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FE Investigation of Design and Quality Control-Related Issues Contributing to Metal-On-Metal Hip Implant Failures

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Abstract

High levels of cobalt and chromium ions were detected in the bodies of multiple recipients of modular cobalt chrome molybdenum metal-on-metal hip implants, necessitating the revision of their implants. A forensic engineering investigation of provided discovery documents and existing literature regarding the design, manufacturing, and clinical testing of these modular hip implants was performed. The investigation revealed that the modular interfaces of the implant allowed for micromotion to induce mechanically assisted crevice corrosion at these surfaces. The debris from this corrosion resulted in the release of metal ions into the bodies of the users, forming pseudotumors and compromising the user's health and wellbeing. The effect of this corrosion was enhanced by the galvanic couple that existed between the modular components of the implant. In addition, scanning electron microscopy (SEM) and electron dispersive spectroscopy (EDS) analysis identified silicon carbide (SiC) and aluminum oxide (AL_2O_3) particles left behind from polishing, which were embedded in the ball and liners. These particles accelerated the wear of the hip implant and further exacerbated the release of metal ions. The designers of future hip implants should take care in preventing the occurrence of the above-stated factors.

Keywords

Hip implant, tribocorrosion, taper wear, metallosis, forensic engineering, design, quality control

Introduction

Three types of operations are currently performed to replace the hip of a patient: 1) total hip arthroplasty (THA), which replaces both the natural acetabulum and femoral head; 2) hemiarthroplasty, which only replaces the femoral side of the hip; and 3) hip resurfacing, which replaces the acetabulum, but only shaves down (or resurfaces) the femoral head. A comparison of these operations and their utilized components is shown in **Figure 1**.

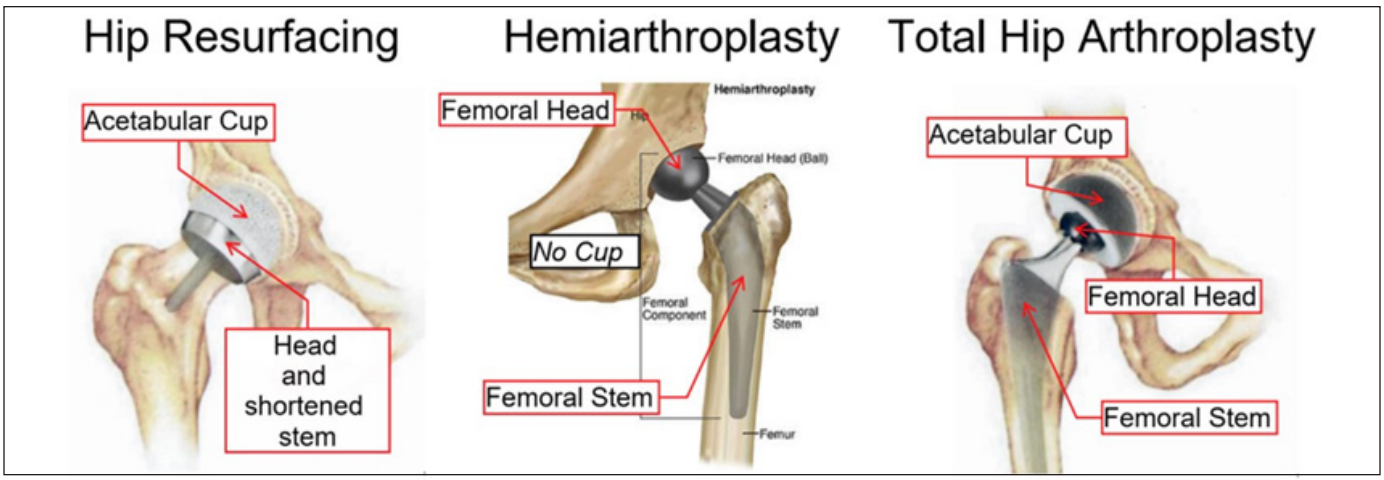

Figure 1
An illustration from discovery documents showing the components of a natural hip and the typical components utilized in total hip arthroplasty.

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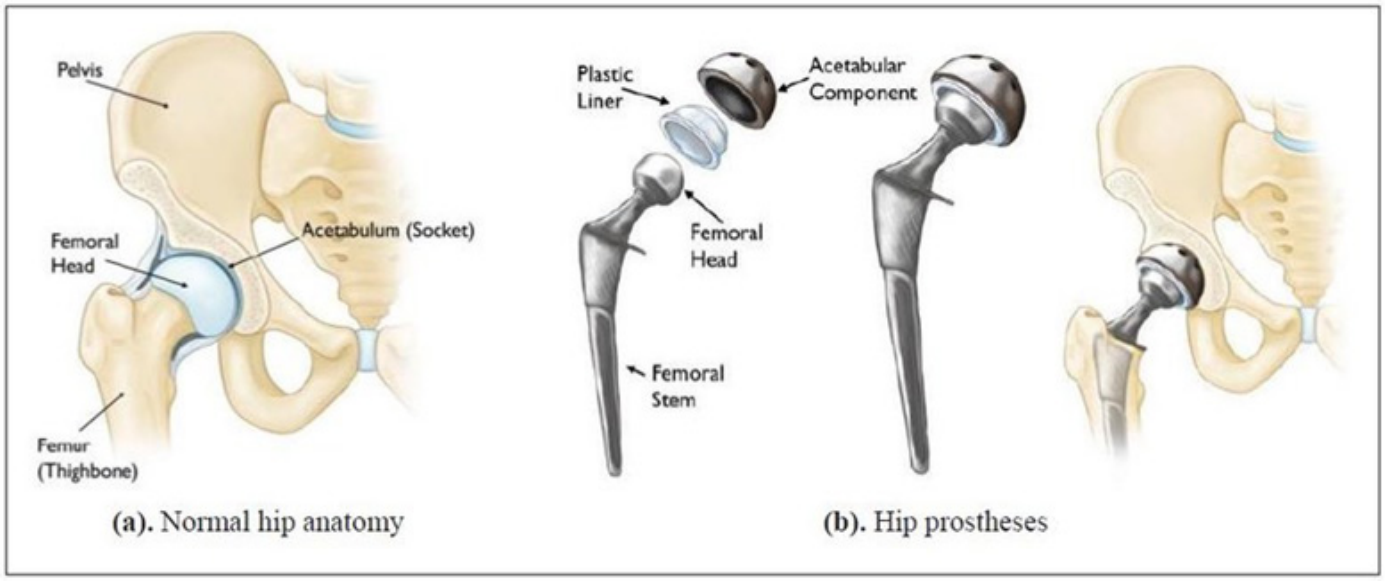

Figure 2
Illustration showing the components of a natural hip and the typical components utilized in total hip arthroplasty[2].

Of these operations, THA is the most common method for the treatment of fatigued or broken hips — with approximately 2.5 million people (or 0.83% of the U.S. population) having undergone such surgery[1]. In THA, the broken, aged, or diseased femoral head is replaced by an artificial femoral head, and a stem is implanted in the patient's femur. This artificial femoral head is then fitted into an acetabular component (cup), which has replaced the natural acetabular socket the femoral hip would fit into. **Figure 2** shows the configuration of components typically utilized in THA.

All prosthetic hips experience wear due to the forces imparted on them during use. In the pursuit of minimizing wear (and the issues wear debris can cause), a variety of different combinations of materials has been used for the head and cup interface: metal on polyethylene (MoP), ceramic on polyethylene (CoP), metal on metal (MoM), ceramic on metal (CoM), and ceramic on ceramic (CoC). Pictures of these material combinations are shown in **Figure 3**. All these material-type combinations have had varying levels of success. At the time of this report, the most commonly utilized combinations are MoP and CoP — due to the high wear resistance of crosslinked polyethylene.

Early hip implants, such as those marketed in the 1950s and '60s, primarily utilized MoM bearings. However, these early devices suffered from high wear and loosening of the implants, causing high failure rates that necessitated the surgical removal and replacement of the devices. MoP soon came to the forefront of the field due to the success of the Charnley hip prosthesis device in the '60s. As a result, MoM implants became less commonly utilized. However, as time passed, it became apparent that MoP implants were susceptible to high wear, and the wear particulate of the polyethylene liners caused the decay of nearby tissue and loosening of the implant. These problems with MoP devices lead to the development of CoC

Figure 3
Illustration showing five of the various material combinations that have been utilized in hip replacement[3].

and CoP implants in the ’70s, yet these bearings displayed high rates of fracture, both with Alumina ceramics in the 1970s and the Zirconia ceramics in the ’80s and ’90s. The growing concerns regarding MoP wear debris and the failure of these early ceramic devices led to a renewed interest in MoM devices due to their greater wear resistance and higher mechanical strength compared to ceramic alternatives. This newer generation of MoM THA implants were alleged to offer reduced wear (generating 1% to 5% of the total volumetric wear that MoP devices produce), increased stability, and increased range of motion, elevating these devices back to the forefront of the field and the market[4].

Case Background

A medical implant manufacturer developed a modular MoM hip prosthesis system (**Figure 4**) for use in THA surgery. By offering the device in a modular format, the operating surgeon can implant the femoral stem and then use a modular taper to affix an appropriately sized femoral head, providing surgeons with the intra-operation flexibility they need to select components that properly match the patient’s unique geometry, thus decreasing the number of failures that occur due to mispositioning of the device[5]. Modularity in THA devices can be provided through a variety of methods, such as, but not limited to, modular necks and adapter sleeves. The modularity provided by the manufacturer of the subject MoM THA device was in the form of an adapter sleeve. At the time of publication for this paper, modular hip components are commonly used in THA devices, yet the materials utilized for these connections have shifted toward titanium alloys instead of the CoCr utilized on the device at issue[6].

