

RETRIEVAL AND ANALYSIS OF DEVICES: A NEW APPROACH

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AMERICAN SOCIETY FOR TESTING AND MATERIALS, INTERNATIONAL

ORTHOPAEDIC DEVICE FORUM

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AAOS

AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

RETRIEVAL AND ANALYSIS PROGRAM (1970-2010) University of Alabama at Birmingham (UAB)

7000 prior analyses

800-1000/year revision and post mortem

2005-2009 NIBIB-BRP grant for infrastructure

<p>Fracture and wear of PMMA and PTFE</p>  <p>wear/PMMA</p>	<p>Constrained THA designs</p>  <p>constrained/PMMA</p>	<p>Wear and Fracture of Ceramics</p>  <p>ceramic</p>
50-60's		
<p>Wear of PE-C composite articulation</p>  <p>composite</p>	<p>Heat pressed and restructured PE articulations</p>  <p>wear</p>	<p>Gamma Irradiated and Oxidized PE</p>  <p>oxidized</p>
70-80's		
<p>Microstructure and residue in porous surfaces</p>  <p>porous metal</p>	<p>Fretting of Morse taper modular connections</p>  <p>taper corrosion</p>	<p>Modular component locking designs</p>  <p>locking</p>
90-00's		

CO-SPONSORED: EXAMPLES-AAOS/ASTM/FDA/ORS/SFB

1. Porous Implants for Hard Tissue Application, ASTM STP 953, 1987.
2. Calcium Phosphate Coatings for Implants, ASTM STP 1196, 1994.
3. UHMW Polyethylene, ASTM STP 1307, 1998.
4. Synthetic Bioabsorbable Polymers for Implants, ASTM STP 1396, 2000.
5. Bone Graft Substitutes, ASTM/AAOS, 2003.
6. Spinal Implants: Are We Evaluating Them Appropriately, ASTM STP 1431, 2003.
7. Crosslinked and Thermally Treated, UHMWPE, ASTM STP 1445, 2004.
8. Titanium, Niobium, Zirconium and Tantalum for Surgical Application, ASTM, 1471, 2006.
9. Osteolysis and Implant Wear: AAOS/NIH, Nov, 2007.
10. Proposed Regulatory Strategy for Neurotoxicity Testing, ASTM/FDA, Nov, 2009.
11. Fretting Fatigue of Metallic Medical Devices and Materials, ASTM E8/F04, Nov, 2009.

NEEDS

Evidence Based Assessments including key factors where all stakeholders participate and determination of N=1=xxxx

References, University of Alabama at Birmingham (UAB)

1. Lemons, J., et al, Evolving Implant Retrieval Program, What's New, AAOS-SE41, 2008.
2. Chowdhury, S., et al, Accelerating Aging of Zirconia Femoral Head Implants: Change of Surface Structure and Mechanical Properties, JBMR-B, 81, 2007.
3. Moore, et al, "Early Failure of a Cross-Linked Polyethylene Acetabular Liner: A Case Report," JBJS, 2008.
4. Eberhardt, et al, "Surface Roughness of CoCr and ZrO2 Femoral Heads with Metal Transfer: A Retrieval and Wear Simulator Study," Int J. Biomat, 2009.
5. Lemons, J., Biological Considerations of Orthopaedic Implants: Implant Retrieval, In Lindsey R Ed, Orthopaedic Implants, Marcel Dekker, Inc., NY, NY, 2010.

