Differences between Standard Methods Used to Characterize Particulate Implant Debris

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INTRODUCTION: Particle size analysis of implant debris (ASTM 1877) has typically been conducted by particle counting using scanning electron microscopy (SEM). Technologies such as Laser Diffraction (LD), which provide both volume and number distribution, call into question when is each technique appropriate and to what degree are they equivalent, given the import of implant debris analysis. We hypothesize that both SEM particle counting and Low Angle Laser Light Scattering (LALLS or laser diffraction) analysis are equivalent and will thus make available the same particle size information for implant debris. We tested this hypothesis by analyzing simulated implant debris using both methods of characterization on two different sizes of Co-alloy and ultra-high molecular weight polyethylene (UHMWPE) particles (small particles were <5 microns and medium were 5 to 100 microns).

MATERIALS AND METHODS: *Materials:* Cobalt alloy (ASTM F-75) particles were prepared from Co-Cr-Mo alloy total hip arthroplasty femoral components (Versys, Zimmer Inc. Indiana) using a proprietary technique (BioEngineering Solutions, Illinois) into large and small sizes (A. Co-alloy-med, B. Co-alloy-small, C.UHMWPE-med and D. UHMWPE-small all with 10mg samples). *Methods:* Laser Diffraction (MicroTrac- X-100) and SEM analysis of particles were conducted using a Scanning Electron Microscopy Hitachi 3000-SN (SEM/EDS) after filtration (0.1 micron alumina ceramic filter) under vacuum, where 8 randomly selected low power fields (100x), 8 medium power fields (1000x) and 8 high power fields (10,000x) yielding 24 fields per sample were image processed using NIH Image automated particle analysis software to characterize particles.(1,2) Samples were significantly above to the detection limits of either technique, i.e. >0.1mg.

RESULTS: A summary of the particle analysis of 4 particulate debris samples (2 Co-alloy and 2 UHMWPE) is shown in Table 1. A discrepancy between SEM and LALLS analysis was found, e.g. Co-alloy medium sized (5-100um) were an average of 6.8 and 0.66 microns on a number basis, using LALLS and SEM respectively (see differences in histograms shown in Fig 1 and 2). For smaller particles this discrepancy was less and surprisingly reversed with SEM yielding a larger particle size than LALLS (Table 1, e.g. 0.16um LALLS and 0.99um SEM Sample B).

TABLE 1. Laser Diffraction (LD) and SEM analysis results

Implant Particles	Method	Av Size Vol (mv)	Av Size Num (mn)	Aspect Ratio	LD mass >mn SEM
A. Co-alloy-Med	LD	30.53	6.81	*	>99%
	SEM	*	0.66	2.19	**
B. Co-alloy-Small	LD	3.61	0.16	*	2%
	SEM	*	0.99	1.91	**
C. UHMWPE-Med	LD	63.93	45.92	*	>99%
	SEM	*	0.68	2.74	**
D. UHMWPE-Small	LD	4.09	0.56	*	15%
	SEM	*	1.39	1.93	**

**Data not available for that technique, ** Not Applicable*

DISCUSSION: This data refutes the hypothesis that both methods generate equivalent particle characterizations. There seems to be an SEM bias towards smaller particles identified in high magnification images because their average is weighted at 10,000 times that of the low magnification SEM images for distribution calculations. SEM analysis (like a coulter analysis) does provide for a indirect calculation of total debris per volume where typically LALLS does not. In this study, SEM surprisingly identified particles smaller than that shown on LALLS in the Co-alloy and Poly medium size particles, presumably because they represent an unidentifiably small % of the total sample masses, i.e. <0.01%. More surprisingly, SEM resulted in a greater particle sizes compared to LALLS in samples with smaller particles (e.g. B. small particles of Co-alloy and D. UHPWPE), again because SEM seems biased towards over weighting the statistically most numerous particles, with a selection of 24 fields (not a more appropriate 2,400 fields). Laser diffraction analysis measures millions of particles, yet lacks the capability to yield morphologic data, e.g. aspect ratios of specific size subsets within any given sample, see Table 1. Thus it depends on what critical distribution characteristics are desired to determine method of selection. Generally, the greater the % mass of small particles (i.e. <2um) the greater agreement between the two techniques. Alternatively the greater the percentage of larger particles the greater the discrepancy. These differences are critical to all areas of implant debris analysis, i.e. retrieval analysis, simulator analysis or biologic challenge agent, where if the inappropriate method is chosen, inappropriate conclusions will be drawn, i.e. all 10mg of Samples A and C, medium Co alloy and UHMWPE particles were submicron in size using SEM.

