Modularity in orthopaedic device for total hip and total knee replacements allow for enhanced pre-operative planning and intraoperative adjustment

**Total Knee Replacement**
- Adjustment of polyethylene thickness and degree of constraint
- The use of the femoral and tibial stems of different lengths
- The addition of different inserts such as blocks, wedges, and other devices in order to restore the level of the joint line and customize the revision associated with lost bone stock

**Total Hip Replacement**
- Flexibility with bearing couple choices
- Ability to use acetabular liners with hoods and different levels of constraint
- Optimization of femoral fit and fill of the body and stem portion of a primary or revision stem separately
- More options to restore femoral head size, length and offset
- Intra-operative alterations of the above parameters depending on stability testing during ROM
HISTORY OF MODULAR JOINT ARTHROPLASTY TAPER CONNECTIONS: A PERSPECTIVE FROM DEVICE RETRIEVAL & ANALYSIS

Considerations – Decades of experience exist from Device Retrieval and Analysis where concerns have focused on stabilities of overall device construct, articulating surfaces, and fixation to tissue – with some concerns continuing today.

Factors – Opportunity for selection of biomaterials and biomechanics of device designs and to better understand relationships to longer-term clinical function (decades) through an approach for assessment of overall benefit vs. risk through consensus based on peer-reviewed information supporting Quality of Life Years including relative costs of device systems and treatments

1960 – 2000

Modular Total Joint Arthroplasty (TJA with taper connections included metallics (Fe, Co, Ti, Zr, Ta alloys), (UHMWPE, PMMA polymeric), (Al₂O₃, ZrO₂ ceramics), and combinations and composites of these biomaterials.

Benefits of taper connections – Selection and exchange of component parts and biomaterials to optimize procedures and outcomes considering size and geometry of constructs with flexibility related to patient anatomy, function and revision situation where components became controlled by Computer Assisted Design and Manufacturing (CAD/CAM).

Risks of taper connections – Fretting was experienced at some device taper interfaces leading to corrosion and debris and factors included alignment and distortions of components where damaged tapers limited options at assembly and revision – General consensus existed by 2000 that Co/Ti/Al₂O₃/ZrO₂ combinations without damage and fretting could provide longer-term taper stability, however damage and fretting resulted in debris and corrosion where some aspects could be mitigated by taper interface surface modifications.

>2000

Benefits of taper connections – Systems available combining Ti-Ti, Co-Co, Ti-Co, ZrO₂, or Al₂O₃-Ti, Co, Fe, or Zr with some alloy – UHMWPE connections. General acceptance existed for taper connections with considerable evidence supporting in vivo stabilities of most taper connections.

Risks of taper connections – Introductions of larger diameter articulations (>36mm components) to increase range of motion and decrease subluxation/dislocations of THA with hard-hard articulations [primarily Metal-on-Metal] for more youthful, active and obese patient populations has resulted in evidence and concerns related to debris products influencing in vivo device and treatment stabilities with decision made from data based on international registries of THA applications and revisions.

A new focus of research, development, and testing of taper connections is in-progress, in part within Standards Development Organizations.
Introduction: Mechanically assisted crevice corrosion (MACC) or fretting crevice corrosion is the principle mechanism by which modular taper junctions are corroded in vivo\textsuperscript{1,2}. This mechanism, described in the literature for over 20 years, is a complex, multifactorial set of interacting processes that includes biomaterial surfaces and surface mechanics, electrochemistry, and biological interactions. Modular tapers, regardless of material combination, geometry, location or component have exhibited MACC in vivo\textsuperscript{1,2}. The elements of MACC can be studied at the basic science level as well as at the device or component level. This scientific exhibit will provide some of the latest insights into the science behind modular taper corrosion and will explore the complex interplay between the factors involved.

**Mechanically Assisted Crevice Corrosion**

Complex Interactions: Taper corrosion starts with fluid ingress into the taper crevice and mechanical loading across asperity-asperity contacts. Both bulk and surface mechanics affect relative loading and movement. Flexural rigidity (EI) and elastic displacements affect abrasion of oxide films which repassivate rapidly but corrode as well. Oxidation liberates electrons in the metal which causes voltages to become more negative. Oxygen is depleted, pH goes down and [Cl\textsuperscript{−}] increases in the crevice. Voltage drops and solution changes decrease oxide stability.

