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Using metrology to bridge the gap in understanding between engineering and biological failure: the case of metal-on-metal hip replacements.

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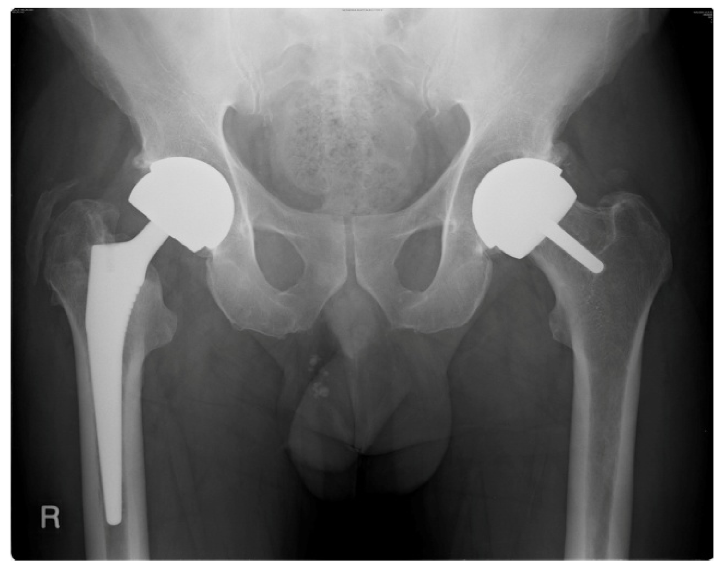
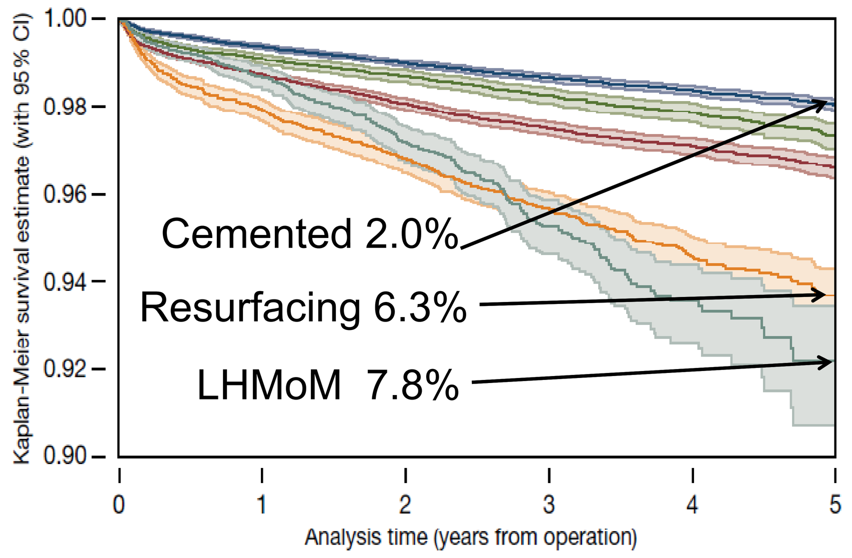
Background

- Worldwide interest in failure of Metal-on-Metal (MoM) hips.
- >150,000 large diameter MoM hips implanted in UK.
- Failure rate of 29% reported in some Large Head MoM at 6 years **[1]**.
- Three designs of MoM hips have been removed from the market in past 4 years
- NJR data suggests 43% of hip failures are unexplained
- Edge loaded cups have greater linear wear rate than non-edge loaded
- Disparity between wear of LHMoM & observed blood ion levels could be due to taper wear/corrosion



