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A Randomized Trial Of Ceramic-On-Ceramic Bearing Versus Ceramic-On-Crossfire-Polyethylene Bearing In Total Hip Arthroplasty: Five-Year Outcomes

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ABSTRACT

This study determined how ceramic-on-ceramic bearing THA affected joint-specific pain, function and stiffness in the first five postoperative years compared with ceramic-on-highly-crosslinked-polyethylene bearing THA. Subjects less than 61 years of age were randomized to ceramic-on-ceramic (CERAMIC) [n = 48] or ceramic-on-highly-crosslinked-polyethylene (POLYETHYLENE) [n = 44] bearing THA. Subjects were assessed using the Western Ontario McMaster Osteoarthritis Index (WOMAC) and the RAND 12-Item Health Survey (RAND-12) preoperatively, and at one and five years postoperatively. 92 subjects(50 (54%) males; average age = 52 (SD 6.6) years) were enrolled. 78 (85%) subjects returned five years postoperatively. All subjects reported improvements at one and five years in all measured indices with no group differences detected. Seven (8%) subjects experienced postoperative THA complications, none related to bearing surfaces; two subjects (POLYETHYLENE) required revision for instability. Both bearing surfaces provided excellent short-term results in younger subjects.

Total hip arthroplasty (THA) has become a more common treatment for end-stage arthritis in younger, more active individuals; in fact, those who are less than 60 years of age represent one of the fastest growing groups of patients undergoing THA [1,2]. Thus, alternative bearing surfaces are being explored as a means to extend the longevity of the THA through prevention of osteolysis and subsequent aseptic loosening.

Hard-on-hard bearing surfaces have been suggested as a means to prevent late stage revisions due to osteolysis. A recent systematic review suggested that survival of these implants was greater than 94% at five years follow-up [3]. Ceramic-on-ceramic bearings, based on four high quality randomized clinical trials (RCT) were reported at 96% at 8 years postoperatively [3].

In addition, the manufacturing of polyethylene continues to evolve as another means of improving implant longevity. Highly cross-linked and thermally treated polyethylenes were introduced in the late 1990s and are now being used clinically. Early results suggest that these newer polyethylenes have much lower wear rates than previous generations of polyethylene [4].

To date, there have been very few RCTs that have compared ceramic-on-ceramic bearings to ceramic-on-highly-crosslinked-polyethylene or ultra high molecular weight polyethylene bearings in subjects who were 60 years of age or younger at the time of THA [5,6]. Thus, the primary purpose of this randomized trial was to determine if there was a significant difference in patient-reported hip specific outcomes (pain, function, stiffness) between subjects who received either a ceramic-on-ceramic bearing (CERAMIC group) or ceramic-on-Crossfire [highly cross-linked]-polyethylene bearing (POLYETHYLENE group) THA over the first five postoperative years. Secondarily, complication / revisions and health status were also compared between groups. As highly crosslinked polyethylene was relatively new when we started the study, we hypothesized that the Ceramic-on-ceramic bearing THA would have better clinical results than the ceramic-on-Crossfire bearing THA.

Materials And Methods

We performed a randomized clinical trial comparing bearing surfaces in patients less than 61 years of age undergoing primary THA. Randomization occurred via computer-generated blocks of 20 subjects. Randomization codes were stored in sequentially-numbered opaque envelopes that were opened just prior to surgery. The study received ethical approval from the regional institutional review board

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and all subjects provided signed informed consent. The trial is registered at clinical trials.gov (NCT01522014).

The study was powered based on superiority of ceramic-on-ceramic bearings over ceramic-on-Crossfire bearings to detect a 10-point difference between groups on the sub-scales of the Western Ontario McMaster Osteoarthritis Index (WOMAC) measure ($\alpha = 0.05$; $\beta = 0.20$; power = 80%) [7].

Subjects were recruited preoperatively from 1998 until 2003 from seven orthopaedic surgeons' practices in one Canadian health region, which performs greater than 1000 THAs each year. All surgeons were experienced arthroplasty surgeons who performed more than 50 THAs annually.

Eligible subjects were scheduled for primary THA to treat non-inflammatory arthritis, less than 61 years old, able to speak and read the English language or have an available translator, had Dorr Index A or B bone quality on preoperative radiographs [8] and were willing to return for follow-up visits. Subjects were excluded if they had femoral or acetabular bone deficiency requiring augmentation, ongoing corticosteroid use, Dorr Index C bone quality [8] on the preoperative radiograph or required a prosthesis neck length of greater than five millimeters (mm).

Standard surgical technique was utilized and involved either a Hardinge or posterolateral approach at the surgeons' discretion. A standardized regional clinical pathway was in place throughout the study, ensuring all patients received similar perioperative and postoperative care. All patients were weight-bearing as tolerated using walking aids for the first six postoperative weeks.

Study prostheses were manufactured by Stryker Orthopaedics (Mahwah, New Jersey, USA). All subjects received non-cemented femoral and acetabular fixation and received the same femoral stem (Omni-fit hydroxyapatite [HA]). The ceramic-on-ceramic bearing was introduced in the region in 1997, so surgeons were accustomed to these bearings. The highly-crosslinked polyethylene insert was introduced in 1998, but was similar to its predecessor in form and should not have affected surgical technique.

