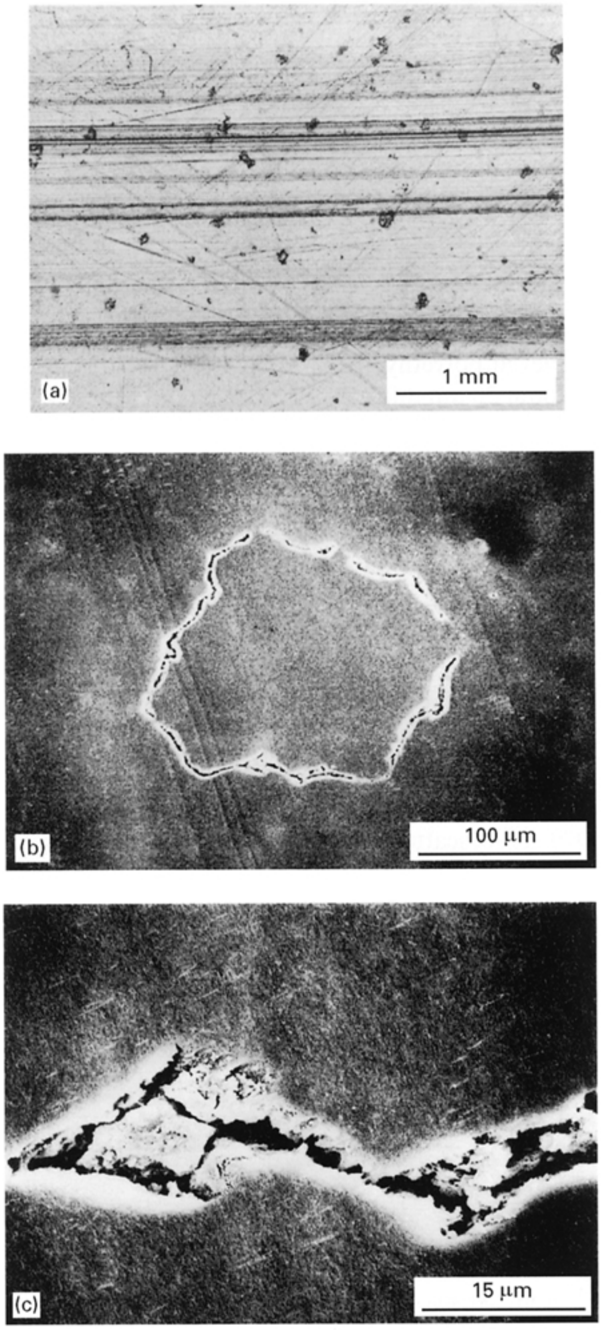


Figure 7 Fusion defects in a polyethylene cup: (a) observation by light stereo-microscopy; (b, c) observation by SEM. (c) is higher magnification of (b).

TABLE III Prostheses on which fusion defects were observed

Prostheses	Number of joints	Implanted periods
Charnley	18	5–18 y
Bioceram	17	1 y 9 mon to 13 y 4 mon
Müller	8	7–15 y
T-28	4	8 y 5 mon to 15 y

than 100 defects/mm^3 and in only one case was the number of fusion defects 200/mm^3. In Bioceram prosthetic cups, the number of fusion defects has been less than 100 defects/mm^3 since 1980 (Fig. 7a).

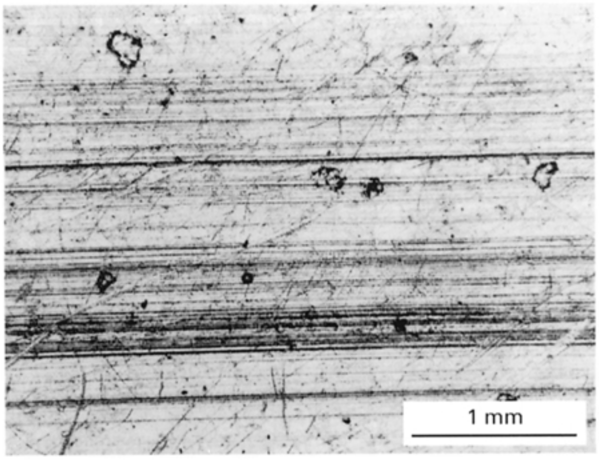


Figure 8 Maximum size of fusion defects (Müller).

