The Role of Backside Wear in Osteolysis

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Disclosure

- *Designer (Royalty income)* - **DePuy A Johnson & Johnson Company**
- *Consultant* on Knee Products for **Smith & Nephew Orthopaedics**
- *General Research Funding* – **Inova Health System and the U.S. Army Medical Research & Materiel Command and the Telemedicine & Advanced Technology Research Center**
- *Investor* - **Alexandria Research Technology**

Disclosures made in accordance with Anderson Orthopedic Research Institute Policy

Osteolysis was not reported with non-modular components of the 70s and 80s.

TKA Failure by Polyethylene Wear

- First reported-1988
- Metal-backed, non-modular PCA knee

Engh, JBJS August 1988

Osteolysis After TKA

- 16% incidence
- Modular metal-backed tibial component

Peters, JBJS 74A, 1992

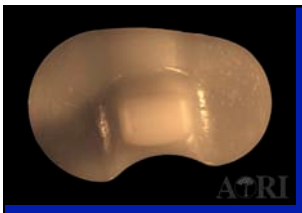
What caused osteolysis in this patient?

- 39 year old, 260 lb. park ranger
- TKA *in situ:* 4 Years

Articular Side Pristine and Baseplate Worn

What caused osteolysis in this patient?

- 69 year old nun
- TKA *in situ* 3.5 years



Articular-side pitting

Baseplate burnishing

Clinical Experience Modular Tibial Trays

- Osteolysis can occur even when there is minimal visible wear on the articular side of the polyethylene

Retrieval Experience Modular Tibial Trays

- Backside wear *does* occur *and* may contribute to the debris that causes osteolysis

Where does debris come from?

the ***Articular*** surface

or

the ***Modular*** surface

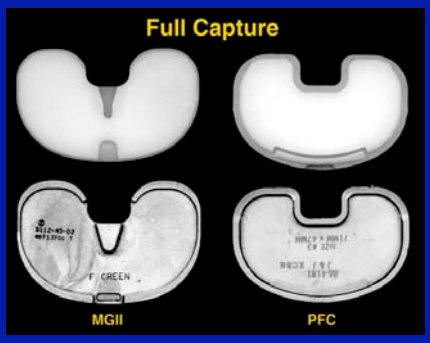
? About Backside Wear

- Do modular interfaces move?
- What is the magnitude of motion?
- Do any locking mechanisms eliminate interface motion?
- Do locking mechanisms deteriorate with time *in vivo*?

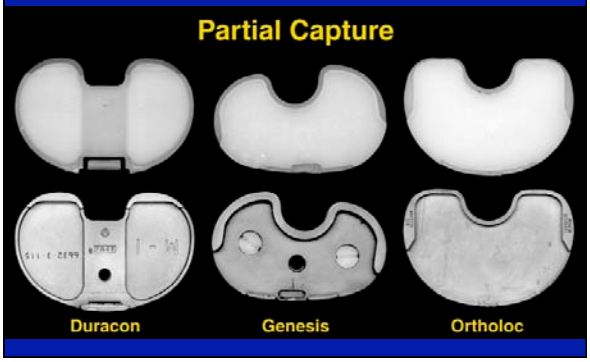
Materials and Methods

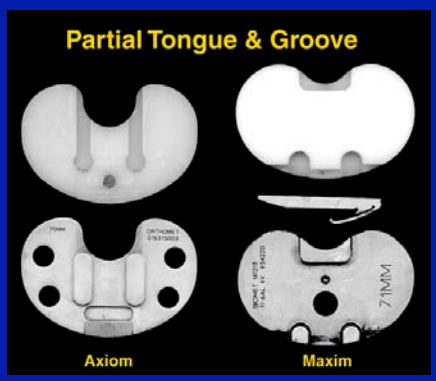
- Nine different implant designs
- Mechanical testing-Instron

Snap Fit



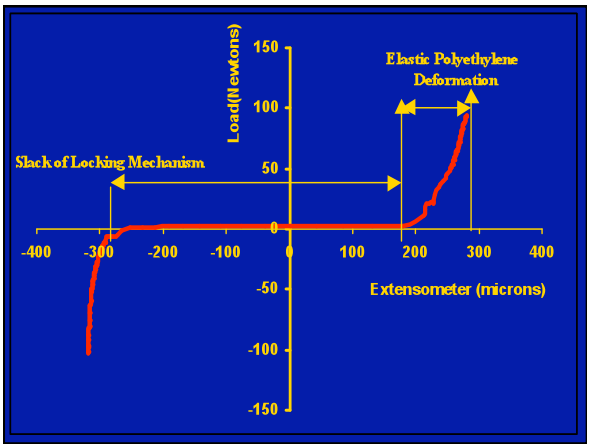
Snap Fit





Mechanical Testing Protocol

- Mount tray in acrylic
- Precondition: 37° water bath for 2 weeks
- Clamp components in 2 individual frames
- Measure motion before resistance is encountered