According to the 2021 data of the Australian Orthopedic Association’s National Joint Registry (AOA NJR), the reported cumulative revision (i.e., surgical removal and replacement of a failed device) rate for hip implants is 4.4% at 10 years and 6.5% at 15 years. The most common reasons for revision are aseptic loosening (23.19%), instability of the system (22.43%), and infection (22.13%)[7,8].

After the new generation of MoM THA systems went on the market around 1997[10], the reoperation and revision rates of the device rapidly climbed to unacceptable levels.

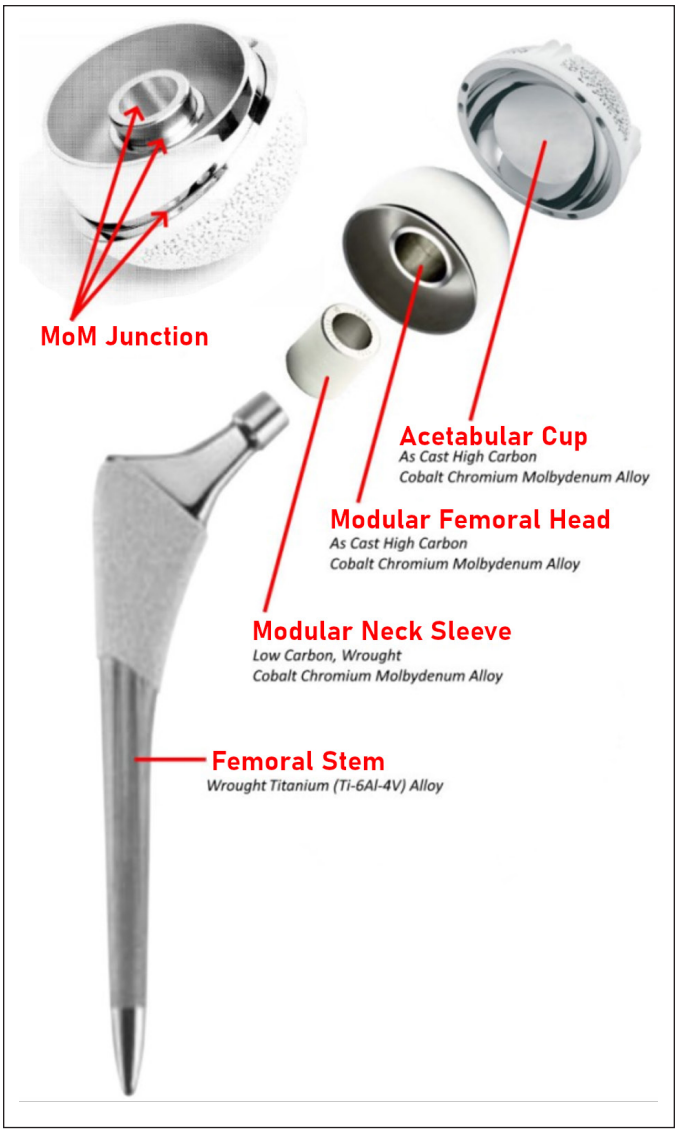

Figure 4
Exploded view of components used by the manufacturer and their relative position during a total hip arthroplasty.

The five-year revision rate of all MoM implants has been recorded to be on average 7.5% — more than twice the rate of alternative THA devices (3.15%).[9,11]. It should be noted that even back in 2011 (the latest year by which the devices the authors investigated were implanted), the 10-year revision rate of all THA system was 6.4%, relatively similar to the current 10-year revision rate[12]. As shown in **Figure 5**, the modular MoM implant at issue was found to exhibit revision rates far in excess of those recorded in

	5-Year Revision Rate	10-Year Revision Rate	15-Year Revision Rate
All THA Implants	3.7%	6.1%	9.1%
Modular MoM Implant at Issue	Data not available	14.3%	20.8%

Figure 5
Table showing the revision rates for all THA device and the modular MoM device investigated in this paper[9].

alternative THA devices. In contrast to the common failure modes seen in the other types of hip implant, the modular MoM THA system at issue was primarily noted to fail due to adverse reactions to metal ion and other metal-related pathology (44.8%), implant loosening (14.5%), and tissue lysis — cell breakdown resulting from damage to the outer membrane (9.2%)[9].

The authors were approached with 11 different incidents involving the revision of THA or resurfacing devices produced by the implant manufacturer and asked to analyze the evidence regarding these incidents. The device combinations and sizes of each component are listed in **Figure 6**.

Five of the devices were noted to utilize a combination of a cobalt-chromium-molybdenum (CoCrMo) liner affixed to a titanium alloy (Ti6Al4V) shell, which functioned as a substitute for the acetabular cup. **Figure 7** shows the difference in configuration between devices that utilize acetabular cups versus those that use a combination of liner and shell. Materials such as polyethylene or ceramic offer desirable wear characteristics for the articulating joint. However, due to lack of strength and other material property issues, they cannot be used for acetabular cups. Therefore, the liner-and-shell concept was developed to permit the incorporation of mixed materials in order to optimize performance. Occasionally, metal liners were utilized for MoM THA systems. Since a metal shell could be implanted with fixation screws, the use of a metal shell allowed for improved fixation on atypically shaped hip sockets.

Out of the 13 devices in these 11 incidents, only 11 were available for physical analysis. The remaining devices were noted to have been disposed of or destroyed by the corporate representative attending the revision surgery, violating the requirements of ASTM E11885 and the manufacturer's own corporate policies. ASTM E11885 outlines the standard practice for documenting and preserving evidence when investigating an incident that could become the subject of litigation[13]. The likelihood that the premature failure of an implanted medical device would likely become the source of litigation should have been apparent at the time the device was removed. As such, the destruction of medical devices — which more likely than not were a significant contributing cause of a user undergoing revision surgery — is intentional spoliation of evidence.

Metal Ions and Metallosis

All of the recipients of the devices in the presented cases were stated to have underwent revision surgery (i.e., removal and replacement of their implants) due to high levels of cobalt and chromium ions in their blood. According to the manufacturer as well as available literature on the subject, wear and corrosion of the implanted THA devices resulted in the release of these metal ions. The build-up of metallic debris and metal ions in soft tissues results in development of a phenomenon known as "metallosis" (shown in **Figure 8**). Metallosis has been found to result in aseptic fibrosis, neurotoxicity, local necrosis, or loosening of nearby implanted medical devices (commonly referred to as the development of "pseudotumors")[14]. These metal ions are able to spread through the body's lymphatic system to locations distant from the implanted device, such as the liver, spleen, and brain, causing metallosis and toxicity in these organs[15,16].

While essential in small amounts for the proper function of the human body, the toxic nature of the elements cobalt and chromium is well documented and has been widely known to the engineering and medical communities for the past century. Chromium toxicity was first noted by the modern scientific community in the late 19th century, when Scottish chrome pigment workers were found to be developing nasal tumors. Since then, the development of cancer and other toxicological responses in chromate workers and individuals exposed to chromium has become a well-known issue with various government bodies establishing regulations to prevent its occurrence[18].

The 20th century saw a number of incidents involving cobalt poisoning, ranging from exposure to industrial dust, medical treatment utilizing cobalt, and cobalt additives in beer. Given the widespread knowledge surrounding cobalt and chromium toxicology, a reasonably prudent manufacturer should have been aware of the fact that the release of cobalt and chromium ions from MoM implants would lead to toxicological responses.

Macroscale Analysis of Retrieved Hip Implants

All retrieved devices were cleaned in accordance with ASTM Standard F561-19. Examination of the retrieved implants showed the presence of a significant amount of corrosion particulate present on the interface of contacting components. As shown in **Figures 9** and **10**, black corrosion debris was observed on the interior and exterior surfaces of the taper sleeve in the majority of devices, appearing concentrated in parallel lines (likely due to the micro-grooved surfaces of the mated taper sleeve).