In Müller prosthetic cups, from 1970–1985, in all cases, the number of defects was less than 50 defects/mm^3, which was the smallest number among the three kinds of the prostheses.

3.1.3.2. Relationship between the maximum size of fusion defects and implanted age. The range of maximum sizes of fusion defects was 140–180 μm in Bioceram prosthetic cups, 150–270 μm in Charnley prosthetic cups and 100–400 μm in Müller prosthetic cups. The variance was the largest in the Müller prosthetic cups (Fig. 8). For the three kinds of prosthetic cups, there were differences in the number of fusion defects and in the maximum diameter of the fusion defects; however, there were no differences due to the age of the cup used (Figs 9a–c, and 10a–c).

3.1.3.3. Relationship between volumetric wear, polyethylene thickness and number of fusion defects or maximum diameter of fusion defects. In Charnley prosthetic cups, polyethylene thickness was over 9 mm in all cases. Even when the number of fusion defects increased, the volumetric wear rate did not change (Fig. 11a).

In Bioceram prosthetic cups, when polyethylene thickness was less than 9 mm, volumetric wear rate was apt to increase with increasing numbers of fusion defects. When the polyethylene thickness was 11 mm, the volumetric wear rate did not increase with increasing number of fusion defects. However, as there were only two cups, it was not enough for a conclusion (Fig. 11b).

In Müller prosthetic cups, overall volumetric wear rate tended to decrease with increasing numbers of fusion defects. However, the number of cups was too small for a conclusion (Fig. 11c).

Judging from both cases of Bioceram and Charnley prosthetic cups, when the polyethylene thickness was less than 9 mm, volumetric wear rate tended to increase with increasing numbers of fusion defects. However, when the thickness of the polyethylene cups was greater than 9 mm, the number of fusion defects did not seem to affect the volumetric wear rate. In these cups, the maximum size of fusion defects did not affect the volumetric wear rate (Fig. 12a–c).

