Improved wear performance with crosslinked UHMWPE and zirconia implants in knee simulation

Riichiro Tsukamoto¹, Sam Chen¹, Taiyo Asano³, Mikio Ogino², Hiromu Shoji³, Takashi Nakamura⁴ and Ian C Clarke¹

¹Department of Orthopedics, Loma Linda University Medical Center, Loma Linda, CA, ²Tsukamoto Orthopedics Hospital, Tokyo, Japan, ³The Western Center for Orthopedics Research Foundation, Riverside, CA, ⁴Department of Orthopedic Surgery, Graduate School of Medicine, Kyoto University, Japan

Correspondence ICC: marochinchin@aol.com, ianclarke4@msn.com

Submitted 05-03-01. Accepted 05-08-12

Background Suggestions for improved wear performance of total knee replacements have included replacement of standard CoCr femoral components with ceramic and replacement of 3.5-Mrad ultra-high molecular weight polyethylene (UHMWPE) inserts with 5- or 7-Mrad UHMWPE inserts. The ceramic materials used clinically have included alumina, zirconia ceramic and oxidized zirconium.

Patients and method We compared both CoCr and zirconia versions of the Bi-Surface knee replacement in a 6-station knee simulator using alpha calf serum for lubrication (20 mg protein per mL) to evaluate the relative bearing performance.

Results We studied the 4-way knee simulation of implant materials: zirconia ceramic, CoCr, 3.5-Mrad UHMWPE, and 7-Mrad UHMWPE. With CoCr femoral components, the 7-Mrad UHMWPE resulted in a 5- to 8-fold reduction in wear compared to the 3.5-Mrad insert. With the 3.5-Mrad insert, the zirconia bearing provided approximately 4-fold wear reduction compared to CoCr. These wear rates with standard UHMWPE were similar to published wear studies on entire knees. With the exception of the CoCr/7-Mrad and ZrO₂/3.5-Mrad combinations, the wear differences were statistically significant.

Interpretation The ZrO₂/7-Mrad UHMWPE combination gave the best performance, with no measurable wear over the 5.5 million cycle test duration.

In total hip replacements (THRs), crosslinked polyethylene (XLPE) has been shown to be effective in reducing wear—both experimentally (McKellop et al. 1996, Muratoglu et al. 1996, Clarke et al. 1997, Wang et al. 1997) and clinically, thereby reducing the risk of osteolysis (Oparaugo et al. 2001). It has also been demonstrated that wear with ultra-high molecular weight polyethylene (UHMWPE) on ceramic balls is reduced compared to CoCr balls (Clarke et al. 1996, Wang et al. 1997). Contemporary total knee replacements (TKRs) have not shown the same predilection for osteolysis, and some centers have shown a 95% survival rate at 15 years (Ranawat et al. 1993, Ritter et al. 2001). Improved knee designs should nevertheless be of value in high-risk patients such as the young and active with many more years of life expectancy.

Improvements that have been suggested for TKR bearings (Table 1) have included both tibial inserts of XLPE and either alumina or zirconia ceramic for femoral components. Zirconia was introduced as a ceramic with higher strength and toughness than alumina ceramic (Cales 2000, Blaise et al. 2001, Ueno et al. 2003). Thus, a zirconia femoral component can be manufactured with virtually identical dimensions to a CoCr design. The one-piece (monobloc) ceramic femoral condyles used in Japan (Nakamura et al. 2002, Oonishi et al. 2002) have not yet been approved for use in Europe or the USA. In 2001, however, the FDA did approve the marketing of a unique ceramic
knee concept with an oxidized zirconium surface (White et al. 1994, Spector et al. 2001, Hermida et al. 2004). Thus, contemporary ceramic femoral components feature either 100% zirconia or the metal zirconium treated with a 5-µm-thick zirconia surface (Oxinium; Smith & Nephew, Memphis, TN).

