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CASE SCHOOL OF ENGINEERING

The Role of Retrieval Analysis in Validation of New Polyethylenes

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NIAMS
National Institute of Arthritis and Musculoskeletal and Skin Diseases

"…The National Arthritis Data Working Group estimates that 21 percent of adults have arthritis in at least one joint, a figure that is likely to grow as the population ages."

- NIAMS Long-Range Plan 2010-2014

NIAMS

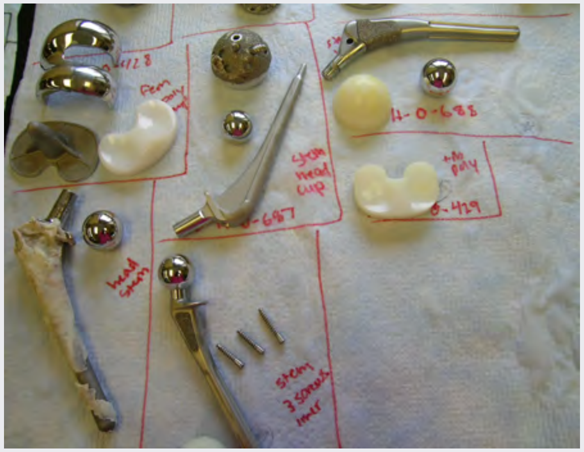
National Institute of Arthritis and Musculoskeletal and Skin Diseases

http://www.niams.nih.gov

TJR in the U.S.

> 600,000 primary total hip and total knee replacement surgeries in the U.S. per year – projected to increase to > 4 million by 2030

Revision surgeries 5-20%



Kurtz et al., JBJS (Am), 2007 and 2005
Paxton et al., The Permanente Journal, 2008

NIAMS Long Range Plan
Cross-cutting - Infrastructure

"Characterize resources and information and increase their availability and utilization by investigators; network existing registries and repositories and link them to data sets."

National Institute of Arthritis and Musculoskeletal and Skin Diseases

http://www.niams.nih.gov

The Kaiser Permanente National Total Joint Replacement Registry (estab. 2001)

Goals:

1) to monitor revision, failure, and rates of key complications (eg, infection, venous thromboembolic disease…, and mortality)
2) to identify patients at risk for poor clinical outcomes following TJA
3) to identify the most effective techniques and implant devices…
4) to track implant usage and costs
5) to monitor and to support implant recalls and advisories …with the FDA.

Paxton et al., The Permanente Journal, 2008

AJRR American Joint Replacement Registry

(trial kickoff 2010)

Mission Statement

Foster a national center for data collection and research on total hip and knee replacement with far-reaching benefits to society including reduced morbidity and mortality, improved patient safety, improved quality of care and medical decision-making, reduced medical spending, and advances in orthopaedic science and bioengineering.

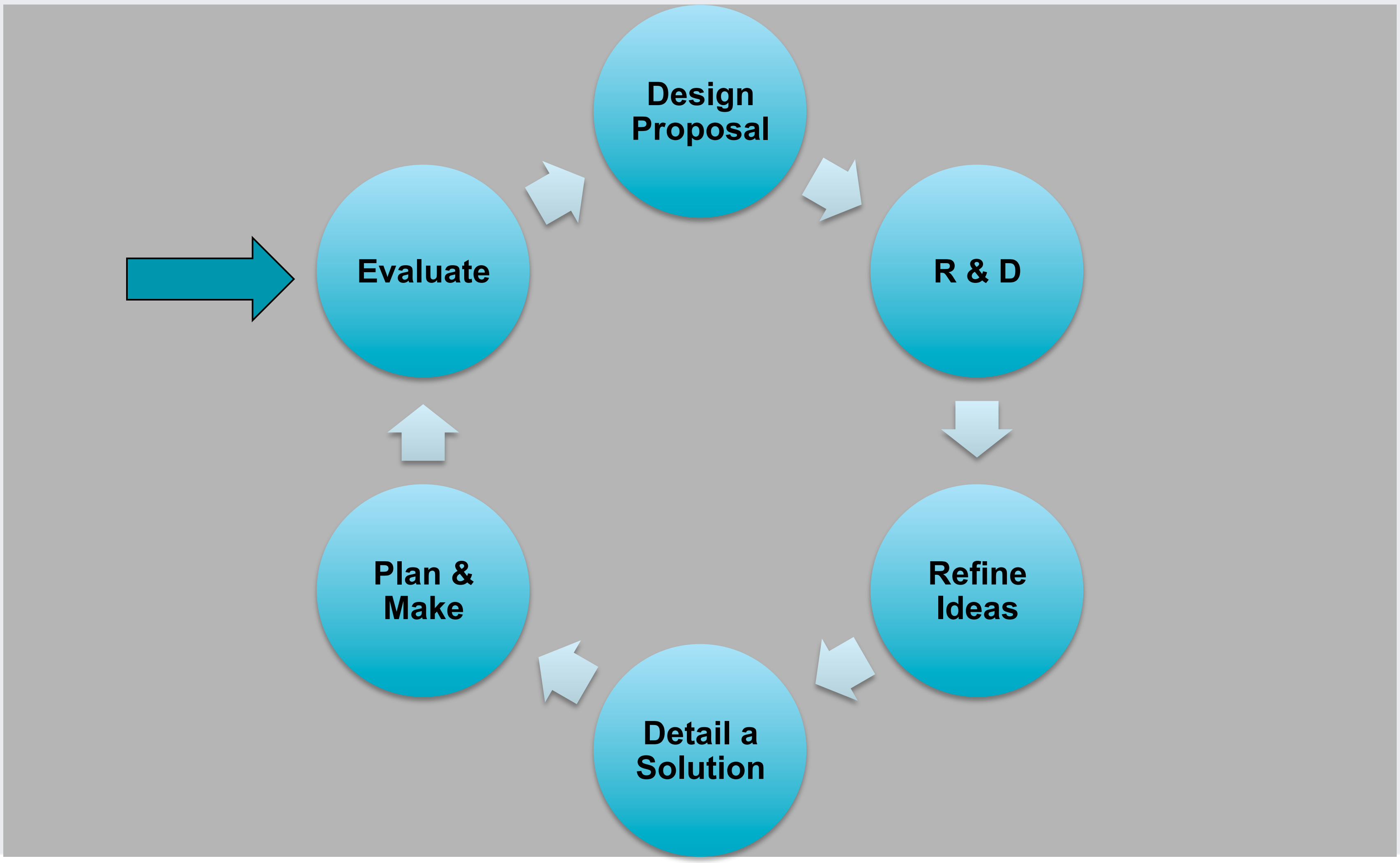
http://orthodoc.aaos.org/ajrr/

Point-of-Care Based Registries

Analysis of point-of-care repository data can provide important information on *what* is occurring, but may to tell us *why*

The value of implant retrieval analysis

Implant retrieval analysis closes the Design Loop



Elements of design

An iterative decision-making process:

- Creation & optimization of a new or improved engineering system that is desired or needed
- Occurs in the context of conservation of resources and with awareness of environmental impact

Responsibility of the designer

- Ensure that the design functions as intended for the prescribed lifetime and that the design is competitive in the marketplace

- Understand how to analyze and predict failure to prevent failure

Design objectives

- Parts must transmit required forces & perform required motions and function w/o interference of function of other parts

