

Comparison of Surgical Outcomes and Implant Wear between Ceramic-on-Ceramic and Ceramic-on-Polyethylene Bearing Surfaces in Total Hip Arthroplasty

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Disclosure

Food and Drug Administration Investigational Device Exemption (IDE)

Reflection® Ceramic-Ceramic Hip System (IDE Number: G980027)

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Background

- Wear Debris Stimulates Osteolysis
- Ceramic-on-Ceramic Couplings
 - low linear wear rate
 - low rate of osteolysis
 - audible component related noise
 - ceramic implant fracture
- A Linear Wear Rate $<50 \mu\text{m}/\text{year}$
 - reduces clinical osteolysis



Dumbleton, et al. (2002) *J Arthroplasty* **17**:649.
Yoo, et al. (2005) *JBJS* **87**: 530.
D'Antonio, et al. (2005) *CORR* **436**: 164.
Capello, et al. (2005) *Instr. Course Lect.* **54**: 171.

D'Antonio, et al. (2003) *Ortho* **26**: 39.
Simon, et al. (1998) *J Arthroplasty* **13**: 108.
Kichner and Willert (1992) *CORR* **282**: 86.
Winter, et al. (1992) *CORR* **282**: 73.



Hypothesis

**Ceramic-on-Polyethylene bearings
may offer a low linear wear rate
while avoiding the Ceramic-specific complications
of Ceramic-on-Ceramic articulations**



Randomization and Attrition

Reflection Ceramic-Ceramic Hip System
Between 1999 and 2001
14 Orthopaedic Surgeons, 9 Institutions
Follow-up for over 5 years

Patients = 312
Hips = 357

THA for osteoarthritis or rheumatoid arthritis
21 to 80 years of age; Harris Hip Score (HHS) <60
Availability for at least 2 years of clinical follow-up
Preoperative medical clearance

↓
Randomized

Ceramic-on-Ceramic

Ceramic-on-Polyethylene

Months

0

3

6

12

24

48

>60

n

196

187

183

182

176

131

125

Patients were lost to
follow-up as a result
of missed appointments,
death, and withdrawal
from the study