Some types of femoral balls made of zirconia have not given universally good clinical results, with early osteolysis reported by some authors (Hama-douche and Sedal 2000, Kim et al. 2001, Norton et al. 2002, Clarke et al. 2003, Hernigou and Bahrami 2003, Walters et al. 2005). Some retrieval reports indicated a deleterious phase transformation from tetragonal to monoclinic, which could be > 80% by 8 years (Table 2: Pr1). The surface roughness of pristine zirconia balls has averaged less than 10 nm (Ra). However, roughness on some transformed zirconia balls has increased by more than 25-fold due to extensive cratering of the articular surface (Haraguchi et al. 2001, Green et al. 2003). This probably increased the polyethylene wear rates.

It should be noted, however, that not all zirconia implants will necessarily become transformed. The manufacture of zirconia ceramic is both an art and a science. Any processing that affects the intermediate densities of the zirconia can result in reduced stability in vivo (Piconi and Maccaroto 1999). The precise descriptions of zirconia-processing parameters are basically unpublished, being proprietary to each vendor (Table 2). Every manufacturer strives for progressive improvement of their material, and therefore the year of manufacturing also plays a role. This has included the introduction of hot isostatic pressing (HIPed) to improve the intermediate density of the zirconia ball, and doping of the zirconia powder with alumina ceramic (< 0.2%) (Villermaux et al. 1999). Laboratory studies have indicated that the HIPed and alumina-doped variants of zirconia may have greater metastability (Blaise et al. 2001, Clarke et al. 2005).

For ceramic knee joints, there are laboratory studies showing a consensus that polyethylene wear can be reduced 2- to 5-fold using zirconia femoral condyles, depending on the test conditions (Table 1). It is surprising that this reduction of wear with zirconia TKRs was much higher than that with zirconia THR (Mckellop and Benya 1992, Derbyshire et al. 1994). Thus, knee arthroplasty may benefit from zirconia used with either standard polyethylene or the more highly crosslinked polyethylenes.

### Table 1. Published wear studies of UHMWPE and XLPE inserts bearing on CoCr, zirconia and oxidized zirconium femoral condyles

| Study | Simulator | Serum | Test duration | TKR | PE | Crosslink | Processing | Femoral | Wear rate | Ratio |
|-------|------------|-------|---------------|-----|----|----------|------------|----------|-----------|-------|
| A     | SWM        | 30% bovine | 5 Mc | KOM | GUR1050 | 3.5 Mrad | Annealed/N2 | Al2O3 | 0.03 | 10 |
| B     | SWM        | (20 mg/mL) | 5 Mc | KOM | GUR1050 | 7.0 Mrad | Annealed/N2 | CoCr | 3.0 | 2.3 |
| C     | AMTI       | 90% bovine | 5 Mc | KOM | GUR1050 | 7.0 Mrad | Annealed/N2 | CoCr | 3.0 | 2.3 |
| D     | AMTI       | (60mg/mL) | 5 Mc | KOM | GUR1050 | 7.0 Mrad | Annealed/N2 | CoCr | 3.0 | 2.3 |
| E     | Instron    | water     | 2 Mc | Genesis 1 | GUR1415 | 3.0 Mrad | GRA | Ox1Zr | 104±5.3 | 1.6 |

---

- **Study: A) Oonishi et al. 2002, B) Asano et al. 2003, C) Hermida et al. 2004, D) Ueno et al. 2003, E) White et al. 1994**
- **Simulator: 6-knee channel.**
- **SWM: Shore-Western Manufacturing Inc.**
- **Mc: million cycles.**
- **TKR: Total knee replacement:** KOM = KOM™
- **XL: crosslinked**
- **EIO: sterilized by ethylene oxide gas, GRA: gamma radiation in air.**
- **Ox1Zr: oxidized zirconium**
- **Wear rate of Oonishi et al. (A): decrease in thickness of the UHMWPE.**
- **Wear rate of White et al. (E): original point score.**
We compare the wear of 3.5-Mrad and 7.0-Mrad UHMWPE tibial inserts run against both Co-Cr and zirconia femoral implants. Our hypothesis was that the combination of ceramic and highly crosslinked inserts would offer superior wear performance.