Digital microscopy of the femoral heads revealed the presence of numerous surface scratches consistent with

Patients	Components				
1	56 mm CoCrMo Acetabular Cup	50 mm CoCrMo Modular Femoral Head	+4 mm offset 12/14 CoCrMo Modular Taper Sleeve	Size 15 Ti6Al4V Femoral Stem	
2	56 mm Ti6Al4V Shell	44 mm CoCrMo Modular Femoral Head	12/14 CoCrMo Modular Taper Sleeve	Size 13 Ti6Al4v Femoral Stem	44 mm ID, 56 mm OD CoCrMo Liner
3	52 mm Ti6Al4V Shell	40 mm CoCrMo Modular Femoral Head	12/14 CoCrMo Modular Taper Sleeve	Size 13 Ti6Al4v Femoral Stem	40 mm ID, 52 mm OD CoCrMo Liner
4	66 mm Ti6Al4V Shell	54 mm CoCrMo Modular Femoral Head	12/14 CoCrMo Modular Taper Sleeve	Size 9 Ti6Al4v Femoral Stem	54 mm ID, 66 mm OD CoCrMo Liner
5	54 mm CoCrMo Acetabular Cup	46 mm CoCrMo Modular Femoral Head	-4 mm offset 12/14 CoCrMo Modular Taper Sleeve	Size 12 Ti6Al4v Femoral Stem	
6	52 mm CoCrMo Acetabular Cup	46 mm CoCrMo Modular Femoral Head	12/14 CoCrMo Modular Taper Sleeve	Size 12 Ti6Al4v Femoral Stem	
7 (Hip 1)	58 mm CoCrMo Acetabular Cup	52mm CoCrMo Modular Femoral Head	12/14 CoCrMo Modular Taper Sleeve	Size 15 Ti6Al4v Femoral Stem	
7 (Hip 2)	58mm CoCrMo Acetabular Cup	52 mm CoCrMo Modular Femoral Head	12/14 CoCrMo Modular Taper Sleeve	Size 15 Ti6Al4v Femoral Stem	
8	54 mm CoCrMo Acetabular Cup	46 mm CoCrMo Modular Femoral Head	+4 Offset 12/14 CoCrMo Modular Taper Sleeve	Size 6 Ti6Al4v Femoral Stem	
9 (Hip 1)	58 mm Ti6Al4V Shell	46 mm CoCrMo Modular Femoral Head	12/14 CoCrMo Modular Taper Sleeve	Size 13 Ti6Al4v Femoral Stem	46 mm ID, 58 mm OD CoCrMo Liner
9 (Hip 2)	56 mm Ti6Al4V Shell	44 mm CoCrMo Modular Femoral Head	12/14 CoCrMo Modular Taper Sleeve	Size 13 Ti6Al4v Femoral Stem	44 mm ID, 56 mm OD CoCrMo Liner
10	54 mm CoCrMo Acetabular Cup	46 mm CoCrMo Modular Femoral Head	CoCrMo Modular Taper Sleeve	Size 15 Ti6Al4v Femoral Stem	
11	52 mm CoCrMo Acetabular Cup	46 mm CoCrMo Modular Femoral Head	-4 mm offset CoCrMo Modular Taper Sleeve	Size 12 Ti6Al4v Femoral Stem	

Figure 6
Table listing the components utilized to form each device implanted in each of the recipients.

abrasive wear in addition to areas of corrosive degradation (**Figure 11**).

Figure 7
Illustration displaying the differences between a THA system with an acetabular cup (left) and a shell and liner combination (right)[3].

On the devices utilizing the combination of CoCrMo liners and Ti6Al4V shells, a series of square imprinted markings was present on the surface of the liners in

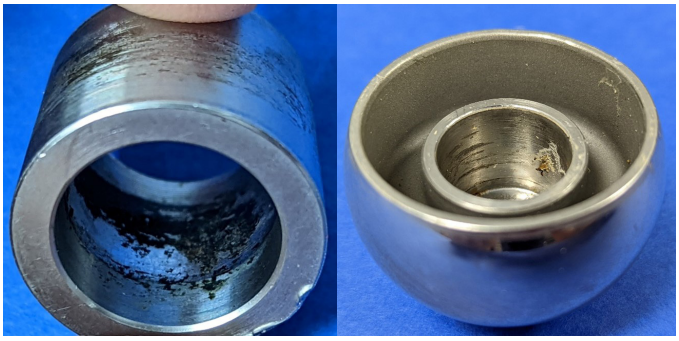

Figure 9
Images of the taper sleeve (left) and femoral head (right) from one of the retrieved devices, displaying black corrosion features and imprinted lines.

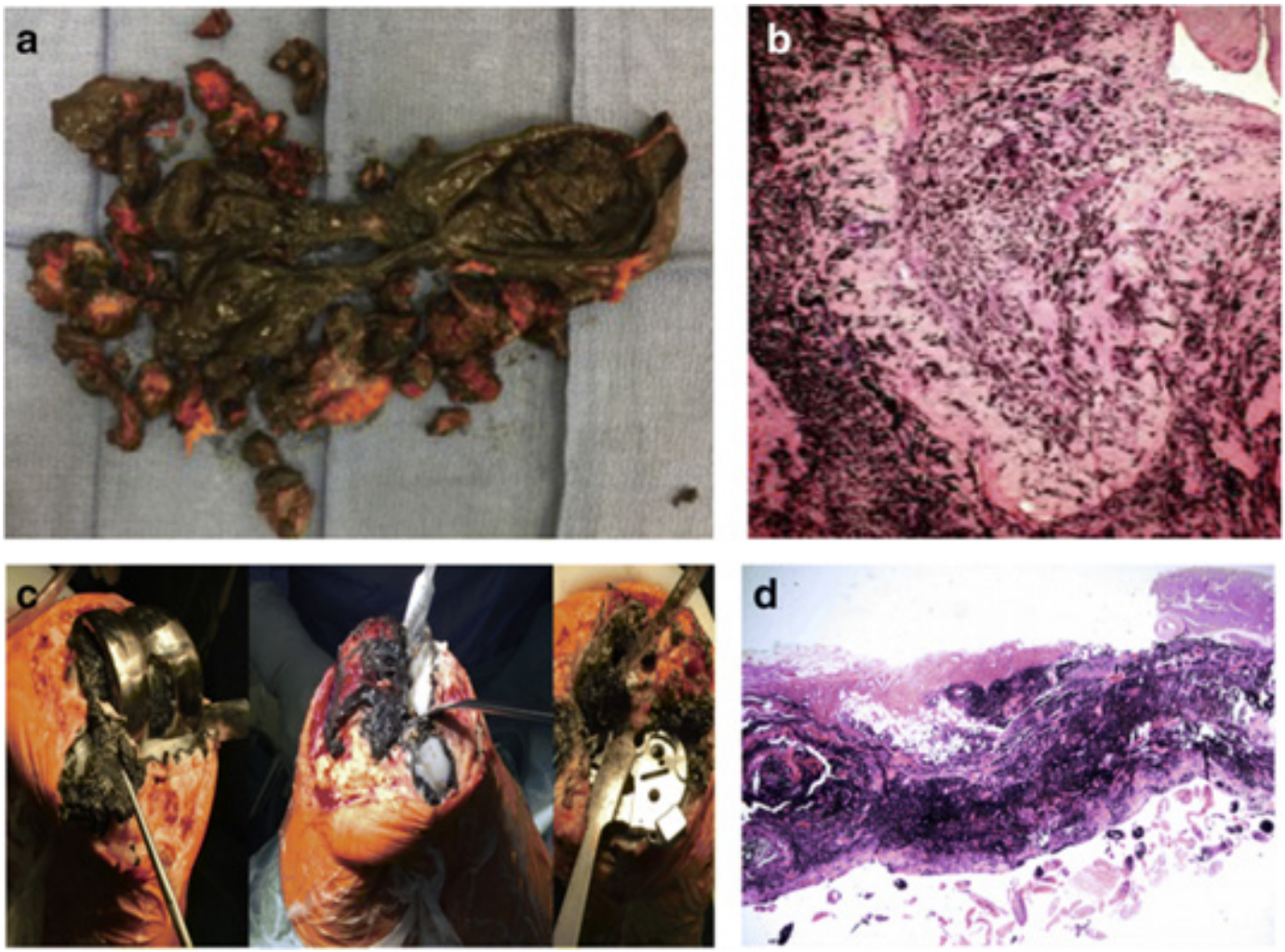

Figure 8
Explanted pseudotumor (a), microscopic view of pseudotumor tissue (b), black staining of tissue around an MoM implant (c), and microscopic photo of stained tissue (d)[17].

contact with the shell (**Figure 12**). These markings matched up with similarly sized square teeth on the shell, and the areas where direct connection existed between the liner and shell showed an increased level of corrosion and discoloration.

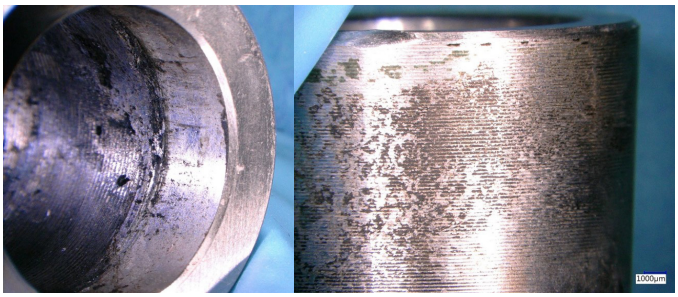

Figure 10
Images of the taper sleeve from one of the retrieved devices, displaying black corrosion features and imprinted lines.