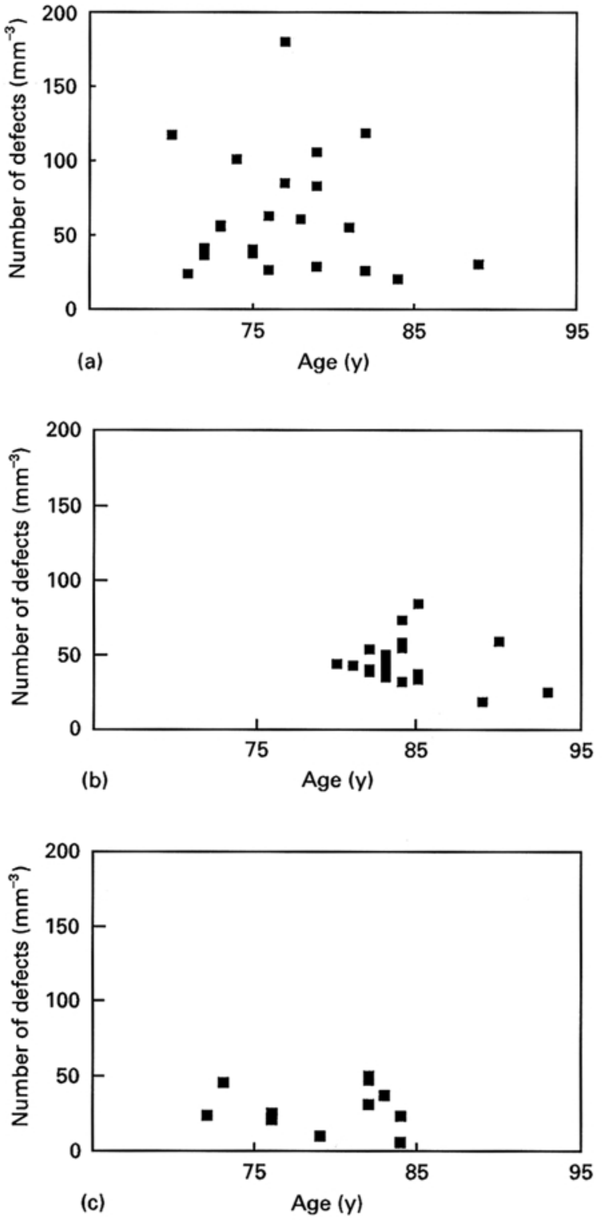


Figure 9 Relationships between number of fusion defects and age: (a) Charnley cup, (b) Bioceram cup, (c) Müller cup.

Judging from these small numbers of cases, no conclusion can be drawn.

3.2. Fusion defects and mechanical properties

3.2.1. Materials

In order to examine changes in the mechanical strength of polyethylene cups over an extended period of time of use, we conducted a tensile strength test on a total of seven kinds of materials, including six retrieved Bioceram cups (RET. 1–6), as well as three unused cups produced over 9 y ago (NEW 1–3), and polyethylene plate produced by compression moulding as a raw material (412 GUR) (PLATE).

The specifications for the examined retrieved cups are as listed in Table IV.

The control specimens were three unused cups (NEW 1–3) and five polyethylene plates as raw materials (PLATE).

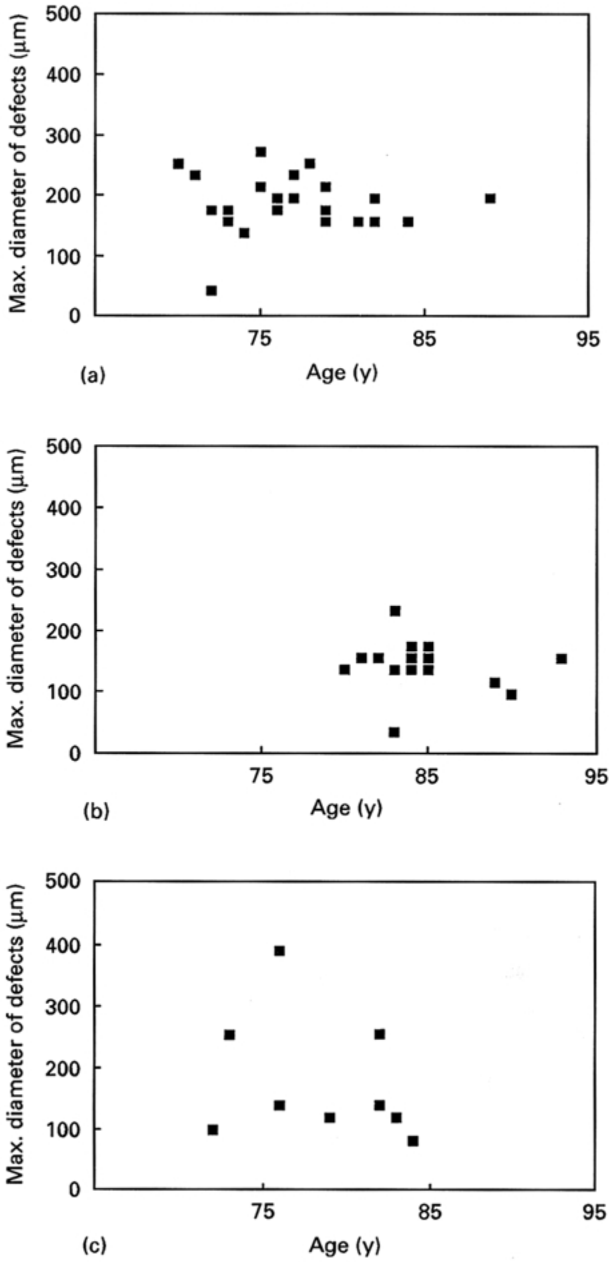


Figure 10 Relationships between maximum diameters of fusion defects and periods: (a) Charnley, (b) Bioceram, (c) Müller.

3.2.2. Methods

The test pieces were made from the inner part of the cups. JIS No. 2 (1/5) was used for preparing the specimens (Fig. 13).