**Methods**

The Bi-Surface knee (Figure 1), a posterior-cruciate sacrificing design, was studied with both zirconia and CoCr condyles (Japan Medical Materials; JMM Inc., Osaka, Japan). Alumina doping in this zirconia was reported to be < 1% (Table 3). Tibial inserts were made from one lot of ram-extruded UHMWPE (Table 4). Radiation sterilization to doses of 3.5 Mrad and 7 Mrad was performed under vacuum. Additional tibial inserts were used as soak controls and stored unloaded in deionised water for 60 days prior to testing.

A 6-channel, displacement-controlled knee simulator was used (Shore-Western Manufacturing Inc., Monrovia, CA) with the following test parameters: stance-phase kinematics of 20° flexion-extension, 6 mm of anterior-posterior translation, and ±5° of internal-external rotation. The lightly-loaded, swing phase (40% of gait cycle) was deleted from the kinematics profile (Asano et al. 2003). The Paul load profile was used with 2.6 kN peak-load running at a frequency of 1.8 Hz.

The lubricant was 50% alpha calf serum (20 mg protein/mL) with added ethylenediamine tetraacetic acid (EDTA) (McKellop et al. 1992). All inserts were cleaned and weighed every 0.5 Mc during a test duration of 5.5 million cycles. An advantage of the gravimetric method of wear assessment is that creep or cold flow in the UHMWPE inserts was not an issue. The disadvantage was that weight changes due to fluid absorption into the UHMWPE had to be compensated for. Thus wear rate and fluid absorption assessments were done simulta-
neously at 0.5-Mc intervals and the net wear rates computed using linear regression techniques. As an assessment of experimental variance in the sets of 3 implants, we computed total percentage scatter as the \( \frac{\text{max} - \text{average}}{\text{average}} \) and \( \frac{\text{min} - \text{average}}{\text{average}} \).

**Statistics**

Linear regression analysis was performed for each specimen. One-way ANOVA and non-parametric (Kruskal-Wallis) tests were performed, with subsequent tests for multiple comparisons (critical p-value = 0.05). We used SPSS version 10 (SPSS Inc., Chicago, IL).

**Results**

Initial technical challenges were encountered with the weight-loss measurements from 0 to 1 Mc duration; thus, the wear data were presented from 1 to 5.5 Mc duration (Table 5). The weight-loss patterns showed uniform linear trending with all regression coefficients > 0.96. Wear of the control implants (CoCr/3.5-Mrad) averaged 4.89 mm³/Mc with good control of experimental variance (Figures 2 and 6A, B). The experimental CoCr/7.0-Mrad combination averaged over 5-fold lower wear (Figures 3 and 6A, B) but the variance was much degraded. The ZrO\(_2\)/3.5-Mrad combination showed similar wear reduction with better control of variance (< 16%). The ZrO\(_2\)/7.0-Mrad combination was the exception, with net weight gain throughout the study. This wear rate was undetectable despite good linear regression trends and comparable control of variance (Figures 5 and 6A, B). Comparisons of ZrO\(_2\)/3.5-Mrad and CoCr/7.0-Mrad combinations showed no statistically significant difference (p > 0.05, power = 0.1). Compared to the control set, however, all other implant combinations were statistically significantly different (p < 0.05).
Figure 2. Linear wear trends for 3.5-Mrad UHMWPE/CoCr component (n = 3).

Figure 3. Linear wear trends for 7-Mrad UHMWPE/CoCr component (n = 3).

Figure 4. Linear wear trends for 3.5-Mrad UHMWPE/zirconia component (n = 3).

Figure 5. Linear wear trends for 7-Mrad UHMWPE/zirconia component (n = 3).

Figure 6. A. Average trends for 3.5-Mrad UHMWPE/CoCr, 7-Mrad UHMWPE/CoCr, 3.5-Mrad UHMWPE/Zr, and 7-Mrad UHMWPE/Zr combinations.

