

## In vivo change of elastic property in polyethylene acetabular components

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**Abstract** Polyethylene is an elastic material. It is known that oxidative degradation of polyethylene occurs after sterilization by means of gamma irradiation. However, there have been few detailed reports with regard to the effects of this degradation on the mechanical property, especially in total hip prostheses. The purpose of this study was to examine the change in mechanical property of irradiated and non-irradiated polyethylene cups after implantation. Fifty-six ultra-high molecular-weight polyethylene (UHMWPE) cups retrieved at revision surgery were evaluated. Thirty-two cups were sterilized by gamma irradiation in air and 24 by ethylene oxide gas (EtO). To evaluate the mechanical property of the cup and its regional distribution, Vickers hardness was measured at nine points at the cross-section of the cups. In the irradiated cups, the hardness increased in proportion to the time from sterilization. This phenomenon was not found in the cups sterilized by EtO. Less change of hardness was observed in the cups sterilized by EtO than in those sterilized by irradiation. The gamma-irradiation in air actually affected the elastic property of cup polyethylene *in vivo*, although any difference in the wear rate was not detected between two sterilization methods. In cases with accelerated wear of the acetabular cup, other factors affecting wear should also be considered.

**Keywords** Degradation · Mechanical property · Polyethylene · Total hip prosthesis · Wear

### Introduction

As reported by many authors, oxidation of polyethylene in artificial joints occurs after sterilization by gamma irradiation in air [1–11]. Some authors have reported that oxidation may change the mechanical properties of polyethylene and reduce the wear resistance [11–13], while ethylene oxide gas sterilization has been known not to have the same effects [10, 14]. However, there are few papers that document the change in mechanical property of polyethylene, especially with regard to cups in artificial hip joints [4, 5]. Furthermore, few studies report the regional and quantified changes of mechanical properties in acetabular cups [4, 5]. The goal of our study was to examine retrieved polyethylene cups to understand the influence of different sterilization methods on mechanical and wear properties. The mechanical property was evaluated by means of measuring Vickers hardness at nine points on the cups.

### Materials and methods

Between January 1991 and November 1996, 56 polyethylene (ultra-high molecular-weight polyethylene: UHMWPE) cups were retrieved from 54 patients (3 males and 51 females) and examined. There were two types of cups: 32 Weber cups (Sulzer\*, Winterthur, Switzerland: PE thickness 8 mm, 32 mm at the internal diameter) and 24 Kyocera cups (Kyocera, Kyoto, Japan: PE thickness 9 mm, 28 mm at the internal diameter). All Weber cups had been sterilized by gamma irradiation (2.5–4.0 MRad) in air, packed in nitrogen gas and stored on the shelf. All Kyocera cups had been sterilized and packed by means of ethylene oxide gas and stored on the shelf. The resin type used for the polyethylene of the Weber cups was GUR412

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(Hoechst, Frankfurt, Germany:  $4.5 \times 10^6$  g/mol molecular weight, 0.94 density) and GUR415 (Hoechst, Frankfurt, Germany:  $7.3 \times 10^6$  g/mol molecular weight, 0.93 density) for the Kyocera cups. Both the Weber and Kyocera cups were machined from a RAM extruded bar and had no metal backing. All cups had been fixed to the bone by means of polymethylmetacrylate (PMMA) cement and had been implanted in combination with alumina heads. The overall average time in situ was 7.4 years (range 2.4–14.2); Weber cups  $7.2 \pm 3.2$  (range 3.4–13.2), Kyocera cups  $7.7 \pm 2.6$  (range 2.4–14.2,  $t = 0.627$ ,  $P = 0.267$ ). The overall average time from the moment of sterilization until revision was 9.6 years (range 4.5–16.0); Weber cups  $9.4 \pm 3.5$  (range 4.7–16.0), Kyocera cups  $10.0 \pm 2.0$  (range 4.5–15.7,  $t = 0.794$ ,  $P = 0.431$ ). Revision surgery was performed for aseptic loosening of the cup and/or stem in all hips. In the Weber cups, the revision rate at the end of this study was 29% (101/344) at a follow-up of  $12.8 \pm 3.9$  years. In the Kyocera cups, the revision rate was 27% (25/94) at  $12.5 \pm 3.5$  years. These rates include the hips revised prior to this study. There was no significant difference of the revision rate ( $t = 2.259$ ,  $P = 0.611$ ) or follow-up period ( $t = 1.147$ ,  $P = 0.253$ ) between the two implants. The removal was performed with great care in order not to damage the cups during surgery. Nevertheless, three Weber cups and one Kyocera cup were broken during removal and were, thus, excluded from this study. The diagnosis at the initial surgery was dysplastic osteoarthritis in all patients. The same surgeon performed all initial and revision surgeries. The overall average age at the time of revision surgery was 53 years (range 30–69); Weber cups  $51.9 \pm 9.6$  years (range 30–69), Kyocera cups  $54.6 \pm 5.9$  years (range 39–64,  $t = 1.287$ ,  $P = 0.204$ ).