**Fretting Corrosion Causes Voltage Drops**

**Bulk and Surface Mechanics**

**Electrochemistry:**

The electrochemical reactions involved in fretting corrosion include:

\[ \text{M} + \text{H}_2\text{O} \rightarrow \text{MO} + 2\text{H}^+ + 2\text{e}^- \]

**Tribocorrosion:**

Abrasion and oxidation play a significant role in tribocorrosion, where oxidation and wear occur simultaneously. This can be represented by:

\[ \text{M} \rightarrow \text{M}^+ + n\text{e}^- \]

**Materials Surface Structure and Chemistry**

**Electrical Impedance and Transport Phenomena**

**Mechanically Assisted Crevice**

**Solution Chemistry**

**Surface Mechanics**

**Electrochemistry: Voltage and Currents**

**Biological Interactions**

**Modular Taper**

**Elastically Based Fretting Motion**

**Rigidity = EI**

**Friction**

**Normal Force**

**Gilbert and Mali\textsuperscript{3}, Degradation of Implant Materials, Springer Science 2012**

Liu et al\textsuperscript{4}, Trans Soc for Biomat, Boston, MA, 2013
Fretting Corrosion: Basic Science Tests

Fretting Corrosion Basics: Fretting Regimes and Corrosion Currents: The instrumented POD test captures the three fretting corrosion regimes: 1. Slip (low normal stress, full sliding), 2. Stick-Slip (intermediate stress, partial sliding), 3. Stick (high stress, no sliding). Fretting work (area under sliding) stress, the force 3. Stick (high stress, no sliding). Fretting work (area under sliding), stress, the force...Corrosion many of the fundamental relationships present in fretting crevice corrosion can be explored and understood. Corrosion currents generated5,6. The normal load (stress) and voltage on the fretting couples was performed to look at the effect of mixed (Ti-CoCr) and similar (Ti-Ti or CoCr-CoCr) couples was performed to look at the effect of normal load (stress) and voltage on the fretting corrosion currents generated5,6. Ti-Ti couples have the highest COF, highest fretting currents and lowest sticking stresses. CoCr-CoCr couples show lower fretting currents and high sticking stresses (they continue to slide at high normal loads), and Ti-CoCr show the lowest fretting currents and intermediate sticking stresses. COF for Ti-Ti was double that of Ti-CoCr or CoCr-CoCr.

Voltage Effects and a Lack of Galvanic Corrosion Interactions: Polarization plots (Voltage vs Log Current Density) for POD tests of combinations of Ti-6Al-4V and CoCrMo show up to three orders of magnitude increases in currents densities during fretting corrosion. Baseline and fretting currents show no affect of galvanic coupling of Ti-6Al-4V with CoCrMo. The voltage ranges where fretting currents are detected are different for Ti-Ti couples than CoCr-CoCr couples (Ti fretting corrosion is evident to ~1 V vs Ag/AgCl). Ti-CoCr couples behave like CoCr-CoCr couples with voltage and show no fretting currents below ~0.5 V. Again, no galvanic effects are evident. Mixing Ti with CoCr does NOT result in galvanic effects but does alter the mechanics (COF and sticking interactions).

Modular Taper Corrosion: Implant Performance Tests

Combined Motion and Fretting Corrosion Current Monitoring of Implant Taper Assemblies: Recent efforts at combining fretting corrosion test methods7 with micromotion measurements have been undertaken. Simple combined analysis of loading, micromotion and corrosion can be captured together. These methods allow for assessment of the relationships between design, seating and materials on the motion and corrosion processes.
MODULAR TAPER CORROSION: IMPLANT PERFORMANCE TESTS

Recent Clinical Examples of Corrosion of Modular Tapers

MACC in Modern Taper Connections: Taper corrosion occurs in all material combinations in which metal is present in one-half of the junction. This includes CoCr-CoCr and CoCr-ceramic taper junctions, Ti-Ti junctions and all other combinations.

Fretting Corrosion Damage in CoCr-CoCr Tapers

Ti-6Al-4V/Ti-6Al-4V tapers can exhibit severe corrosion resulting in deep pitting and stress corrosion cracking. The altered crevice environment can become so severe that penetrating pitting, hydrogen embrittlement and stress corrosion cracking can develop.

MACC: Biological Affects and Effects

The biological environment adds more complexity. Corrosion may influence the biological state and the biological state may affect the corrosion. When MACC occurs, the voltage of the surface drops. If the drop is below -400 mV (vs Ag/AgCl), cell death can occur in vitro. Cell death is by apoptosis with negative voltage and is driven not by ions and particles, but by reduction reactions.

Inflammatory Cells Directly Corrode CoCrMo Alloy In-vivo:

Recent retrieval analyses of CoCrMo implant components show evidence of direct inflammatory cell corrosion. Corrosion attack of retrieved CoCrMo implant non-bearing surfaces show cell-derived patterns of corrosion reflective of ruffled-border patterns and other cell-derived morphology. These corrosion features have been identified on CoCrMo surfaces in MOP and MOM implants in hips and knees. Inflammatory cells (phagocytes) appear to use reactive oxygen species and Fenton reactions to attack the foreign body. These solution-based chemical species include hydrogen peroxide.

Hydrogen Peroxide Significantly Increases Corrosion of CoCrMo

Recent work has shown that when low concentrations of hydrogen peroxide are added to phosphate buffered saline in vitro, CoCrMo alloy corrosion potential becomes much more positive and the corrosion rate increases significantly based on impedance and polarization tests. These results, when taken together, show that CoCrMo corrosion rate is sensitive to a reactive oxygen species known to be part of the inflammatory cell (phagocyte) system. Evidence of direct cell attack from retrieved CoCrMo surfaces further confirms the susceptibility of CoCrMo implant surfaces to direct attack from the inflammatory system.

