Effect of Uncertainty on Wear Measurement of Metal-on-metal Total Hip Replacement Components

P Bills[1], R Racasan[1,4], J Skinner[2,4], A Hart[3,4], L Blunt[1]

[1]EPSRC Centre for Innovative Manufacturing in Advanced Metrology, University of Huddersfield, UK; [2]Royal National Orthopaedic Hospital, Stanmore, UK; [3]Department of Musculoskeletal Surgery, Imperial College London, UK; [4]London Implant Retrieval Centre, London, UK.

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

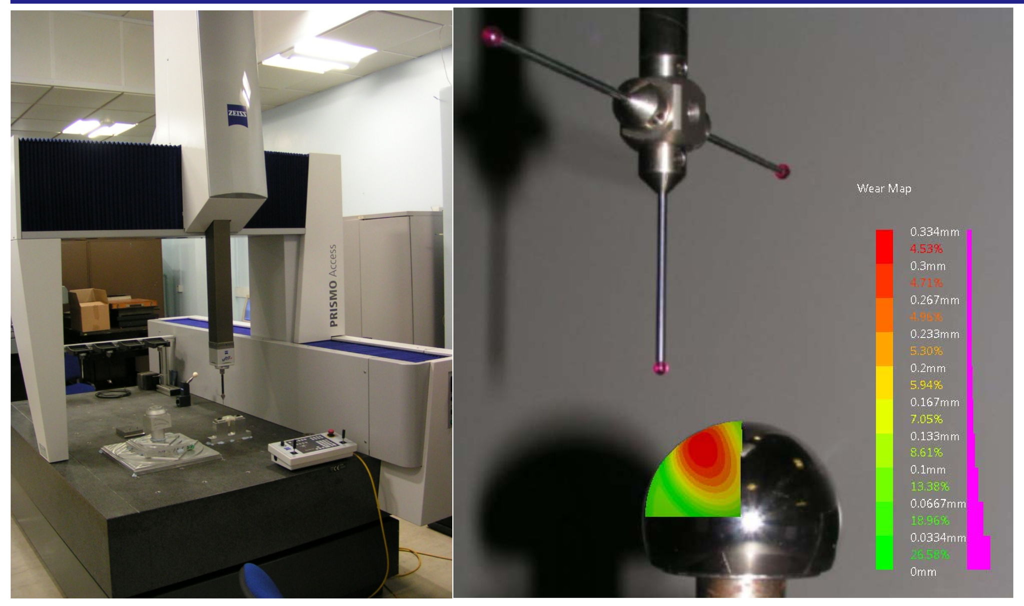
Measurement Requirements

- Wear analysis is vital tool in understanding failure mechanisms
- 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.
- Determining volumetric and linear wear based without a priori knowledge of the initial surface

Measurement Method



Measurement method:
Zeiss Prismo Access CMM

MPE = 1.9µm + L/300
DIN EN ISO 10360-2
Probing error: 0.7µm
DIN EN ISO 10360-4
Scanning Error: 1.3µm

