An Orthopaedic Surgeon’s Perspective on Implant Design

Neil Rushton

Emeritus Professor of Orthopaedics
University of Cambridge
The Acetabular Component Remains the Weak Link


The Swedish National Arthroplasty Register

Website: www.jru.orthop.gu.se
## Reason for Revision

11,543 observations 1979-1998

<table>
<thead>
<tr>
<th>Reason</th>
<th>N</th>
<th>Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aseptic loosening</td>
<td>8,735</td>
<td>75.7%</td>
</tr>
<tr>
<td>Primary deep infection</td>
<td>828</td>
<td>7.2%</td>
</tr>
<tr>
<td>Fracture only</td>
<td>582</td>
<td>5.0%</td>
</tr>
<tr>
<td>Dislocation</td>
<td>576</td>
<td>5.0%</td>
</tr>
<tr>
<td>Technical error</td>
<td>399</td>
<td>3.5%</td>
</tr>
<tr>
<td>Implant fracture</td>
<td>179</td>
<td>1.6%</td>
</tr>
<tr>
<td>Secondary infection</td>
<td>100</td>
<td>0.9%</td>
</tr>
<tr>
<td>Polyethylene wear</td>
<td>60</td>
<td>0.5%</td>
</tr>
<tr>
<td>Pain</td>
<td>43</td>
<td>0.4%</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>41</td>
<td>0.4%</td>
</tr>
<tr>
<td>Missing</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>11,543</strong></td>
<td><strong>100.0%</strong></td>
</tr>
</tbody>
</table>
Particle disease
All articulating materials wear and therefore produce particles

- Polyethylene
- Bone cement
- Metals
- Ceramics
- “Biological” materials
- Suture & ligament materials
- Ectopic tissue
The effect of persistent particles

Surprising extent of the biological effect of wear particles

Bone defects heal if movement is reduced (Per Aspenberg)

Particles inhibit healing
Bone Atrophy
Bone wasting
Optifix Prosthesis

% BMD Difference at 6 months

% BMD Difference

R1  R2  R3  R4  R5  R6  R7
Particles and Stress Shielding are Additive
Aims for a New Hip

- Modulus-matched acetabular component
- Bone is subject to normal forces
- Biological fixation
- Large heads
- Conserve bone
Hole for bifurcated peg

Compare cut-out size
Materials used for Cambridge Cup

- Carbon Fibre Reinforced Polybutylene Terephthalate (CF-PBT)
- Ultra High Density Polyethylene (UHDPE)
- Hydroxyapatite (HA) coating
100° arc
Recessed arms

2 part snap fit
Early implantation
Retrieval Analysis
Cambridge Hip
Retrieved Specimen
Embedded Specimen
Specimen in Accutom
Three top cuts
Sections from face, spikes and cut-out
Image Analysis

Marrow

Bone

1.1mm

HA

CFRPBT

1.5mm
Histology comparison
HA Resorption
13 Year Survivor
Clinical trial:

10+ year prospective study
50 female patients
Displaced subcapital femoral neck fracture
Addenbrooke’s Hospital, Cambridge and St Helier Hospital, Carshalton
>70yrs of age
All walking with no more than one cane prior to fracture
All of sound mind, able to give informed consent and agreeable to follow-up
DEXA
Comparison With Other Results

<table>
<thead>
<tr>
<th></th>
<th>Overall Mean % change of BMD at 6 months</th>
<th>Overall Mean % change of BMD at 24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cambridge cup</td>
<td>-13%</td>
<td>-6%</td>
</tr>
<tr>
<td>Females with Mecron threaded</td>
<td>-19%</td>
<td>-20%</td>
</tr>
<tr>
<td>Females with titanium cup</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

N.B. surgical bone loss
Improvements in Design
Finite Element Analysis

- Partners: Exponent Philadelphia
- Sponsored by Stryker
- At least 500,000 elements
- FE studies agree with our clinical study
Cadaver Trials
Cadaveric Trials
Prevention of Binding

- Precision reaming
- Relief of arms
MITCH PCR™ Cup
Cup Deformation Analysis

- Polar contact (Interference 0mm)
- Polar contact (Interference 0.1mm)
- Polar contact (Interference 0.3mm)
- Polar contact (Interference 0.5mm)
- Polar contact (Interference 0.7mm)
- Annular contact (Interference 0.9mm)
Bearing shape

* Care required with reaming
Wear
Wear Studies

25 million cycles

Wear rate of 0.05mm$^3$ +/- 0.0.05 mm$^3$/ mc. (volumes actually negative owing to fluid absorption)

Surface roughness at start = 944nm, at end of test = 605nm with machine marks still evident.
Independent Wear Tests

Fig. 1: Durham hip joint wear simulator II
Results for 25 Million Cycles

Fig. 5: Estimated volumetric wear loss – cups 1 to 5 (corrected using cup 6 as a control)
MITCH

C/F PEEK

Titanium

HA
Instrument Development
Mitch PCR™
Clinical Trial
Pre-operative AP Radiograph
02 004
6 Week
Post-operative
AP
Radiograph
02 004
3 Month
Post-operative
Lateral
Radiograph
Clinical trial
Squeaking!
REF squeaker
After 1 year
Did not improve – noise disruptive
Arthroscopy – no abnormality
Revision - excellent fixation
  minimal black material
  not tight
Lab analysis - small patch of wear outside congruent zone
  some wear around keyhole

NR squeaker
After 1 year
Improving – not disruptive
No surgery
The original concept was to develop a system that was sympathetic with the existing tissue.
*Modular system
*Interchangeable components
*Augments existing Stryker components
Some Lessons from Recent Experiences
Transformation of Cells in Response to Metal Ions
Treatment of Avascular Necrosis
Pseudotumour

- Destructive, locally invasive tumour
- Difficult to treat
- Class action
- Cessation of use
Capital Hip

- Made by 3M
- Designed to be cheap
- Copy of Charnley Hip
- High failure rate
- Class action
- 3M leave orthopaedic business
Cosmetic Products

- Cosmetic surgery is going from boom to bust
- Competition to make it cheaper (or make more profit)
- Some Dow Corning implants failed
- Class action
- Dow Corning out of orthopaedics
The True Story

- Class action
- Claimed to interfere with immune defences (not correct)
- Claimed to rupture more frequently (not correct)
- $4 billion paid in settlements!
Swanson Prosthesis
Poly Implant Prostheses

- Made cheaply
- Non-medical grade filler
- Poor quality
- High failure rate
- Company vanished!
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Politicians and public do not differentiate between different prostheses!
Titanium Troubles
Trunnion Wear

- Titanium and Ti alloys are not suitable for some Morse taper junctions
- Worse problems when counterface is CoCr
- Leads to dramatic bone loss
- Biological mechanism not known
Some Messages

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• Do not believe your own marketing!
Details of O.R.U. publications and activities can be found on

www.orthopaedics.cam.ac.uk