Institute of Medical & Biological Engineering

Surface Characterisation of Total Ankle Replacement: Retrieved vs. In-vitro Simulation

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Ashley A Stratton-Powell[1], Alexandra Smyth[1], Sophie Williams[1], Anthony C Redmond[2], Joanne L Tipper[1], John Fisher[1], Claire Brockett[1]
[1] Institute of Medical & Biological Engineering, University of Leeds, UK, [2] NIHR LMBRU, Leeds Teaching Hospitals Trust, UK

Introduction

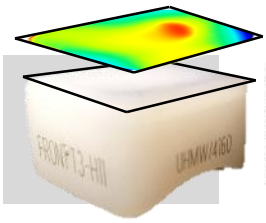
- Total ankle replacement (TAR) is less successful than other joint replacements with approximately 77% survivorship at 10 years [1].
- No international standard for pre-clinical testing TAR devices exists and only limited pre-clinical testing has been reported.
- Retrieval analyses can determine changes in bearing form (i.e. shape) as a result of plastic deformation or wear.

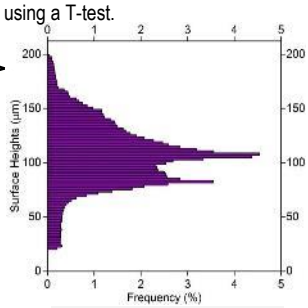
Corin Zenith TAR

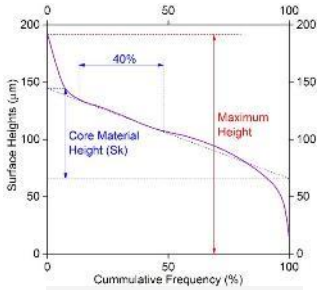
- Replication of in-vivo wear/deformation behaviour is important in the validation of effective in-vitro pre-clinical testing regimes.
- **This study compared the surface characteristics of UHMWPE mobile bearing inserts between retrieved TARs and devices tested in an ankle wear simulator.**

Materials and Methods

- Forty-four mobile-bearing TARs were retrieved (HRA ethics ref: 09/H1307/60). Mean implantation time was 7.8 years (range: 1.5-15.0).
- Concurrently, six unimplanted Zenith (Corin, UK) TARs were tested in an ankle joint simulator for 3 million cycles aligned optimally, followed by 2 million cycles with 7.5 ° coronal malalignment, lubricated with 25% bovine serum.
- An InfiniteFocus microscope (Alicona, AT) measured the superior surface of all mobile-bearing TAR inserts.
- Form-change was identified visually, quantified using surface characterisation parameters (ISO 25178-2:2012) and compared (retrieved vs. simulation) using a T-test.

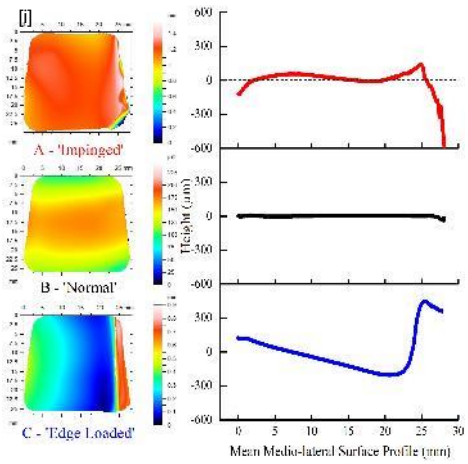




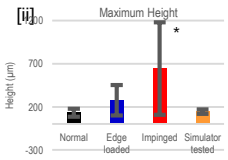


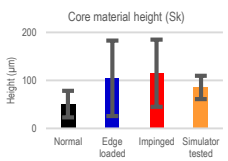
Explant retrieval & **In-vitro testing** → **Surface measurement** → **Identify surface heights** → **Surface characterisation**

Results

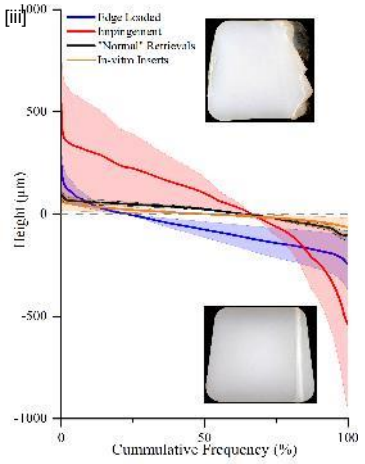


- Fifteen retrievals (34.1%) were impinged showing insert destruction, 21 (47.7%) were edge-loaded, identified by an inflection of deformed material, and eight (18.2%) were considered 'normal', without edge-loading or impingement.
- Of the inserts tested in-vitro, one exhibited evidence of edge-loading and the remaining inserts were 'normal' in appearance.
- In-vitro tested inserts were not significantly different to 'normal' retrievals for any surface height parameters (p>0.05).





Figures i, ii, iii.
[i] Three examples from the cohorts of A- edge-loaded (n=21), B- impinged (n=15) and C- 'normal' (n=8) retrieved TAR inserts alongside their mean medio-lateral surface profile (normalised to zero).
[ii] Mean maximum height and core material height (Sk) for each defined category.
[iii] The mean Abbott-Firestone curves for each category of retrievals compared to those tested in-vitro (n=6).



Significance

- Edge-loading and impingement were frequent (81.8%) damage modes in retrieved failed TARs, which may negatively affect device function and patient outcomes.
- Visualisation and surface characterisation using non-contacting 3D profilometry highlighted form-changes that could otherwise be overlooked and underreported.
- Current in-vitro ankle joint simulation can replicate in-vivo insert form-changes to an extent, although enhanced ankle simulation methods are required to represent more diverse in-vivo conditions and to better simulate conditions of failure.

[1] Gougoulias, N., et al (2010). *Clinical Orthopaedics and Related Research®*, *468*(1), 199-208.

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