

Hip-simulator ranking of polyethylene wear

Comparisons between ceramic heads of different sizes

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We carried out simulator studies on ceramic-polyethylene total-hip combinations to determine the volumetric wear-rates of 22 mm, 26 mm and 28 mm femoral-head sizes. Bovine-serum lubrication and 2 kN peak sinusoidal load-profile were used with polyethylene (UHMWPE) cups. Wear was assessed by gravimetric technique. Precision (9%) was ensured by the use of multiple specimens, multiple wear-events, and the linear-regression method of estimating the average wear trend, thereby reducing the in-

herent, unpredictable nature of each wear-event. Volumetric wear-rates for polyethylene averaged 23 mm³ per 10⁶ cycles for the 22 mm ceramic head and up to 32 mm³ per 10⁶ cycles for the 28 mm head. The difference between 22 mm and the larger head-sizes was significant. This may well be the first laboratory confirmation of Charnley's original clinical Low-Friction Arthroplasty concept with regard to wear rate. The wear penalty increased linearly at the rate of 6% to 9% per mm of diameter increase.

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The Low-Friction Arthroplasty concept developed by the late Sir John Charnley was based on his view of low-frictional torque for total hip-replacements (THR). However, the development of the Charnley hip began with the 41.5 mm femoral head common to other designs of that time. Unfortunately, Charnley found that his polytetrafluoroethylene cups showed significant short-term loosening with this size of femoral head. He reasoned that a large femoral head would create more frictional torque which may have contributed to his cup-loosening problem. Therefore, Charnley reduced his femoral-head size from 41.5 mm to 28.5 mm, then to 25.25 mm and finally to 22.25 mm diameter. Subsequent observations at revision surgery indicated that the smaller femoral heads

also caused the least polytetrafluoroethylene wear (Charnley et al. 1969). Thus, the 22.25 mm head-size became the foundation of his Low-Friction Arthroplasty concept introduced with polyethylene cups. However, from the 1960s to the 1990s simulator-wear studies provided no clear guidance on the relevance of femoral-head size (Table 1). Thus, from 1970 onwards, total-hip replacement systems developed worldwide with femoral heads varying from 26 mm up to 54 mm diameter.

Our objective was to investigate Charnley's femoral-head size concept by comparing the wear of 22 mm, 26 mm and 28 mm sizes of femoral heads articulating against polyethylene cups in a hip simulator. Ceramic femoral heads were selected for their precise

Table 1. Summary of simulator studies relating volume of UHMWPE wear to diameters of femoral heads. Note that the femoral-head materials included alumina ceramic, 316 stainless steel, CoCr, Ti-6Al-4V alloy and Ti-6Al-4V alloy with titanium-nitride coating

Study	Load	Lubricant	Method	Wear ranking vs diameter
Weightman et al. 1973	walking	serum	dimensional	22 = 32 mm
Rose et al. 1979	walking	serum	dimensional	variable
Wright and Scales 1980	walking	serum	dimensional	32 < 25 mm
Clarke et al. 1993	sinusoidal	serum	gravimetric	22 < 26 < 28 mm
Derbyshire et al. 1994	walking	water	dimensional	22 < 26 < 32
Pappas et al. 1995	walking	water (spray)	gravimetric	47 << 32 mm
McKellop et al. 1995	walking	serum	gravimetric	22 < 28 mm

tolerances and abrasion-resistant surfaces (Clarke and Kabo 1991, Clarke and Willmann 1994). Thus the main variable was the diameter of the femoral head articulating against polyethylene with serum lubrication.

Methods

Custom ultra-high-molecular-weight polyethylene liners were made to the ATH (Amstutz et al. 1989) design (Cycam, Houston, Texas, USA) from 2-inch bar stock (American Hoechst; 415 GUR annealed). Minimum wall thickness for the cups was 10 mm. The minimum and maximum ball/cup tolerances were 0.25 mm and 0.5 mm diametrical range, respectively. 3 wear cups were used per head-size and 3 identical cups were stored (nonloaded) in bovine serum for equivalent test duration as soak-controls. The cups were not sterilized prior to testing. The ATH alumina femoral heads (22 mm, 26 mm and 28 mm) were made by Kyocera Inc. (Kyoto, Japan) and supplied by Kinamed Inc. (Los Angeles, CA, USA).

