

Optimum Combination of Femoral Head Size, Femoral Head Material, and Acetabular Cup Liner's Highly-Cross-Linked Polyethylene Brand for Hip Implant

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Abstract

Clinical two-dimensional linear wear rate data for acetabular cup liners fabricated using approved brands of highly cross-linked ultra-high-molecular-weight polyethylene, as reported in 39 articles in the literature, were analyzed using a statistical technique called response surface methodology. The output was a series comprising 16 acceptable combinations of femoral head diameter (HD), femoral head material (HM), and HXLPE brand (PB), each of which would yield the optimum wear rate (herein taken to be a wear rate of practically zero). An example of such a combination is 28-mm-diameter Oxinium[®] femoral head articulated against an acetabular cup liner fabricated from Reflection[™] HXLPE. The findings in this work may guide an orthopaedic surgeon's selection of the combination of HD, HM, and PB to use in a primary total hip joint replacement.

Keywords

Highly-Cross-Linked Ultra-High Molecular-Weight Polyethylene, Acetabular Cup Liner, Linear Wear

1. Introduction

In recognition of the detrimental role that ultra-high-molecular-weight polyethylene (UHMWPE) wear particles

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play in osteolysis in total joint replacements (TJR), research and development attention, over the past 30 or so years, has focused on methods to reduce the wear of UHMWPE in counter-surfaces in TJRs. The state-of-the-art involves highly cross-linking the UHMWPE using radiation. There are two variants. The first involves gamma irradiating the fabricated polymer component at, typically, between 65 kGy and 100 kGy. The free radicals, which are produced by the breakage of the C-H bonds in the polymer, react with each other to form cross-links between adjacent molecule chains. The residual free radicals (that is, those that remain after the cross-linking) are completely quenched or reduced substantially with the aid of a thermal stabilization treatment, namely, annealing (heating the polymer to about or below 135°C, which is its melt temperature) or remelting (heating to a temperature > 135°C) [1]. In the second variant, the fabricated polymer component is exposed to electron beam radiation at, typically, between 65 kGy and 100 kGy. The method used for thermal stabilization of the residual free radicals is, usually, remelting [1]. There are a number of commercial HXLPE brands that belong to one of the two aforementioned variants and which are approved, by the appropriate regulatory bodies (such as the US Food and Drug Administration), for fabricating bearing surfaces for TJRs. Currently, the predominant use is for acetabular cup liners in primary total hip joint replacements (THJRs) [1].

There is a very large body of literature on two-dimensional 2D clinical wear rate of HXLPE acetabular cup liners in primary THJRs and the influence of three important variables (femoral head size (HD), femoral head material (HM), and HXPLE brand (PB)) on this rate [2]-[47] (Table 1). There is, however, no guidance on the optimum combination of the aforementioned variables. The purpose of the present study was to provide such guidance. This was done through using 2D linear wear rate results, given in 39 literature reports, and an optimization computation carried out with the aid of a technique called response surface methodology (RSM) [48].

2. Data and Method of Analysis

Femoral head 2D linear penetration rate (the accepted proxy for linear wear) results for HXLPE acetabular cup liners given in 39 peer-reviewed articles published in archival journals were collected. To do this, a detailed computerized search was conducted of relevant databases (such as MEDLINE®/PubMed and PubMed Central) and the table of contents of relevant journals (such as Acta Orthopaedica, Archives of Orthopedic Trauma and Surgery, Clinical Orthopaedics and Related Research, European Journal of Orthopaedic Surgery and Traumatology, Journal of Bone and Joint Surgery-American edition, The Bone & Joint Journal (formerly known as Journal of Bone and Joint Surgery-British edition), The Journal of Arthroplasty, and Seminars in Arthroplasty) for articles published, through September 2014, in English as well as in other languages (provided English translations were available). The keywords used were: HXLPE, HXLPE wear, femoral head penetration, total hip arthroplasty, THJR, and TJR. In addition, the list of references in each article found in the search was manually examined in order to identify additional relevant and acceptable articles. (Conference abstracts and presentations were not regarded as “acceptable” articles because they were not published in peer-review archival journals.) Through this process, a final total of 39 articles that contained all the details on clinical wear of HXLPE acetabular cup liners relevant to our study, namely, HD, HM, PB, method of 2D linear wear determination, and steady-phase linear wear rate result was obtained. The steady-phase linear wear rate results, taken from these articles (Table 1), were used in the RSM work.