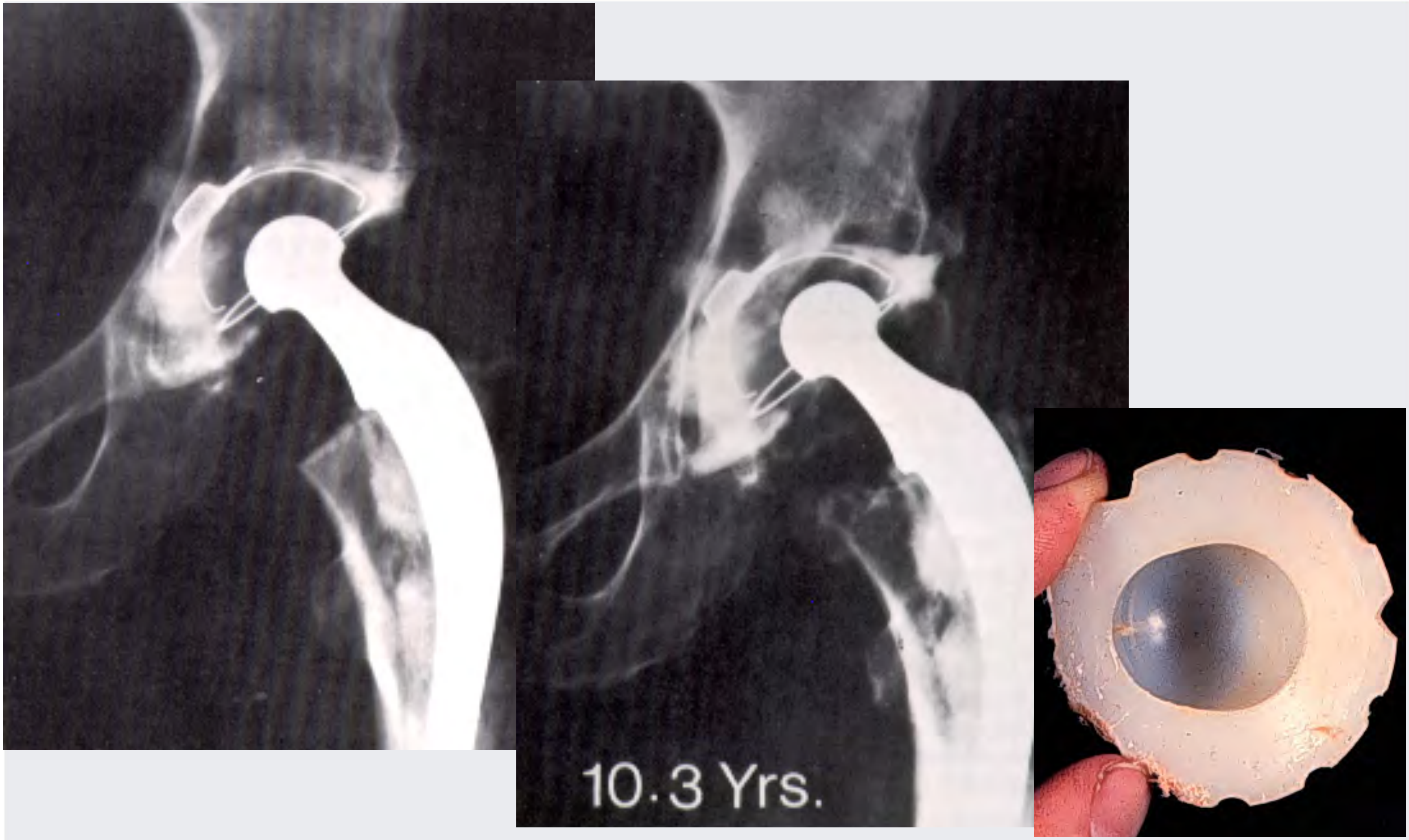
- Weight and space of part within application guidelines

- No failure before operating life span

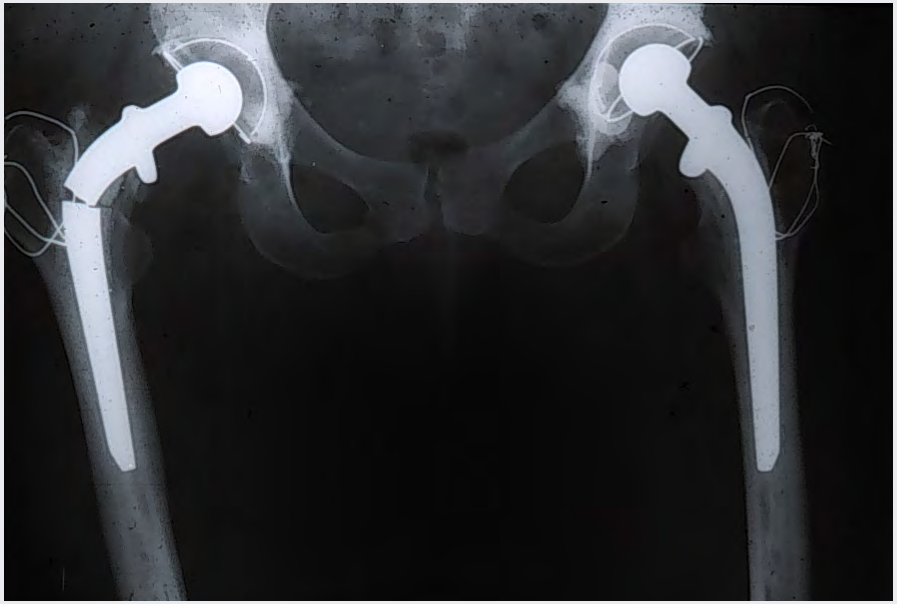
- Possible to inspect critical parts in assembly for detection & correction; possible to service & maintain parts

- Safe and efficacious while also competitive & profitable!

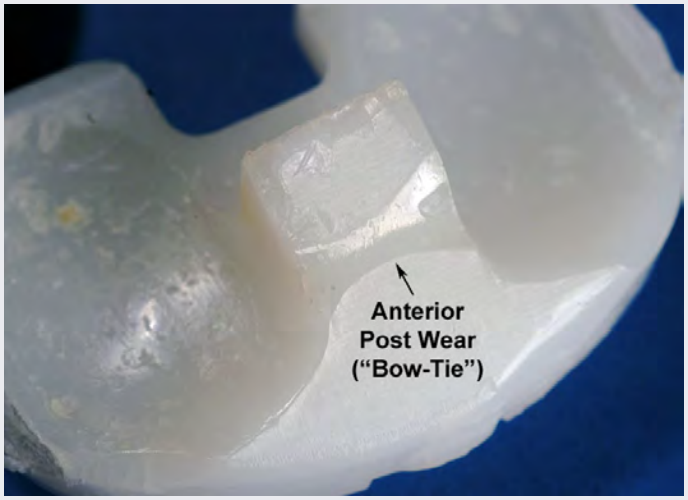
Acetabular liner wear can be monitored in vivo

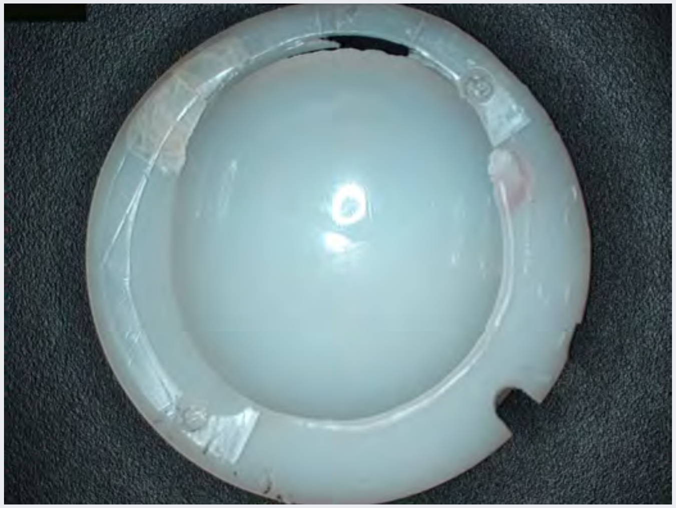


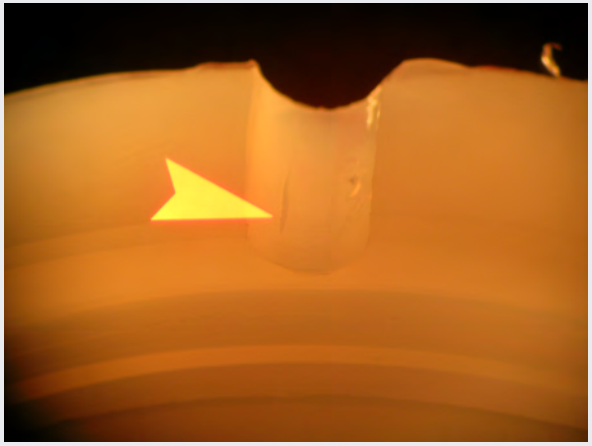
But in vivo inspection can also be a challenge!