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REFERENCES: 1. Campbell P, et al *JBMR* 29:127-131, 1995.
2. Scott M et al *JBMR-B Appl:* 73:325-337, 2005.

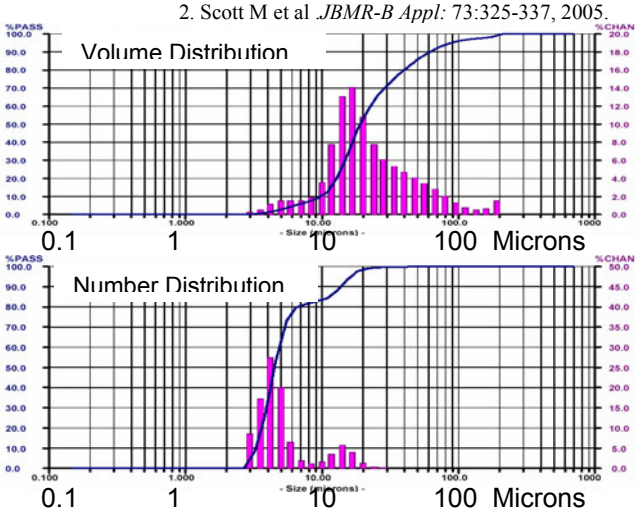

Figure 1. Laser Diffraction Analysis of A. Co-alloy-Med particles (5-100microns) using a: (a) volume distribution, (b) number distribution. Both graphs y-axis = % total

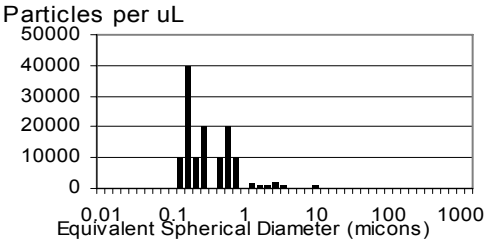

Figure 2. SEM Number distribution for A.

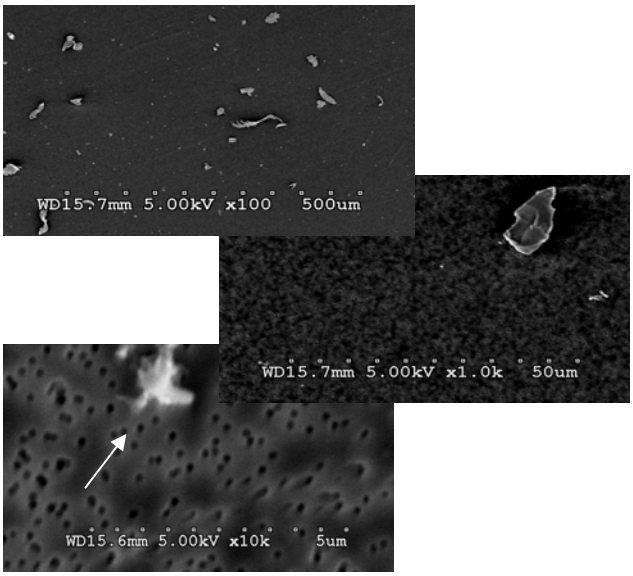

Figure 3. SEM Micrographs showing the 3 ranges at which 8 micrographs were each taken to generate 24 fields/sample for SEM particle size and distribution analysis.