Design-of-experiments (DOE) is a statistical method that is used to determine the optimum conditions for a process that involves many independent variables with the minimum of experimental replications. One widely used DOE method is called response surface methodology (RSM). In RSM, a response variable may be expressed using a second-order polynomial (regression) model; in other words, the equation (model) is given by

$$\text{Response variable} = b_0 + \sum b_i X_i + \sum b_{ii} X_i^2 + \sum b_{ij} X_i X_j + \varepsilon, \quad (1)$$

where X_i and X_j are raw values of the factors (independent/explanatory variables), b_0 is the constant coefficient, b_i is the coefficients of the linear parameters, b_{ii} is the coefficients of the quadratic parameters, b_{ij} is the coefficient of the interaction parameters, and ε represents the error in the observed value of the variable.

Two common outputs from a RSM analysis are 1) analysis of variance (determination of the adequacy of the developed model and the statistical significance of the regression coefficients in Equation (1) and their influence on the response variable); and 2) combination of values of the explanatory variables that yield the optimum value of the dependent variable. In the present work, attention was limited to optimization of the response variable, namely, 2D steady-phase linear wear rate (WR).

Table 1. Summary of salient features of the dataset on clinical two-dimensional mean steady-phase linear wear rate of highly cross-linked UHMWPE Acetabular liners.

Head Diameter (mm)	Head Material	HXLPE Brand	Mean Wear Rate (mm/year)	Source
28	Co-Cr (3)	Crossfire (2)	0.12	Martell <i>et al.</i> [2]
28	Co-Cr (3)	Marathon (6)	0.08	Hopper <i>et al.</i> [3]
28	Co-Cr (3)	Crossfire (2)	0.05	Krushell <i>et al.</i> [4]
28	Co-Cr (3)	Crossfire (2)	0.036	D'Antonio <i>et al.</i> [5]
28	Co-Cr (3)	Longevity (5)	0.018	Manning <i>et al.</i> [6]
28	Co-Cr (3)	Durasul (3)	0.010	Manning <i>et al.</i> [6]
28	Co-Cr (3)	Durasul (3)	0.029	Dorr <i>et al.</i> [7]
28	Co-Cr (3)	Marathon (6)	0.010	Engl <i>et al.</i> [8]
32	Co-Cr (3)	Durasul (3)	0.010	Bragdon <i>et al.</i> [9]
28	Al ₂ O ₃ (1)	Aeonian (1)	0.006	Oonishi <i>et al.</i> [10]
28	Co-Cr (3)	Marathon (6)	0.010	Leung <i>et al.</i> [12]
28	Co-Cr (3)	Crossfire (2)	0.006	Rohrl <i>et al.</i> [13]
28	Co-Cr (3)	Durasul (3)	0.025	Triclot <i>et al.</i> [14]
28	Co-Cr (3)	Longevity (5)	0.050	Olyslaegers <i>et al.</i> [15]
28	Co-Cr (3)	Longevity (5)	0.030	Glynn-Jones <i>et al.</i> [16]
28	Co-Cr (3)	Marathon (6)	0.031	Bitsch <i>et al.</i> [17]
28	Oxinium (4)	Longevity (5)	0.004	Garvin <i>et al.</i> [18]
28	Co-Cr (3)	Crossfire (2)	0.022	Rajadhyaksa <i>et al.</i> [19]
28	Co-Cr (3)	Marathon (6)	0.0239	Calvert <i>et al.</i> [20]
28	Al ₂ O ₃ (1)	Marathon (6)	0.060	Kim <i>et al.</i> [21]
28	Co-Cr (3)	Duration (4)	0.088	Geerdink <i>et al.</i> [22]
22.225	ZrO ₂ (6)	Aeonian (1)	0.067	Ise <i>et al.</i> [24]
22.225	Stainless Steel (5)	Aeonian (1)	0.068	Ise <i>et al.</i> [24]
26	Co-Cr (3)	Aeonian (1)	0.010	Kawate <i>et al.</i> [25]
26	ZrO ₂ (6)	Aeonian (1)	0.000	Kawate <i>et al.</i> [25]
28	Co-Cr (3)	Longevity (5)	0.028	Lachiewicz <i>et al.</i> [28]
28	Co-Cr (3)	Marathon (6)	0.007	Campbell <i>et al.</i> [29]
26	ZrO ₂ (6)	Longevity (5)	0.010	Fukui <i>et al.</i> [30]
28	Co-Cr (3)	Reflection (7)	0.026	Whittaker <i>et al.</i> [31]
28	Co-Cr (3)	Longevity (5)	0.025	Whittaker <i>et al.</i> [31]
44	Co-Cr (3)	Durasul (3)	0.021	Hammerberg <i>et al.</i> [32]
26	Co-Cr (3)	Longevity (5)	<0.001	Nakahara <i>et al.</i> [33]
26	ZrO ₂ (6)	Longevity (5)	<0.001	Nakahara <i>et al.</i> [33]
28	Co-Cr (3)	Marathon (6)	0.050	Mutimer <i>et al.</i> [35]

