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

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Background
- Worldwide interest in failure of Metal-on-Metal (MoM) hips.
- >150,000 large diameter MoM hips implanted in UK.
- Typical linear wear rates for explanted hips are:
  - Head 0 – 750 μm/year
  - Cup 0 – 180 μm/year
- Accuracy required ~ 1 μm.
- Three designs of MoM hips have been removed from the market in past 4 years
- NJR data suggests 43% of hip failures are unexplained
- Volumetric accuracy not quoted or incorrectly determined.
- Characterizes the dispersion of the values that could reasonably be attributed to the measurement method.

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 = 1.9 μm + L/300
- DIN EN ISO 10360-2
- Probing error: 0.7 μm
- DIN EN ISO 10360-4
- Scanning Error: 1.3 μm
- Measurement parameters:
  - Speed: 3 mm/s
  - Stylus: 2 mm 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 measurement method.
- 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.

\[ U = K \times \sqrt{u_{cal}^2 + u_p^2 + u_w^2} + |b| + |c| \] ⁴

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

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 assess 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 50 mm (see table).

<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Scan line spacing</td>
<td>0.9 mm</td>
<td>1.05 mm</td>
<td>2.1 mm</td>
</tr>
<tr>
<td>Point spacing</td>
<td>0.1 mm</td>
<td>0.5 mm</td>
<td>1 mm</td>
</tr>
<tr>
<td>Number of points</td>
<td>175,988</td>
<td>36850</td>
<td>120,490</td>
</tr>
</tbody>
</table>

- The measurement uncertainty associated with the measurement process includes:
- position of centre of the spherical component for the alignment of the measurement coordinate system
- the appropriate definition of the scanning boundary of the component's surface

<table>
<thead>
<tr>
<th>Hardware</th>
<th>Measurement Strategy</th>
<th>Analysis</th>
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<tbody>
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<td></td>
<td></td>
<td>Expanded Uncertainty</td>
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Analysis related uncertainty
- The wear patch influences the mean error of the LSO fitting process.
- The LSO 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.

Measurement errors
- Wear area must be isolated from unworn geometry prior to fitting.

Conclusions
- Measurement uncertainty is multi-factirical
- 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

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http://www.hud.ac.uk/cimam/

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