The test conditions were tensile speed 10 mm min^{-1}; elongation, the shifting distance between chucks; number of test pieces, the three test pieces from each cup, and five test pieces from polyethylene plate.

3.2.3. Results and discussion

Retrieved cups excluding nos 2 and 5, showed almost the same tensile strength test results as unused cups and the plates (Figs 14–16).

The maximum diameter of the fusion defects of no. 2 was especially large, and yield strength, tensile strength and per cent elongation were the lowest in all specimens. The maximum diameter of the fusion

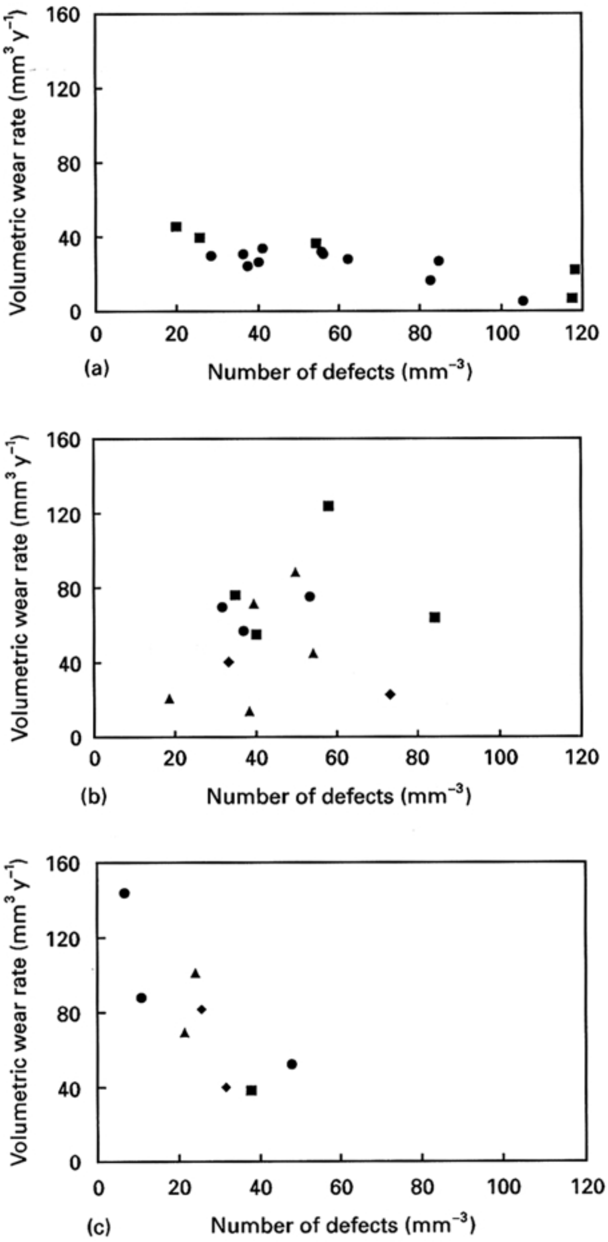


Figure 11 Relationship between volumetric wear number of fusion defects and polyethylene cup thickness: (a) Charnley, (■) 9 mm, (●) 10.5 mm; (b) Bioceram, (■) 7 mm, (●) 8 mm, (▲) 9 mm, (◆) 11 mm; (c) Müller, (■) 6 mm, (●) 8 mm, (▲) 8.5 mm, (◆) 9 mm.