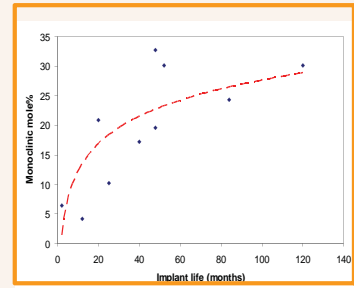
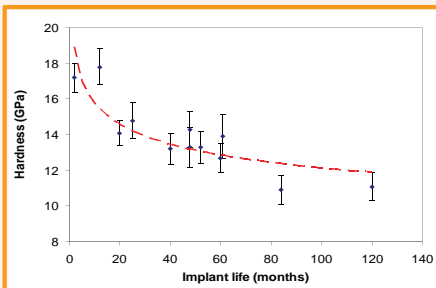
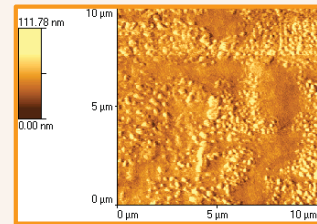
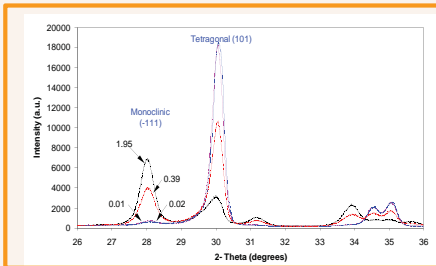
EXAMPLES OF REVISION EXPLANT STUDIES(2005-2010), (UAB)

DEVICE/PROPERTY FACTORS

Study results are separated to include selected examples associated with factors/properties of the Device, Technology and Patient.

Aging/roughness of zirconia ceramic femoral components from THA

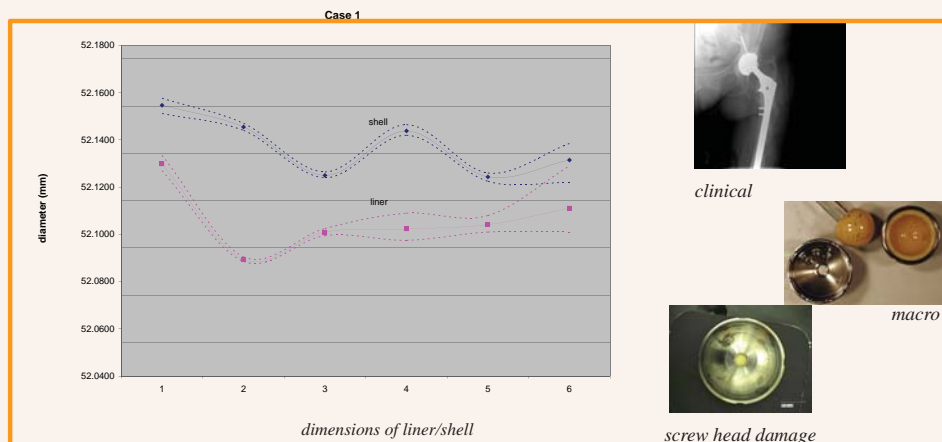
- Revisions: >30
- Implant Time: 1-10 yrs
- Providers (USA): Several
- Etiology: PE Wear > Loosening and Chronic Pain



Atomic alterations at surface (tetragonal to monoclinic).

Ceramic-Ceramic loss of fixation at liner-shell modular connection

- Revisions: 4
- Implant Time: >1 yr
- Provider: Stryker
- Etiology: disassembly



Association with locking design/dimension and/or screw head and distortion

TECHNICAL FACTORS/PROCEDURES

Damage to zirconia on zirconium (metallic substrate) articulating regions of TKA and THA

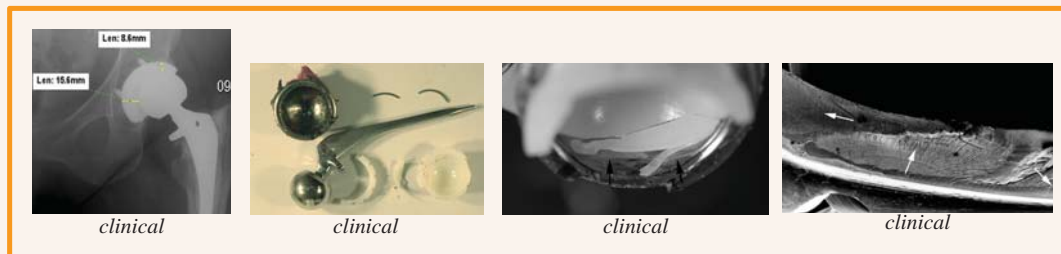
- Revisions: 4
- Implant Time: 1 - 5 yrs
- Provider: Smith and Nephew
- Etiology: PE wear, loosening, chronic pain