Continued

36	Bilox (2)	X3 (8)	0.022	Meftah <i>et al.</i> [36]
36	Bilox (2)	X3 (8)	0.052	Meftah <i>et al.</i> [36]
28	Co-Cr (3)	Crossfire (2)	0.031	Capello <i>et al.</i> [38]
28	Co-Cr (3)	Crossfire (2)	0.002	Rohrl <i>et al.</i> [39]
28	Co-Cr (3)	Crossfire (2)	0.014	Ranawat <i>et al.</i> [40]
28	Co-Cr (3)	Crossfire (2)	0.043	Ranawat <i>et al.</i> [40]
28	Co-Cr (3)	Crossfire (2)	0.011	Ranawat <i>et al.</i> [40]
28	Co-Cr (3)	Crossfire (2)	0.038	Ranawat <i>et al.</i> [40]
28	Co-Cr (3)	Durasul (3)	0.005	Johanson <i>et al.</i> [41]
28	Co-Cr (3)	Durasul (3)	0.010	Bragdon <i>et al.</i> [42]
28	Co-Cr (3)	Marathon (6)	0.014	Callary <i>et al.</i> [44]
28	Al ₂ O ₃ (1)	Marathon (6)	0.031	Kim <i>et al.</i> [45]
26	ZrO ₂ (6)	Longevity (5)	0.045	Fukui <i>et al.</i> [46]
32	Co-Cr (3)	X3 (8)	<0.001	Callary <i>et al.</i> [47]

Head material numeric identifiers are as follows: 1: Al₂O₃; 2: Biolo^x® (a commercially-available zirconia-toughened platelet-reinforced alumina); 3: Co-Cr; 4: Oxinium® (commercially-available oxidized Zr alloy); 5: Stainless steel; 6: ZrO₂ (generic). HXLPE brand numeric identifies are as follows: 1: Aeonian™ (Kyocera Corp., Kyoto, Japan); 2: Crossfire® (Stryker Orthopaedics, Mahwah, NJ); 3: Durasul® (Zimmer, Warsaw, IN); 4: Duration® (Stryker Orthopaedics); 5: Longevity® (Zimmer); 6: Marathon® (DePuy, Warsaw, IN); 7: Reflection™ (Smith & Nephew, Memphis, TN); 8: X3™ (Stryker Orthopaedics).

The dataset (**Table 1**) contains one quantitative explanatory variable (HD), two non-quantitative or categorical explanatory variables (HM and PB), and a quantitative response variable (WR). This meant utilizing a special type of RSM, called the D-optimal fraction method. The first step in this utilization was to assign numerical identifiers for HM and for PB. The next step was to insert these identifiers into the dataset (**Table 1**) and then to specify that the optimum WR is when WR is practically zero. The optimization was performed utilizing a commercially-available DOE software package (Design Expert®, Version 8; Stat-Ease, Inc., Minneapolis, MN, USA).

3. Results

For each combination of HD, HM, and PB, the software package computed, using settings specified by the user, a relative importance score for each variable and then combined these scores into a single number, called the desirability index, which ranged from zero (minimum desirability) to 1 (maximum desirability). 24 combinations, each with a desirability index of least 0.999999, were obtained. These combinations, together with the associated computed linear wear rates, are given in **Table 2**.