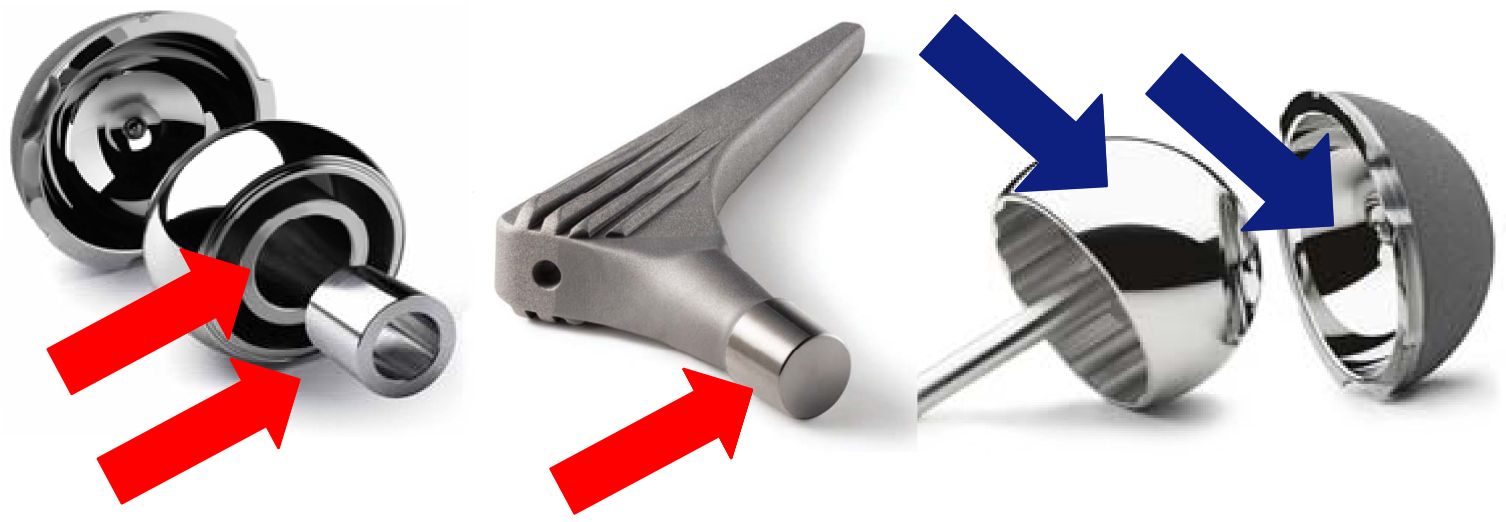


ASTM Symposium on Metal-On-Metal Total Hip Replacement Devices, Phoenix, 8th May 2012

- Bearing surface measurement important.
- Currently no consensus on procedure, strategy etc.
- Need for further development of standards and standardised practices.

Measurement Requirements

- Wear analysis is vital tool in understanding failure mechanisms
- Full material loss determination at both the bearing and taper interface.
- Typical linear wear rates for explanted hips are:
  Cup 0 – 180 μm/year
  Head 0 – 750 μm/year
- Accuracy required ~ 1 μm.



- Volumetric accuracy not quoted or incorrectly determined.
- Determination of volumetric and linear wear based without a priori knowledge of unworn geometry key factor in accuracy of measurement method and is stable only if done post process.
- Small wear volumes and linear wear depths mean that measurement uncertainty must be understood and controlled.

$$U = k \times \sqrt{(u_{cal}^2 + u_p^2 + u_w^2)} + |b| + |c| \quad [2]$$

Bearing surface method

Equipment and setup:

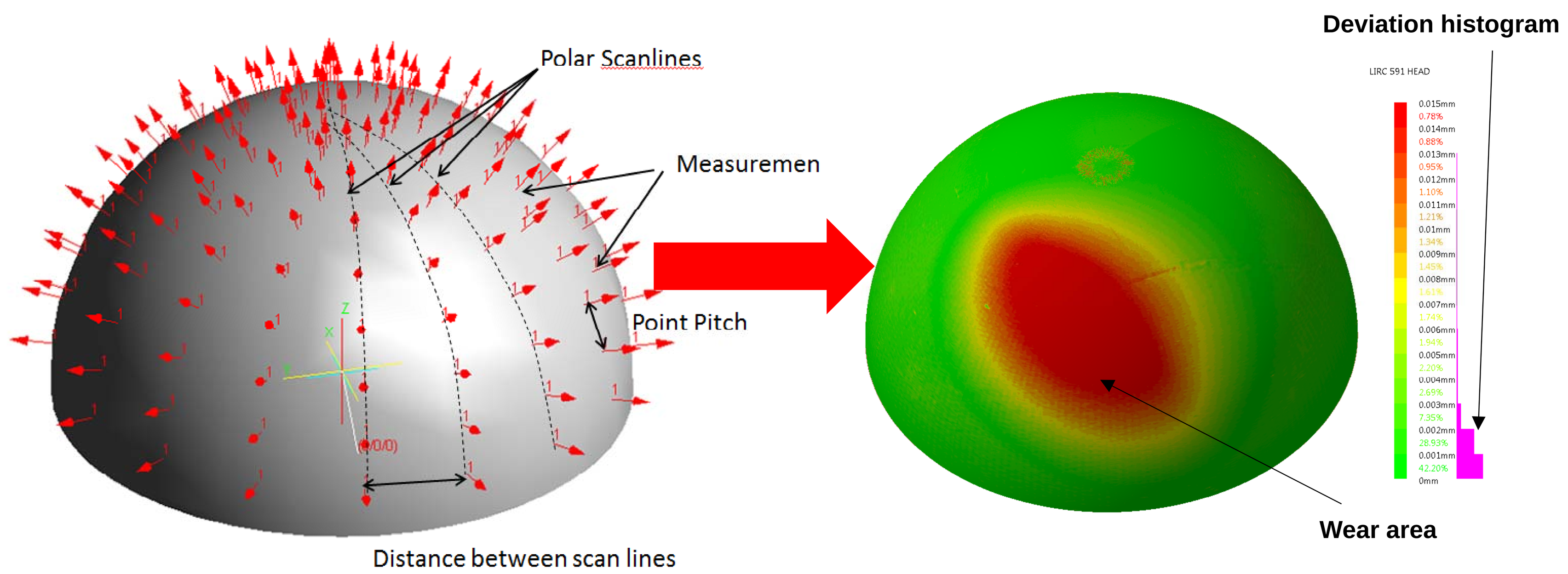
- Zeiss PRISMO CMM with an MPE = 1.9μm + L/300
- Stylus: 2mm ruby ball
- Measurement speed: 3mm/s

Strategy

- The bearing surface is digitised using 400 polar scan lines. Angular spacing between traces is 0.9° with linear point pitch of 0.1mm
- Total number of data points per scan is150,000-300,000.

Data analysis

- Iterative intelligent least squares fitting is employed to determine the unworn geometry, linear wear, volumetric wear and material loss distribution.



Taper Method

Equipment and setup:

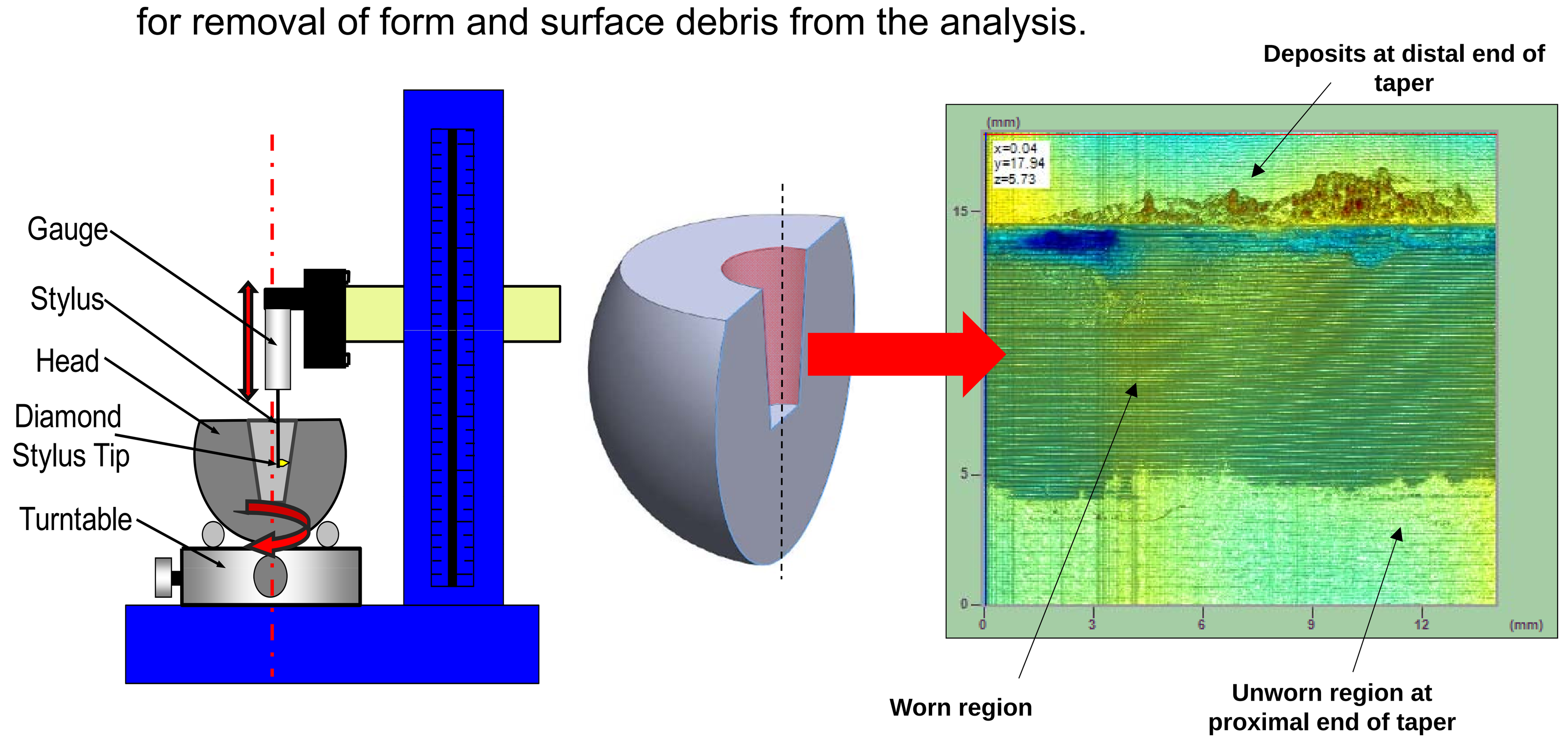
- Taylor Hobson Talyrond 365 Roundness Measurement Machine
- Head/stem mounted on rotating table, stylus measures deviations in profile.
- Series of vertical straightness profiles combined into cylinder maps.
- Gauge resolution 30 nm, spindle run out 20 nm.