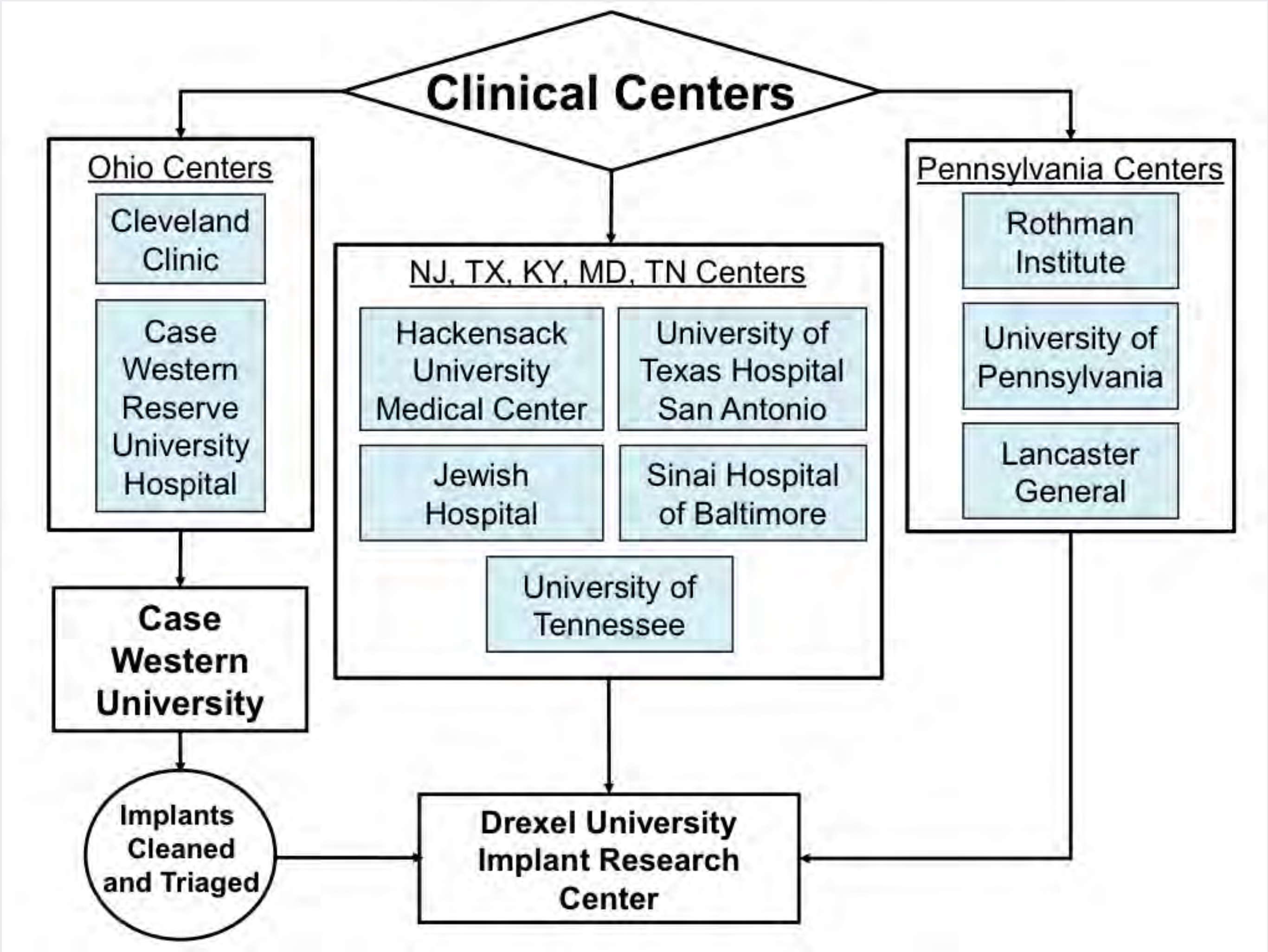
UHMWPE implant retrieval







Polyethylene Implant and Tissue Repository
Steve Kurtz, P.I., NIH-supported, 2000-



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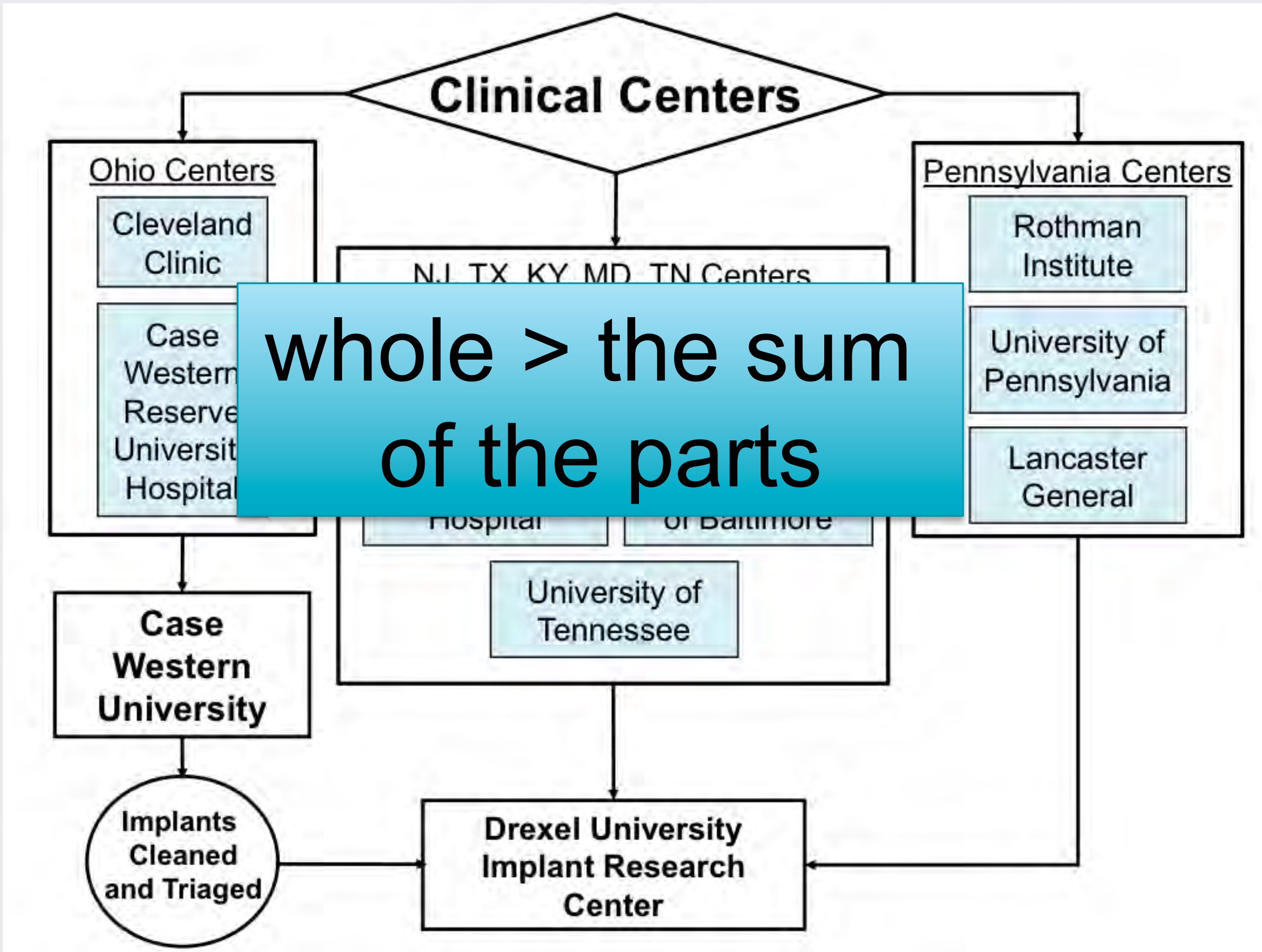


