Can We Trust Hip Simulator Predictions: Ceramic-on-Ceramic Micro-Separation Wear Model?

McKenzie, S; Williams, P A, Green, D D, Clarke, I C
Loma Linda University, Loma Linda, CA
iclarke@llu.edu

Statement of Purpose: With laboratory studies now predicting ultra-low wear, the accuracy and reliability of such data becomes even more important. It has been shown that the experimental variance (95% confidence interval, CI) could exceed ±50% of the wear rate [1]. With the introduction of micro-separation test for all-ceramic bearings, the wear magnitudes increased, but there may be additional variance inherent with these models [2-5]. Therefore, our objective was to assess the associated accuracy for all-ceramic bearing wear under micro-separation conditions. We also examined the effects of different ceramic materials.

Methods: Femoral balls (36mm) and liners of alumina (Al) (Biolox-forte®, CeramTec, Germany) and alumina matrix composite (AMC) (Biolox-delta®, CeramTec, Germany) were run on a commercial orbital hip simulator. Four ceramic combinations were studied (Table 1). A Paul load curve (max 2kN) was used with alpha-calf serum (Hyclone®, Ogden, UT) as lubricant (10mg/ml of protein). The liners were positioned at 50º to the horizontal with a maximum of 2mm micro-separation (MSX) introduced in each cycle. Run-in wear was 0 to 1Mc and steady state was 1.25 to 4Mc. The wear accuracy for each group was evaluated as previous described [1].

Results/Discussion: The ranked wear performance for the groups was Al/Al > Al/AMC, AMC/Al > AMC/AMC for both run-in and steady state wear (Figure 1). Although Al/Al had the highest wear-rate during both run-in and steady-state, it also had the largest variance (Tables 1 and 2). In contrast, AMC/AMC had the lowest wear-rate for both run-in and steady state with the lowest variance. Having a 95% CI less than 15% of the wear rate (slope) and an r-value of >0.64 would yield a theoretical error of approximately 20% [6]. In this study, AMC/AMC & Al/AMC had variances of 15% to 21% while Al/Al & AMC/Al had 27% to 30% during run-in. Overall there was little difference in reliability between ball and cups (Tables 1 and 2). Previously it was shown that during steady state, Al/Al cups (without micro-separation) had variances as high as 120% of the wear magnitude. However, under microseparation test mode, the Al/Al cup exhibited a variance of only about 25% (state-state wear) (Table 2).

Conclusions: This study of large diameter all-ceramic THR with micro-separation suggested:
1) Good accuracy (±20%) obtained with low wear.
2) Overall, ball and cup variances were comparable.
3) There was good reliability with micro-separation test mode.
4) Micro-separation test mode was reliable as or better than historical simulator test modes.
5) Bearing material influenced reliability of data.

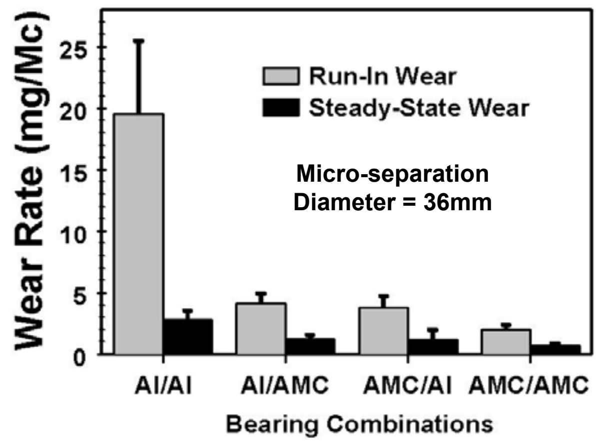

Figure 1: Run-in and steady state wear (mg/Mc) averages for THR combinations (ball + cup). Error bars represent 95% confidence intervals (CI).

Table 1: Variances of wear estimates for run-in (0 to 1Mc) expressed as the 95% CI (as a percentage of wear gradient) for the ball, cup, and combined THR.

Combination (Ball/Cup)	95% Confidence interval		
	Ball	Cup	Combined
Al/Al	32%	29%	30%
Al/AMC	20%	22%	21%
AMC/Al	28%	27%	27%
AMC/AMC	23%	14%	17%

Table 2: Variances of the wear estimates for steady-state (1.25 to 4Mc) expressed as the 95% CI (as a percentage of the wear gradient) for ball, cup, and combined THR.

Combination (Ball/Cup)	95% Confidence interval		
	Ball	Cup	Combined
Al/Al	29%	25%	27%
Al/AMC	23%	28%	25%
AMC/Al	73%	47%	66%
AMC/AMC	14%	27%	18%

References: [1] H. Richardson et al., *Proc Inst Mech Eng [H]* **219**, 401-5, 2005. [2] M. Manaka *et al.*, *J Biomed Mater Res* **69B**, 149-57, 2004. [3] J. Nevelos *et al.*, *J Arthroplasty* **15**, 793-5, 2000. [4] T. Stewart et al., *J Mater Sci Mater Med,* **12**, 1053-1056, 2001. [5] T. D. Stewart *et al.*, *J Biomed Mater Res,* **66B**, 567-573, 2003. [6] P. Williams, I. C. Clarke, Trans 29th Ann Meet Soc Biomater, Reno, Nevada, p. 107, 2003.

Acknowledgements: The authors gratefully acknowledge and thank CeramTec and Biomet for their support.