Molded GUR1050 Resin Type Performance Versus ArCom 1900H In Knee Wear Simulation Study

Tsukamoto, R; Ogino, M; Shoji, H; Yamada, K; Pezzotti, G; Clarke, I C
Loma Linda University, Department of Orthopaedics, 11406 Loma Linda Drive, Suite 606, Loma Linda, California, USA

Statement of Purpose: Wear of UHMWPE is a major factor that affects the longevity of total joint replacements. In total replacements (THR, TKR), crosslinked polyethylene (XLPE) has been shown to be effective in reducing wear experimentally [1, 2]. However one important parameter that was perhaps underestimated two decades ago was the benefit of molded UHMWPE tibial inserts. There are now clinical reports in the USA with over 95% good clinical results were found with 15 years follow-up of the AGC Knee and its molded tibial inserts [3-5]. With the 1900H resin no longer commercially available, the alternative polyethylene appears to be the molded high molecular weight GUR1050 resin. Therefore the aim of this study was to compare wear of the new alternative GUR1050 resin versus the control 1900H inserts run against CoCr femoral implants. Our hypothesis was that GUR1050 would be equivalent to 1900H under our pristine laboratory test conditions.

Methods: As controls, we used direct compression molded 1900H tibial inserts (Biomet Inc, Warsaw, IN). Radiation sterilization was 3.2-Mrad under argon atmosphere and there was no subsequent treatment. Test inserts were GUR1050 molded UHMWPE inserts. The direct compression molded GUR1050 tibial inserts were processed identically to ArCom inserts. Additional tibial inserts were used for soak control and stored unloaded in deionised water for 60 days prior to testing. Knee simulation was conducted on a 6 station simulator (Shore Western Manufacturing, Monrovia, CA). Motion included 20 degrees of flexion/extension, ±5 degrees of internal/external rotation and 6mm of anterior/posterior translation. All knee components were subjected to 5 million cycles of normal walking (2.9 kN max, freq 1.4 Hz). Lubricant was 50 % α-calf serum (20mg/ml protein) with additive EDTA. Serum was changed every 0.5million cycles until completion of study at 5 Mc. Wear was measured gravimetrically. Microscopic characterization was carried out on the polyethylene tibial inserts using SEM and confocal Raman microprobe spectroscopy (irradiation with a blue laser with wavelength 488 nm) at end of study.

Results: The weight-loss trends to 2.5 Mc duration showed uniform linear trending (regression coefficients > 0.95). Wear of the control implants (CoCr / 1900H) averaged 3.6 mm^3/Mc with good control of experimental variance (Fig 1; ± 4%). Wear of the GUR1050 implants (CoCr / GUR1050) averaged 3.4 mm^3/Mc, also with good control of experimental variance (Fig 2; ± 10%).

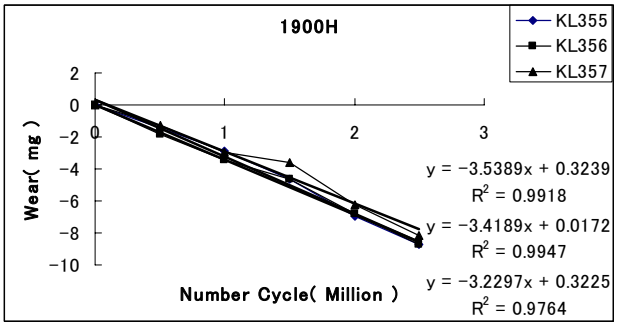

Figure1. Gravimetric wear trends of control 1900H tibial inserts against Co-Cr femoral implants.

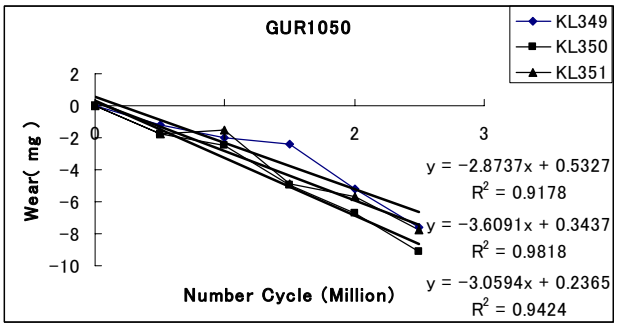

Figure2. Gravimetric wear trends of GUR1050 tibial inserts against Co-Cr femoral implants.

Discussion: Current test duration achieved was still short at just 2.5Mc duration. However both materials showed excellent linear trending (minimum r>0.95) with good control of experimental variance. Overall the GUR1050 inserts average showed 7 % wear reduction over control. That did not appear to represent statistically significant difference at this stage. Thus GUR1050 was equivalent to 1900H. The molded 1900H has been very successful in TKR and thus our current knee study suggests that the molded GUR1050 will also provide excellent results.

Acknowledgements: We greatfully acknowledge financial support of Biomet Inc, (Warsaw, Indiana USA), Kyoto Institute of Technology (Kyoto, Japan), Tsukamoto Orthopaedic Clinic (Tokyo, Japan), the Western Center for Orthopaedics Research Foundation (California) and the Department of Orthopaedics LLUMC.

References:

1. Wang et al. Trans 23th Soc Biom, 1997, p 154.
2. Asano et al. Trans 29th Soc Biom, 2003; p 037.
3. Ranawat et al. Clin Orthop Rel Res. 1993; 286: 94
4. Ritter et al. Clin Orthop Rel Res. 2001; 388: 51.
5. Emerson et al. J of Arthro. 2000; 15: 418.