4. Discussion

Although there were 24 combinations of femoral head size, femoral head material, and HXLPE brand that yield a HXLPE liner 2D linear wear rate of practically zero, in making a selection of a combination to use, other issues should be considered. One such issue is the reported surface degradation of zirconia femoral heads over time *in vivo* (>5 years) associated with phase transformation of the ceramic [49]. Thus, in **Table 2**, all combinations involving a zirconia femoral head were removed, leaving 16 acceptable combinations.

The study has a number of limitations. The first comprises issues with the studies from which the dataset (**Table 1**) was derived (hereafter, referred to as the “surveyed studies”). One of these issues is that large femoral heads (HD ≥ 36 mm) were used in only a few of the surveyed studies. The consensus is that, in a primary THJR, when a large femoral head is used instead of one with HD < 36 mm, the dislocation rate is significantly lower although other measures, such as implant survivorship clinical outcomes (for example, incidence of loosening

Table 2. Summary of two computed features of combinations of femoral head size, femoral head material, and Acetabular cup liner HXLPE brand with desirability > 0.99999 .

Head Diameter (mm)	Head Material Numeric Identifier	HXLPE Brand Numeric Identifier	Computed Mean Wear Rate (mm/year)	Computed Desirability Index
25.31	4	3	1.58×10^{-9}	0.99999999
26.47	4	1	2.64×10^{-9}	0.99999998
25.72	3	1	6.66×10^{-9}	0.99999994
30.89	5	8	9.70×10^{-9}	0.99999992
27.28	1	3	2.08×10^{-8}	0.99999983
28.96	4	7	3.37×10^{-8}	0.99999972
27.18	1	7	3.93×10^{-8}	0.99999967
26.26	6	3	4.67×10^{-8}	0.99999961
27.14	1	6	5.26×10^{-8}	0.99999956
26.87	1	1	5.70×10^{-8}	0.99999953
26.99	1	2	6.72×10^{-8}	0.99999944
23.97	4	8	7.16×10^{-8}	0.99999940
36.96	2	8	7.25×10^{-8}	0.99999940
31.98	1	8	7.49×10^{-8}	0.99999938
27.08	1	5	7.68×10^{-8}	0.99999936
26.00	6	1	8.64×10^{-8}	0.99999928
25.99	1	4	1.00×10^{-7}	0.99999914
26.39	6	5	1.19×10^{-7}	0.99999901
26.33	6	6	1.19×10^{-7}	0.99999901
27.49	6	4	2.71×10^{-7}	0.99999774
26.49	6	2	3.13×10^{-7}	0.99999739
24.80	3	8	3.73×10^{-7}	0.99999689
26.29	6	7	5.90×10^{-7}	0.99999508
25.42	6	8	8.33×10^{-7}	0.99999306

and migration of acetabular components), radiographic results (for example, subsidence of acetabular components), functional outcomes (for example, Harris hip score and UCLA activity score), and complications (for example, wound drainage and atrial fibrillation), are similar [50] [51]. The second issue is that among the surveyed studies there were differences in many important variables, such as patient age, patient weight, acetabular cup design, number of surgeons, implantation technique, and method of anchorage of the acetabular cup to the contiguous bone (Table 3). The third issue is that although, in each of the surveyed studies, anteroposterior and/or lateral radiographs of the pelvis were taken, an assortment of methods were used to determine 2D linear wear rates, such as the computer-assisted edge-detection method introduced by Martell *et al.* [4] [6] [11] [12] [14] [17] [19] [20] [28] [31] [35] [37] [42], radiostereometry [13] [16] [29] [39] [41] [44], a dedicated computer software package [21] [22] [24] [30] [40] [43] [45], utilization of a manual method based on the Microsoft Power Point software package [23], and the concentric circle method introduced by Livermore *et al.* [36] [38]. The literature on comparison of methods of determination of clinical 2D linear wear rate utilizing measurements made on HXLPE acetabular cup liners, in a specified patient set, is very limited [23] [40]. However, it is worth noting

Table 3. Comparison of some study features in selected literature clinical reports.

