RETRIEVAL AND ANALYSIS OF DEVICES: A NEW APPROACH

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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

Fracture and wear of PMMA and PTFE
Constrained THA designs
Wear and Fracture of Ceramics

70-80’s
Wear of PE-C composite articulation
Heat pressed and restructured PE articulars
Gamma Irradiated and Oxidized PE

50-60’s

90-00’s
Microstructure and residue in porous surfaces
Fretting of Morse taper modular connections
Modular component locking designs

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

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

References, University of Alabama at Birmingham (UAB)
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

![Graph showing 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

![Graph showing dimensions of liner/shell, screw head damage, and clinical images.]

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

Disassembly of enhanced cross-linked polyethylene liner in metallic shell for THA
- Revisions: 1
- Implant Time: < 5 yrs
- Provider: Zimmer
- Etiology: disassembly

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
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).
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)
**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)

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FUTURE
DEVICE RETRIEVAL AND ANALYSIS (DRA)

WORKSHOPS/SYMPOSIA: ASTM F04, AAOS-BME, FDA, ORS, SFB
- Current Status and Future Directions for Biologic and Synthetic Bone Grafts, May, 2010.
- Static and Dynamic Spinal Implants: Are We Evaluating Them Appropriately? 2010.

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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