The end of the taper disaster

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Disclosures

• Consultant, Speakers Bureau, Research Grants:
  - Aesculap
  - Biomet
  - Corin
  - Lima
  - Mathys
  - S&N
  - Bayer
  - Ceramtec
  - DePuy
  - Link
  - Peter Brehm
  - Zimmer

• No Royalties
Which disaster?

• Disaster 1

The taper disaster - how could it happen?

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Figure MM6 Cumulative Percent Revision of Metal/Metal Primary Total Conventional Hip Replacement by Gender and Head Size (Primary Diagnosis OA)

- Male ≤32mm vs Male >32mm
- Male >32mm vs Female >32mm
- Female ≤32mm vs Female >32mm

HR - adjusted for age

<table>
<thead>
<tr>
<th>Group</th>
<th>HR (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male ≤32mm vs Male &gt;32mm</td>
<td>1.57 (0.89, 2.79)</td>
<td>0.14</td>
</tr>
<tr>
<td>Male &gt;32mm vs Female &gt;32mm</td>
<td>0.81 (0.53, 1.23)</td>
<td>0.34</td>
</tr>
<tr>
<td>Female ≤32mm vs Female &gt;32mm</td>
<td>0.71 (0.46, 1.09)</td>
<td>0.08</td>
</tr>
</tbody>
</table>
Friction in hip-joint prostheses and its influence on the fixation of the artificial head

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The head of an implanted hip joint endoprosthesis is exposed to torques, which are transferred during gait due to the friction between the head and the cup prosthesis. In prostheses with ceramic ball heads, which are widely used now, and in which the head is fixed onto the stem by conical clamping, these torques could possibly affect the connection. In this study, torques transferred from the cup to the head are compared to the torques which are required to loosen the head from the metallic spigot. The results show that for the investigated head and taper types and sizes, under normal conditions the connection is safe with respect to undesired rotation. However, it is shown that for polluted sliding surfaces the fixation strength could possibly be exceeded. © 1998 Kluwer Academic Publishers

ORIGINAL ARTICLE

European multidisciplinary consensus statement on the use and monitoring of metal-on-metal bearings for total hip replacement and hip resurfacing

Which disaster?

- Disaster 1
- Disaster 2

“Prevalence of 1.1% in a series of 1356 contemporary Zimmer uncemented THAs followed for a minimum of 2 years. Delay in treatment led to irreversible soft tissue damage in three patients.” (AAOS 2016: 2.6%)
History 1

• It has always been there

Formation of a Fulminant Soft-Tissue Pseudotumor after Uncemented Hip Arthroplasty

BY OLLE SVENSSON, M.D., PH.D., ERIK B. MATHIESEN, M.D., FINN P. REINHOLT, M.D., PH.D., GUDMUND BLOMGREN, M.D., PH.D., HUDDINGE, SWEDEN

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Introduction

• It has always been there
• Magnitude of attention / occurrence is new
History Taper Disease

- It has always been there
- Magnitude of attention / occurrence is new
- How big is the problem?

Revision Reasons AOA 2015

Table HT10  Primary Total Conventional Hip Replacement by Reason for Revision

<table>
<thead>
<tr>
<th>Reason for Revision</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loosening/Lysis</td>
<td>2935</td>
<td>28.0</td>
</tr>
<tr>
<td>Prosthesis Dislocation</td>
<td>2528</td>
<td>24.2</td>
</tr>
<tr>
<td>Fracture</td>
<td>1907</td>
<td>18.2</td>
</tr>
<tr>
<td>Infection</td>
<td>1811</td>
<td>17.3</td>
</tr>
<tr>
<td>Pain</td>
<td>191</td>
<td>1.8</td>
</tr>
<tr>
<td>Leg Length Discrepancy</td>
<td>145</td>
<td>1.4</td>
</tr>
<tr>
<td>Malposition</td>
<td>125</td>
<td>1.2</td>
</tr>
<tr>
<td>Implant Breakage Stem</td>
<td>99</td>
<td>0.9</td>
</tr>
<tr>
<td>Instability</td>
<td>94</td>
<td>0.9</td>
</tr>
<tr>
<td>Implant Breakage Acetabular Insert</td>
<td>81</td>
<td>0.8</td>
</tr>
<tr>
<td>Implant Breakage Acetabular</td>
<td>79</td>
<td>0.8</td>
</tr>
<tr>
<td>Incorrect Sizing</td>
<td>79</td>
<td>0.8</td>
</tr>
<tr>
<td>Wear Acetabular Insert</td>
<td>77</td>
<td>0.7</td>
</tr>
<tr>
<td>Metal Related Pathology</td>
<td>74</td>
<td>0.7</td>
</tr>
<tr>
<td>Implant Breakage Head</td>
<td>30</td>
<td>0.3</td>
</tr>
<tr>
<td>Other</td>
<td>209</td>
<td>2.0</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>10464</strong></td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>

Note: All procedures using metal/metal prostheses with head size larger than 32mm have been excluded.