Study Feature	Martell <i>et al.</i> [2]	Dorr <i>et al.</i> [7]	Triclot <i>et al.</i> [14]	Lachiewicz <i>et al.</i> [28]	Capello <i>et al.</i> [38]	Kim <i>et al.</i> [45]
Patient age (yr)	60.0 (28 - 76.0)	60.2 ± 16.2	70.6 (44 - 85)	61.1 (27 - 87)	55.8 ± 10.0	28.3 (21 - 29)
Patient body mass index (kg/m ²)	30.6 (18.1 - 48.0)	NS	26.2 (17.6 - 39.6)	29.0 (18.9 - 46.4)	27.4 ± 4.5	25.0 (22.4 - 27.2)
Number of surgeons	>1	1	1	1	1	1
Acetabular cup design and fixation method	Secur-Fit HA (Stryker);	NS	Fitmore (Zimmer); uncemented	Trilogy (Zimmer); uncemented	Secur-Fit HA PSL (Stryker); uncemented	Duraloc 100/1200 (DePuy); uncemented
Femoral stem design and fixation method	Secur-Fit or Secur-FitPlus HA (Stryker)/ cemented or uncemented	Anatomic Porous Replacement (Zimmer)/ uncemented; Apollo (Zimmer) cemented; Anatomic Medullary Locking (DePuy)	Emeraude (Zimmer)	NS	Omnifit HA (Stryker); uncemented	Immediate Postoperative Stability (DePuy); uncemented
Follow-up ^a (yr)	2	“at least 5”	4.9 (4.2 - 6.1)	5.7 (5 - 8)	8.6 (7.0 - 10.3)	10.8 (10 - 12)
Number of hips available for analysis at latest follow-up	36	37	49	102	42	60

NS: Information not stated in report. Patient age given as mean with range in parentheses.

that comparable wear rates were found when determinations were made using either two manual methods (PowerPoint versus Livermore; Longevity; 28 mm Co-Cr femoral head) [23] or two computer-assisted methods (Martell versus Livermore with Roman software; Crossfire; 28 mm Co-Cr femoral head; mean follow-up of 5.7 yr) [40].

The second limitation is that although in the majority of the reports of the surveyed studies, it was explicitly stated that the 2D linear rate was corrected for deformation without attendant wear (principally, creep) suffered during the bedding-in period, in other reports, this was not the case [3] [14] [23] [40] [45]. Furthermore, in cases in which it was explicitly stated that correction for bedding-in was done, there was variation in the duration considered as the length of the bedding-in period, examples being 2 months [13], 6 months [20], 1 year [5], and 2 years [19] post-implantation.

Since results from the surveyed studies were utilized, none of the matters discussed in the above-mentioned two limitations could be circumvented because these matters are intrinsic features of these studies. In fact, the only way to avoid these issues is to conduct prospective clinical studies specifically designed with the study purpose in the present work in mind; that is, hold all variables, except for HD, HM, and PB, constant.

The third limitation is that the analysis was of reported 2D linear wear rates, rather than three-dimensional (3D) volumetric wear rates. This was because 2D linear wear rate is the commonly used parameter; thus, of the 39 articles used in the analysis, 3D volumetric wear was reported in only 14 of them (30%) [2] [8] [10] [12] [14] [17] [20] [24] [25] [28] [32] [35] [42] [46]. In the determination of the wear rate of HXLPE acetabular cup liners, there is very little discussion, in the literature, of the relative attractions and shortcomings of 2D linear versus 3D volumetric methods, for the same patient set, except to note that the latter method has higher accuracy but lower precision compared to the former one [52].

One of the challenges in using RSM is to demonstrate that the parameter estimation in the equation used (in the present study, Equation (1)) is robust. This is especially germane in a case, such as in the present work, in which the initial independent/explanatory variables dataset is a mixture of qualitative parameters (head material and HXLPE brand) and a quantitative parameter (head diameter). One manifestation of this challenge is that, in the results, a phenomenon known as “aliased matrix” is encountered, which is where, in the computation, some rows of data are skipped. The fourth study limitation is that we assumed that the RSM design used was robust [53].

5. Conclusion

From a statistical analysis of clinical 2D linear wear rates of HXLPE acetabular cup liners in primary total hip joint replacements, reported in 39 literature studies, 24 combinations of femoral head diameter, femoral head material, and HXLPE brand that would lead to the optimum wear rate (herein, taken to be a rate of practically zero) were found. However, given widespread concerns about *in vivo* surface degradation of zirconia femoral heads, all combinations involving this type of head were removed from further consideration, leaving 16 combinations that are deemed acceptable. An example acceptable combination is 28 mm diameter Oxinium[®] femoral head articulated against a Reflection[™] HLXPE acetabular cup liner.

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