Mechanical property and wear of these cups were evaluated by the method described below. Furthermore, six unused cups of each type were also examined. In the unused Weber cups, the duration from sterilization until evaluation was 7.1 years (range 3.0–12.8). Because of this variation in shelf life, the six unused cups were divided into two groups, defined as *Wn* and *Wa*. *Wn* cups were aged 3.0, 3.0, and 3.2 years from sterilization until evaluation, and *Wa* cups were aged 9.5, 11.3, and 12.8 years. In the unused Kyocera cups, the duration from sterilization until evaluation was 5.4 years (range 3.1–8.3). These unused cups were also divided into two groups, defined as *Kn* and *Ka*. Time from sterilization until evaluation was 3.1, 3.4, and 3.6 years for *Kn* cups and 6.8, 7.4, and 8.3 years for *Ka* cups. The packages of all unused cups were opened just before the evaluation.

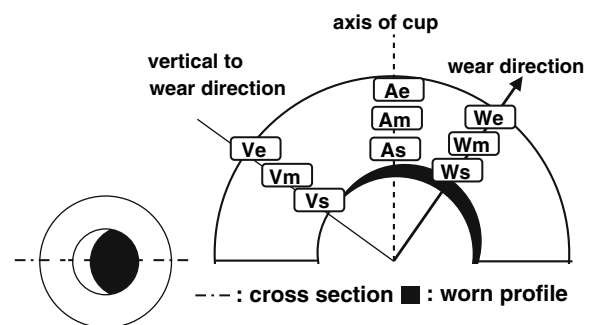
The Vickers indentation hardness test (ISO6507) was performed to study the regional difference of elastic property in the cups, as is suitable for evaluating the property of small areas [12]. Each retrieved cup was cut into two pieces with a plane vertical to the rim, and which also included the axis of

the direction of wear, so that the worn area was divided symmetrically. Nine measuring points were determined on the cross-section (Fig. 1). The measurement was taken at these nine points on both sides of the cross-section of the divided cup, and the mean of the two values of the corresponding points was defined as the hardness of the point. In the unused cups, the measurement was performed at the points corresponding to those of the retrieved cups.

The hardness was measured by a hardness meter (MVK-D: Akashi Seisakusho Co. Ltd, Hyogo, Japan). An indentation scar was created by pressing an indenter made of diamond on the cross-section of the cup. Then the scar was measured under a microscope. As the apex of the indenter has a pyramidal shape, it makes a congruent scar on the polyethylene. The softer the polyethylene, the deeper the indentation will be, i.e., the larger the scar. The Vickers hardness is calculated from the surface area of the indentation and the load applied to the indenter by the following equation:

$$Hv = 0.102 \frac{F}{S} = 0.102 \frac{2F \sin \frac{\theta}{2}}{d^2} = 0.189 \frac{F}{d^2}$$

- Hv* Vickers hardness value  
*F* load applied to the indenter: 0.025 kg of load applied for 45 s  
*S* surface area of the indentation (square millimeters)  
*d* mean length of the diagonals of the indentation (millimeters)  
 $\theta$  angle between opposite faces of the diamond indenter ( $136^\circ$ )



**Fig. 1** Nine measuring points of Vickers hardness were determined at the cross-section of the cups, as follows: *Ws* on the wear direction line, 1 mm from the articulation (worn) surface. *We* on the wear direction line, 1 mm from the external surface. *Wm* on the wear direction line, midpoint of *Ws* and *We*. *As* on the cup axis line, 1 mm from the articulation (worn) surface. *Ae* on the cup axis line, 1 mm from the external surface. *Am* on the cup axis line, midpoint of *As* and *Ae*. *Vs* on the line vertical to the wear direction, 1 mm from the articulation (worn) surface. *Ve* on the line vertical to the wear direction, 1 mm from the external surface. *Vm* on the line vertical to the wear direction, midpoint of *Vs* and *Ve*. The measuring points in the unused cups were determined to correspond to the points of the retrieved cups

Thus, a larger hardness value indicates that the specimen is harder.