Strategy:

- The surface map consists of 360 vertical profiles, angular spacing of 1°, max linear spacing of 120 μm.
- Each profile contains 7000 points with spacing of 2 μm
- Total number of points in each data set is 2.5 million

Data analysis

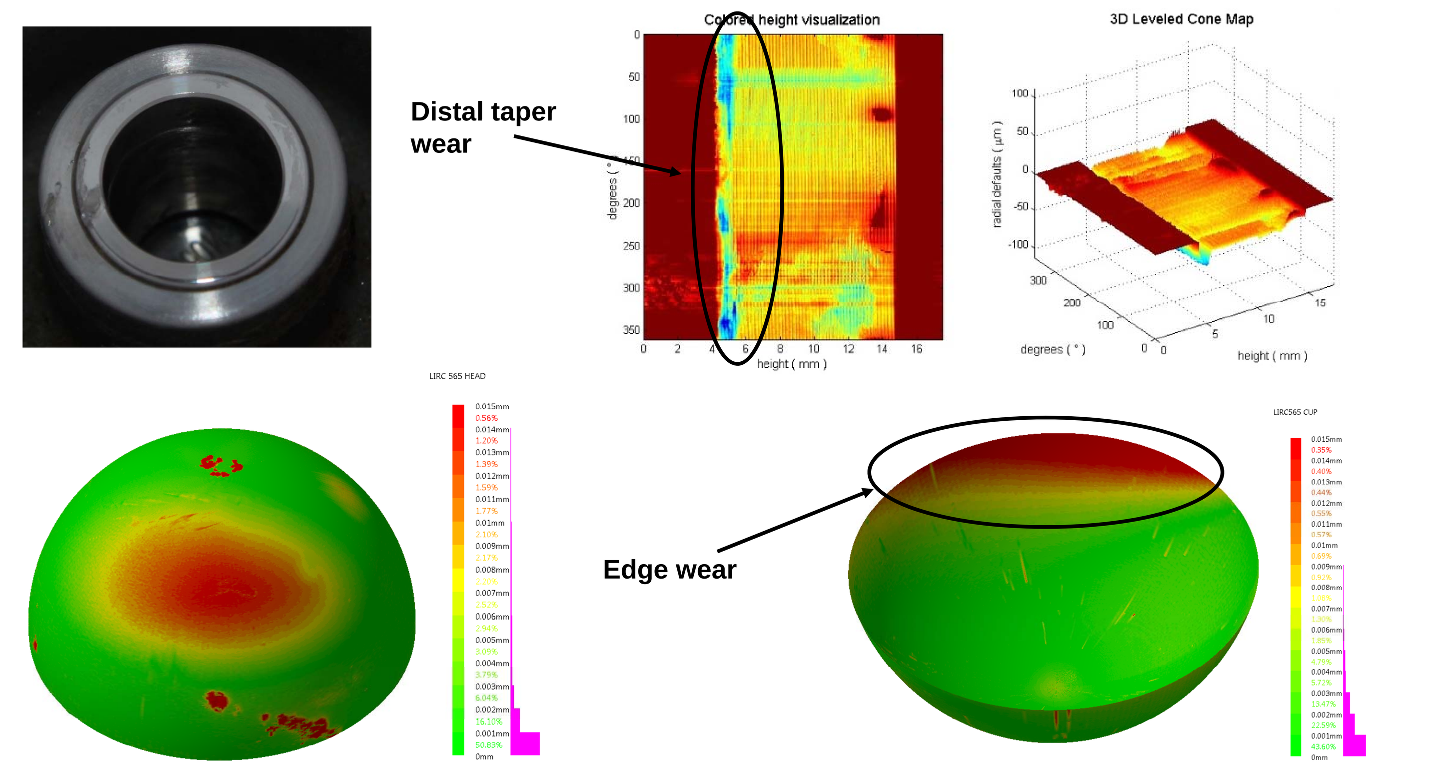
- Proprietary software allows the calculation of volumetric and linear wear with tools for removal of form and surface debris from the analysis.