Surface damage from instrumentation: altered polyethylene wear phenomena

Disassembly of enhanced cross-linked polyethylene liner in metallic shell for THA

- Revisions: 1
- Implant Time: < 5 yrs
- Provider: Zimmer
- Etiology: disassembly

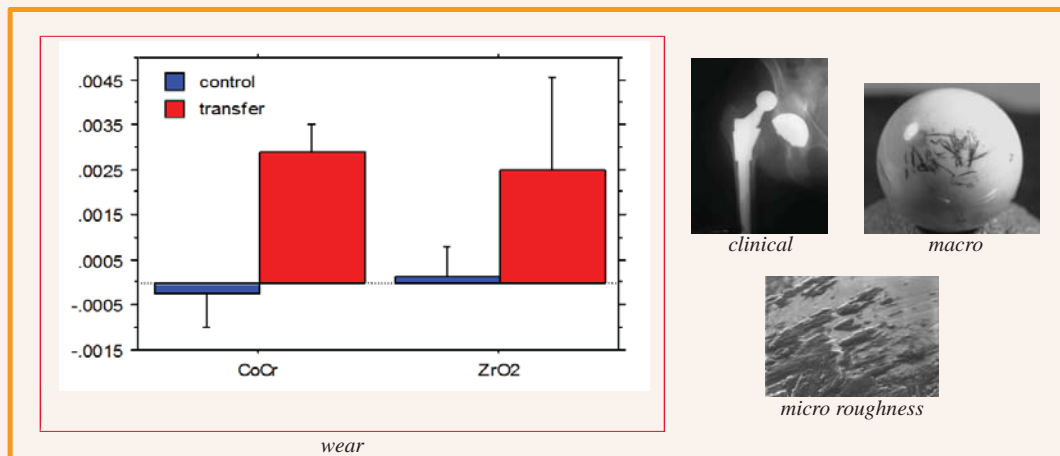


Non-locking of snap ring: minimally invasive procedure

PATIENT FACTORS

Metallic transfers to articulating regions from THA dislocations

- Revisions: >30
- Implant Time: 2 - 10 yrs
- Provider: Several
- Etiology: PE wear, loosening, chronic pain



Dislocation and reduction resulting in contact between femoral head and acetabular shell (or other metallics) leading to material transfer and altered wear phenomena.

WELL FUNCTIONING TKA RETRIEVAL ANALYSIS

InMotion Orthopaedic Research Center, Campbell Clinic Orthopaedics, Memphis, TN

THE RETRIEVAL PROGRAM

- Through the local Medical Education Research Institute (MERI) a cadaveric donation program receives over 600 specimens per year.
- From this set of specimens about 20-25% have a total hip or knee replacement.
- Basic medical history is available on most of these specimens. A total knee replacement analysis protocol has been established to analyze the functionality of the retrieval to better understand the commonalities between well functioning and failed total knee replacements.

CASE REPORT #1:

- A primary total knee replacement specimen was harvested and handled according to ASTM standard F561 - 05a.
- The anatomical and soft tissue stability parameters in flexion and extension were then recorded using a digital caliper.
- The capsular and synovial tissues were then harvested for standard light microscopy with Hematoxylin and Eosin staining to look for signs of inflammation and wear debris.
- The implants were then removed and the polyethylene insert analyzed for polyethylene oxidation and wear utilizing methylene blue staining of the surface for optical evaluation.
- If a PCL retaining implant was harvested the PCL was inspected for integrity and function and then excised.
- The PCL was then prepared for H&E and immunohistochemistry with S100 and neurofilament protein (NFP) to reveal the presence of mechanoreceptors in the ligament.
- The crimp pattern was then evaluated and any poly debris noted.

RESULTS CASE #1

- The PCL was inspected and was grossly intact (Figure 1C).
- The implant was identified as a Howmedica Duracon (East Rutherford, NJ)
- The tibia polyethylene showed evidence of paradoxical motion with wear in the anterior half of the medial surface and this was associated with oxidative changes and delamination (Figure 4).
- From the implant records the shortest functioning time of the implant was 10 years.
- Histology showed that on H&E staining an organized crimp pattern was evident (Figure 2).
- The IHC investigation revealed evidence of stained elements with both S100 protein and NFP. (Figure 3)
- Morphologically, these elements appear to correspond to pacini, lamellar and golgi types of mechanoreceptors (Figure 3A, B).
- There was evidence of innervations to the mechanoreceptors in many cases as well (Figure 3B).