Measurement parameters:
Speed: 3mm/s
Stylus: 2mm ruby ball

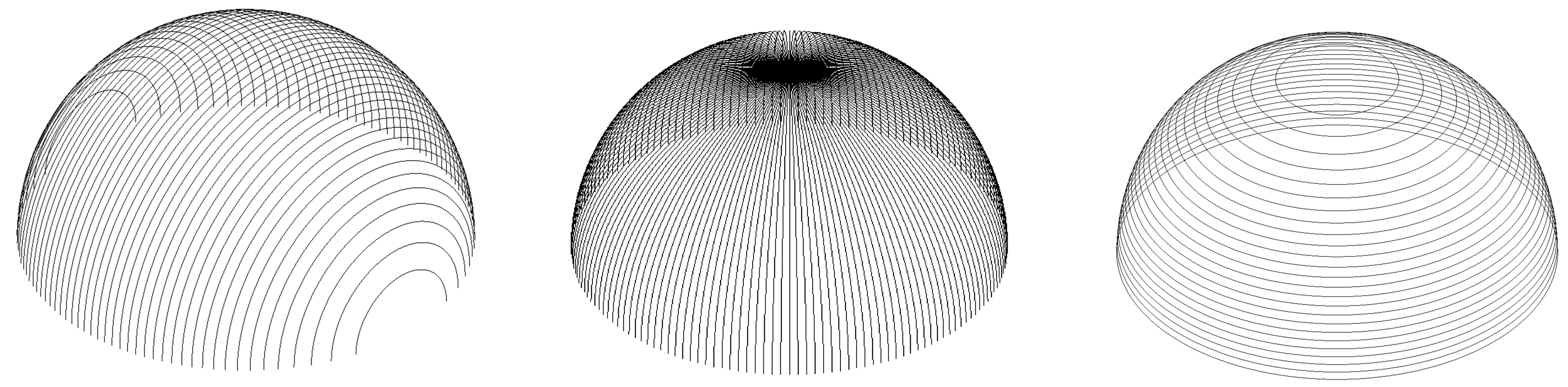
Measurement uncertainty

- Uncertainty is 'a parameter associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand'. **[2]**
- Expansion of method described in ISO **[3]**
- k is coverage factor
- 4 terms relate to interaction between hardware and measurement strategy
- c is the uncertainty contribution of the analysis method.

$$U = k \times \sqrt{(u_{cal}^2 + u_p^2 + u_w^2)} + |b| + |c| \quad \textbf{[4]}$$

Measurement related uncertainty

- Scanning strategy is a visual representation of the path of the stylus across the surface of the component. Minimizing the uncertainty through appropriate point spacing parameters.
- A study has been conducted to asses the impact of scanning strategies and parameters on point spacing distribution, stylus travel and volume difference when compared to a nominal hemisphere volume with a diameter of 50mm (see table).



Number of lines	Dist. between scanlines	Point spacing on scan lines	Number of points	Length of scan lines (mm)	Volumetric difference (mm3)
49	1mm	1	3704	3075	111.147
	1mm	0.5	7042	3075	105.107
	1mm	0.1	33568	3075	102.976
	1mm	0.05	66060	3075	102.905
98	0.5mm	1	7438	6161	35.496
	0.5mm	0.5	14138	6161	29.284
	0.5mm	0.1mm	67230	6161	27.09
	0.5mm	0.05mm	132372	6161	27.018
499	0.1mm	1mm	37402	30836	7.398
	0.1mm	0.5mm	71128	30836	3.143
	0.1mm	0.1mm	337106	30836	1.278
	0.1mm	0.05	663000	30836	1.203
999	0.05mm	1mm	74872	61677	6.183
	0.05mm	0.5mm	142334	61677	2.071
	0.05mm	0.1	674068	61677	0.399
	0.05mm	0.05	1326430	61677	0.322

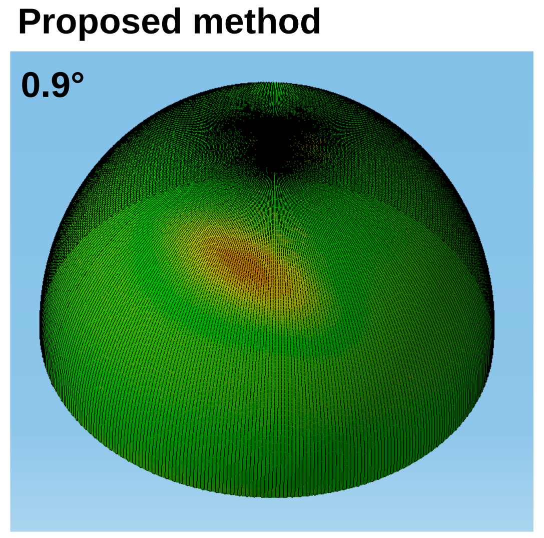
Num ber of lines	Max point spacing at the equator	Point spacing on scan lines	Number of points	Length of scan lines (mm)	Volumetric difference (mm3)
160	0.981mm	1mm	6560	6282.7816	21.008
	0.981mm	0.5mm	12800	6282.7816	11.63
	0.981mm	0.1mm	63040	6282.7816	8.526
	0.981mm	0.05mm	125920	6282.7816	8.428
200	0.785mm	1mm	8200	7853.4770	17.981
	0.785mm	0.5mm	16000	7853.4770	8.603
	0.785mm	0.1mm	78800	7853.4770	5.499
	0.785mm	0.05mm	157400	7853.4770	5.401
400	0.392mm	1mm	16400	15706.9540	13.945
	0.392mm	0.5mm	32000	15706.9540	4.566
	0.392mm	0.1mm	157600	15706.9540	1.462
	0.392mm	0.05mm	314800	15706.9540	1.364
600	0.262mm	1mm	24600	23560.4310	13.198
	0.262mm	0.5mm	48000	23560.4310	3.818
	0.262mm	0.1mm	236400	23560.4310	0.714
	0.262mm	0.05mm	472200	23560.4310	0.616