The cups were mounted facing upwards in the SWM9.0 multi-channel hip simulator (Shore Western Manufacturing Inc., Monrovia, CA, USA) to ensure an adequate supply of lubricant during tests. The load profile was sinusoidal, with peak magnitudes of 2 kN and a frequency of 1 Hz. The oscillatory cup motion was $\pm 20^\circ$ about a horizontal axis which rotated 1 cycle per second relative to the load axis. The simulator had no self-alignment device, frictional-torque sensors or lubricant temperature-control. Bovine serum was used with standard additives of sodium azide and EDTA (McKellop et al. 1992, 1995). The specimen chambers were replenished with distilled water during the tests and lubricant temperature was measured during each test. The serum was changed at each weight-event measurement, and a standard cleaning procedure was used for the implants (ASTM 1982, 1994).

Wear was assessed by gravimetric techniques (ASTM 1994). A microbalance was used (Sartorius, Goettingen, Germany) which communicated with a Macintosh LC-II computer for data storage and analysis. Each set of weight measurements was repeated twice to check for either human error or instability in specimen weights. The average weights were used in subsequent calculations. The individual wear-rates were calculated for each weight-measurement "event". After 9 such wear-events, linear regression techniques were used to estimate the overall wear-rate (mg/106 cycles) for each specimen and the average for each set of specimens. The density of 415-GUR

polyethylene (certified as 0.931 mg/mm³) was used to convert to volumetric wear-rates (mm³/106 cycles). Linear wear-rates were calculated using Charnley's observations of a cylindrical wear-track (Charnley et al 1969). However, this is not meant to imply that the SWM9.0 simulator necessarily produced such wear tracks.

A simple parameter that we used routinely in our laboratory to provide comparisons of data was the estimate of the experimental scatter of a small amount of data set about its mean value. This was useful for estimating the scatter in the average wear-rate data, usually given sets of only 2–5 specimens, where

$$\text{Scatter}\% = \frac{100 \times (\text{maximum value} - \text{minimum value})}{2 \times \text{mean value}}$$

For ease of comparison with varied ball-sizes, a wear term was created to simplify comparisons to the 22.25 mm ball diameter as the standard. A volumetric wear index (VWI) was defined so that the proportionate increase or decrease in wear of the larger femoral heads and material combinations could be easily compared to the Charnley prosthesis. For large ball-A with a volumetric wear-rate (V_a mm³/10⁶ cycles) relative to the Charnley wear-rate (V_c mm³/10⁶ cycles), the percentage difference in volumetric wear $100(V_a - V_c)/V_c$ was divided by the difference in head diameters ($D_a - D_c$ mm), i.e.,

$$\text{VWI (\% per millimeter)} = \frac{100 \times (V_a - V_c) / V_c}{(D_a - D_c)}$$

Following the wear tests, the ATH implants and wear debris were analyzed at the Joint Replacement Institute, Orthopedic Hospital, Los Angeles, CA, USA. The surface finish for each ceramic ball was measured (Campbell 1995) with a diamond stylus Perthometer S8P (Mahr/Feinpruf, Goettingen; 5 μ stylus, 0.010 inch cut-off length). The dome region on each femoral head represented the worn surface, while the peripheral region represented the unworn surface. In addition, the wear debris was collected and compared to data from retrieved ATH implants (Campbell et al. 1995).

Results

There were initially some small disturbances in the weight measurements of both soak and wear cups (Figure 1). However, from 2×10^5 cycles onwards,

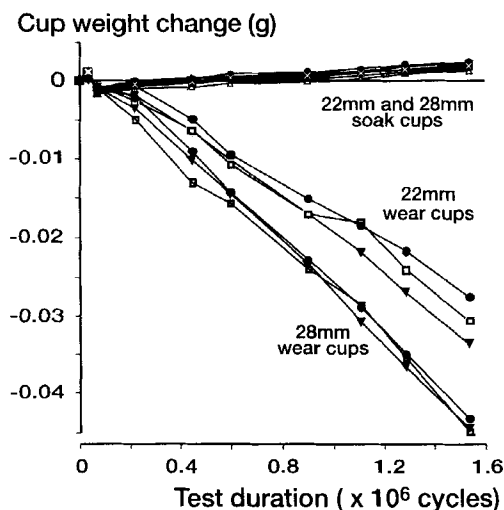


Figure 1. Weight-changes measured for 22.25 mm and 28 mm ID UHMWPE acetabular cups during 1,534,000 wear cycles (26 mm ID cup soak and wear sets omitted for clarity). Weight-gain (+ve) measured in 6 cups due to fluid absorption, and progressive weight-loss (-ve) measured in each of 3 sets of wear specimens (combined soak and wear phenomena). The UHMWPE cup weights drifted during the hour required for the weight measurement protocol within the range ± 0.14 mg ($\pm 0.0005\%$).