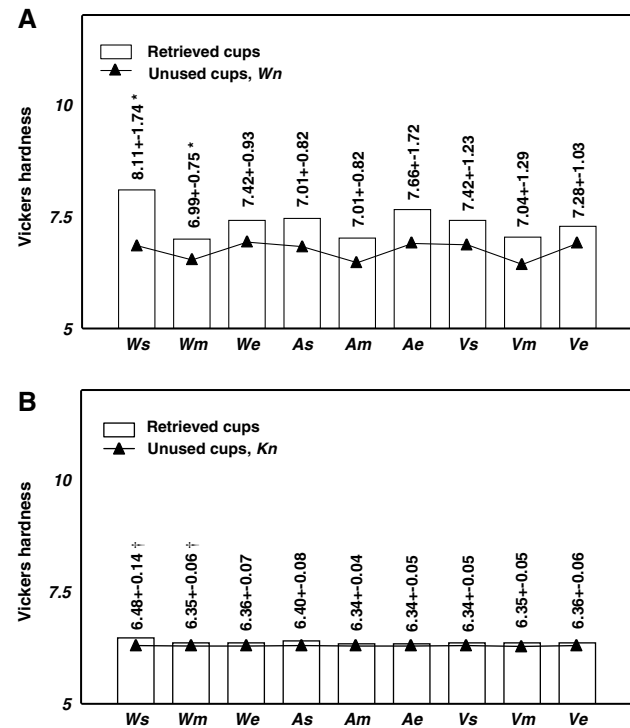
Polyethylene wear

The linear wear was measured by using Wroblewski's method as the penetration depth of the retrieved cups [15].

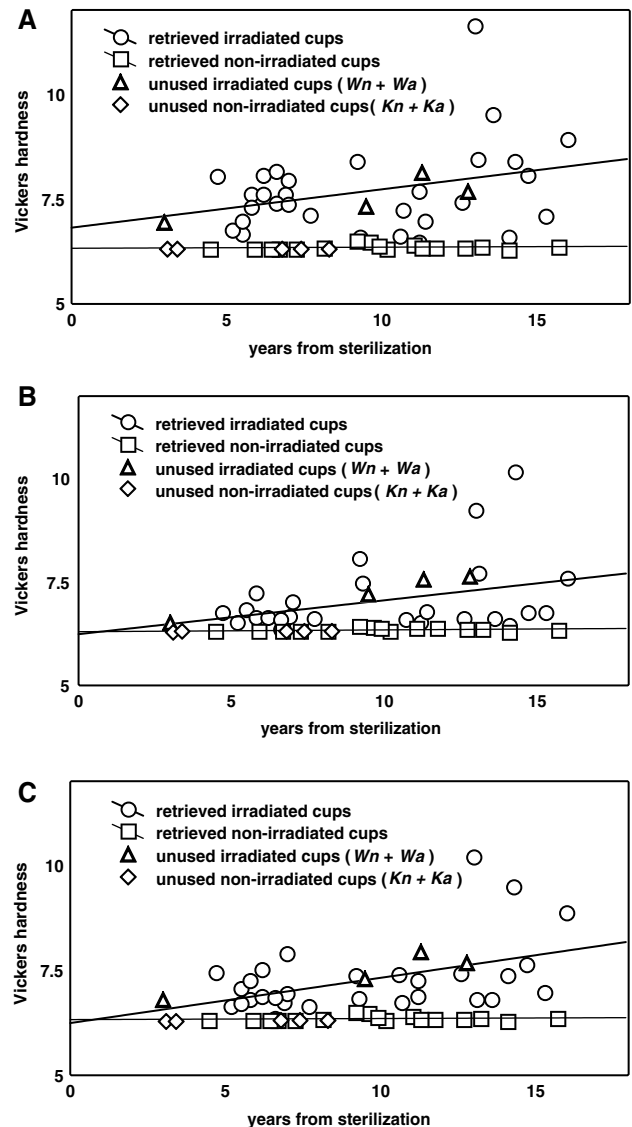
Statistical analysis

Statistical analyses were carried out with the paired Student's *t* test or the unpaired Student's *t* test or Pearson's correlation coefficient and Fisher's *Z* transformation. A significant difference was reported at *P* < 0.05 in all statistical analyses.