Subjects randomized to the CERAMIC group received an arc-deposited HA-coated shell (Secure-Fit™ arc-deposited HA surface ceramic) and an Alumina Bearing Couple (ABC) ceramic insert and Ceramic C-taper head. Subjects randomized to the POLYETHYLENE group received the Secure-Fit™ shell, a Crossfire insert and a Ceramic C-taper head.

The following operative and perioperative measures were recorded: surgical approach, length of operating time (incision to wound closure), and any adverse events related either to the surgery or occurring in the immediate postoperative period.

During preoperative evaluation, a physical therapist explained the study and obtained signed informed consent from willing participants. The subject completed the WOMAC and RAND 12-Item Health Survey (RAND-12). In addition, subjects were rated as 'low', 'moderate' or 'high' demand using a standardized form based on their age, weight, health status and activity level. Subjects were randomized after the baseline assessment, thereby blinding the evaluator to group allocation.

Ninety-two subjects were enrolled with 48 subjects randomly allocated to the CERAMIC group and 44 subjects allocated to the POLYETHYLENE group. The participating surgeons contributed similar proportions of subjects to each group ($P = .41$), so that the surgeon should not affect reported group differences. Differences were also not seen in preoperative or demographic (e.g. age, gender) characteristics between groups (Table 1). Most subjects in both groups were considered at least 'moderate' demand with less than 5% of subjects scored as 'low' demand subjects (Table 1). Subjects in the CERAMIC group were more likely to receive a 32-millimeter femoral head while subjects in the POLYETHYLENE group were more likely to receive a 28-mm femoral head ($P < .001$). Aside from the differences in femoral head component size, there were no other significant differences in surgical characteristics between the two groups (Table 1).

Table 1
Baseline Characteristics of 92 Subjects less than 61 years of age undergoing Primary Total Hip Arthroplasty randomized to Ceramic on Ceramic (CERAMIC) or Ceramic on Highly Crosslinked Polyethylene (POLYETHYLENE) Bearing Surfaces.

	CERAMIC (n = 48)	POLYETHYLENE (n = 44)
Demographics		
Mean Age (SD)	51.3 (6.9)	53.6 (6.5)
Number of Males (%)	26 (54)	24 (54)
Physical Demand Level*		
High Physical Demand (%)	6 (13.6)	4 (9.3)
Moderate Physical Demand (%)	37 (84.1)	37 (86.0)
Low Physical Demand (%)	1 (2.3)	2 (4.7)
Baseline Characteristics		
WOMAC		
Mean Pain Score (SD)	42.1 (12.8)	44.4 (17.2)
Mean Function Score (SD)	45.2 (13.9)	46.6 (15.8)
Mean Stiffness Score (SD)	41.2 (18.2)	42.7 (16.9)
RAND-12		
Mean Physical Health Score (SD)	33.6 (8.7)	35.0 (8.5)
Mean Mental Health Score (SD)	47.7 (9.3)	45.5 (10.0)
Mean Global Health Score (SD)	40.7 (8.5)	40.0 (9.1)
Surgical Characteristics		
Number with Posterior Surgical Approach (%)	30 (63)	29 (66)
Mean OR time in minutes (SD)	77 (19)	68 (17)
Number with 32 mm head size (%)	39 (81)	4 (9)†
Number with 28 mm head size (%)	9 (19)	40 (91)†

Legend: CERAMIC = Ceramic on Ceramic Bearing; POLYETHYLENE = Ceramic on Highly Crosslinked Polyethylene; SD = Standard Deviation; WOMAC = Western Ontario McMaster Osteoarthritis Index; OR = Operating Room.
* Missing 5 responses.
† Significant at $P < .001$ as measured using a Fisher's Exact Test.

Subjects were re-assessed independent of the orthopaedic surgeon at one and five years postoperatively by physical therapists not involved in the subjects' clinical care. The subjects completed the same questionnaires and plain radiographs were taken. Subjects were also asked about complications and re-operations at each follow-up visit. A chart review was also performed at the end of the five-year evaluation period using regional administration records to capture any re-operations done at other health facilities within our health region that occurred in those lost to follow-up or those that were not reported by participants.

Outcome Measures

The WOMAC, shown to be valid, reliable and sensitive to change in pain and function in patients with osteoarthritis receiving a THA, was used to determine patient-reported joint-specific pain, function and stiffness [9–11]. Each WOMAC subscale score was transformed to a range from zero to one hundred points, with a score of 100 indicating no pain or dysfunction, so that the RAND-12 and WOMAC scores were unidirectional [12].

The RAND-12 was used to determine overall health status. The RAND-12 is a valid and reliable 12-item general health questionnaire that contains identical items as the Short Form 12 (SF-12) [13]. Three dimensions of health are reported — a composite physical health (PCS), a composite mental health (MCS) and a global health (GCS) score.

Statistical Methods

All of the analyses were performed as per "intention to treat", in which patients' data are analyzed as per their group allocation. Descriptive statistics (means, standard deviations and proportions) were generated for all preoperative variables using standard bivariate tests (independent t-tests and chi-square) to assess for potential