n

161

154

147

144

137

99

95

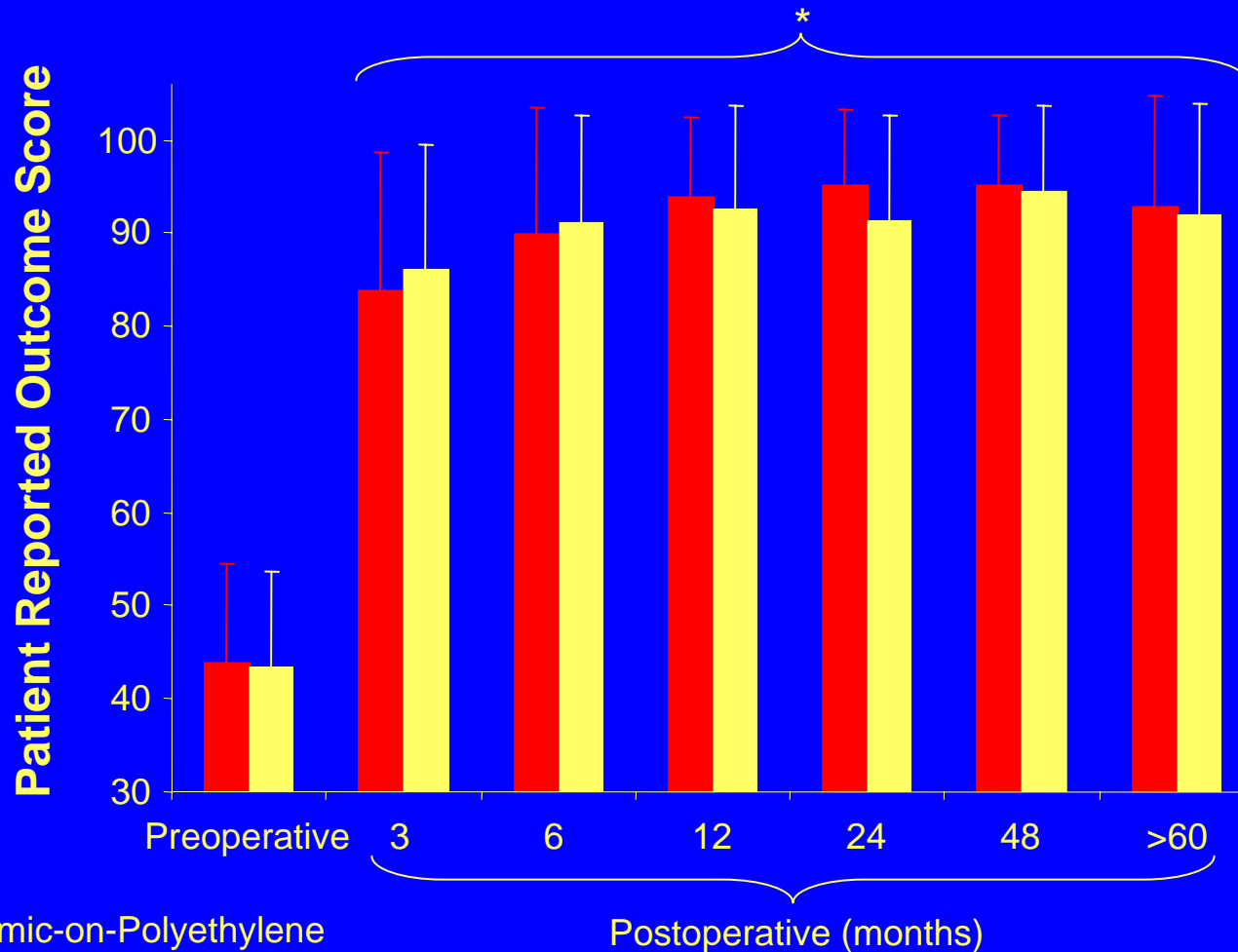


Statistically Random Patient Characteristics

	<u>Ceramic-on-Ceramic</u>	<u>Ceramic-on-Polyethylene</u>	<u>p-value</u>
Patients	166	146	-
Total Hip Arthroplasty (THA)	196	161	-
Bilateral THA (%)	30 (15.3%)	15 (9.3%)	0.061
Men (%)	106 (63.9%)	84 (57.5%)	0.152
Mean Age (years) ± SD	50.4 ± 12.8	54.7 ± 12.9	0.003* ←
Mean Height (cm) ± SD	173.2 ± 10.1	172.3 ± 9.7	0.357
Mean Weight (kg) ± SD	86.9 ± 20.0	83.7 ± 18.5	0.116
Mean BMI (kg/m ²) ± SD	29.6 ± 12.4	28.0 ± 5.1	0.133
Contralateral Hip Involvement (%)	64 (38.6%)	57 (39.0%)	1.000
Joint Involvement Other than Hip (%)	47 (28.3%)	46 (31.5%)	0.621
Physical Activity Prior to Surgery			0.245
None (%)	14 (7.1%)	5 (3.1%)	
Light (%)	123 (62.8%)	111 (68.9%)	
Moderate (%)	54 (27.6%)	38 (23.6%)	
Intense (%)	5 (2.6%)	6 (3.7%)	
Operative Blood Loss (ml) ± SD	527 ± 371	510 ± 396	0.822
Operative Time (minutes) ± SD	110 ± 52	114 ± 64	0.534
Hospital Stay (days) ± SD	4.4 ± 2.0	4.4 ± 1.7	0.675



