Gender Differences Impact the In-Vivo Head Penetration of Conventional and Cross-linked Polyethylene in Total Hip Arthroplasty

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Introduction: Conventional, non-gamma-in-air sterilized polyethylene (CPE) and cross-linked polyethylene (XLPE) have become widely utilized as bearing materials in total hip replacements [1,2,3]. The amount of femoral head penetration *in-vivo* is a favorable method to gain insight about the in-vivo wear process of such components. However, a recent study suggested that polyethylene (PE) wear *in-vivo* is related to gender differences, with male patients having higher PE wear than female patients [4]. Therefore, the purpose of this study was two-fold: A) Does XLPE reduce femoral head penetration *in-vivo*? B) Do differences in gender impact femoral head penetration *in-vivo*?

Materials and Methods: O
ne hundred patients were enrolled in a prospective randomized clinical trial. 15 male (M) and 35 female (F) received conventional PE (Trilogy (4MRads; gamma-in-nitrogen sterilization), Zimmer Inc., Warsaw) inserts and 17 M and 33 F received XLPE (Longevity (10MRads gas-plasma sterilization); Zimmer Inc., Warsaw) inserts. The PE liners were machined from ram extruded GUR 1050. All patients received the identical hybrid total hip replacement system with 28 mm heads. Patients were followed for 5 years post operative with radiographs taken 6 weeks post-operative and yearly thereafter. Patients with sufficient quality postoperative radiographs were included in the analysis. Measurements were repeatedly performed using Hip Analysis Suite 8.0.1.1 (courtesy of Dr. J.M. Martell, Chicago, IL) by one of the co-authors (K.D.C) who received extensive training by the software developer. Only 2 patients were lost to follow-up, however, 9 patients deceased before their 5 year follow-up. 19 patients were excluded due to poor visibility of the head to cup edge in the post operative radiographs which could render computer analysis inadequate [2, 5]. 70 patients with sufficient quality post operative radiographs and a minimum on two follow up radiograph were included in the study (34 XLPE (M = 10, F = 24) and 36 CPE (M = 9, F = 27)) and analyzed in two steps (Table 1).

Table 1: Group-specific analyses.

ANALYSIS	GROUP
1	CPE, XLPE
2	M-CPE, F-CPE, M-XLPE, F-XLPE

Statistical analysis was performed independent from the Martell software package with the assistance of a statistics consultant (E.P.H). Individual linear regression analysis was performed on each patient, representing the patients' specific penetration rate where the slope represents the penetration rate from 1 to 5 year follow-up. The total mean penetration rate was calculated from each patient's individual penetration rate for each group. The Independent students t-test was utilized to compare the head penetration rates between CPE and XLPE. Analysis of variance (ANOVA) with Fishers-LSD as the post-hoc method was used to compare the penetration rates between gender specific PE groups The distribution of penetration rates for each group was assessed using histograms and the Kolmogorov-Smirnov test. The level of significance was set at $p < 0.05$.

Results: The penetration rates and standard deviations for each group are shown in table 2. Based on the utilized test for normality the data for each group was found to be parametric.

Table 2: Group Specific Penetration Rates.

ANALYSIS	GROUP	N	Mean	St.Dev.
1	CPE	36	0.045	0.067
	XLPE	34	0.004	0.083
2	M-CPE	9	0.081	0.084
	F-CPE	27	0.032	0.056
	M-XLPE	10	-0.013	0.104
	F-XLPE	24	0.011	0.074

The mean penetration rate for CPE was 10 times greater than the penetration rate for XLPE ($p = 0.029$). The mean penetration rate for the M-CPE group was significantly higher than M-XLPE and F-XLPE ($p = 0.007$ and $p = 0.018$, respectively). However, there was no significant difference between M-CPE and F-CPE ($p = 0.090$). There was no statistical difference between F-CPE and F-XLPE was found ($p = 0.375$).

Discussion: To our knowledge this is the first study using Hip Analysis Suite as the measurement tool independent of the software developer. It was reassuring to observe that XLPE had a lower mean penetration rate than CPE, as has been shown in hip simulator wear testing [6]. Interestingly, the wear rates between F-XLPE and F-CPE were not statistically different. This may indicate that male patients may greater benefit from the use of the expensive XLPE than female patients which is perhaps due to differences in activity and body mass [4]. Traditionally, hip penetration rates from *in-vivo* studies have been determined by performing linear regression analysis on the entire group without considering individual patients [1,2,3]. As a comparison, in *in-vitro* simulator wear studies, linear regression analysis is utilized for determining the wear rate for each individual PE component throughout an entire test period [7]. Therefore, it is suggested to be more appropriate to determine the head penetration rate for each patient using linear regression analysis and then to average obtained rates of individual linear regressions to determine the mean penetration rate for each group.

References: [1] Manning et al, J Arthrop., 20 (7) 2005; [2] Bragdon et al, J Arthrop., 21 (7) 2006; [3] Martell et al, J Arthrop, 18 (7) 2003; [4] Schmalzried et al, CORR, 381, 2000; [5] Bragdon et al, CORR, 448, 2006.; [6] McKellop et al, J Orthop Res, 17, 1999; [7] Clarke et al, Wear 250, 2001.