General approach

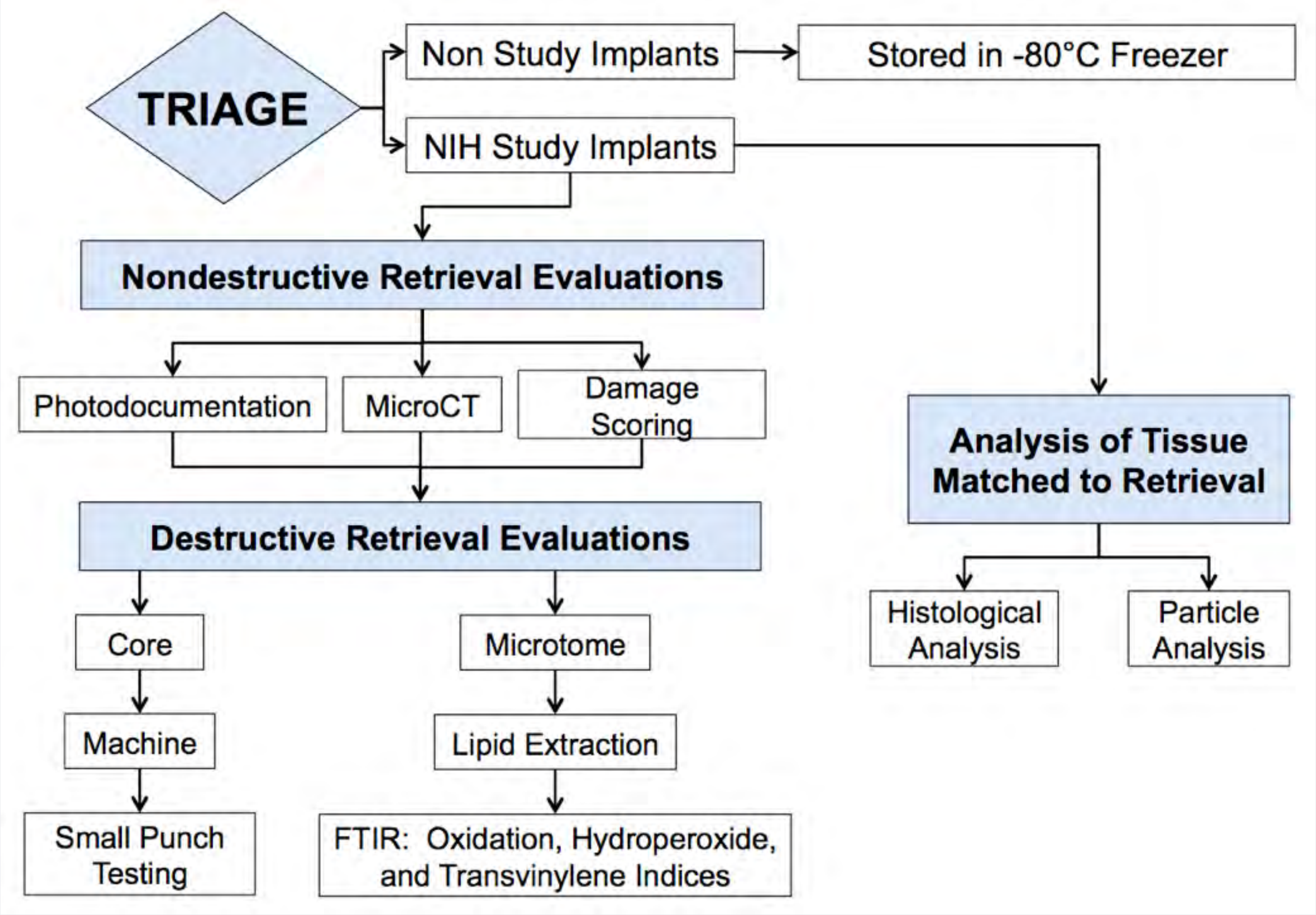
- Hypothesis-driven research
- Document in vivo implant performance (via implant retrieval analysis, periprosthetic tissue analysis, clinical and radiographic information
- Identify contributions of material selection and structural design in the context of in vivo functional demands (materials characterization; physical, chemical, mechanical)
- Evaluate impact on clinical performance

The need for UHMWPE component implant retrieval analysis

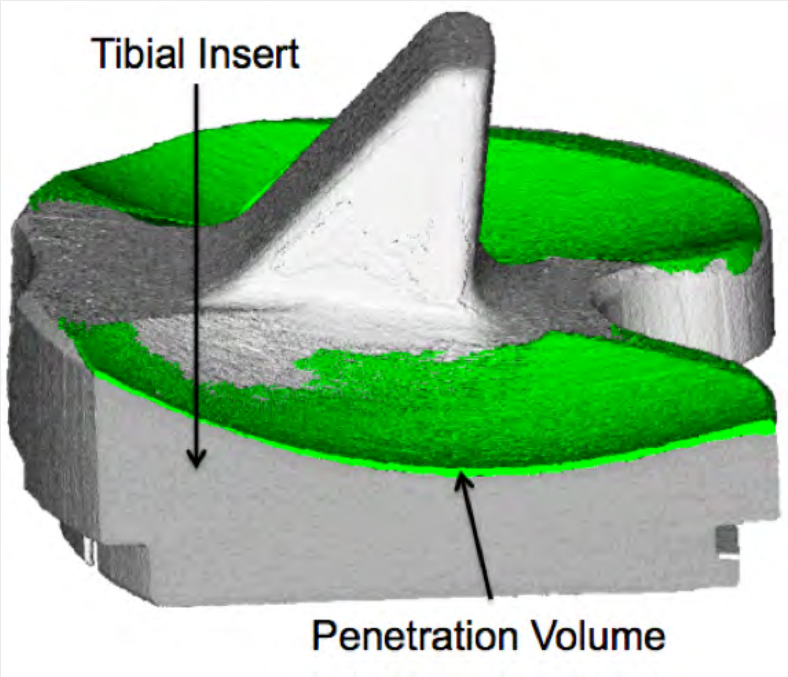
Implant retrieval analysis is a major tool in understanding the natural history of UHMWPE THR component behavior

It is the *primary* tool for UHMWPE TKR component behavior

Polyethylene Implant and Tissue Registry - Flow of analyses



MicroCT



MicroCT – can provide analysis of wear and creep from retrievals; particularly useful for UHMWPE TKR components where radiographic assessment of wear is poor

Four generations of UHMWPE

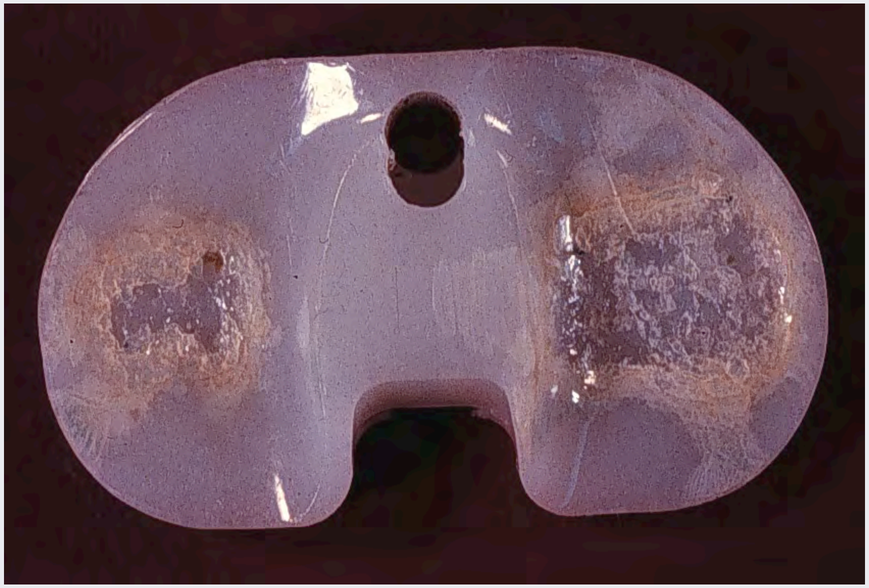
- Historical
- Conventional contemporary
- 1st generation crosslinked
- 2nd generation crosslinked