No Significant Change in Patient Reported Outcome Scores at Any Time Interval

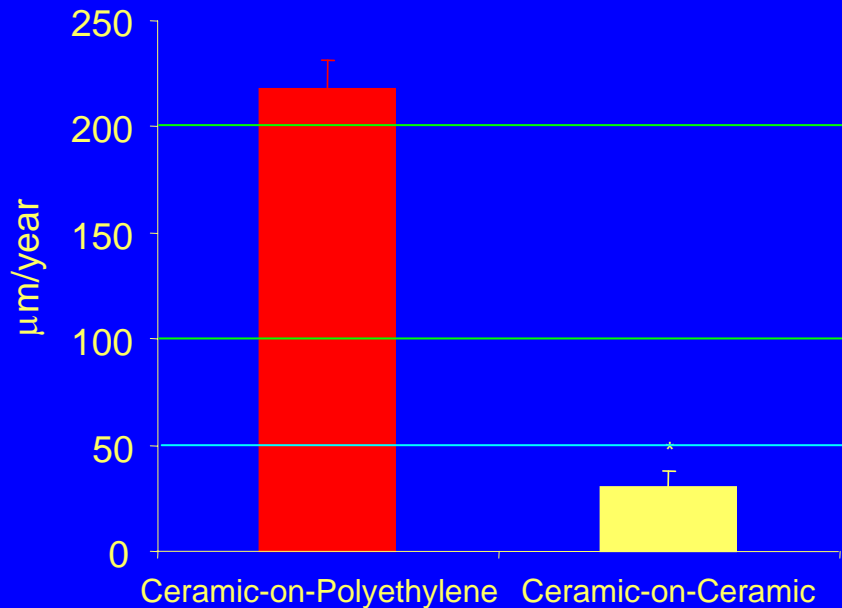


■ Ceramic-on-Polyethylene
■ Ceramic-on-Ceramic

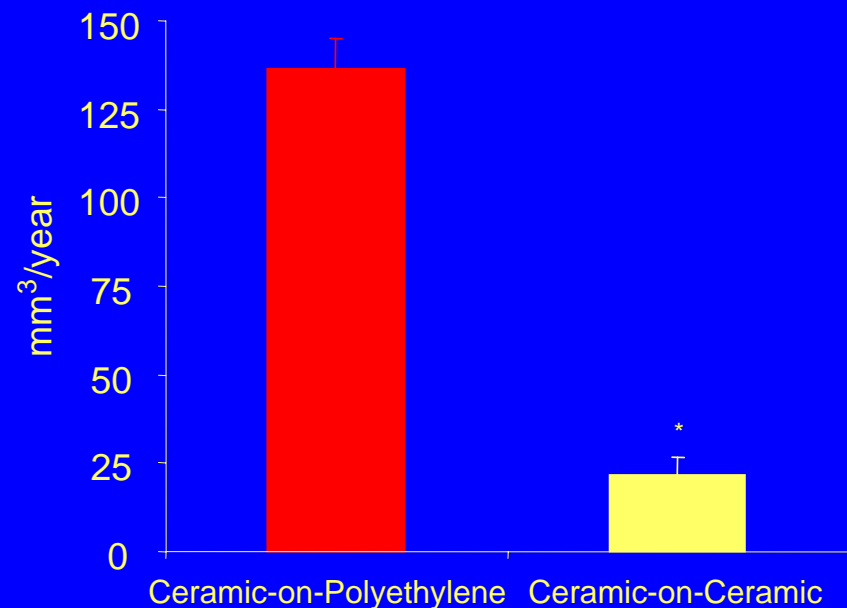


Higher Radiographic Wear Rates with Ceramic-on-Polyethylene Bearings

Linear Wear Rate



Volumetric Wear Rate



- Ceramic-on-Polyethylene
- Ceramic-on-Ceramic

Livermore, et al. (1990) *JBJS* 72: 518.
Dumbleton, et al. (2002) *J Arthroplasty* 17:649.
Yoo, et al. (2005) *JBJS* 87: 530.
D'Antonio, et al. (2005) *CORR* 436: 164.



