Effects of Big-Ball Concepts for Wear of New Crosslinked UHMWPE Cups under the Microseparation Wear Mode

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Introduction:
The recent THR trend has been using much larger diameter femoral heads (≥36mm) component to give greater stability and increased range of motion, thereby reducing the risk of impingement/dislocation. However, conventional polyethylene (PE) material (3Mrad) has been shown to increase in wear-rate as ball diameter increased [1 and 2]. While crosslinked polyethylene (XLPE) has shown improved wear performance, effects of increased radiation (oxidation; degraded mechanical properties) have remained as potential patient risks. Recent alternate XLPE processing claims to have minimized the oxidation risk while maintaining mechanical properties. This study investigated performance of a new XLPE material using a 'severe', micro-separation test-mode (MSX). Three ball diameters were compared to the control THR (28mm) to establish related wear performance and effect of increased diameter.

Methods: Cups were made from sequentially-crosslinked (SXL) UHMWPE produced from compression-molded GUR 1020. This was irradiated to 3Mrad followed by annealing at 130°C (8 hours). This process was repeated twice more for a cumulative dose of 9Mrad. The acetabular cups were machined from this bar stock and sterilized by gas plasma. Conventional UHMWPE was sterilized to 3Mrad (under nitrogen) and paired with 28mm CoCr ball diameter was used as the control THR. Our 'severe' MSX test mode was run on an orbital hip simulator modified to produce up to ~2mm of micro-separation (Paul load curve; peak 2.2kN; 1Hz). Cups were mounted anatomically (on top) 50° to the horizontal. Alpha-calf serum (Hyclone®, Ogden UT) was used as lubricant (diluted to 20mg/ml protein).

Table: 1 – Simulator test matrix (N=12 total)

Pair #	Samples (N)	Ball Diameter ●	Cup Material ◠
1	3	28	Std. 3Mrad
2	3	28	SXL 9Mrad
3	3	32	SXL 9Mrad
4	3	36	SXL 9Mrad

Cups were marked superiorly to allow for consistent mounting and un-mounting between events. Wear was determined gravimetrically every 500k cycles to 5.0Mc duration. Both static and dynamic soak controls were used for fluid-absorption correction. Weight loss was converted to volumetric wear using density 0.93g/cm^3. Individual wear trends were determined by liner regression technique.

Results / Discussion:
No implants were lost to failure under our severe MSX model. No cups presented evidence of sub-surface cracking, delamination, rim fracture or visual evidence of oxidation. Under our severe MSX model a wear reduction of ≥3-fold was observed for all diameters compared to the control (Fig: 1). SXL wear rates are one order of magnitude greater than non-MSX data that has been reported elsewhere [3] for 32mm cups, where the controls wore at similar wear rate (46.7±9.4mm^3/Mc).

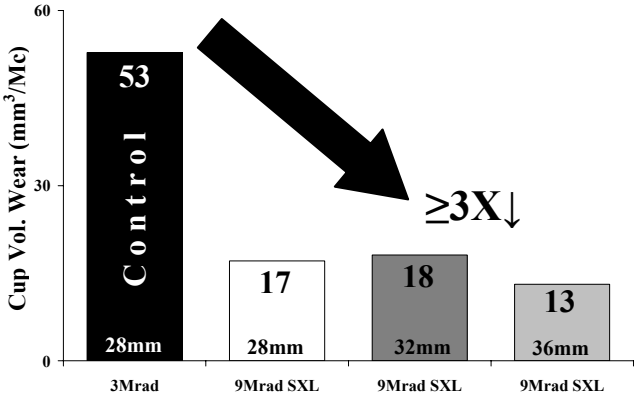

Figure: 1 – Cup volumetric wear rate at 5.0Mc duration.

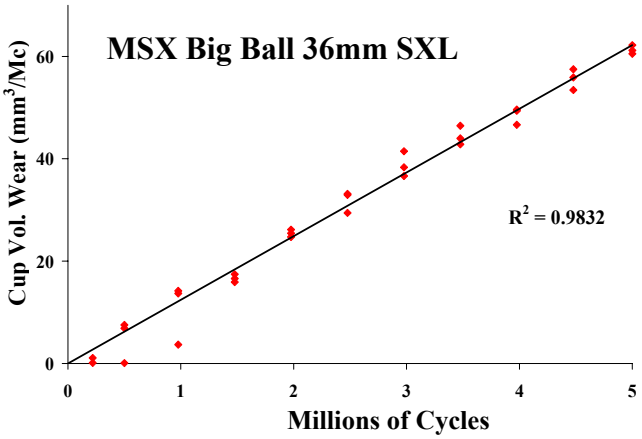

Figure: 2 –Wear trends for 36mm cup over 5.0Mc duration.

Conclusions:

1. Compared to our control cups, the new SXL cups decreased wear by 3-fold under severe MSX mode.
2. The 36mm SXL cup had the most consistent linear wear-trend (R^2=0.9832) and presented an encouraging concept for today's advocated large-diameter THRs.
3. Increased diameter of femoral head (28mm-to-36mm) did not produce a measurable increase in cup wear as was seen in studies with conventional PE.
4. The limitation of this study was that only pristine CoCr femoral heads were used; metal roughening effects *in-vivo* were not addressed

References:

[1] Charnley J. *et al.* Med. Biol. Eng. 7:31, 1969.
[2] Clarke I C. *et al.* Proc. Inst. Mech. Eng[H], 211(1): 25-36, 1997
[3] Essner A. *et al,* ORS, poster #0830, 2005.

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