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**Fig. 2** **a** Vickers hardness on cross-section of Weber (irradiated) cups. \**t* = 4.430, *P* < 0.001. **b** Vickers hardness on cross-section of Kyocera (non-irradiated) cups. †*t* = 4.450, *P* < 0.001



**Fig. 3** **a** Vickers hardness points at the depth of 1 mm from the articulation surface (average of Ws, As, and Vs) versus years from sterilization. **Bold line** Weber (irradiated) cups.  $Y = 0.10X + 6.82$ ,  $r^2 = 0.097$ ,  $P = 0.076$  [ $r^2 = 0.090$ ,  $P = 0.096$ ]\*. **Fine line** Kyocera (non-irradiated) cups.  $Y = -0.00X + 6.39$ ,  $r^2 = 0.002$ ,  $P = 0.832$  [ $r^2 = 0.000$ ,  $P = 0.962$ ]\*. **b** Vickers hardness points in medium layer (average of Wm, Am, and Vm). **Bold line** Weber (irradiated) cups.  $Y = 0.08X + 6.24$ ,  $r^2 = 0.128$ ,  $P = 0.044$  [ $r^2 = 0.130$ ,  $P = 0.044$ ]\*. **Fine line** Kyocera (non-irradiated) cups.  $Y = 0.00X + 6.30$ ,  $r^2 = 0.066$ ,  $P = 0.227$  [ $r^2 = 0.028$ ,  $P = 0.436$ ]\*. **c** Vickers hardness at the depth of 1 mm from the external surface (average of We, Ae, and Ve). **Bold line** Weber (irradiated) cups.  $Y = 0.11X + 6.23$ ,  $r^2 = 0.213$ ,  $P = 0.006$  [ $r^2 = 0.236$ ,  $P = 0.004$ ]\*. **Fine line** Kyocera (non-irradiated) cups.  $Y = 0.00X + 6.33$ ,  $r^2 = 0.011$ ,  $P = 0.629$  [ $r^2 = 0.005$ ,  $P = 0.745$ ]\*. \*The relation between the years in situ and the hardness was almost the same as that between years from sterilization and the value. Its  $r^2$  and *P* values are described in the brackets

**Results**

Vickers hardness

The average Vickers hardness of the nine points was 6.94 (range 6.28–10.30) in all retrieved cups. The average in the retrieved Weber cups was 7.38 (range 6.57–10.30) and in the retrieved Kyocera cups 6.35 (range 6.28–6.50). The average of the nine points in the unused Weber cups was 7.20 (range 6.71–7.95, 6.75 in *Wn*, 7.64 in *Wa*) and in the unused Kyocera cups 6.30 (range 6.29–6.31, *Kn* was 6.29, *Ka* 6.30). The hardness of each point is shown in Fig. 2a and b. The hardness in the Weber cups showed a tendency to increase in proportion to the years the cups were in situ, while there was no considerable change in the Kyocera cups (Fig. 3a–c).

Polyethylene wear

The overall linear wear value was 0.9 (range 0.3–1.9) mm in all cups. The linear wear value in the Weber cups

amounted to  $0.9 \pm 0.3$  (range 0.3–1.6) mm and in the Kyocera cups to  $0.9 \pm 0.3$  (range 0.3–1.9) mm ( $t = 0.094$ ,  $P = 0.926$ ). Thus, the overall linear wear rate was 0.13 (range 0.04–0.34) mm/year in all cups. For the Weber cups, this rate was  $0.14 \pm 0.06$  (range 0.04–0.34) mm/year, and for the Kyocera  $0.12 \pm 0.02$  (range 0.07–0.14) mm/year ( $t = 1.983$ ,  $P = 0.055$ ). While the wear rate of the Weber cups may be higher than that of the Kyocera cups with a larger sample size, there was no significant difference between the two types of cups. No significant correlation was detected between the linear wear value and the hardness (Table 1). Similarly, no significant relation was detected between the wear rate and the hardness (Table 2). Table 3 shows the relation between shelf life and wear. No significant correlation was found between the duration of shelf life and wear rate (Table 3).