If we exclude disaster 1
History Taper Disease

- It has always been there
- Magnitude of attention / occurrence is new
- How big is the problem? (not that big in comparison to other revision reasons - IF we exclude large MoM)

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Hip replacement survival

Modular primary THA is unbelievable successful!

| Stem/cup brand | Bearing surface | n   | Median (CP) age at primary | Percentage | Cumulative probability of revision (95% CI) at:
<table>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 year</td>
</tr>
<tr>
<td>Uncemented</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>McP</td>
<td>36,776</td>
<td>71</td>
<td>(65-77)</td>
<td>40%</td>
<td>0.86</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(0.76-1.06)</td>
</tr>
<tr>
<td>Coral / Pinnacle</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CoP</td>
<td>12,187</td>
<td>64</td>
<td>(59-68)</td>
<td>44%</td>
<td>0.88</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(0.79-0.97)</td>
</tr>
<tr>
<td>CoC</td>
<td>32,309</td>
<td>63</td>
<td>(53-66)</td>
<td>47%</td>
<td>0.83</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(0.74-0.94)</td>
</tr>
</tbody>
</table>
History Taper Disease

• It has always been there
• Magnitude of attention / occurrence is new
• How big is the problem (not that big in comparison to other revision reasons - IF we exclude large MoM)
• What causes it?

Findings
• Flexural rigidity of the neck predictor
• Larger diameter necks have higher increased stiffness and may reduce fretting corrosion
• Mechanically assisted crevice corrosion
• Corrosion and fretting more observed inside the head
Taper and head size development

2016

Loading development

Figure 2. Obesity rates


2016
Why is anybody surprised?

The complete story...

• Every metal being put in the body corrodes and the alloy components will be released
• Looking for it will always reveal corrosion
• Every (!) taper junction can get loose
• Tapers are made for loading along taper axis NOT bending
• The larger the head (friction), offset, distance of the taper from the load - the larger the bending moment (bad......)
What is the decisive parameter to make corrosion (which always takes place) a clinical problem?

There is no single one...

Movement / separation at the taper interface is a prerequisite for the start of mechanically induced tribocorrosion (fretting).
Movement / separation at the taper interface is a prerequisite for the start of mechanically induced tribocorrosion (fretting). No movement - no problem.

Example

• Active patient
• 9 years in situ
Example

- Active patient
- 9 years in situ
- Dislocated without warning
- Taper „problem“ - what caused it?

Taper Corrosion

Movement / separation at the taper interface is a prerequisite for the start of mechanically induced tribocorrosion (fretting).

No movement - no problem.

Goal: Prevent (minimize) micromotion at the taper interface!

How?
Taper corrosion

Factors:
• Design (material, diameter, length, TAD, tolerances)

What is best?
For nearly all taper types, some failures are reported (only descriptive)
• Little hard data yet, how taper design influences the rate of problems
• No valid pre-clinical testing set-up
Factor assembly

- Prevent major mismatch

Major mismatch

76 y female
16 years in situ
Little biological reactions since little Co or Cr

JBJS Case Connect 2014;4:e25
76 y female
16 years in situ

Little biological reactions since
little Co or Cr

14/16 head
on a
12/14 taper

“Type I” instead of V40 taper, (Gührs et al, 2015 in press)
Taper corrosion

- Prevent major mismatch
- Prevent „minor“ mismatch

Taper geometry

A

Biomet BiMetric

DePuy Corail

Symbios ARCAD

B

C

5μm
150μm 300μm 450μm 600μm
150μm 300μm 450μm 600μm
Factor assembly

• Prevent major mismatch
• Prevent „minor“ mismatch
- no idea whether it is important
- don‘t take any risk..