Numb er of lines	Point spacing between scanlines	Point spacing on scan lines	Number of points	Length of scan lines (mm)	Volumetric difference (mm3)
50	0.500mm	1mm	6682	6239.8454	37.063
	0.500mm	0.5mm	12870	6239.8454	29.622
	0.500mm	0.1mm	62842	6239.8454	27.109
	0.500mm	0.05mm	125218	6239.8454	27.03
100	0.250mm	1mm	13290	12409.5533	17.245
	0.250mm	0.5mm	25584	12409.5533	9.757
	0.250mm	0.1mm	124976	12409.5533	7.158
	0.250mm	0.05mm	249056	12409.5533	7.077
150	0.166mm	1mm	19902	18578.1932	13.305
	0.166mm	0.5mm	38324	18578.1932	5.952
	0.166mm	0.1mm	187280	18578.1932	3.317
	0.166mm	0.05mm	373262	18578.1932	3.235
200	0.125mm	1mm	26514	24746.4981	11.844
	0.125mm	0.5mm	51034	24746.4981	4.555
	0.125mm	0.1mm	249228	24746.4981	1.943
	0.125mm	0.05mm	496676	24746.4981	1.861

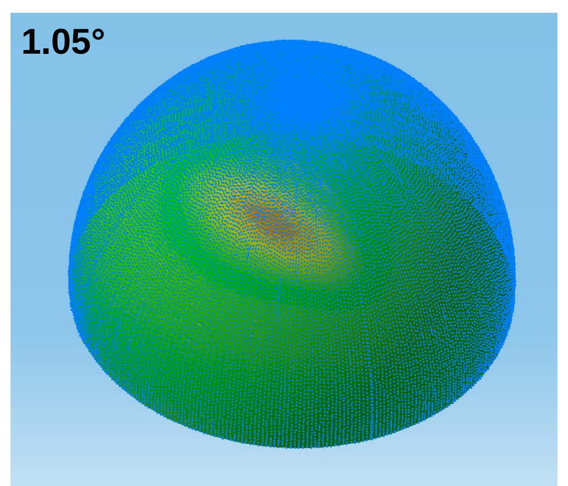
- The proposed method of scanning complies with current or under development ISO and ASTM standards

	Proposed method	ASTM	ISO 14242-2
Scan line spacing	0.9 °	1.05°	2.1°
Point spacing	0.1mm	0.5mm	1mm
Number of points	170 000	39850	12240

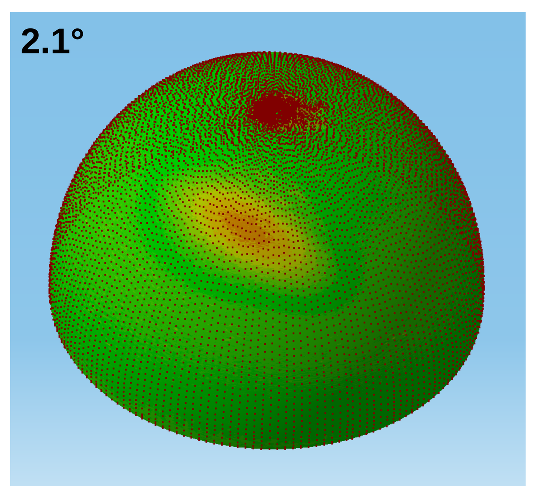
Proposed method



ASTM (under development)