Conclusions

The Science of modular taper corrosion is complex, multifactorial and highly sensitive to multiple factors that include material combination, taper design, mechanics of the surfaces and the biological interactions of the body environment with the materials. Galvanism is not a significant factor in the corrosion of couples, but the mechanical and electrochemical properties of these oxide film covered alloys influence the response. All alloys used in orthopedics are susceptible to MACC. Voltage drops during MACC can kill locally adhered cells in vitro. The role of local biology, including the inflammatory system and direct cell attack is not well understood and this new observation of direct cell attack of CoCrMo implants significantly alters our understanding of the overall processes of corrosion. Reactive oxygen species, including hydrogen peroxide, increases the rate of corrosion of CoCrMo in PBS solutions.
WHAT ARE THE BIOLOGIC EFFECTS AND LOCAL TISSUE REACTIONS FROM MODULAR JUNCTIONS?

Modular junctions of implants for joint replacement consist of similar or dissimilar metallic devices. For example, in total hip replacement, the majority of femoral heads are made of cobalt chrome alloy which articulates with a femoral neck made out of cobalt chrome alloy or an alloy of titanium such as titanium-6 aluminum-4 vanadium. Another location with the potential for corrosion is the junction of the body of the stem and a modular femoral neck. Particles and ions of one or more metals form in the local tissues due to mechanically assisted crevice corrosion during prosthesis loading. These particles and ions may stimulate the innate and adaptive immune systems. The innate immune system is orchestrated by macrophages, which phagocytose small metallic particles. These cells become activated, and begin to liberate pro-inflammatory factors such as cytokines (e.g. TNFα, IL-1, IL-6), chemokines (e.g. MCP-1, MIP-1), reactive oxygen species (e.g. iNOS) and other molecules that facilitate the degradation of bone by enhancing osteoclastic bone resorption and inhibiting bone formation. In addition, areas of fibrous tissue scar formation may result from chronic inflammation. High local levels of metallic particles and ions can also lead to cell death due to their toxic effects. Thus, activation of the innate immune system may lead to a variable reaction resulting in areas of acute and chronic inflammation, foreign body reaction, fibrosis and necrosis.

The adaptive (T cell associated) immune system can also be activated by metallic byproducts. The metal byproduct can act as a hapten, and when complexed with serum protein, can evoke a T cell mediated reaction, i.e. a Type IV immune reaction. This results in activation of different cells of the immune system including T cells (killer cells, memory cells and others), macrophages, dendritic cells (that help to process antigens) and other cells that enhance the inflammatory response, leading to further local tissue destruction and memory of the antigenic stimulus.

Thus biologic reactions to metal byproducts from joint replacement may vary from local inflammatory reactions with fibrosis and cell death, to larger more locally aggressive reactions that can destroy bone and soft tissue. The latter reactions are called pseudotumors and may have solid and cystic components. The presence of lymphocytes in histological sections of retrieved tissues (Figure 1) is often seen in conjunction with metal particles, but is not pathognomonic of a metal-on-metal articulation or modular junction. Thus, adverse local tissue reactions (ALTRs) to metal particulates and their byproducts can present with a wide spectrum of clinical, radiological, histological and immunological findings.
HOW HAS MODULARITY AFFECTED IMPLANT SURVIVORSHIP?

A 2013 AAOS Fellows survey found:

56% decreased use of head sizes >36 mm because of literature reports of corrosion of metal taper modular junctions;

46% decreased use of modular femoral stems and necks;

43% increased use of ceramic heads because of literature reports of corrosion of metal taper modular junctions.

To answer the questions highlighted in the survey, a systematic review of the literature and a review of national total joint registries were performed. Specifically, we investigated whether modularity of TKA primary baseplates and modularity of acetabular and femoral stems in primary THA have shown evidence basis for their use clinically.

Only studies that reported a five year or greater results were included.

For monoblock tibial prostheses, TKA registries showed a 5-year survival of 95%, compared to 97% for all-poly implants; literature review showed monoblock survivorship of 97% and all-poly survivorship of 95%.

For modular neck femoral components, THA registries reported revisions at 7 years in 9%, compared to 4% with fixed neck femoral stems; literature review showed survivorship of 92% (95% for SROM modular stem/body).

An average 9-year survivorship of 99% reported for monoblock acetabular components; 2013 systematic review found no difference in wear, osteolysis, or aseptic loosening between monoblock and modular components.

THE ANSWER

TKA monoblock vs modular tibial baseplate: no increase in survivorship/longevity

THA monoblock acetabular components: no increase in survivorship/longevity

THA modular femoral stems: no increase in survivorship/longevity

Modularity in Primary THA and TKA overall seems to have made no difference in SURVIVORSHIP according to both literature and registry reviews.