B. Mean wear rates and statistical correction for 3.5-Mrad versus 7-Mrad UHMWPE tibial inserts against CoCr and zirconia femoral implants.
Discussion

An initial technical limitation of our study was the lack of wear trends up to 1 million cycles duration (1 Mc). However, comparing our control set (CoCr/3.5-Mrad) from 1 to 5.5 Mc duration, the implants showed an excellent linear trend. Total variation in wear rates was also excellent (< 7% overall) and the average wear rate of 4.89 mm$^3$/Mc corresponds to mid-range values in previously published knee studies (Table 1). Thus, our wear trends appeared to be satisfactorily robust from 1 to 5.5 Mc (Figure 6A, B). However, our experimental CoCr/7-Mrad set revealed a disappointing variance (62% overall, n = 3). The variance estimate (62%) was due to one tibial insert (Figure 3, KL279) that showed 2.7 times higher wear on average than the other two inserts. This may signify that KL279 had been inadvertently damaged at the beginning of the wear study. However, either inclusion or exclusion of this tibial insert did not alter the conclusions in any way. Deleting the outlying TKR provided satisfactorily robust with excellent linear trending ($r > 0.96$) and variance (< 10% overall). The 7-Mrad UHMWPE wear was nevertheless unmeasurable with the gravimetric method. Unfortunately, there have been no comparable studies. In our previous study of the CoCr KOM knee, we found only 2.3-times wear reduction when using the 7-Mrad UHMWPE (Asano et al. 2003). Thus, these new wear data support our initial hypothesis. The zirconia/7-Mrad UHMWPE combination appears to offer a synergistic wear reduction below the current level of detection of wear in knee simulation studies.

Contributions of authors

RT experiment and writing the manuscript. SC experiment. TA, MO, HS, TN design of experiment. ICC training and supervision, writing the manuscript.

We greatly acknowledge the financial support of Japan Medical Materials (JMM Inc., Osaka, Japan), the Western Center for Orthopaedics Research (Riverside, CA), and the Department of Orthopedics, Loma Linda University Medical Center (LLUMC). The authors also wish to thank Paul Allen Williams, Department of Orthopedics, LLUMC, for assistance with the statistical analysis.

JMM Inc. provided the implants but took no part in data collection, analyses and writing of the manuscript.

Asano T, Clarke I C, Williams P, Akagi M, Shisido T, Mizoue T. Knee simulator wear of cross-linked UHMWPE with normal and mal-rotation kinematics. In 29th Ann Proc Soc Biomat 2003; 307 Reno.

Blaise L, Villermont F, Cales B. Ageing of zirconia: everything you always wanted to know. Key Eng Mat 2001; 13: 553-6.
Cales B. Zirconia as a sliding Material: histologic, laboratory, and clinical data. Clin Orthop 2000; (379): 94-112.

Clarke I C, Gustafson A, Jung H, Fujisawa A. Hip-simulator ranking of polyethylene wear: comparisons between ceramic heads of different sizes: Acta Orthop Scand 1996; 67 (2): 128-32.

Clarke I C, Good V, Williams P, Oparaugo P, Oonishi H, Fujisawa W. Simulator wear study of high-dose gamma-irradiated UHMWPE cups. In 23th Ann Proc Soc Biomat New Orleans 1997: 71.

Clarke I C, Manaka M, Green D D, Williams P, Pezzotti G, Kim Y H, Ries M, Sugano N, Sedel L, Delaney C, Nissan B B, Donaldson T, Gustafson GA. Current status of zirconia used in total hip implants. J Bone Joint Surg (Br) 2003; 85: 73-84.

Clarke I C, Green D D, Pezzotti G, Donaldson T. Zirconia review. 10th Ceram Tec Symposium 2005, Washington D.C.

Derbyshire B, Fisher J, Dowson C, Hardaker C, Brummitt K. Comparative study of the wear of UHMWPE with zirconia ceramic and stainless steel femoral heads in artificial hip joints. Med Eng Phys 1994; 16: 229-36.

Green D D, Pezzotti G, Sakakura S, Ries D M, Clarke I C. Zirconia ceramic femoral heads in the USA. In 49th Ann MtgaOS, New Orleans 2003: SE203.

Hamadouche M, Sedal L. Ceramics in orthopaedics. J Bone Joint Surg (Br) 2000; 82 (8): 1095-9.

Haraguchi K, Sugano N, Nishii T, Miki H, Oka K, Yoshikawa H. Phase transformation of a zirconia ceramic head after total hip arthroplasty. J Bone Joint Surg (Br) 2001; 83: 996-1000.