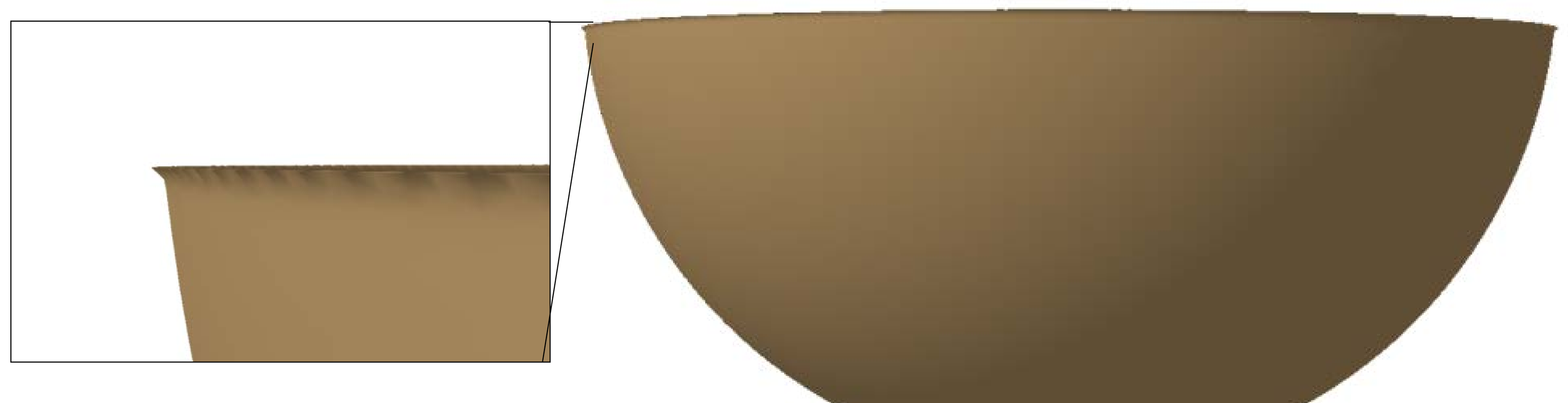
ISO 14242-2:2000



Measurement errors

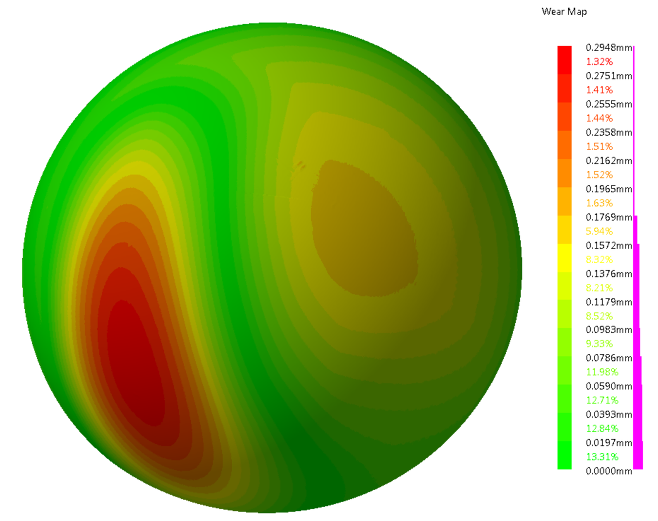
The measurement uncertainty associated with the measurement process includes:

- position of centre of the spherical component for the alignment of the measurement co-ordinate system
- the appropriate definition of the scanning boundary of the component's surface