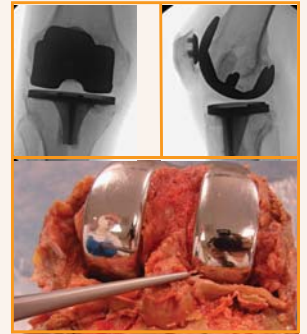


Figure 1: (A-B) Fluoroscopic images of the specimens are first obtained to determine any signs of implant interface lucencies or osteolysis which were not present in this case. (C) The PCL was functional in this case.



Figure 2: H&E staining of the PCL in this case revealed an organized collagen crimp pattern and evidence of polyethylene embedded particles in this case.

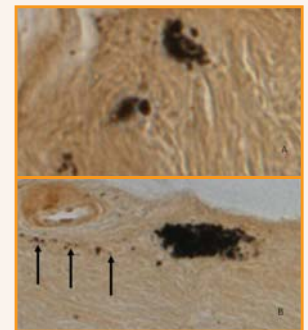


Figure 3: (A) Pacini and golgi type receptors were evident as well as lamellar type (B) when NFP and S100 IHC staining was carried out. Evidence of innervations was also noted (arrows).



Figure 4: Methylene blue allows edge impingement, pitting, and delamination to be recorded for each poly insert. The wear scar is outlined with the black line for analysis of area for each insert as well.

WELL FUNCTIONING TKA RETRIEVAL ANALYSIS

InMotion Orthopaedic Research Center, Campbell Clinic Orthopaedics, Memphis, TN

CASE REPORT #2:

- A primary total knee replacement specimen was harvested and handled according to ASTM standard F561 - 05a.
- According to records the TKA had been in place for over 12 years.
- The anatomical and soft tissue stability parameters in flexion and extension were then recorded using a digital caliper.
- The capsular tissue was harvested and examined according to the same listed procedure for case #1.
- The PCL was again harvested for IHC analysis with S100 and neurofilament protein (NFP) to reveal the presence of mechanoreceptors in the ligament.

RESULTS:

- The implant was identified as an Intermedics natural knee. (Figure 5A and B)
- The PCL was inspected and was grossly intact (Figure 5D).
- The tibia polyethylene showed evidence of paradoxical motion with wear in the anterior half of the medial surface and This was associated with oxidative changes and delamination (Figure 6).
- Histology showed that on H&E staining of the capsule had multiple areas of embedded wear debris from the delaminated segments of polyethylene. (Figure 7).
- The IHC investigation revealed evidence of stained elements with both S100 protein and NFP. (Figure 8)

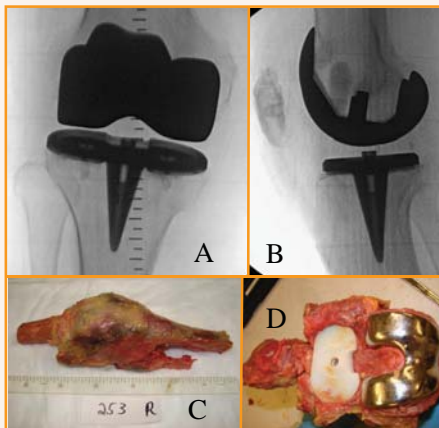


Figure 5: The fluoroscopic images were utilized to identify the implant. No implant interface changes were evident. The specimen removed en bloc (C) was evaluated for soft tissue balancing and then the knee incised for implant removal (D).

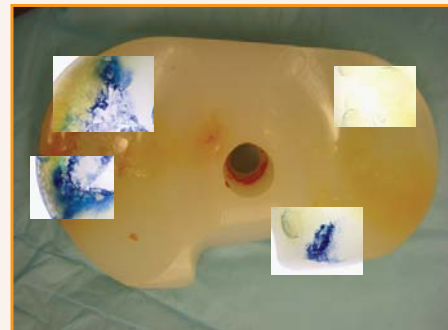


Figure 6: The insert showed significant areas of delamination on the medial side with a large wear scar on the anterior two thirds of the insert.