Hermida J, Patil S, D’Lima D D, Colwell C W, Ezzet K A. Oxidized zirconium femoral component reduce polyethylene wear in a knee wear simulator. In 50th Ann MtgaOS Trans San Francisco 2004: 138.

Hernigou P, Bahrami T. Zirconia and alumina ceramics in comparison with stainless-steel heads. J Bone Joint Surg (Br) 2003; 85 (4): 504-9.

Kim Y H, Kim J S, Cho S H. A comparison of polyethylene wear in hips with cobalt-chrome or zirconia heads. J Bone Joint Surg (Br) 2001; 83 (5): 742-50.

McKellop H, Lu B, Benya P. Friction lubrication and wear of CoCr, alumina and zirconia hip prostheses compared on a joint simulator. In: 38th Ann Mtg ORS Washington DC 1992: 402.

McKellop H, Yeom B, Sun D C, Sanford W M. Accelerated ageing of irradiated UHMWPE for wear evaluations. In: 42th Ann Mtg ORS Atlanta 1996: 483.

Muratoglu O, Liu A, Jasty M, Bradon CR, Elder JR, Harris WH. Oxidative degradation and embrittlement of ultra molecular weight polyethylene: Analysis of 107 components. In 5th World Biomaterials Congress 1996: 808 Toronto.

Nakamura T, Akagi M, Yasuda T, Nakagawa Y, Shimizu M. A new knee prosthesis with bisurface femoral component made of zirconia ceramic. Key Eng Mat 2002; 14: 567-72.

Norton M R, Yarlagadda R, Anderson G H. Catastrophic failure of the Elite Plus total hip replacement, with a Hylamer acetabulum and zirconia ceramic femoral head. J Bone Joint Surg (Br) 2002; 84 (5): 631-5.

Oonishi H, Fujita H, Itoh S, Kin S, Amino H. Development and improvement of ceramic TKP for 19 years and clinical results. Key Eng Mat 2002; 14: 479-82.

Oparaugo P C, Clarke I C, Malchau H, Herberts P. Correlation of wear debris-induced osteolysis and revision with volumetric wear-rates of polyethylenes. Acta Orthop Scand 2001; 72 (1): 22-8.

Piconi C, Maccuro G. Zirconia as a ceramic biomaterial. Biomaterials 1999; 20 (1): 1-25.

Ranawat C S, Flynn W F, Saddler S, Hansraj K K, Maynard M J. Long-term results of the total condylar knee arthroplasty. Clin Orthop 1993; (286): 94-102.

Ritter M A, Berend M E, Meding J B, Keating E M, Faris P M, Crites B M. Long-term followup of anatomically graduated components posterior cruciate-retaining total knee replacement. Clin Orthop 2001; (388): 51-7.

Spector M, Ries M D, Bourne R B, Sauer W S, Long, M, Hunter G. Wear performance of UHMWPE on oxidized zirconium total knee femoral components. J Bone Joint Surg (Am) 2001; 83: 80-6.

Ueno M, Ikuchi K, Nakamura T, Akagi M. Comparison of the wear properties of polyethylene plate in total knee prostheses using different femoral component materials. Key Eng Mat 2003; 15: 801-4.

Villermaux F, Blaise L, Cales B, Drouin J M. Zirconia-alumina total-lip prosthesis: the logical evolution of alumina-alumina system. In 25th Ann Proc Soc Biomat 1999: 135.

Walter W L, Skyme A D, Richards S, Chia M, Green D D, Waiker W K, Zicat B. Polyethylene wear rates with zirconia and cobalt chrome heads. In: 51th Ann Mtg ORS 2005: 1194.

Wang A, Polineni V K, Essner A. Effect of radiation dosage on the wear of stabilized UHMWPE evaluated by hip and knee joint simulators. In 23th Ann Proc Soc Biomat 1997: 154.

White S E, Whiteside L A, McCarthy D S, Anthony M, Poggie R A. Simulated knee wear with cobalt chromium and oxidized zirconium knee femoral components. Clin Orthop 1994; (309): 176-84.