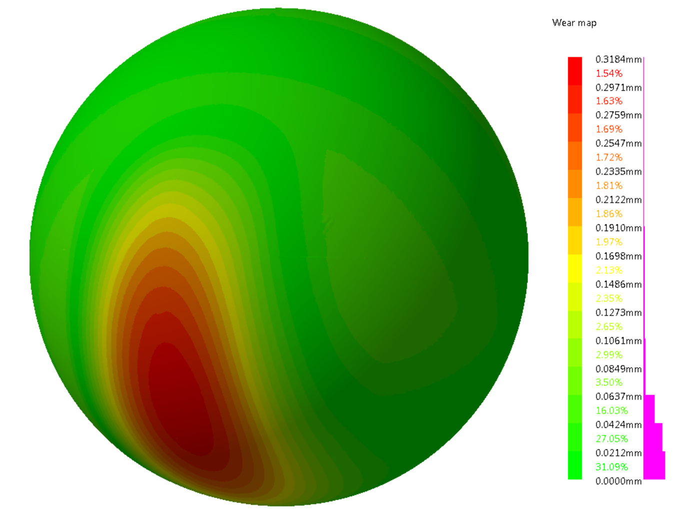


Analysis related uncertainty

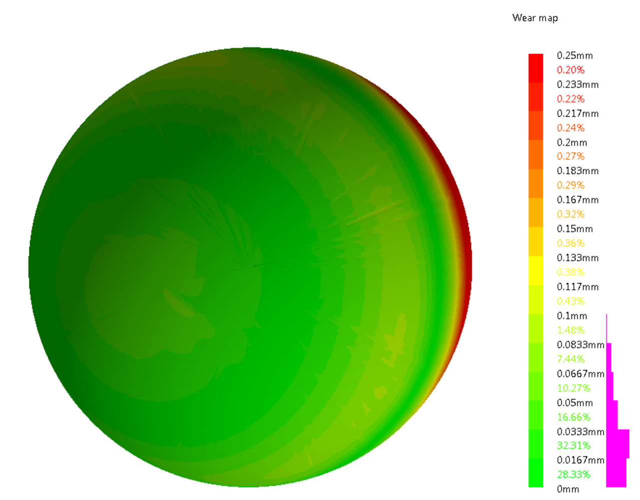
- The wear patch influences the mean error of the LSQ fitting process.
- The LSQ fitting determines the centre and radius of the unworn bearing surface.
- The wear area influences the position of the fitted sphere as well as the radius.
- Depending on the magnitude and position of wear patch the fitting process can produce bogus result.
- Interactive user selection of the unworn surface is critical in minimizing analysis uncertainty.



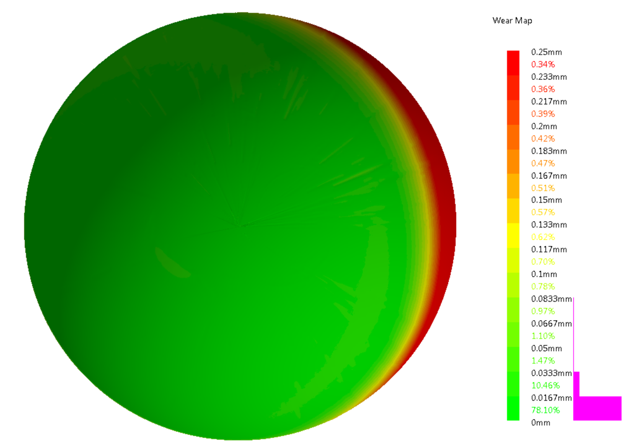
Automatic LSQ fit	Results
Radius unworn	22.7393 mm
Mean error	0.0630 mm
Standard deviation	0.0478 mm
Linear wear	0.215 mm
Wear volume	**10.053 mm³**



Intelligent LSQ fit	Results
Radius unworn	22.7628 mm
Mean error	0.0312 mm
Standard deviation	0.0236 mm
Linear wear	0.318 mm
Wear volume	**129.802 mm³**



Automatic LSQ fit	Results
Radius unworn	22.9384 mm
Mean error	0.0366 mm
Standard deviation	0.0393 mm
Linear wear	0.371 mm
Wear volume	**11.873 mm³**



Intelligent LSQ fit	Results
Radius unworn	22.7983 mm
Mean error	0.0030 mm
Standard deviation	0.0037 mm
Linear wear	0.553 mm
Wear volume	**87.820 mm³**

Conclusions

- Measurement uncertainty is multi-factorial
- Analysis method must be controlled and understood
- Determination of unworn geometry key factor in accuracy of measurement method and is stable only if done post process.
- Wear area must be isolated from unworn geometry prior to fitting.

References

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

[2] GUM, ISO/IEC Guide 98-3:2008, Uncertainty of measurement -- Part 3: Guide to the expression of uncertainty in measurement.

[3] ISO 15530-3:2007, Geometrical product specifications (GPS) -- Coordinate measuring machines (CMM): Technique for determining the uncertainty of measurement -- Part 3: Use of calibrated work pieces or measurement standards

[4] 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

Presented at ASTM Symposium on Metal-On-Metal Total Hip Replacement Devices, Phoenix, 08 May 2012

p.j.bills@hud.ac.uk
john.skinner@ucl.ac.uk

http://www.hud.ac.uk/cimam/
http://www1.imperial.ac.uk/medicine/hipcentre

l.a.blunt@hud.ac.uk
a.hart@imperial.ac.uk

LIRC London Implant Retrieval Centre