**Discussion**

Sterilization by irradiation causes oxidative degradation in polyethylene [1, 3, 5, 8]. This oxidation begins from both

**Table 1** Mechanical property versus linear wear

	Linear wear all	Linear wear Weber	Linear wear Kyocera
Microhardness: average of all points	$r = -0.125$ $P = 0.358$	$r = -0.223$ $P = 0.219$	$r = 0.119$ $P = 0.580$
Microhardness: internal layer (1 mm from the articulation surface = average of <i>Ws</i> , <i>As</i> , and <i>Vs</i> )	$r = -0.155$ $P = 0.253$	$r = -0.263$ $P = 0.147$	$r = 0.056$ $P = 0.795$
Microhardness: medium layer (average of <i>Wm</i> , <i>Am</i> , and <i>Vm</i> )	$r = 0.021$ $P = 0.876$	$r = -0.100$ $P = 0.518$	$r = 0.285$ $P = 0.178$
Microhardness: external layer (1 mm from the external surface = average of <i>We</i> , <i>Ae</i> , and <i>Ve</i> )	$r = -0.009$ $P = 0.946$	$r = -0.014$ $P = 0.940$	$r = 0.171$ $P = 0.424$
Microhardness: <i>Ws</i>	$r = -0.250$ $P = 0.064$	$r = -0.400$ $p = 0.023^*$	$r = 0.171$ $P = 0.426$
Microhardness: <i>Wm</i>	$r = -0.142$ $P = 0.297$	$r = -0.223$ $P = 0.220$	$r = 0.166$ $P = 0.439$
Microhardness: <i>We</i>	$r = -0.061$ $P = 0.654$	$r = -0.097$ $P = 0.596$	$r = 0.083$ $P = 0.701$
Microhardness: <i>As</i>	$r = -0.001$ $P = 0.967$	$r = 0.011$ $P = 0.953$	$r = -0.123$ $P = 0.568$
Microhardness: <i>Am</i>	$r = 0.041$ $P = 0.467$	$r = 0.060$ $P = 0.746$	$r = 0.239$ $P = 0.261$
Microhardness: <i>Ae</i>	$r = -0.234$ $P = 0.132$	$r = -0.312$ $P = 0.082$	$r = 0.329$ $P = 0.117$
Microhardness: <i>Vs</i>	$r = -0.068$ $P = 0.619$	$r = -0.100$ $P = 0.593$	$r = 0.019$ $P = 0.928$
Microhardness: <i>Vm</i>	$r = 0.105$ $P = 0.441$	$r = 0.149$ $P = 0.417$	$r = 0.220$ $P = 0.323$
Microhardness: <i>Ve</i>	$r = -0.069$ $P = 0.613$	$r = -0.102$ $P = 0.580$	$r = 0.044$ $P = 0.840$

\* Statistically significant

**Table 2** Mechanical property versus linear wear rate

	Wear rate all	Wear rate Weber	Wear rate Kyocera
Microhardness: average of all points	$r = -0.157$ $P = 0.249$	$r = -0.281$ $P = 0.120$	$r = 0.130$ $P = 0.545$
Microhardness: internal layer (1 mm from the articulation surface = average of $Ws$ , $As$ , and $Vs$ )	$R = -0.117$ $P = 0.390$	$r = -0.461$ $P = 0.008^*$	$r = 0.130$ $P = 0.545$
Microhardness: medium layer (average of $Wm$ , $Am$ , and $Vm$ )	$R = -0.117$ $P = 0.390$	$r = -0.280$ $P = 0.120$	$r = 0.364$ $P = 0.080$
Microhardness: external layer (1 mm from the external surface = average of $We$ , $Ae$ , and $Ve$ )	$r = -0.183$ $P = 0.177$	$r = -0.424$ $P = 0.156$	$r = 0.260$ $P = 0.219$
Microhardness: $Ws$	$r = -0.229$ $P = 0.089$	$r = -0.443$ $P = 0.011^*$	$r = 0.141$ $P = 0.511$
Microhardness: $Wm$	$r = -0.116$ $P = 0.394$	$r = -0.290$ $P = 0.110$	$r = 0.350$ $P = 0.093$
Microhardness: $We$	$r = -0.049$ $P = 0.720$	$r = -0.259$ $P = 0.152$	$r = 0.264$ $P = 0.212$
Microhardness: $As$	$r = -0.048$ $P = 0.726$	$r = -0.214$ $P = 0.240$	$r = -0.004$ $P = 0.985$
Microhardness: $Am$	$r = -0.040$ $P = 0.771$	$r = -0.186$ $P = 0.308$	$r = 0.199$ $P = 0.351$
Microhardness: $Ae$	$r = -0.067$ $P = 0.625$	$r = -0.211$ $P = 0.263$	$r = 0.224$ $P = 0.293$
Microhardness: $Vs$	$r = -0.138$ $P = 0.312$	$r = -0.318$ $P = 0.008$	$r = 0.210$ $P = 0.324$
Microhardness: $Vm$	$r = -0.138$ $P = -0.130$	$r = -0.247$ $P = 0.172$	$r = 0.217$ $P = 0.308$
Microhardness: $Ve$	$r = -0.149$ $P = 0.274$	$r = -0.337$ $P = 0.060$	$r = 0.144$ $P = 0.501$