the weight-change trends appeared to be steady and linear. The wear cups lost weight at the rate of 19.2 mg (22 mm) to 29.3 mg (28 mm) per 10^6 cycles (Table 2). In contrast, the soak-control cups steadily gained weight at the average rate of 1.3 mg per 10^6

cycles. This absorption phenomenon represented 4–8% of the apparent wear magnitude. There were no significant differences in soak rates with regard to cup sizes. The calculated wear-rates after correction for fluid absorption averaged 21.6 mg, 29.7 mg and 30.6 mg per 10^6 cycles for 22, 26 and 28 mm ball sizes, respectively. The individual wear rates from the 22 mm cups exhibited the most scatter at $\pm 9\%$ of their overall mean; the scatter in the 26 mm and 28 mm cups stayed within $\pm 5\%$. The wear rates for both the 26 mm and 28 mm cups were significantly different from the 22 mm cups ($p < 0.0001$) whereas the difference between the 26 and 28 mm cup wear-rates was not significant ($p 0.3$).

The corresponding volumetric wear-rates averaged 23.2, 31.9 and 32.8 mm^3 per 10^6 cycles, respectively. Thus the 26 and 28 mm diameter heads produced 38% and 41% more wear volume than the Charnley size. The volumetric wear indices (VWI) were 9.4% and 6.9% for the 26 and 28 mm ball sizes, respectively. In terms of equivalent linear wear-rates, the corresponding values were 0.06 mm, 0.06 mm and 0.05 mm per 10^6 cycles (Table 2).

The Ra surface-finish parameter was the only one which varied between size groups ($p < 0.01$), averaging 0.095, 0.083 and 0.076 micrometers for 22 mm, 26 mm and 28 mm balls, respectively. It was interesting that the surface finish (Ra) was highest for the smallest heads and lowest for the largest heads. Otherwise, there was no difference between size-groups or between dome (worn) and peripheral (unworn) areas.

Table 2. Summary of alumina: UHMWPE soak-control and cup wear data in serum lubricated tests under 2 kN sinusoidal load-profile

Ball diameter mm	Average weight change mg/ 10^6 cycles	CL ^a	Individual wear mg/ 10^6 cycles	Scatter	Volumetric wear rate $\text{mm}^3/10^6$ cycles	Volum. wear ratio	Volum. wear index	Cross-sec. area ^b mm^2	Equivalent linear wear ^c mm/ 10^6 cycles	Linear wear ratio
All soak	1.3	0.5	NA		NA					
Wear			19.8							
22.25	-21.6	1.2 23.5	21.1	9%	23.2	Ref.	Ref.	389	0.06	Ref.
26	-29.7	1.2 30.4	29.7	5%	31.9	1.38	9.4%	531	0.06	1.0
28	-30.6	1.2 30.5	29.7	3%	32.8	1.41	6.9%	615	0.05	0.89

^a CL \pm 95% confidence limits in linear regression analysis.

^b Cross-sectional area of femoral head.

^c Linear wear-rate, based on assumption of cylindrical wear (Charnley et al. 1969). Note that this is for comparison only and is not meant to imply necessarily that the SWM9.0 simulator provided cylindrical wear-tracks.
NA not applicable.