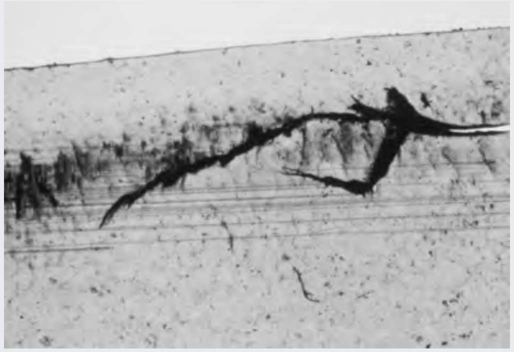
Four generations of UHMWPE

- Historical ←
- Conventional contemporary
- 1st generation crosslinked
- 2nd generation crosslinked

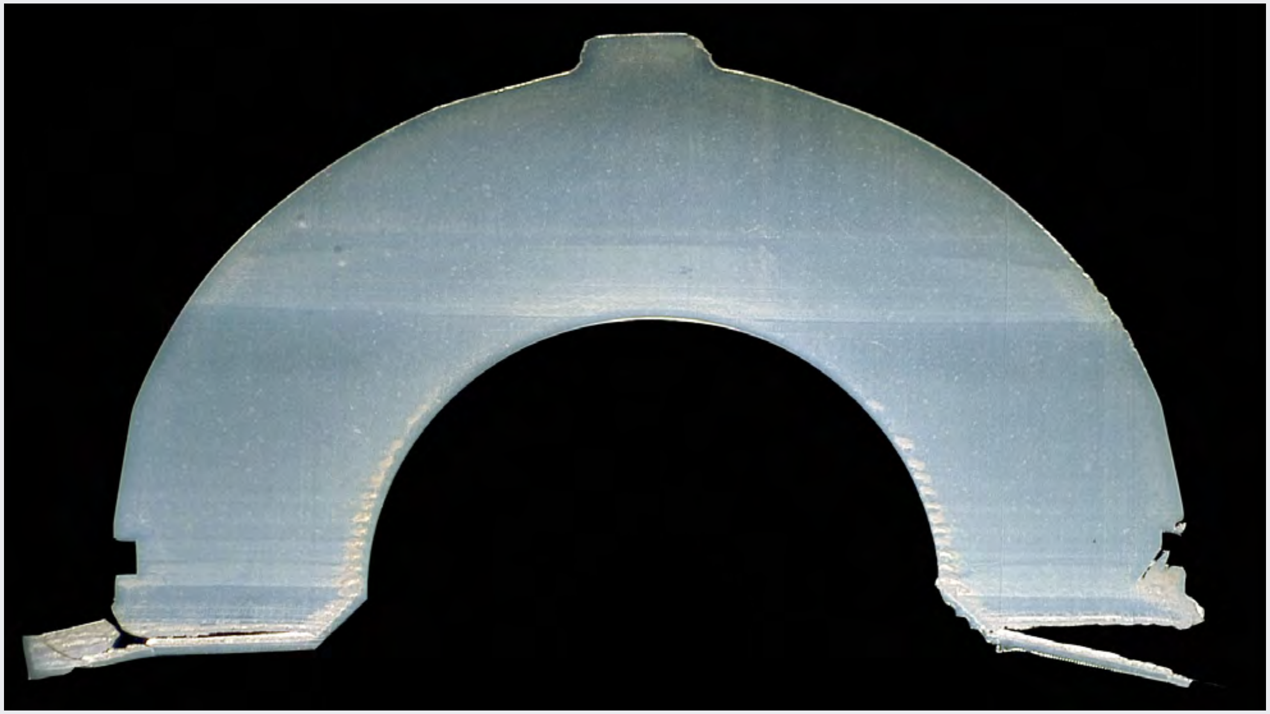
Challenges:
- Wear resistance
- Oxidation
  (in vitro and in vivo)
- Loss of fracture resistance with oxidative aging

Subsurface oxidation drives delamination of historical generation UHMWPE components