\* Statistically significant

**Table 3** Shelf life versus linear wear and wear rate

Linear wear			Wear rate		
All	Weber	Kyocera	All	Weber	Kyocera
$r = 0.189$	$r = 0.348$	$r = -0.083$	$r = -0.138$	$r = -0.193$	$r = 0.111$
$P = 0.164$	$P = 0.051$	$P = 0.697$	$P = 0.310$	$P = 0.290$	$P = 0.605$

the internal and external surfaces of the cup and progresses toward the core [6, 8, 10]. The oxidative degradation decreases the elasticity of polyethylene and stiffens it [8, 16]. The Weber cups were sterilized by gamma irradiation in air and packed in the inert gas. During the storage, the oxidation at the cup surface does not progress due to the lack of contact with air, while the internal residual energy by the radiation accelerates the cross-linking at the surface [6, 8, 10, 13]. This cross-linking might affect the results that the hardness near the surface increased.

Some authors reported that mechanical stress also affects the change in elastic property [4, 16, 17]. In the Kyocera cups, the hardness near the wear surface was more than that in the core; the hardness of  $Ws$  was more than that of  $Wm$ . Contrary to this result, Kurtz observed that the loaded surface of the liners exhibited less degradation than

the unloaded surface, probably because degraded material had been removed by wear [18]. In another study, Kurtz speculated that the femoral head limits the in vivo oxidation of polyethylene at the bearing surface [3]. These two studies may support our result that the hardness near the internal surface had a rather negative correlation with the wear measured in the Weber cups.

In the Weber cups, the hardness increased. The irradiation of the cups in this study was performed in air, but the method was recently changed to sterilization by irradiation in inert gas or in a vacuum atmosphere. The cups sterilized by the new irradiation methods show far better tolerance against oxidative degradation than those sterilized by the previous method, and some authors reported that the wear property was better in cups sterilized by the new irradiation methods than in those sterilized by ethylene oxide gas [19, 20].

The elastic property of a polyethylene cup plays an important role in total hip prostheses in terms of lubrication, shock absorption and stress distribution [2]. The results of this study suggest that ethylene oxide gas sterilization provides less change in elastic property than irradiation in air.

In the Weber cups, the radiation-induced cross-linking during the storage in the inert gas, as described above, might have a beneficial effect on polyethylene wear resistance [21], while concerning wear property, the interpretation of the results of this study may be debatable. Not only degradation, but also multiple other determinants influence wear. Oonishi reported the effect of femoral head sizes on polyethylene wear. This report found that, when the cup thickness was less than 9 mm, a larger femoral head resulted in a higher linear wear rate. However, when the cup thickness was more than 9 mm, this finding was inverted: the larger the femoral head, the lower the linear wear rate [22]. In our study, the internal diameter and the thickness of the cups were different. Thus, we could not accurately determine the effect of the sterilization method on wear. To precisely evaluate the effect of sterilization methods on wear, the comparison should be made between irradiated and non-irradiated cups of the same thickness and internal diameter. They should also be used in combination with a ball head of the same material. Furthermore, the evaluation must be done on cups that show no signs of failure.

Kyocera cups showed a considerable amount of wear, while they had only a slight change in mechanical property. Further, the different methods of sterilization did not reflect in the revision rate. The sterilization methods affected the mechanical property of UHMWPE, but not so much the wear property as far as the failed cups are concerned. In conclusion, wear and failure could still occur, even in a cup that almost keeps its original mechanical property.

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