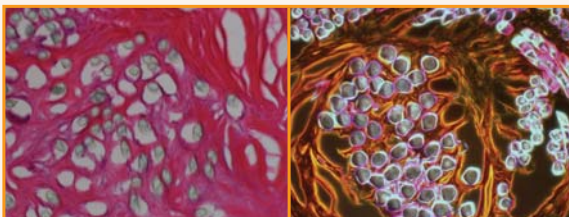


Figure 7: H&E staining of the capsule revealed multiple areas of embedded wear debris.



Figure 8: IHC staining revealed multiple areas of positive staining consistent with different types of mechanoreceptors.

CT Scan Analysis:

- Using CT scans of the retrieval lower extremities a Pro E model can be reconstructed.
- From these models multiple anatomical parameters to aid in the analysis can be recorded including: mechanical axis, rotational alignment of the femoral and tibial implants, and patellar alignment (Figure 9).
- The CT models can then give significant information as to how the surgical parameters may have affected the wear scar of the implant and can also be utilized for computer modeling.

CONCLUSIONS AND FUTURE ANALYSIS:

- Retrieval analysis of these two well functioning TKA has revealed the presence of mechanoreceptors in retained PCLs and has provided information that has not been previously reported.
- Even with the evidence of significant polyethylene wear and evidence of roll forward motion on the medial side of the TKA these specimens had no signs of loosening of the implant interfaces, no osteolysis and outlasted the life of their recipients.
- The next steps in our laboratory are now taking place to analyze the polyethylene inserts as well as the functional kinematics of the specimens to be able to create a three dimensional dynamic model. (Figure 10)
- These steps are being taken to be able to validate a model which will tell us what wear patterns may result from a given set of patient, anatomical and surgical parameters to be able to better predict longevity of the implant on an individual patient basis. (Figure 11)

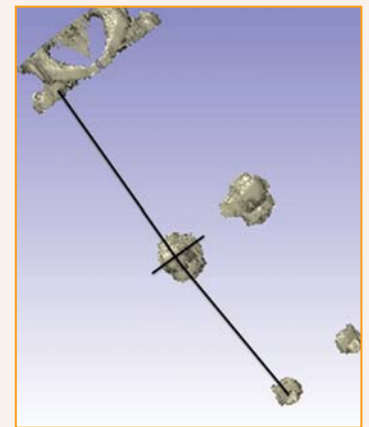


Figure 9: An example of a Pro E model reconstructed from CT scan data to analyze the surgical placement of the implant with respect to the mechanical axes of the femur and tibia as well as analyze placement of the implants in the transverse plane. The data is very useful to input parameters into the computer modeling aspect of the analysis to predict how the total knee functioned.

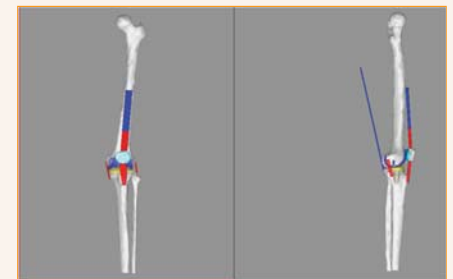


Figure 10: The dynamic model allows for muscle forces and anatomical parameters along with capsule and ligamentous elements to be included.