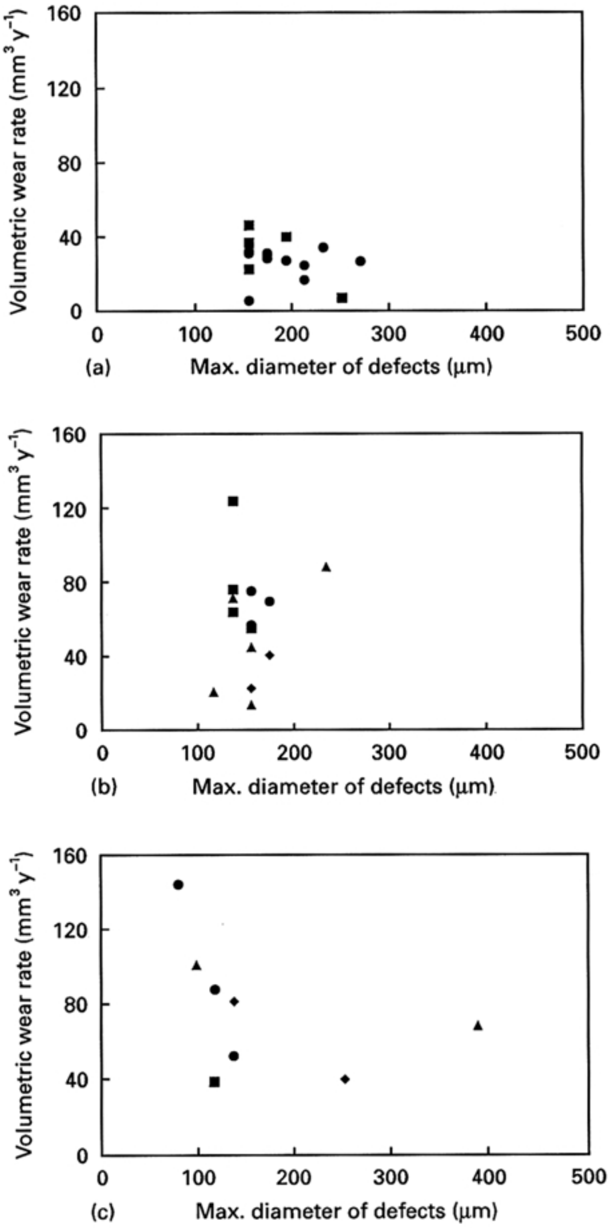


Figure 12 Relationships between volumetric wear, maximum diameter of fusion defects and polyethylene cup thickness: (a) Charnley, (■) 9 mm, (●) 10.5 mm; (b) Bioceram, (■) 7 mm, (●) 8 mm, (▲) 9 mm, (◆) 11 mm; (c) Müller, (■) 6 mm, (●) 8 mm, (▲) 8.5 mm, (◆) 9 mm.

TABLE IV Materials on which yield strength, tensile strength and per cent elongation were measured

No.	Cup thickness (mm)	Implanted periods	No. of fusion defects	Max. diam. of fusion defects (μm)	Volumetric wear (mm^3 y^{-1})	Yield strength (MPa)	Tensile strength (MPa)	Elongation (%)
RET.1[a]	9	12 y 10 mon	57.8	136	124.2	22.4	28.4	186.3
RET.2	9	12 y 2 mon	49.7	233	88.4	19.2	19.2	5.2
RET.3	11	10 y	73.2	155	22.7	23.0	36.8	172.8
RET.4	9	7 y 4 mon	54.1	155	45.0	23.8	35.5	209.4
RET.5	8	7 y 11 mon	31.6	174	69.6	24.4	31.3	139.2
RET.6	9	10 y 2 mon	40.0	155	55.0	24.5	38.7	230.8
NEW.1[b]			42.2	78	–	22.8	35.3	181.3
NEW.2			70.1	97	–	21.2	36.0	182.2
NEW.3			40.8	174	–	22.5	35.0	169.2
PLATE			18.8	136	–	23.1	38.1	161.4

[a] RET, Retrieved cup.
[b] NEW, New cup.

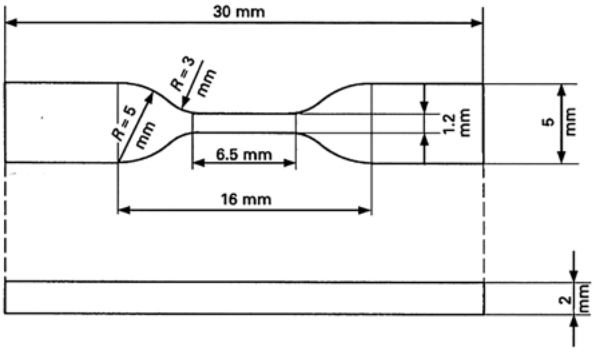


Figure 13 Specimen for tensile testing: proportionate to JIS K7113.