Results

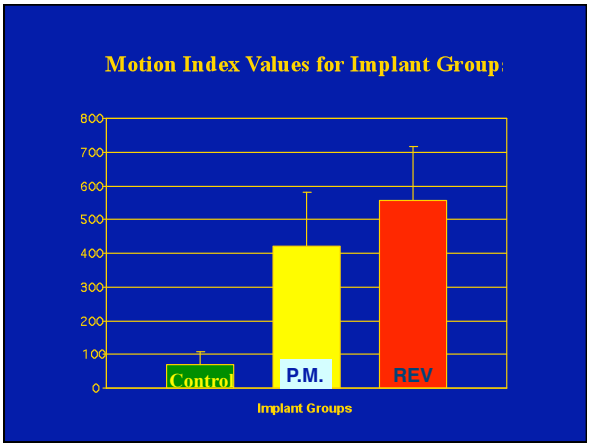
- All implants out of the box had a mean 90 microns of motion
- Wide variation within any implant type
- Wide range of motion for all implants

Do locking mechanisms become looser in vivo?

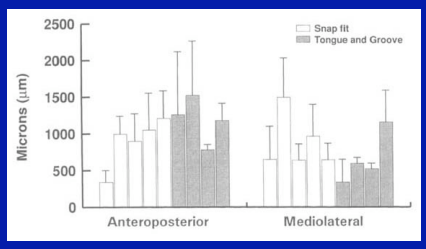
Do both snap-fit and tongue-in-groove become looser?

Study Group (N=29)

- **12 Postmortem implants**
  (2 snap-fit, 10 tongue-in-groove)
- **17 Components from revision surgery**
  (9 snap-fit, 8 tongue-in-groove)

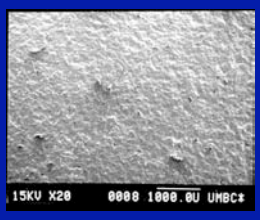


Modular Tibial Insert Micromotion



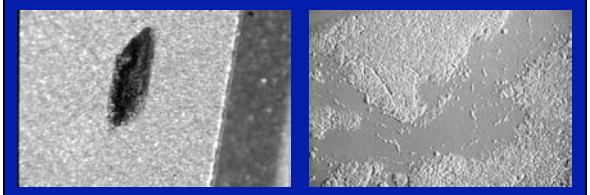
Parks et al, CORR, 1998

Titanium Tray
Average Surface Roughness: 3.79μ

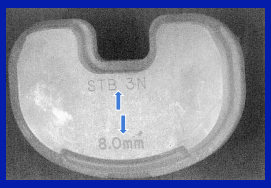


- ISO recommended surface finish for articulating medical devices: 0.1μ

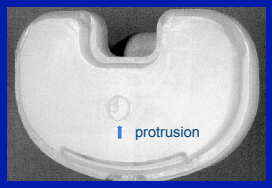
Baseplate Stippling



Backside Wear
Gamma-in-Air



Stamped markings



Loss of backside markings

Backside Wear & Length of Implantation

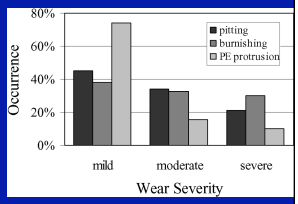
- 55 retrieved inserts-4 designs
- Removal of stamped markings and poly protrusions correlated with time in vivo
- 2 to 4X wear rates in total hips

Removal of Stamped Markings	none	Poly protrusions <.25mm	>.25mm	(Months)
– None	16	14		1–60
– Partial	5	11		5–60
– Complete		1	7	25–73

Li et al, CORR, 2002

Backside Wear
Fixed Bearing (Gamma-in-Air)

- 124 retrievals (12 different designs)
- In situ: 51 months
- Moderate / severe:
  - Pitting-55%
  - Burnishing-62%
  - Protrusions-26%



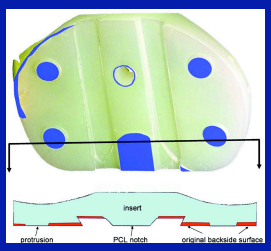
Conditt et al, JBJS 2004

Backside Wear
Fixed Bearing (Gamma-in-Air)

- 15 AMK implants
- In situ: 36-146 months (mean-91 months)
- Backside volumetric wear: 138 ± 95mm^3 / Yr.