Metal-on-Metal Wear

Devices with contacting metal surfaces in motion relative to one another are known to be susceptible to both abrasive and adhesive wear. According to Donald Askeland's "The Science and Engineering of Materials," adhesive wear:

> *"...occurs when two solid surfaces slide over one another under pressure. Surface projections, or asperities, are plastically deformed and eventually welded together by the high local pressures. As sliding continues, the bond between these welded surfaces breaks, producing cavities on one surface, projections on the second surface, and frequently tiny, abrasive particles — all of which contribute to further wear of the surfaces."*[20]

A diagram illustrating adhesive wear is shown in

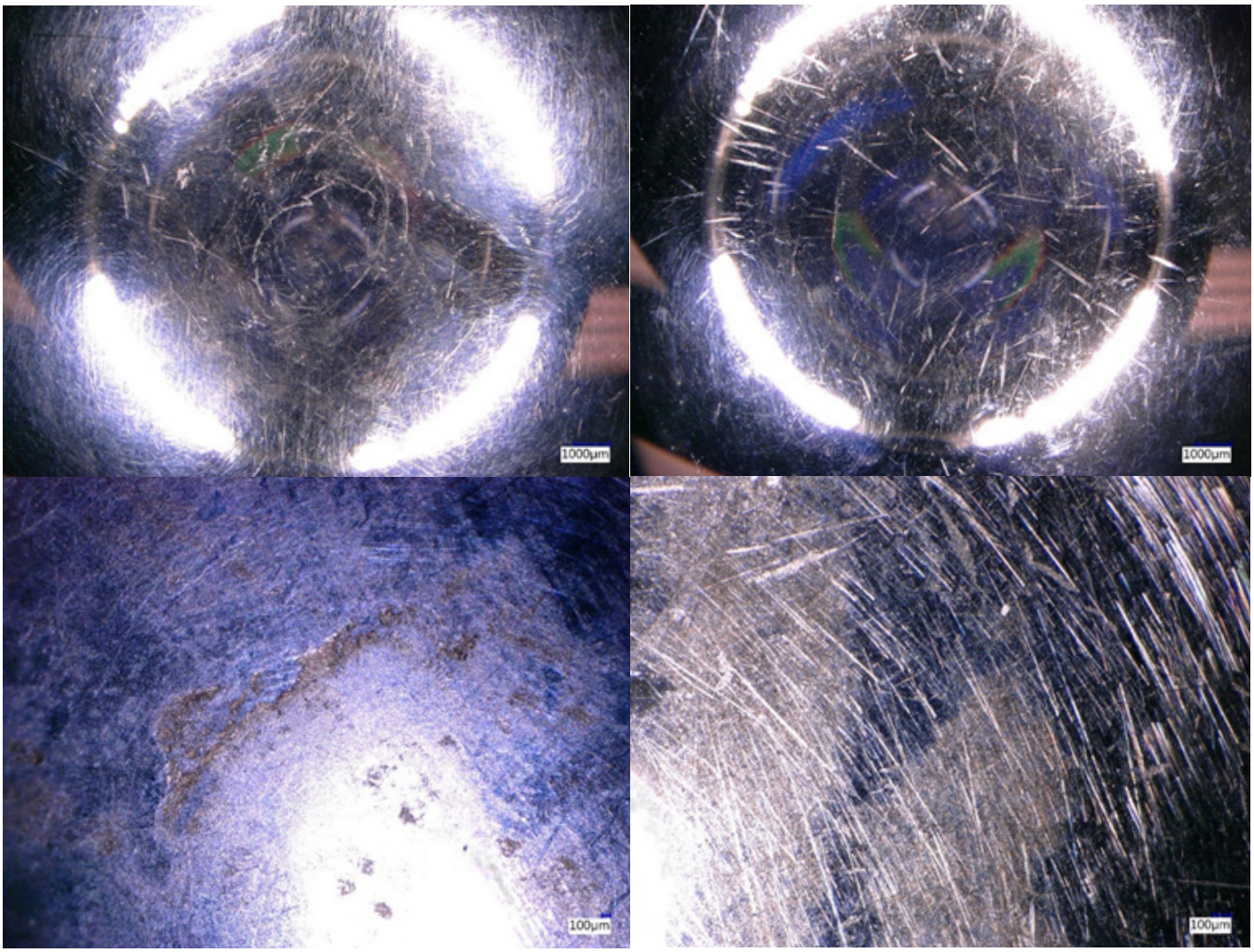

Figure 11
Image of the top of two femoral heads, showing a large number of surface scratches indicative of abrasive wear as well as corrosion.

Figure 12
Image of the imprinting marks left behind on the outer surface of the metal liner (top) and a Ti6Al4V shell similar to the one it was connected to, displaying similarly sized rectangular teeth (bottom).

Figure 13.

Abrasive wear, on the other hand, occurs when a hard material moves across a surface, removing particulate material from this surface. These hard particles can exist either as particles on a surface or as loose particles between two surfaces. According to Dieter and Schmidt's *Engineering Design*:

> *"abrasive wear is usually divided into low-stress and high-stress abrasive wear. In low-stress wear, the particles plow wear scars like shallow furrows or scratches, but they do not fracture off chips. In high-stress abrasive wear, the stress is sufficient to cause the abrasive particles to fracture or crush, producing many sharp edges that remove material by plowing the surface into deep scratches."*[21]

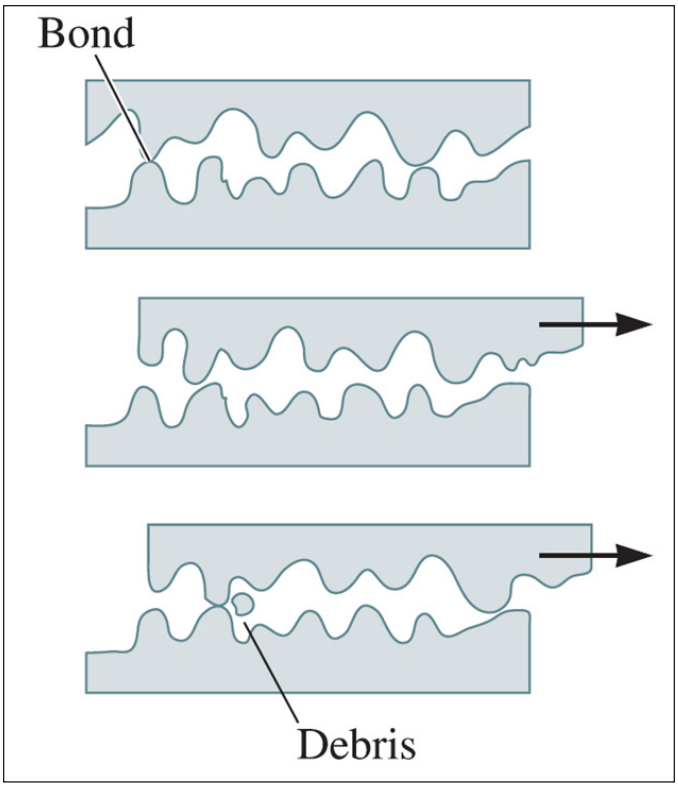

Figure 13
Diagram of adhesive wear[20].

When relative motion occurs between two contacting surfaces where debris or foreign particles are trapped at the interface of the surfaces, the debris can dig into the mating surfaces, resulting in "furrows" and additional debris (**Figure 14**), which, in turn, will result in further occurrence of abrasive wear.

To prevent adhesive and abrasive wear from occurring on articulating surfaces, a variety of factors must be considered. Low loads, smooth surfaces, and effective lubrication are effective methods of reducing wear, but material properties of the mating surfaces are equally important. Generally, if both surfaces have high hardness values, the wear rate is considerably decreased. High strength, high toughness, and general ductility that also help prevent the tearing of material from surfaces can be beneficial under certain loading environments[20].

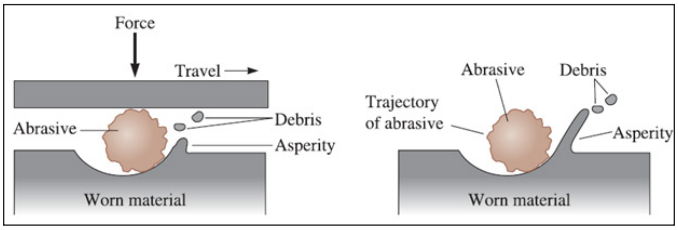

Figure 14
Diagram of abrasive wear[20].

The occurrence of abrasive and/or adhesive wear due to small, oscillatory movements is referred to as "fretting." The modular interfaces within the MoM THA at issue are known to be susceptible to micromotion, creating the conditions necessary for fretting wear to occur.

A study by the manufacturer investigated the wear rates between MoM and MoP bearings. While they found that the volumetric wear rate of the MoM bearings was lower than MoP, the number of particles generated was significantly higher (around 13 to 500 times more, according to another study[22]). In addition, these particles were an order of magnitude smaller than those generated in the MoP bearings, and due to their high specific surface area, promoted the dissolution of the metal into ions and promoted their travel (migration) into the surrounding tissues. As a result, they concluded that MoM wear debris was significantly more hazardous than MoP debris.

Micromotion and Its Causes

The combination of a person's weight and external forces acting upon one's body results in the transmission of loads approximately 3.3 times an individual's weight through the hip joint during day-to-day activities[23]. As a result of these loads, individuals with a modular hip implant are known to experience movement and rotation at the modular connections of such implants. This phenomenon, referred to as "micromotion" in the medical community, will result in fretting wear[24]. **Figure 15** diagrams the loads causing micromotion.

In modular MoM THAs, such as the device at issue, an angular "mismatch" exists between the interface of the taper sleeve and the head as well as the interface of the taper sleeve and the femoral stem[16]. According to the manufacturer, the purposes of these angular mismatches are to avoid higher tension on the assembly, provide less variation in the final position of the head, and allow physicians to assemble the device more easily.

In contrast to conventional hip implants, which only have a single angular mismatch between the head and stem, modular designs present angular mismatches at the interface of the taper sleeve and the head as well as the interface of the taper sleeve and the femoral stem (**Figure 16**). As the presence of angular mismatches are known to accelerate wear, the existence of an additional interface (where angular mismatch occurs) results in correspondingly increased wear-particle production by this device[16,25].