Head Size and Wear Rate

	<u>Wear rate</u>	<u>Head Size</u>
Ceramic-on-Polyethylene (28 mm, 100%)	22 $\mu\text{m}/\text{year}$	22.225 mm
	70 $\mu\text{m}/\text{year}$	32 mm
	100 $\mu\text{m}/\text{year}$	Variable
	156 $\mu\text{m}/\text{year}$	28 mm
Ceramic-on-Ceramic (28 mm, 31%, or 32 mm, 69%)	2.1 $\mu\text{m}/\text{year}$	Variable
	4 $\mu\text{m}/\text{year}$	28 mm
	6 $\mu\text{m}/\text{year}$	Variable
	16 $\mu\text{m}/\text{year}$	Variable



Kichner and Willert (1992) *CORR* **282**: 86.
 Tanaka, et al. (2003) *JBJS Br.* **85**: 655.
 Hernigou, et al. (2003) *JBJS Br.* **85**: 504.
 Wroblewski, et al. (1996) *JBJS Br.* **78**: 280.

Livermore, et al. (1990) *JBJS* **72**: 518.
 Walter (1992) *CORR* **282**: 31.
 Jazrawi, et al. (1999) *J Arthroplasty* **14**: 781.
 Clarke, et al. (2000) *Proc. Inst. Mech. Engr.* **214**: 331.



Ceramic Fracture and Component Related Noise Are Risks of Ceramic-on-Ceramic Articulations

	Ceramic-on-Ceramic (%) <u>(n = 196)</u>	Ceramic-on-Polyethylene (%) <u>(n = 161)</u>	<u>p-value</u>
Intraoperative			
Liner Fracture	2 (1.0%)	0 (0.0%)	0.301
Sciatic Nerve Injury	1 (0.5%)	0 (0.0%)	0.549
Greater Trochanter Fracture	1 (0.5%)	1 (0.6%)	0.797
Difficulty Implanting Cup or Liner	2 (1.0%)	2 (1.2%)	0.758
Postoperative			
Heterotopic Ossification (HO)	59 (30.1%)	41 (25.5%)	0.197
Dislocation	10 (5.1%)	9 (5.6%)	0.672
Trochanteric Bursitis	8 (4.1%)	5 (3.1%)	0.422
Component Related Noise	6 (3.1%)	0 (0.0%)	0.026*
Deep Venous Thrombosis	3 (1.5%)	2 (1.2%)	0.592
	2 (1.0%)		
	6 (3.1%)		
	1 (0.5%)		
	2 (1.0%)		
	1 (0.5%)		
	2 (1.0%)		
	3 (1.5%)		
	4 (2.0%)		
	1 (0.5%)		
	11 (5.6%)		
Cumulative Fracture Risk	5 (2.6%)	0 (0.00%)	0.049*



Conclusions

- Prospective, multi-center, randomized clinical trial
- No difference in patient reported outcome measures
- The mean linear wear rate of ceramic-on-ceramic articulations is consistent with protection from osteolysis
- The mean linear wear rate of ceramic-on-polyethylene articulations is inconsistent with protection from osteolysis
- Ceramic-on-ceramic specific complications
 - 2.6% rate of ceramic implant fracture
 - 3.1% rate of audible component related noise

The use of ceramic-on-ceramic or ceramic-on-polyethylene bearing surfaces in THA remains a compromise between the long-term ramifications of wear debris and short-term ceramic-specific complications



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Reasons of Revision

<u>Initial Treatment</u>	<u>Interval</u>	<u>Components Revised</u>	<u>Reason for Revision</u>
Ceramic-on-Ceramic (n = 11)	3 Months	Liner, Head	Recurrent Dislocations
	3 Months	All Components	Infection
	6 Months	Cup, Liner, Head	Recurrent Anterior Dislocations
	1 Year	Head, Stem	Stem Subsidence
	1 Year	Cup, Liner, Head	Recurrent Anterior Dislocations Audible Component Related Noise
	2 Years	Liner, Head	Ceramic Head Fracture
	3 Years	Cup, Liner, Head	Ceramic Liner Fracture
	3 Years	Head, Stem	Loose Femoral Component
	4 Years	Cup, Liner, Head	Recurrent Dislocations
	5 Years	Cup, Liner, Head	Ceramic Liner Fracture
Ceramic-on-Polyethylene (n=3)	6 Years	Head, Stem	Loose Femoral Component
	Before Discharge	Liner, Head	Instability of the Hip
	3 Months	All Components	Infection
	5 Years	Liner, Head	Recurrent Dislocations