Discussion

The effect of the fluid-absorption artifact (Clarke et al. 1985) was less than 8% of the wear magnitude and was corrected for in this study. Therefore, our data demonstrated accurately that the smallest femoral head produced the least volumetric wear. The 26 mm and the 28 mm UHMWPE cups exhibited 1.4 times more volumetric wear than the 22.25 mm cups, confirming the initial clinical impressions of Charnley. The increased wear of the larger balls was not due to their having an inferior surface-finish: the 28 mm ceramic balls had the best surface-finish and the average surface-finish of the ATH ceramic balls run in the simulator was identical with those removed from ATH patients. With regard to magnitudes of wear, the rate of 23 mm³ per 10⁶ cycles (22 mm head size) in this simulator model was comparable to the lower range in most clinical studies (20–80 mm³/year for more elderly patients) (Charnley and Halley 1975, McCoy et al. 1988, Morrey and Ilstrup 1989, Lazcano et al. 1994). The wear debris from the simulator was similar in morphology and size distribution to that seen in ATH retrieval cases, averaging 0.3 µm in diameter and up to 2.5 µm in length. Thus in vivo and in vitro wear phenomena appeared to be comparable. Therefore, these in vitro wear data seem provide a reliable wear model of the in vivo situation.

As well as giving valuable insight into the process of simulating and measuring polyethylene wear, our laboratory study also demonstrated a precise relationship between femoral-head diameter and the volumetric wear-rate. The volumetric wear indices (VWI) for polyethylene were calculated in the range of 6%–9% per millimeter for the 28 mm and 26 mm ceramic heads, respectively (Table 2). The volumetric wear indices calculated from Charnley's polytetra-fluoroethylene retrieval study averaged 5%–6% per mm (Charnley et al. 1969). Considering the many differences between Charnley's studies of three decades ago (steel heads, PTFE cups, in vivo) and our laboratory model (ceramic heads, polyethylene cups, serum, simulator), this agreement provided good confirmation of the major effect that femoral-head diameter had on volumetric wear rates.

Mikami's (1988) clinical studies in Japan compared cup wear-rates in Charnley and Müller patients, with linear wear-rates of 0.104 and 0.088 mm/year, respectively. We calculated the corresponding volumetric wear index to be 8%. A Mayo Clinic study demonstrated linear wear-rates of 0.13, 0.08 and 0.1 mm/year for Charnley, T-28 and Müller THR patients, respectively (Livermore and Morrey, 1990). The corresponding volumetric wear indices we calculated as

–0.4% (T-28 THR) and 6% (Müller THR). Thus, excluding the T-28 data from the Mayo Clinic, the volumetric wear indices calculated from three clinical studies appeared to be in the 5%–8% range. The volumetric wear indices of 6%–9% per mm for UHMWPE cups in our simulator were therefore in excellent agreement. Thus, it would appear that there is a fundamental wear relationship with regard to ball size, i.e., a consistent volumetric-wear penalty which increases at the rate of 5%–9% per mm increase in head size. This may also be independent of simulator test parameters or materials selected.

As Charnley had indicated, his initial "TEFLON" experience provided a valuable reference for evaluating wear rates with regard to femoral-head size from both clinical and laboratory studies (Charnley 1967). Having ascertained in our study the fundamental relationship of head-size to volumetric wear-rate for UHMWPE, it will be possible to run simulator studies of varied implant design, material combinations and lubricants and test these data against this fundamental relationship. For example, a recent simulator study (stainless steel/UHMWPE, serum lubrication) provided wear rates of 41 and 59 mm³ per 10⁶ cycles for 22.25 and 28 mm heads, respectively (McKellop et al. 1995). The volumetric wear index calculated from that study was 5.9%, which fitted the above hypothesis. A simulator study (Derbyshire et al. 1994) with zirconia ceramic/UHMWPE in water-lubrication appeared to agree with the overall femoral-head ranking for volumetric wear (Table 1). However, taking average wear-rates (15, 43, and 74 mm³ per 10⁶ cycles for 22.25, 26 and 32 mm heads, respectively), we calculated the corresponding volumetric wear indices as 41% and 48%. Such data did not fit the above hypothesis.

With volumetric wear increasing at the rate of 5% to 9% per mm increase in ball diameter, it could be anticipated that the 32 mm femoral head would generate 50%–90% more wear debris than the Charnley THA. In view of current awareness of the effects of debris-driven osteolysis, these data may be of clinical importance. It seems clear that the excellent clinical performance of the Charnley prosthesis worldwide (Ritter et al. 1983, Havelin et al. 1993, Malchau et al. 1993) testifies to the pioneer's insight about using the smallest femoral head to limit the polyethylene wear debris.

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