According to studies performed on hip implants, an increase in the diameter of the femoral head results in

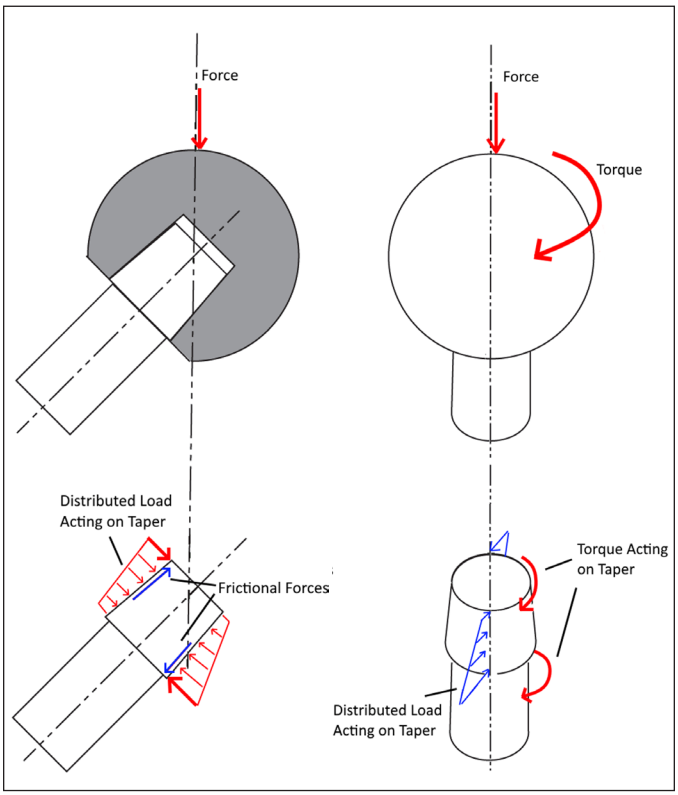

Figure 15
Forces acting at the head/taper interface of a modular hip implant due to downward load and torque applied on top of a femoral head during normal activity.

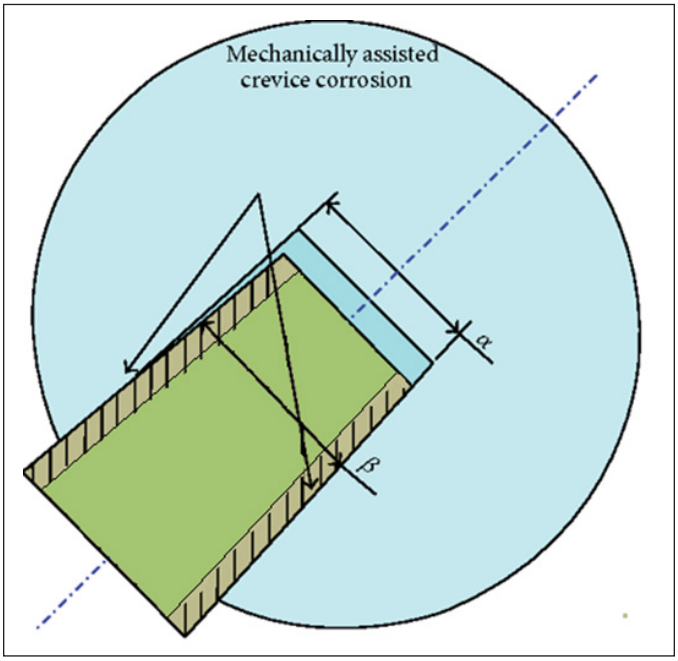

Figure 16
Angular mismatch interface between the tapered sleeve and femoral head[26].

increased micromotion because of the greater magnitude of torque (i.e., effect of a force on an object causing rotation about its axis) applied to the taper. As a result of this, large-diameter femoral heads (i.e., those greater than 36 mm in diameter) have a higher failure rate[27,28,29]. Since the femoral head on the subject devices were all greater than 36 mm in diameter, the micromotion experienced at the taper junction was greater than would have been experienced with the smaller diameter heads used in the average THA. As a result, the wear experienced by the device increased.

Mechanically Assisted Crevice Corrosion

The human body has a highly saline environment containing not only salts and corrosive ions, but also proteins that can lead to immune responses to foreign objects such as medical implants. To ensure that medical devices continue to function as intended without causing detrimental immune responses, medical devices must be designed to resist the highly corrosive environment of the human body[30].

In general, metals are oxidized through anodic reactions, (i.e., $M \rightarrow M+ + e-$), which causes ions of the metal to break off from the bulk material and migrate to the surrounding environment. As previously discussed, these metal ions can lead to the development of metallosis[14,15,16]. Due to their high electrochemical reactivity, cobalt and chromium (metals making up the bulk of the implants at issue) oxidize rapidly, forming a passive "oxide layer" that blocks and protects the metal from the nearby corrosive solution, thereby reducing the amount of corrosion that can occur. However, the protective passive oxide layer can be destroyed by macro- and/or micromotion-induced wear, exposing the bulk metal to the surrounding corrosive environment and resulting in increased levels of corrosion until the passive oxide layer builds up again (**Figure 17**)[24,31].This circular phenomenon of the combined action of wear and corrosion, which creates more material degradation than would have otherwise occurred, is referred to as tribocorrosion[16,32].

The narrow crevices between the modular connections of MoM THAs can allow penetration of bodily fluids that induces a mechanism known as crevice corrosion (or "differential-oxygen corrosion"), an accelerated form of corrosion that occurs when a metal is partially shielded from an environment. Should micromotion-induced fretting wear occur at this interface, the material becomes susceptible to a phenomenon known as mechanically assisted crevice corrosion (MACC)[34].

Documenting the manufacturer's comprehensive understanding of the issue, a report issued by the manufacturer takes their knowledge of MACC and applies it to the modular interface of hip implants. This report explains the phenomenon of crevice corrosion and MACC as follows: "Crevice corrosion occurs when the metal surfaces are partially shielded from the environment… In modular connections, narrow crevices can allow fluid penetration due to the tolerances of the connections. During loading, the passive oxide film of the metal is ruptured, leading to dissolution of metal ions in the crevice fluid. The exposed metal surface reacts with the oxygen in the fluid to form passive oxide and depletes the solution of oxygen. As the fluid is entrapped in a crevice, it has no access to fresh fluid to increase oxygen concentration… This particular model does not require that the mating surfaces be dissimilar for

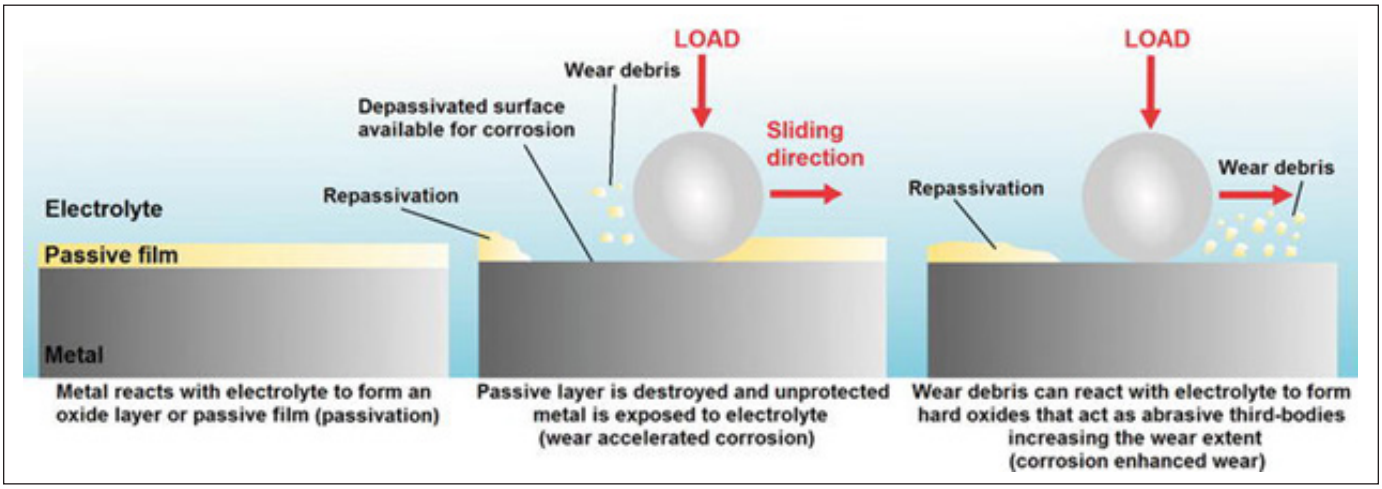

Figure 17
Process of degradation and wear of the passive oxide film layer, known as "tribocorrosion"[33].

galvanic interaction. In the mechanically assisted crevice corrosion, breakage of the surface oxide due to repeated loading/motion, restricted transport of oxygen in the crevice leads to significantly lower pH (as low as 3.5 or lower), which can lead to the active attack of the metals."

MACC can be further accelerated by "cell-assisted corrosion" as a result of the in-vivo environment. Wear particles released from micromotion wear attract inflammatory immune cells to the site. Immune responses to the foreign wear particles cause the cells to release corrosive chemicals, which further accelerate the corrosion occurring due to MACC and cause the crevice environment to become more acidic[35].

