**A Unified Approach for Evaluation of UHMWPE Performance in a Hip Simulator Using Wear Volume and Debris Size Distribution: Effect of Fabrication Method**

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**Statement of Purpose:** The relationship between wear debris, osteolysis, and bioreactivity of polyethylene (PE) particles has been investigated [1]. The particle size and total volume in a specific size range influences the bio-reactivity of the debris [1-4]. This volume concentration is dependent on both the debris morphology and wear volume [1]. To better understand the osteolytic potential, debris analysis needs to incorporate both the number and volume of particles generated in specific size ranges. Therefore, we developed an analytical approach that combined both wear volume and debris size distributions. We evaluated effects of four different fabrication methods on PE wear performance utilizing this approach.

**Methods:** Four processing methods were studied: Extruded GUR 415, non-sterile (Ext), 2) Extruded GUR 415 sterilized with 3Mrad in argon (Ext-G), 3) direct compression molded 1900H sterilized with 3Mrad in argon (DCM), and 4) isostatically molded 1900H sterilized with 3Mrad in argon (ISM). The 28mm implants (Biomet, Inc., Warsaw, IN) were mounted 'inverted' in a hip simulator (Paul curve, 2kN maximum, and 1Hz). Bovine serum was used (Hyclone, Ogden, UT) diluted to 56 mg/ml of protein. Samples were analyzed at 1 and 3 Mc intervals. The particles were measured as previously reported [5]. Data for one and three million cycles were pooled. The total number of particles, $N_T$ ($10^9$/Mc), were computed based on the wear rate, size distribution, and particle volume ($v_p$), where $v_p = \pi/18\times ECD^3$ [6]. This resulted in the following:

$$N_T = (18\times V_w)/(\pi \times \Sigma(NF(ECD)\times ECD^3)) \qquad (1)$$

where $V_w$ is the wear rate ($mm^3$/Mc), NF(ECD) is the number fraction at each diameter, and ECD is equivalent circular diameter (microns). For example: if there were a quantity of100, 1-micron size particles in a population of 1,000 total particles, then the parameter NF(1μm)=0.1.

**Results/Discussion:** Ext-G, DCM, and ISM exhibited lower wear than Ext by 50 to 56% (Table 1). However, the particle sizes (ECD) for Ext-G, DCM, and ISM were smaller than for Ext (Table 1). The median and mean ECD yielded higher number of particles (Table 2). The mean ECD resulted in a 2 to 5-fold increase compared to the distribution method. The particle volume for DCM in the 0.1 to 1 micron range was comparable to Ext (Figure 1). In contrast the ISM material in this submicron range had the lowest. Thus, the computational method greatly influenced the estimated number of particles (Table 2). Particle numbers and volumes have been reported using average diameters or areas in the calculations [6-8]. Since our methodology is based on the distribution, no special techniques, assumptions, or measurements as previously reported were needed [6,7]. Our accuracy was determined by the reliability of the sample distribution and the geometric model assumed for the particle volume.

Table 1: Summary for the four fabrication groups.

| **Groups** | | **Ext** | **Ext-G** | **DCM** | **ISM** |
|---|---|---|---|---|---|
| **Wear ($mm^3$/Mc)** | | 33.8 | 17.2 | 16.6 | 15.0 |
| **ECD (μm)** | **Mean** | 0.60 | 0.50 | 0.40 | 0.40 |
| | **Median** | 0.50 | 0.40 | 0.40 | 0.40 |
| **Σ(NF(ECD)×$ECD^3$ ($\mu m^3$)** | | 0.65 | 0.40 | 0.18 | 0.51 |

Table 2: The estimated number of particles generated based on three computational methods.

| **# of Particles ($10^9$/Mc)** | **Ext** | **Ext-G** | **DCM** | **ISM** |
|---|---|---|---|---|
| **N (Median ECD)** | 1,401 | 2,169 | 1,593 | 2,106 |
| **N (Mean ECD)** | 866 | 962 | 1,095 | 955 |
| **N (ECD Distribution)** | 299 | 245 | 531 | 170 |

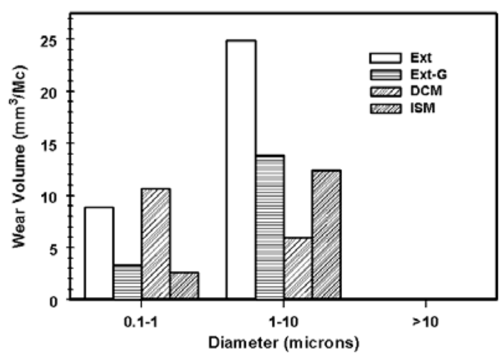


Figure 1: Total wear volume ($mm^3$/Mc) for each range of particle size (ECD) by fabrication method studied.

**Conclusions:** In conclusion, the fabrication method effected both wear and debris production. However, decreased wear did not necessarily result in a reduction of submicron particles. This could present a clinical scenario of two materials with different wear rates, yet having similar clinical results and osteolysis rates [9].

**References:** [1] J. Fisher *et al.*, *Proc Inst Mech Eng [H]* **215**, 127 (2001) [2] M. Endo et al., *Proc Inst Mech Eng [H]* **216**, 111, 2002. [3] E. Ingham, J. Fisher, *Proc Inst Mech Eng [H]* **214**, 21, 2000. [4] J. Ingram et al, *Biomaterials* **25**, 3511, 2004 [5] P. Williams et al., Trans 30th Ann Meet Soc Biomat, Memphis, TN, April 27, p. 691, 2005 [6] M. Scott, et al., *J Biomed Mater Res B Appl Biomater* **73**, 325, 2005. [7] A. A. Besong *et al.*, *J Bone Joint Surg Br* **80**, 340, 1998. [8] J. Tipper *et al.*, *J Mater Sci: Mater Med* **11**, 117, 2000. [9] J. Courpied, et al., *Rev Chir Orthop Reparatrice Appar Mot* **86**, 10, 2000.

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