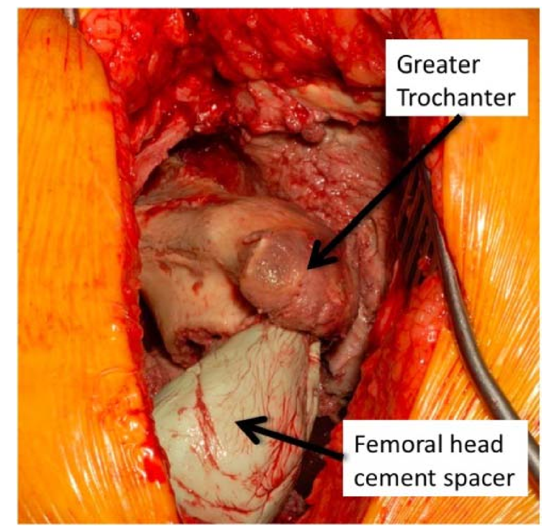
Wear measurement results

Over 100 retrieved component pairs were analysed

- Mean material loss at the bearing surface (pair): 21.2mm³ (0.6 – 309.2 mm³)
- Edge wear found in majority of cups.
- Mean material loss at the taper interface (head taper): 2.4mm³ (0.1 – 25.2 mm³)
- Area of highest wear observed at distal end of taper.



Case study



Revised at 56 months due to sever e tissue reaction

- All trochanteric muscle destroyed

Cup linear Wear (microns)	Cup wear volume (mm^3)	Cup Wear Rate (mm^3/year)	Head Linear Wear microns	Head wear volume (mm^3)	Head Wear Rate (mm^3/year)	Head Taper Wear Volume (mm3)
18.0	2.9	0.6	43.4	20.1	4.3	0.7

Relatively low wear rate of bearing surface and low taper wear

- Suggests patient susceptibility to CoCr

Conclusions

- Interactive user selection of the unworn surface is critical in minimizing analysis uncertainty in bearing analysis.
- Roundness machine ideal for taper measurement due to high resolution and low observed wear volumes .
- Maximum linear taper wear at distal end consistent with taper size mismatch.
- Female head taper surface exhibits imprint of the male stem taper surface.
- What is a clinically relevant level of wear? – Observations suggest any level of wear could trigger failure.

References

[1] National Joint Registry for England and Wales, 8th Annual Report 2011

[2] Bills, P., Racasan, R., Underwood, R., Cann, P., Skinner, J., Hart, A., Jiang, X. and Blunt, L. (2012) 'Volumetric wear assessment of retrieved metal-on-metal hip prostheses and the impact of measurement uncertainty' Wear, 274, pp. 212-219

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