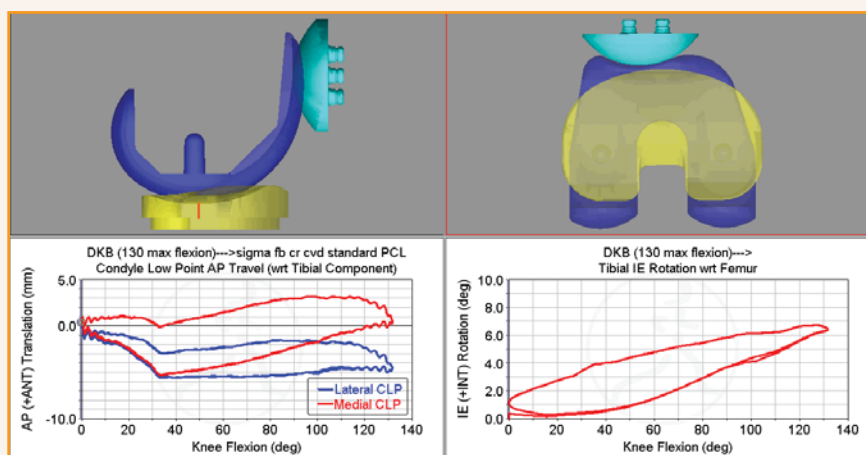


Figure 11: The model can output contact data on the medial and lateral aspects of the insert to compare the wear scar that is predicted with each retrieval specimen to validate the model.

ACKNOWLEDGEMENTS:

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FUTURE DEVICE RETRIEVAL AND ANALYSIS (DRA)

WORKSHOPS/SYMPOSIA: ASTM F04, AAOS-BME, FDA, ORS, SFB

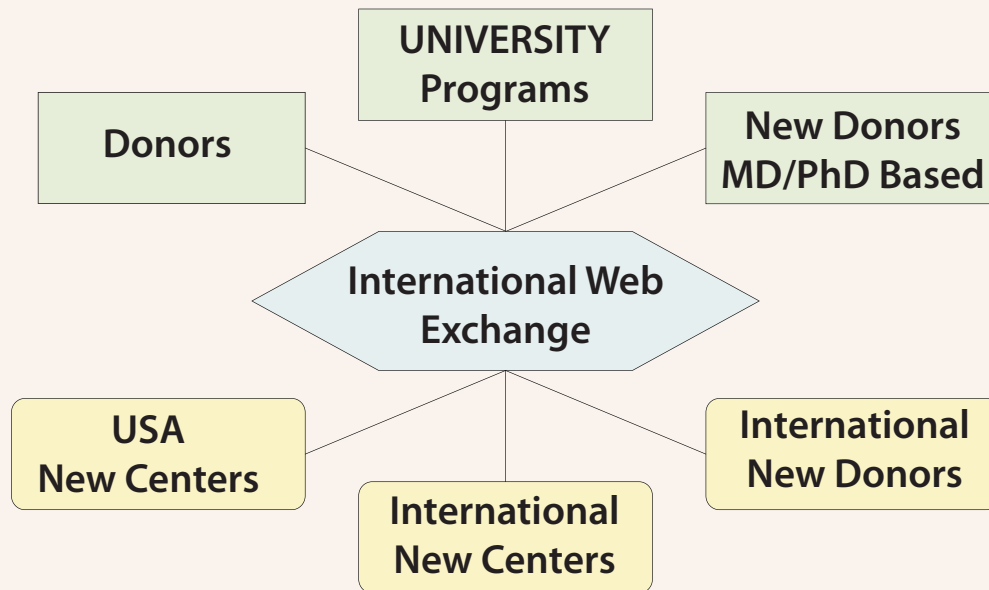
- Symposium on Mobile Bearing Total Knee (MBK) Replacement Devices, May, 2010.
- Current Status and Future Directions for Biologic and Synthetic Bone Grafts, May, 2010.
- Static and Dynamic Spinal Implants: Are We Evaluating Them Appropriately? 2010.
- Imaging, Modeling, and Measurement for Tissue Engineered Scaffolds and Growing Cartilage, May, 2011.

COLLABORATIVE/INTERACTIVE PROGRAMS

- Centers of Excellence Specific to Device Retrieval and Analysis (~10x)
- Orthopaedic Device Registries (In Progress)
- Organ/Tissue/Device Donor Programs
- Comparison of Retrieval Explant (Failure) versus Post Mortem En bloc (Success)

INFORMATION EXCHANGE: NATIONAL/INTERNATIONAL

- Move to a Controlled Internet Based System including TJA Registry



PLAN

- Proactive Exchanges at Consensus-Type Workshops/Symposia to include all Stakeholders Leading to Peer Review and Appropriate/Rapid Actions, as Indicated
- May 18-21: ASTM F04 May Committee Week, St. Louis, MO
- November 16-19: ASTM F04 November Committee Week, San Antonio, TX

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