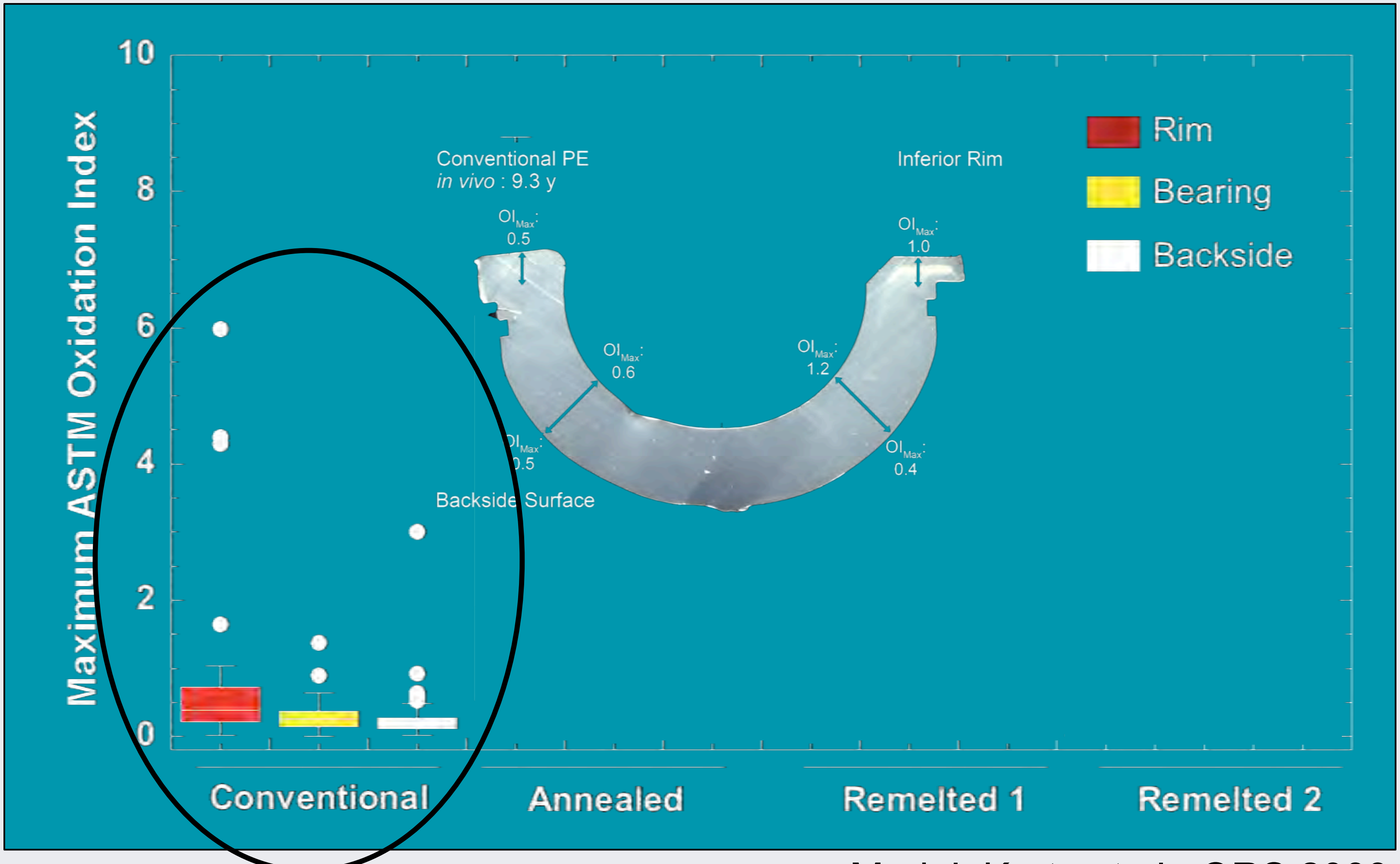




In vivo oxidation occurs even when shelf aging is limited and it is regional

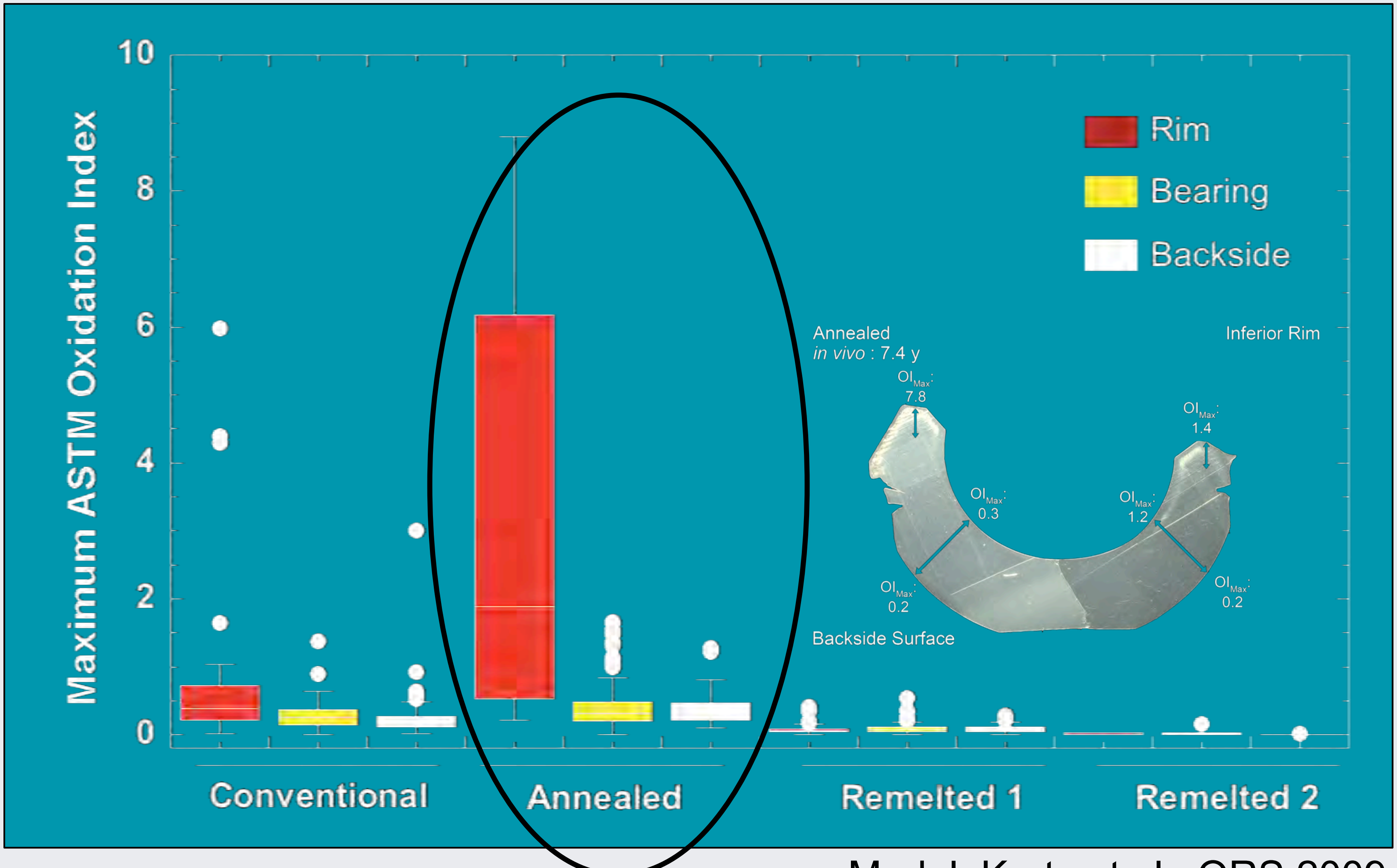


In vivo oxidation occurs even when shelf aging is suppressed and it is regional



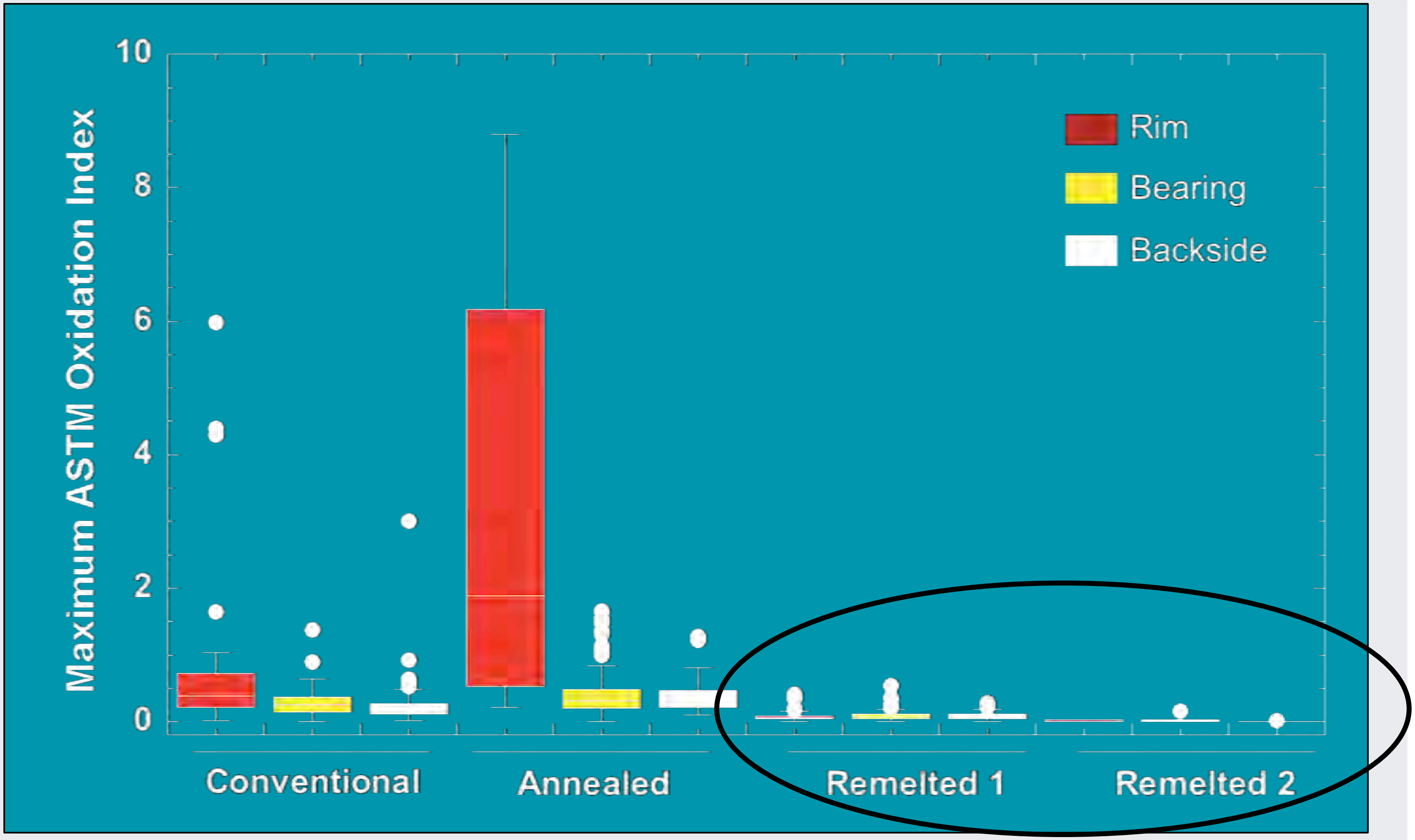
Medel, Kurtz et al., ORS 2009

In vivo oxidation of annealed 1st generation crosslinked UHMWPE occurs and is regional