It is important to point out that MACC is not a linear phenomenon. As the femoral head or taper sleeve experiences wear, the protective oxide film inhibiting corrosion is abraded and destroyed, which allows for the freshly exposed surface to experience corrosion that would have otherwise not manifested. The process of corrosion changes the surface of the material and the local environment around it, causing increased acidity, cathodic excursions, and an altered oxide film, which, in turn, increases the amount of wear experienced. This creates a positive feedback loop where more corrosion causes more wear — and more wear causes more corrosion, causing the number of released metal ions to exponentially increase, as shown in **Figure 18**.

MACC at the Taper Junction and Liner of Modular MoM THA

Prior studies performed by the manufacturer regarding the wear and corrosion of modular MoM THA devices were conducted in simulated (i.e., in-vitro) environments that showed low rates of wear at these modular interfaces.

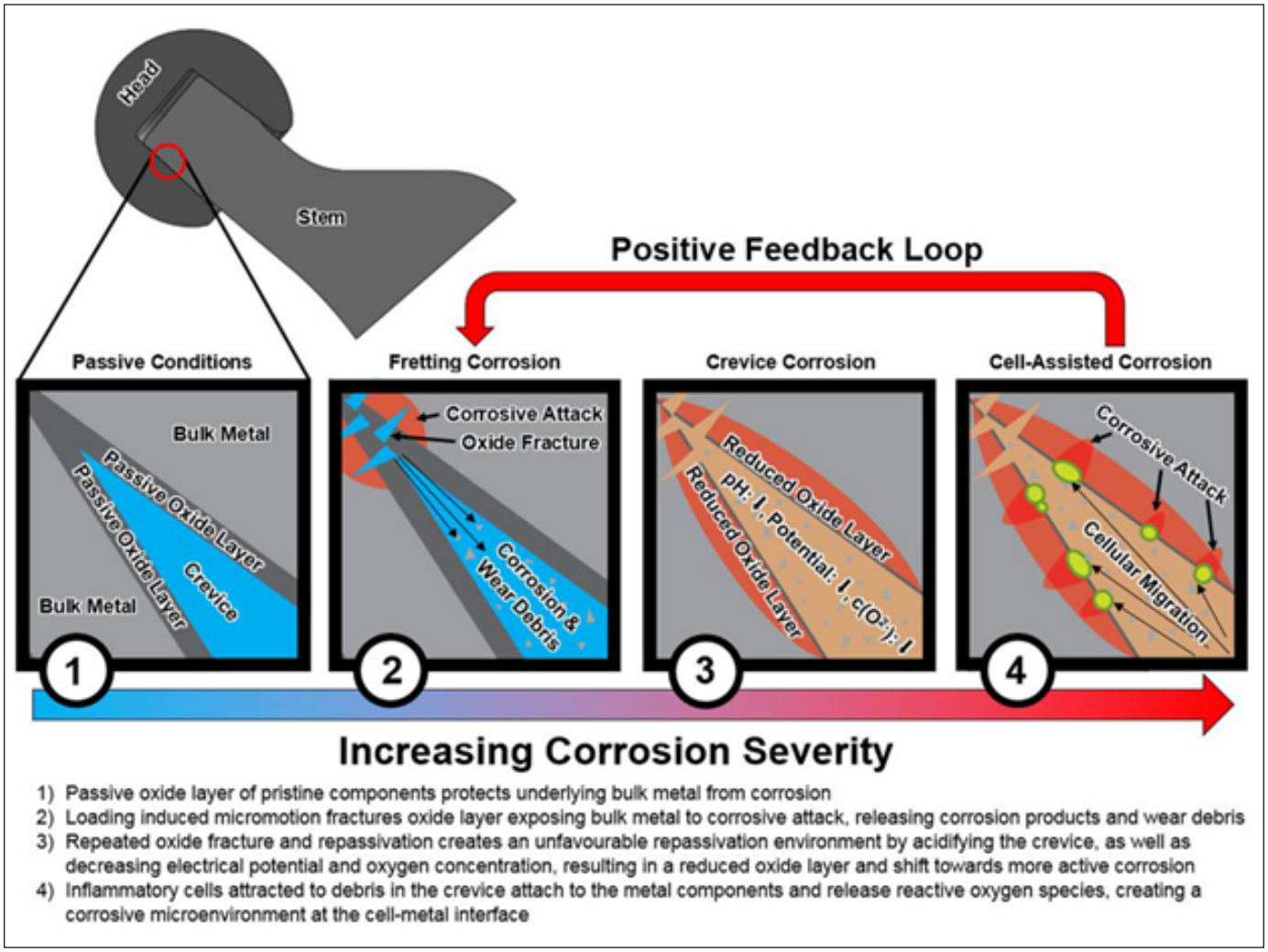

Figure 18
Stages of MACC, showing that the severity of corrosion increases over time[32].

However, once on the market, it was noted that the observed corrosion of the retrieved devices were orders of magnitude higher than their tests had predicted. As these wear and corrosion particles are capable of reducing into metal ions, metallosis and the development of so-called pseudotumors were discovered in recipients of these modular MoM THA devices, necessitating revision.

Based on review of the manufacturer's internal documents as well as publicly available research, metal ions can originate from not only the articulating surface of the femoral head, but also the modular connection at the femoral stem taper[36,37,38,39,40,41] as shown in **Figure 19**. These studies ultimately concluded that the primary cause of wear at this modular connection was due to MACC and fretting wear. Some of these papers detailing the above phenomenon date back as early as 1993. Furthermore, according to available discovery documents, the manufacturer knew about the susceptibility of CoCrMo sleeves to MACC as early as 1997. However, despite this knowledge, there is no indication that any design alterations or measures were implemented to prevent its occurrence.

Studies have revealed that modularity has been shown to give more interfaces where corrosion can occur and lead to an increased number of metal ions[29,43,44]. Both neck modularity and sleeve modularity provide such interfaces for MACC to occur and release a greater number of metal ions. A study from 2014, which reviewed registries and published literature, found that the seven-year revision rate increased from 4.2% to 8.9% when modularity was introduced. The revision rates of these modular systems were stated to further increase when paired with an MoM articulating bearing. This study also found similar revision rates for modular THAs regardless of how the modularity was provided[45].

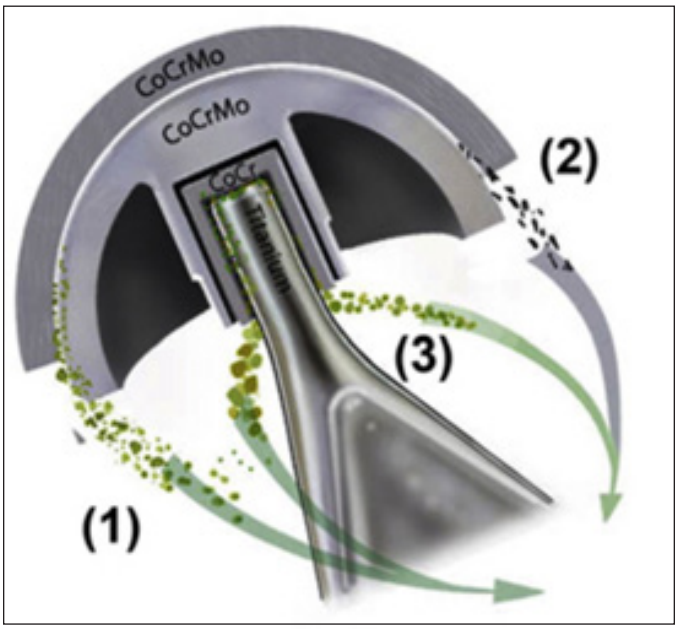

Figure 19
Diagram showing the locations of metal ion release from the modular connection of the hip implant[42].

This suggests that the use of both modular necks or taper sleeves present the same issues in regard to increased rates of revision. A more recent review by Fokter provides further evidence that the number of modular interfaces increases the revision rates of THA implants. Their study found that "dual-modular" systems had a nine-year revision rate of 7.4% as compared to "single-modular" stem, which had a nine-year revision rate of 3%[46].

In addition to the aforementioned data, the National Joint Registry has noted that the revision rates of MoM THAs are approximately 50% greater than MoM resurfacing implants, which lack the taper junction in THAs[47]. Combined with the aforementioned reasons for revisions in MoM THA, this indicates that the use of a taper junction is a significant factor in increased revision. A report by the manufacturer stated that it knew of the increased revision rate for modular devices and theorized that the taper may play a contributing factor in these outcomes.

Modular MoM THA devices that utilized metal liners presented yet another modular interface for MACC to occur. As shown by the square teeth-shaped imprinting marks, there were portions of the liners that were directly mated to the shell with the imprinting marks left behind by the areas that were not directly mated as a result of the square gaps in the shell. The micromotion that took place between the metal liner and shell further generated the release of metal ions into the recipients bodies[48]. More recently, dual mobility components consisting of a polyethylene liner, mated between a metal liner and femoral head, have been noted to suffer from elevated metal ions as a result of the coupling between the CoCrMo liner and Ti6Al4V shell. This adds further support for the conclusion that the use of metal liners significantly increased the level of metal ions in a recipient's body[49,50].