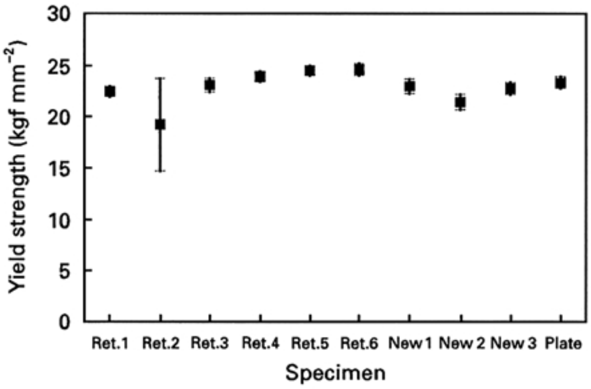


Figure 14 Yield strength of polyethylene cups.

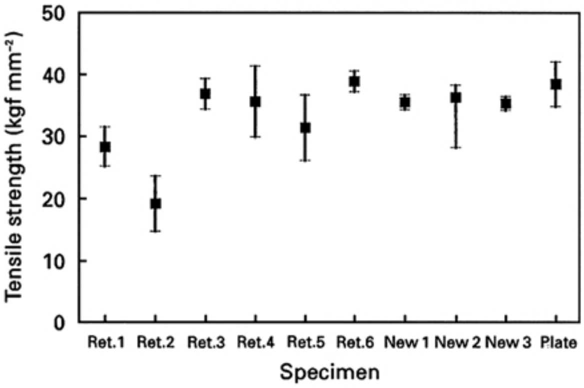


Figure 15 Tensile strength of polyethylene cups.

defect of no. 5 was relatively large, and the per cent elongation was relatively low.

In conclusion, large diameter fusion defects diminished the tensile strength, yield strength and per cent elongation. However, the number of fusion defects did not seem to affect these factors.

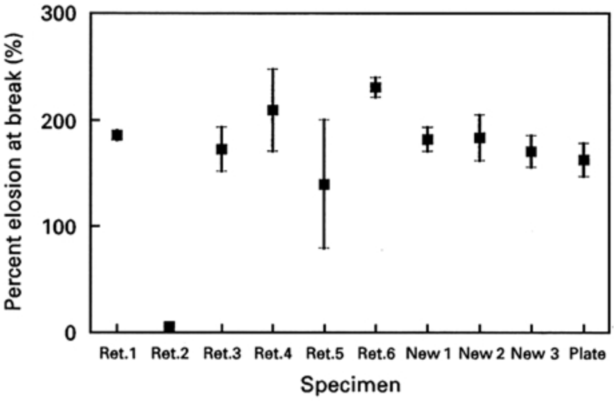


Figure 16 Per cent elongation of polyethylene cups.

4. Conclusion

When polyethylene cup thickness was less than 9 mm, the larger the femoral head, the higher the linear wear rate of the polyethylene cup. When the polyethylene thickness was 9 mm, the linear wear rate of the three kinds of femoral head sizes was the same, 0.15 mm y^{-1} on average.

The linear wear rate of cross-linked polyethylene irradiated with gamma radiation of 100 Mrad was very low, without correlation to polyethylene thickness, that is 0.01 mm y^{-1} on average. When the polyethylene thickness was less than 11 mm, it was estimated, using a graph, that the larger the femoral head, the higher the volumetric wear rate. When polyethylene thickness was more than 11 mm, the volumetric wear rate of the three kinds of the prosthetic cup seemed to become similar, that is 32 mm^3 y^{-1} on average.

When the polyethylene thickness was less than 9 mm, the volumetric wear rate tended to increase with increasing number of fusion defects. However, we could draw no conclusion on this.

In the relationship between fusion defects and mechanical strength, the larger the maximum diameter of the fusion defects, the weaker the yield strength, tensile strength and per cent elongation. However, the number of fusion defects did not affect the mechanical strength of polyethylene.

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