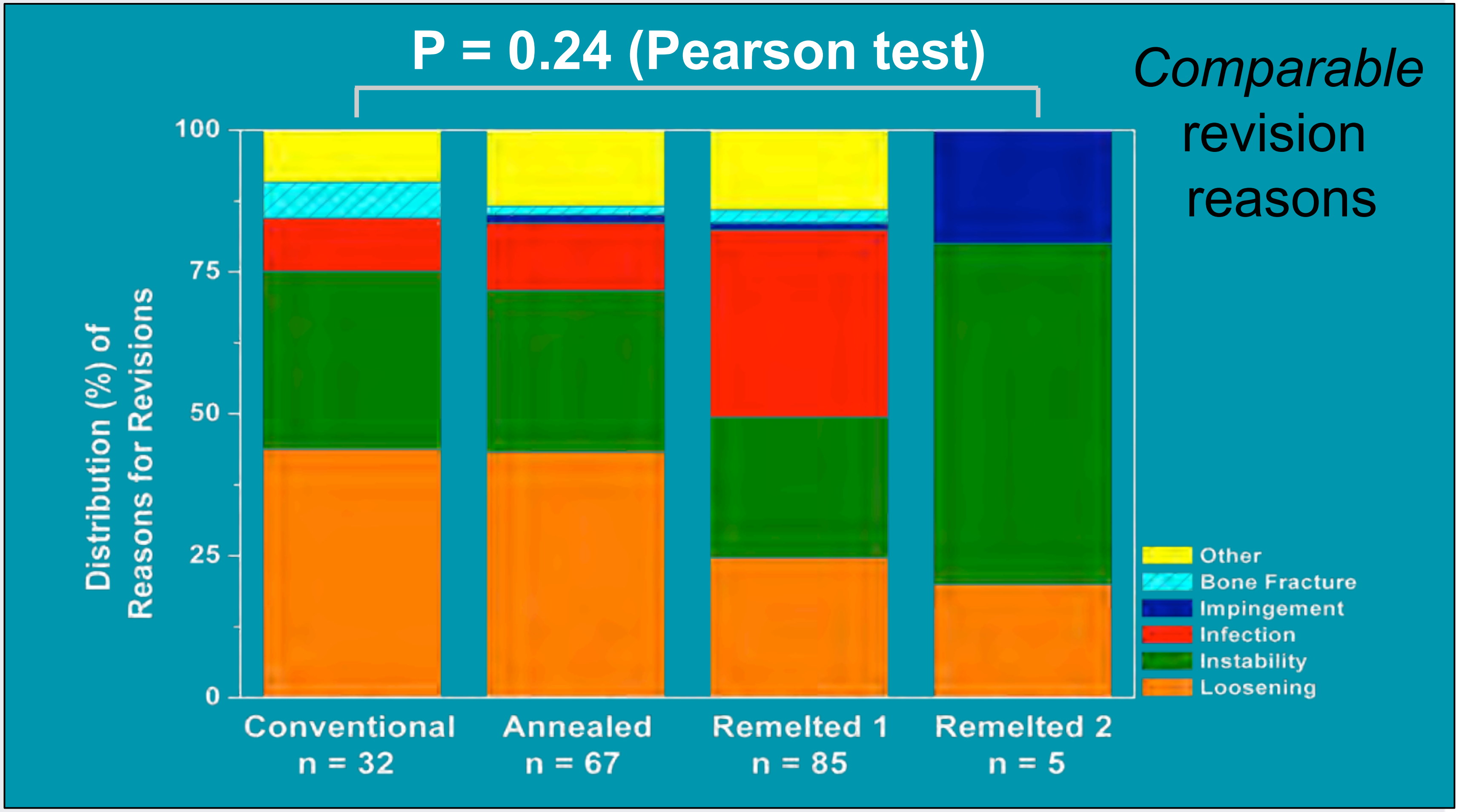
Medel, Kurtz et al., ORS 2009

In vivo oxidation of remelted 1st generation crosslinked UHMWPE is low



Medel, Kurtz et al., ORS 2009

Reasons for revision of 1st generation crosslinked vs. conventional UHMWPE cups



Medel, Kurtz, et al., ORS, 2009

Historical vs. Contemporary Conventional and 1st Generation Crosslinked UHMWPE

Improved wear resistance

Improved resistance to shelf aging

But -

Potential for in vivo oxidation exists for Contemporary Conventional and 1st Generation Crosslinked UHMWPEs

2nd generation crosslinked UHMWPEs

Wear resistance

Oxidation resistance

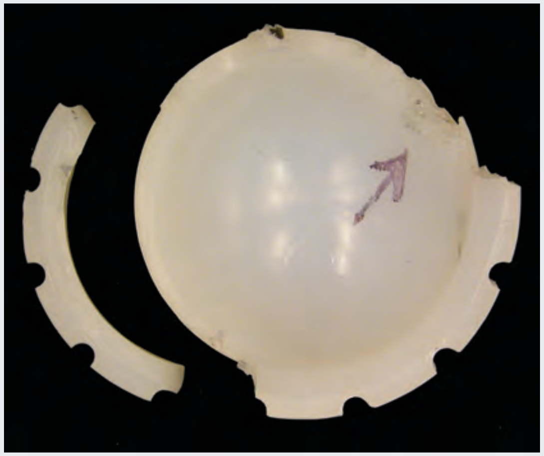
Fracture resistance

Goals:

- Maintain or improve wear resistance vs. 1st generation
- Further reduce or eliminate free radicals to eliminate in vivo oxidation
- Provide better mechanical properties (fracture resistance) vs. 1st generation

The challenge for improving fracture resistance

- A modification that improves a material’s wear resistance generally reduces the ductility of the material; the material is more brittle and less resistant to fracture (both static and cyclic)
- Fractures emanating from design-related stress concentrations have occurred in highly crosslinked UHMWPE acetabular components



Bradford et al., JBJS 2004
Tower et al., JBJS 2007
Furmanski et al., AAOS 2008

2nd generation crosslinked UHMWPEs

1) Sequentially-annealed UHMWPE
   X3™ - Stryker Orthopaedics, ca. 2005

2) Alpha-tocopherol (vitamin E) UHMWPE
   E Poly™ HXLPE – Biomet, ca. 2007

3) Other antioxidant strategies…e.g.,
   Hindered phenol antioxidants – DePuy
   (in development)