• Prevent major mismatch
• Prevent „minor“ mismatch
• Prevent contamination
Taper contamination

Micromotion + Deformation

Jauch JoR 2013
Factor assembly

- Prevent major mismatch
- Prevent "minor" mismatch
- Prevent contamination
- Sufficient assembly force

Plastic deformation for higher strength

250 µm

2600 N

10 µm
Taper corrosion

Factors:
• Design
• Assembly
• Loading (magnitude, direction, lever arm)

Head length
Taper interface loading
Taper interface loading

- Prevent major mismatch
- Prevent „minor“ mismatch
- Prevent contamination
- Sufficient assembly force
- Offset / Length
Offset of taper from joint load

Fractures in Revision stems and bi-modular primary stems

Taper corrosion

- Prevent major mismatch
- Prevent „minor“ mismatch
- Prevent contamination
- Sufficient assembly force
- Offset / Length
- Head size
Raised levels of metal ions in the blood in patients who have undergone uncemented metal-on-polyethylene Trident–Accolade total hip replacement

The issues surrounding raised levels of metal ions in the blood following large head metal-on-metal total hip replacement (THR), such as cobalt and chromium, have been well documented. Despite the national popularity of uncemented metal-on-polyethylene (MoP) THR using a large-diameter femoral head, few papers have reported the levels of metal ions in the blood following this combination. Following an isolated failure of a 44 mm Trident–Accolade uncemented THR associated with severe wear between the femoral head and the tunnel in the presence of markedly elevated levels of cobalt ions in the blood, we investigated the relationship between modular femoral head diameter and the levels of cobalt and chromium ions in the blood following this THR.

A total of 68 patients received an uncemented Trident–Accolade MoP THR in 2008. Of these, 43 patients (23 men and 20 women, mean age 67.0 years) were recruited and had levels of cobalt and chromium ions in the blood measured between May and June 2012. The patients were then divided into three groups according to the diameter of the femoral head used: 12 patients in the 28 mm group (controls), 18 patients in the 36 mm group and 13 patients in the 40 mm group. A total of four patients had identical bilateral prostheses in situ at phlebotomy: one each in the 28 mm and 36 mm groups and two in the 40 mm group.

There was a significant increase in the mean levels of cobalt ions in the blood in those with a 36 mm diameter femoral head compared with those with a 28 mm diameter head (p = 0.013). The levels of cobalt ions in the blood were raised in those with a 40 mm diameter head but there was no statistically significant difference between this group and the control group (p = 0.152). The levels of chromium ions in the blood were normal in all patients.

The clinical significance of this finding is unclear but we have stopped using femoral heads with a diameter of ≥36 mm, and await further larger studies to clarify whether, for instance, this issue particularly affects this combination of components.

Cite this article: Bone Joint J 2014;96-B:43-7.
• Active patient
• 9 years in situ
• Dislocated without warning
• Taper „problem“ - what caused it?

Example

Soft Ti?
Small Taper?
Large Head (36mm is large!)?
Contamination? Assembly?
High loading?
Discussion

- Corrosion has been, is, and will always be there if metals are put in a physiological environment.
- Taper corrosion is a problem - but not as big as it is currently made, if large heads and high friction and large levers are omitted.
- Ceramic heads minimize the problem.

Do Ceramic Femoral Heads Reduce Taper Fretting Corrosion in Hip Arthroplasty? A Retrieval Study

Steven M. Kurtz PhD, Sevi R. Kozagija BS, Jose A. Harolik MS, Richard J. Underwood PhD, Jeremy L. Gilbert PhD, Daniel W. MacDonald MS, Gwe-Chin Lee MD, Michael A. Mout MD, Matthew J. Kraay MD, Gregg R. Klein MD, Javad Parsizi MD, Clare M. Rinnue PhD

A Comparison of Blood Metal Ions in Total Hip Arthroplasty Using Metal and Ceramic Heads

Peter B. White, IB, Morteza Meftah, MD, Amar S. Ranawat, MD, Chitrnanjan S. Ranawat, MD

Original Article

Discussion

- Corrosion has been, is, and will always be there if metals are put in a physiological environment
- Taper corrosion is a problem - but not as big as it is currently made, if large heads and high friction and large levers are omitted
- Ceramic heads minimize the problem
- No single root cause for failure
Many things have to be done right SIMULTANEOUSLY.

- Corrosion has been, is, and will always be there if metals are put in a physiological environment.
- Taper corrosion is a problem - but not as big as it is currently made, if large heads and high friction and large levers are omitted.
- Ceramic heads minimize the problem.
- No single root cause for failure.
- Laywers and patients and surgeons „like“ problems, which can be directly linked to the product.
Take home

• The taper issue is not going to be solved by a magic idiot prove design - the whole process has to be improved!
• The currently used tapers are designed for 28mm and 32mm heads and work very well (but can also fail if something is wrong)
• They do work for larger heads - BUT -
Take home

- Wear is a „minor“ issue with modern materials, friction related issues comprise the bigger problem (back to Charnley....)
- 36mm is rather large for Me heads, for CE heads it‘s probably o.k.
- Disaster 1 is over (MoM is gone)
- Disaster 2 - is no disaster, can be prevented
- **Technique, head size & material** (orientation, offset, length, CCD, contamination, assembly)
Thank you for your attention!