The occurrence of MACC at the taper junction of modular devices is not limited solely to THA implants. Modular devices that are utilized in hemiarthroplasty or resurfacing have also been reported to experience MACC and adverse tissue reactions as a result of metallosis[51]. Even if the devices at issue were utilized without an

acetabular cup as a hemiarthroplasty device, these devices would still have experienced micromotion and MACC at the taper junction, resulting in the accelerated released of metal ions and the development of metallosis

Scanning Electron Microscopy and Energy Dispersive X-Ray Spectroscopy Analysis

The femoral heads of the implants removed from recipients who required revision were examined using SEM and EDS in order to help determine the mechanisms behind the release of metal particles.

During SEM/EDS examination of the femoral heads, several surface imperfections were discovered, which were found to have an elemental makeup different from the bulk CoCrMo material. EDS results revealed a spike in the amounts of silicon and carbon (**Figures 20** and **21**) as well as aluminum and oxygen (**Figures 22** and **23**) present in the vast majority of these imperfections. Based on the observed geometry of these particles, it was concluded that these imperfections were SiC particles and Al_2O_3 particles — both being very hard materials often used in surface polishing applications.

The manufacturer disclosed that the 600-grit Kemet green silicon carbide powder and Kemet kemox abrasive suspension type -0-800 were used during the polishing process (**Figure 24**). To verify that the embedded surface particles were indeed SiC and Al_2O_3, which were left behind from the polishing process, samples were obtained (**Figure 25**).

SEM and EDS analysis were performed on the SiC powder to determine if it is similar to the microscopic

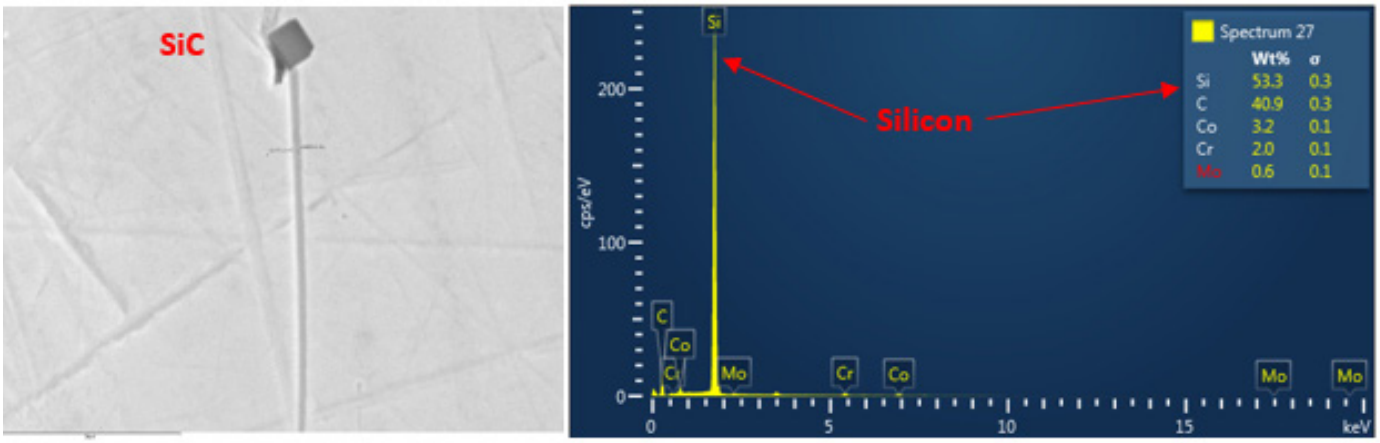

Figure 20
SEM image (left) and EDS results (right) showing a high concentration of silicon and carbon. The silicon-based imperfection was also noted to be embedded at the end of a deep surface scratch, most likely caused by said particle.

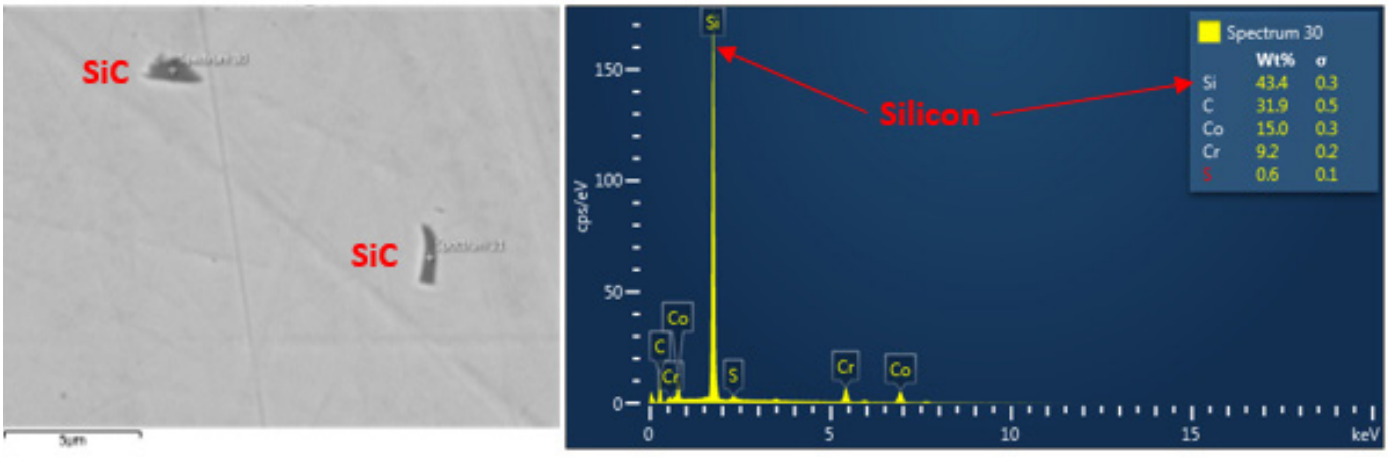

Figure 21
SEM image (left) and EDS results (right) showing embedded particles containing a high concentration of silicon and carbon.

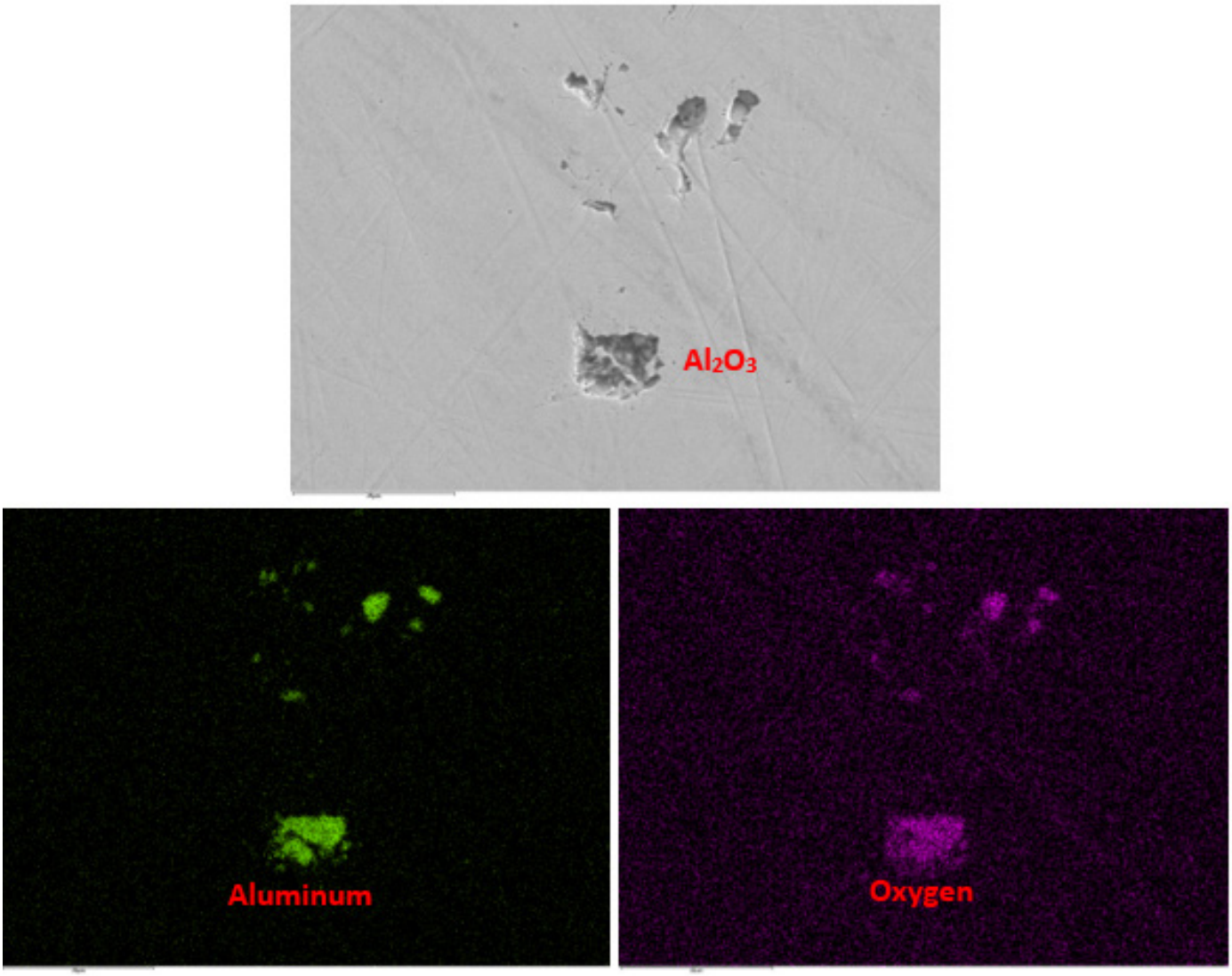

Figure 22
SEM image (top) and its associated EDS maps showing the presence of aluminum (bottom left) and oxygen (bottom right) concentrated in cracks and furrows on the hip, identifying the embedded surface particle as aluminum-oxide, which is routinely used in polishing compounds.