2nd generation crosslinked UHMWPEs

1) Sequentially-annealed UHMWPE

Short history to-date

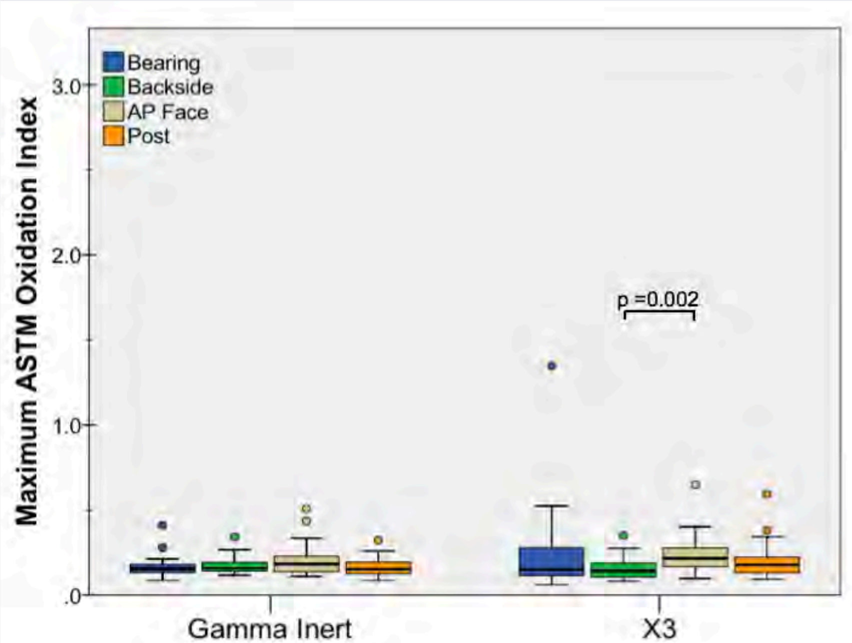
Still important to evaluate in vivo wear, in vivo fractures, and biological response to debris and now, possibly, additives

Hindered phenol antioxidants – DePuy (in development)

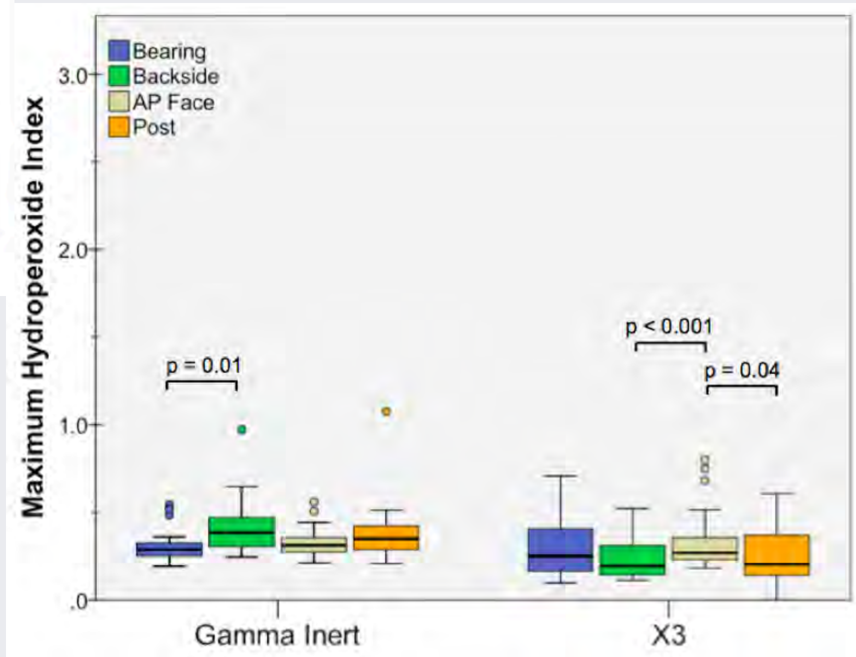
Why continue UHMWPE implant retrieval analyses?

- We have some knowledge of short- and intermediate-term performance of 1st generation crosslinked UHMWPE components in THR; but little knowledge of TKR performance
- We have no knowledge of long-term performance of 1st generation crosslinked UHMWPE components, in THR or TKR
- We have little/no knowledge of the performance of 2nd generation crosslinked UHMWPE components, particularly in TKR, for *any* time period

Retrieved X3 knee components demonstrate (low) oxidation and oxidation potential



Implantation time
≤ 3.25 years



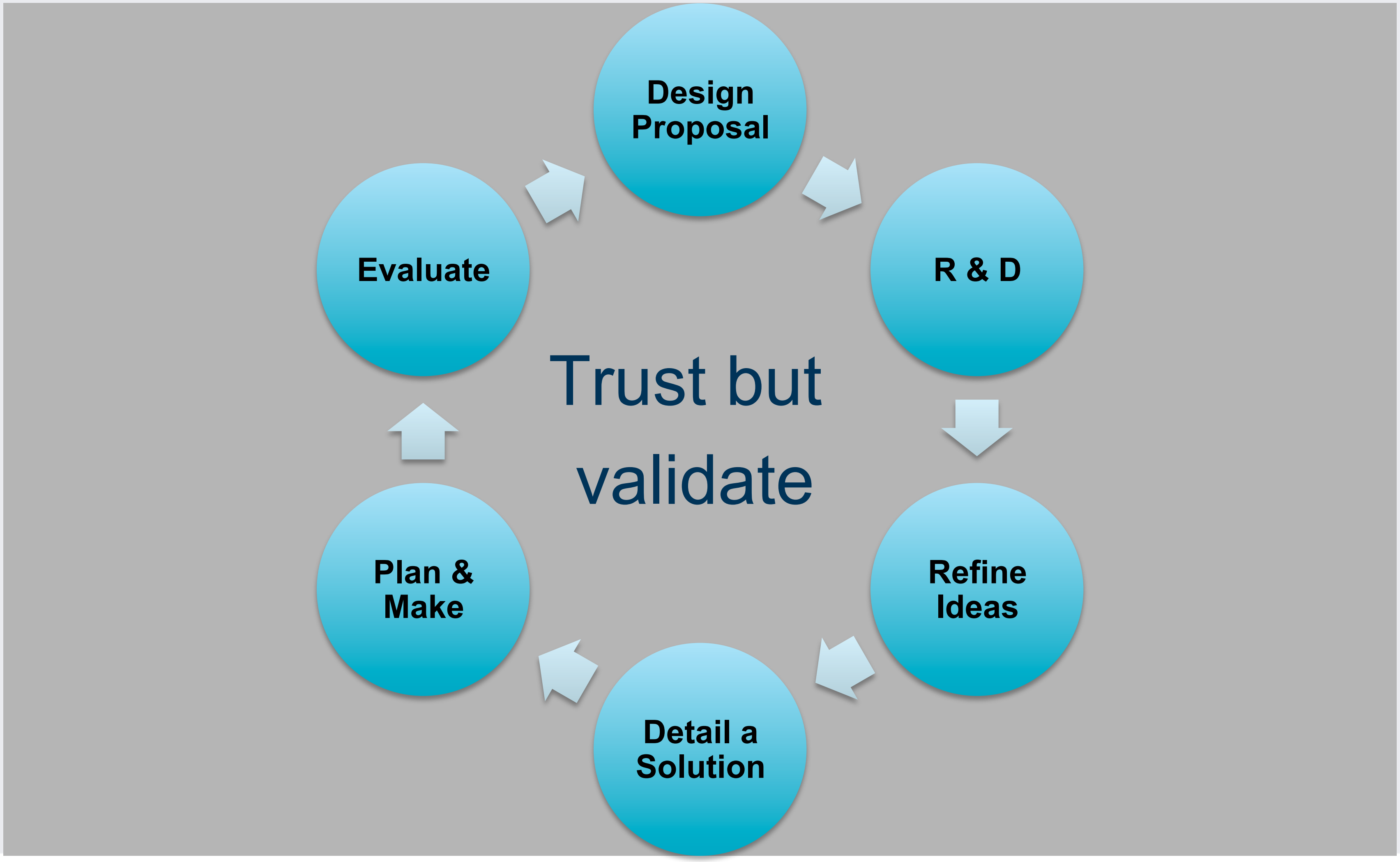
Summary

- Implant retrieval analysis has been a valuable approach that has helped to understand the “why” behind performance of UHMWPE components
- Modifications in material formulation, sterilization methods, and approaches to wear-improvement have occurred as a consequence

Questions

- To validate new UHMWPEs, are the current retrieval analysis “tools” sufficient?
- Are there additional analyses relevant to 2nd generation crosslinked UHMWPEs that we should be also be conducting?

The value of implant retrieval analysis



Thank You

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