Submicron and Micron Sized Particle Can be represented as a Composite of Two Distributions

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Statement of Purpose: The size, shape, composition, and quantity of debris particles are critical to the biological response and resulting osteolysis [1-3]. Models have been introduced to express the bioreactive index of debris, but lump parameters were used yielding general approximations [1]. Histograms and box plots of particle size and shape have been important in the understanding of debris morphology. However, a better understanding of the distribution could aid in relating debris and bioreactivity [2]. A representation of data using distribution models could provide additional information on debris morphology. In addition, computations relating to bioreactivity could be employed to better understand osteolysis [1]. Therefore, our objective was to investigate distribution models relating to their application in describing wear debris morphology.

Methods: Three criteria were employed to select distributions for the model. The appropriate distributions were required to be: 1) Continuous, 2) Bounded for positive numbers only, and 3) Possessing a shape comparable to the data. After all these considerations two distributions (Gamma and Weibull) emerged as suitable candidates [4,5], and were evaluated for this study. Wear debris data (cumulative number and volume fractions of equivalent circular diameter, ECD) from non-crosslinked extruded UHMWPE [6] (Figure 1) were used to evaluate the fit of these distribution models.

Results/Discussion: The 2-parameter Gamma (α=1.03; β=1.09) and Weibull (α=1.06; β=1.12) distributions [4] appeared to fit the cumulative number distribution (Figure 2), but did not fit well to the cumulative volume distribution (Figure 3) of the ECD data. A 6-parameter Bi-Weibull model [4] was utilized and the resulting curve compared to the data. The number distribution seemed a little less comparable to the data than either of the mono-distributions (Figure 2). However, the Bi-Weibull volume distribution was more comparable in shape to the debris data than either the Gamma or Weibull distributions (Figure 3). This would suggest that the ECD data was better represented by a composite of two distributions instead of a single distribution. This could suggest two phases of a single process or two processes in wear debris production.

Conclusions: The results of this study suggested that:

1) Both number and volume distributions were needed to develop a mathematic model.
2) Single, uni-modal distributions did not match both volume and number distributions.
3) A Bi-Weibull distribution more appropriately described number and volume debris distribution.

References: [1] J. Fisher *et al.*, *Proc Inst Mech Eng [H]* **215**, 127, 2001. [2] J. Ingram et al., *Biomaterials* **25**, 3511, 2004. [3] E. Ingham, J. Fisher, *Proc Inst Mech Eng [H]* **214**, 21, 2000. [4] M. Evans, N. Hastings, B. Peacock, *Statistical Distributions*, John Wiley & Sons, Inc., New York, 2000. [5] H. M. Wadsworth, *Handbook of Statistical Methods for Engineers and Scientists*, Ch 2, McGraw-Hill, New York, 1990. [6] K. Yamamoto *et al.*, *J Biomed Mater Res* **56**, 65, 2001.

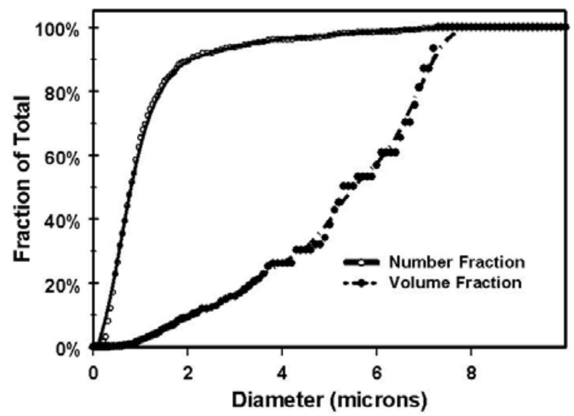

Figure 1: Cumulative number and volume fractions for non-irradiated extruded UHMWPE [6]. Diameter on the x-axis is represented by the ECD of the particles.

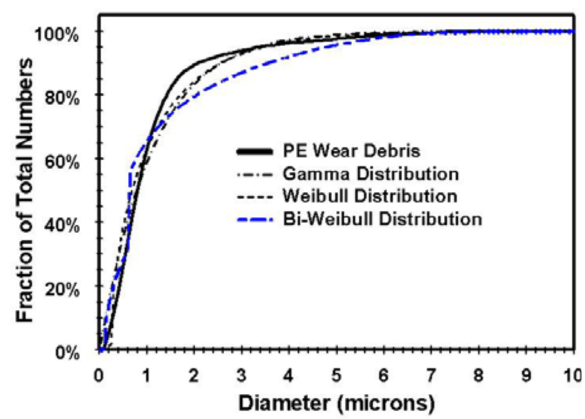

Figure 2: Cumulative number distributions comparing the three models with the extruded PE debris.

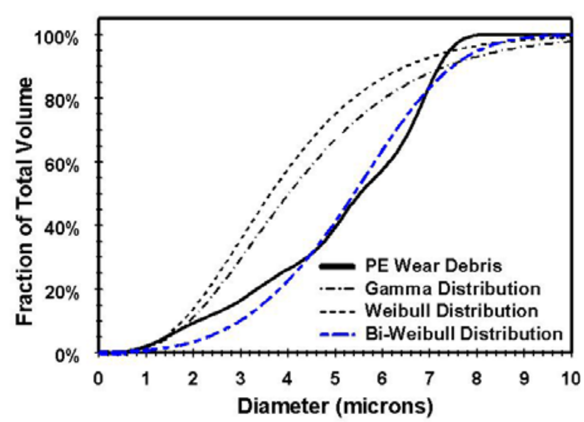

Figure 3: Cumulative volume distributions comparing the three models with the extruded PE debris.