Conditt et al, JBJS 2005

Backside Volumetric Wear
Fixed Bearing (Gamma-in-Air)



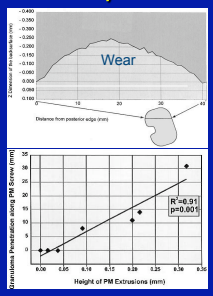
Laser profilometry-computer reconstructions

Burnishing, pitting, & protrusions

Conditt et al, JBJS 2005

Backside Wear
Fixed Bearing (Gamma-in-Air)

- 25 MG post-mortem retrievals
- Mean: 64 months in vivo
- Concave deformation: 96%
- Screw hole impression: 100%



Surace et al, CORR 2002

AORI retrievals
Good Poly

- Fixed Bearing
  - 49 Sigma PFC inserts
  - Gamma in Barrier
  - In situ: 32 months
- Mobile Bearing
  - 23 LCS RP inserts
  - Gas Plasma
  - In situ: 29 months

Mobile & Fixed Bearing Articulating Surface Scores

Good poly
(non gamma in air retrievals)
No delamination

Is backside wear a problem with non-irradiated poly & with mobile-bearings ?

AORI retrievals

- Fixed Bearing
  - 49 Sigma PFC inserts
  - Gamma in Barrier
  - In situ: 32 months
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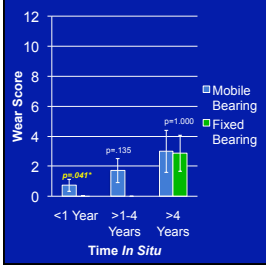
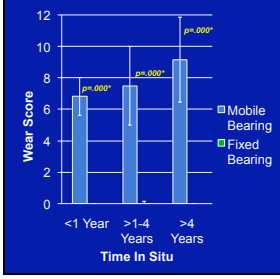
  - In situ: 29 months

MB vs. FB Backside Pitting



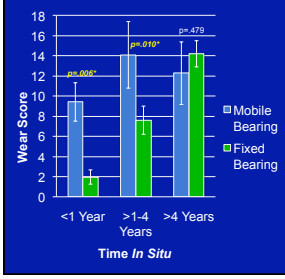
- Pitting early for mobile bearing
- Similar pitting at >4 years

MB vs. FB Backside Scratching



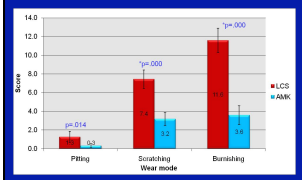
- Scratching not seen on fixed bearing inserts

MB vs. FB Backside Burnishing



- Burnishing early for mobile bearing
- Similar burnishing at >4 years

Backside Wear



Mobile Bearing Tray

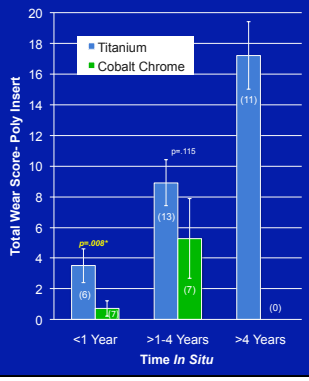
LCS Rotating Platform Tibial Tray

- Scratches go beyond the expected rotation of the knee suggesting 3rd body debris wear
- Scratching on metal tray closely mimics scratching on inserts

Does the tray material impact wear?

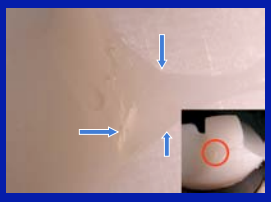
Titanium

CoCr Polished



Post Wear on PS Knees

31 Posterior Stabilized



γ in Barrier PFC Inserts

>4 years:

- 100% had deformation & burnishing
- Post contact may accelerate backside wear

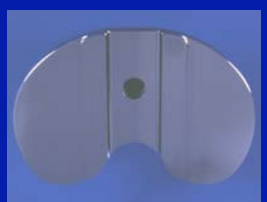
Why was wear not a problem with the IB & AGC implant?

1) Himont 1900 - Compression molded
   less sensitive to oxidation
2) Non-modular interface
   eliminates backside wear

Conclusions

- Backside wear is a significant source of wear debris with both mobile and fixed bearing modular implants
- Industry standards are needed to minimize tibial component micromotion

For primary fixed-bearing TKA's consider:



Polished cobalt chrome baseplate

One-piece tibial component

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