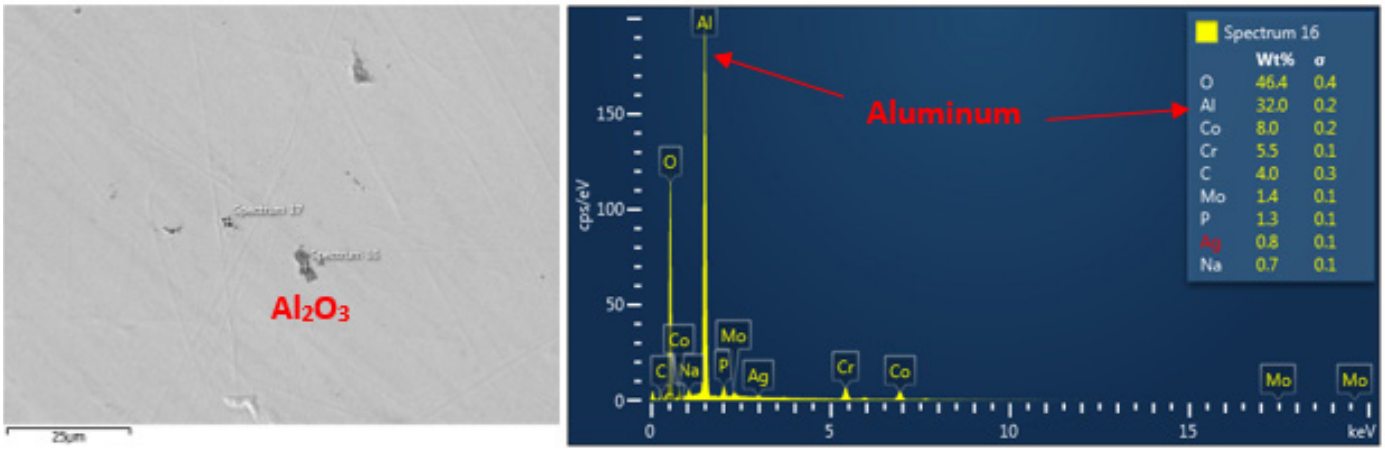

Figure 23
SEM image (left) and EDS results (right) showing high concentration of aluminum and oxygen, indicative of the presence of a micron-sized particle consisting primarily of aluminum and oxygen.

particles found on the manufacturer's modular femoral heads.

As shown in **Figures 26** and **27**, EDS of the SiC powder and Al_2O_3 cleaning slurry showed similar elemental weight percentages to the previously identified embedded silicon-rich particles and aluminum-rich particles. High amounts of carbon were detected in the Al_2O_3

- Rolol Ultragrind Carbide – Code 51719
- Kemet w3 Lubricating Fluid
- Kemet silicone carbide Green powder 600 Grit.
- Kemet 3KC 697 – Paste Diamond
- Kemet 1-05-C3 – Paste Diamond
- Kemet CO-42 Cleaning Fluid
- Hydra Clean DGL4
- Kemet Cleaning Fluid Type A
- Kemet kemox abrasive suspension type -0-800
- Kemet Liquid Type K
- Distilled water.
- *Components then Ultrasonic cleaned in items 8 & 11.*

Figure 24
Table of known contaminants as represented in the design history file with SiC and Al_2O_3 indicated by the red rectangles.

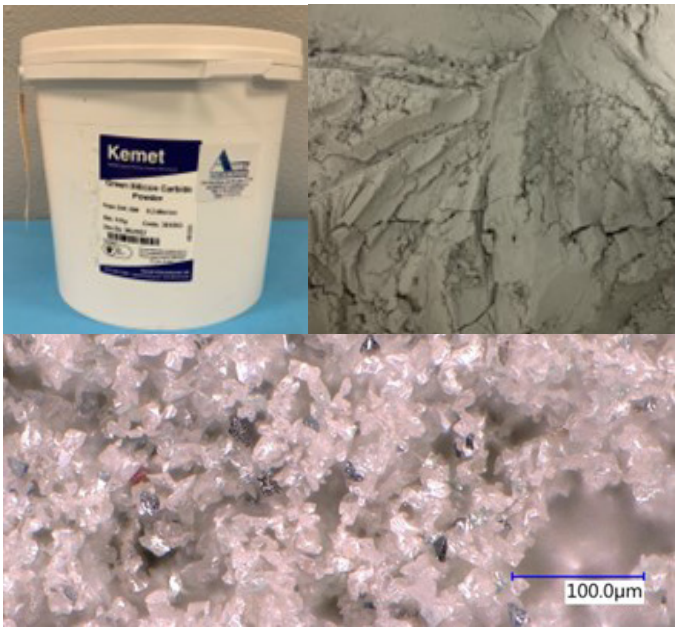

Figure 25
Photographs of the Kemet green silicon carbide powder container (top left) and the silicon carbide powder (top right) and image of silicon carbide particles taken with a digital microscope under 500x magnification (bottom).

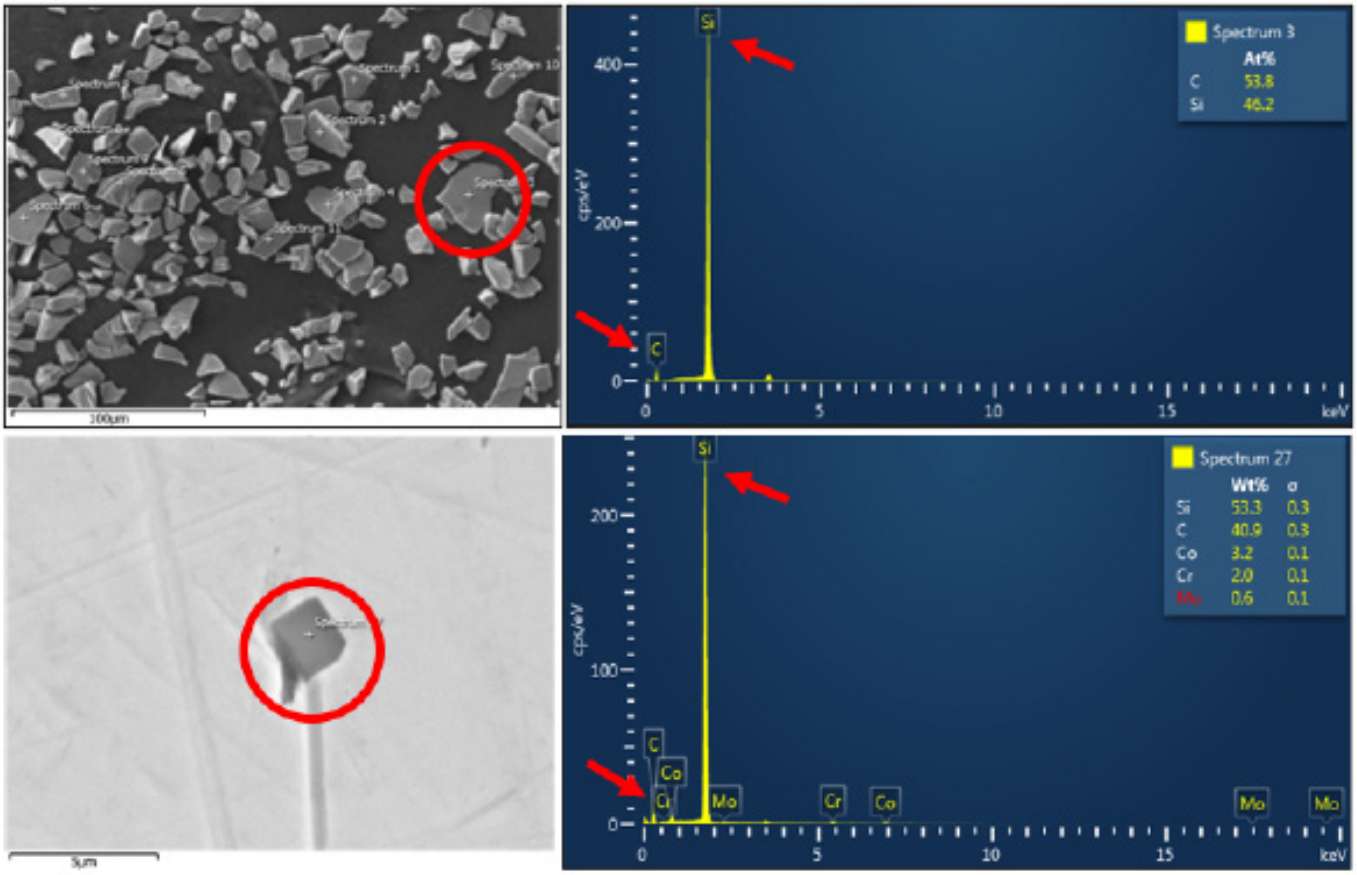

Figure 26
Comparison between exemplar SiC powder (top) and subject explant surface (bottom) with SEM images (left) and EDS results (right). Location of EDS analysis indicated by red circle. Silicon (Si) and carbon (C) EDS results are indicated by red arrows.

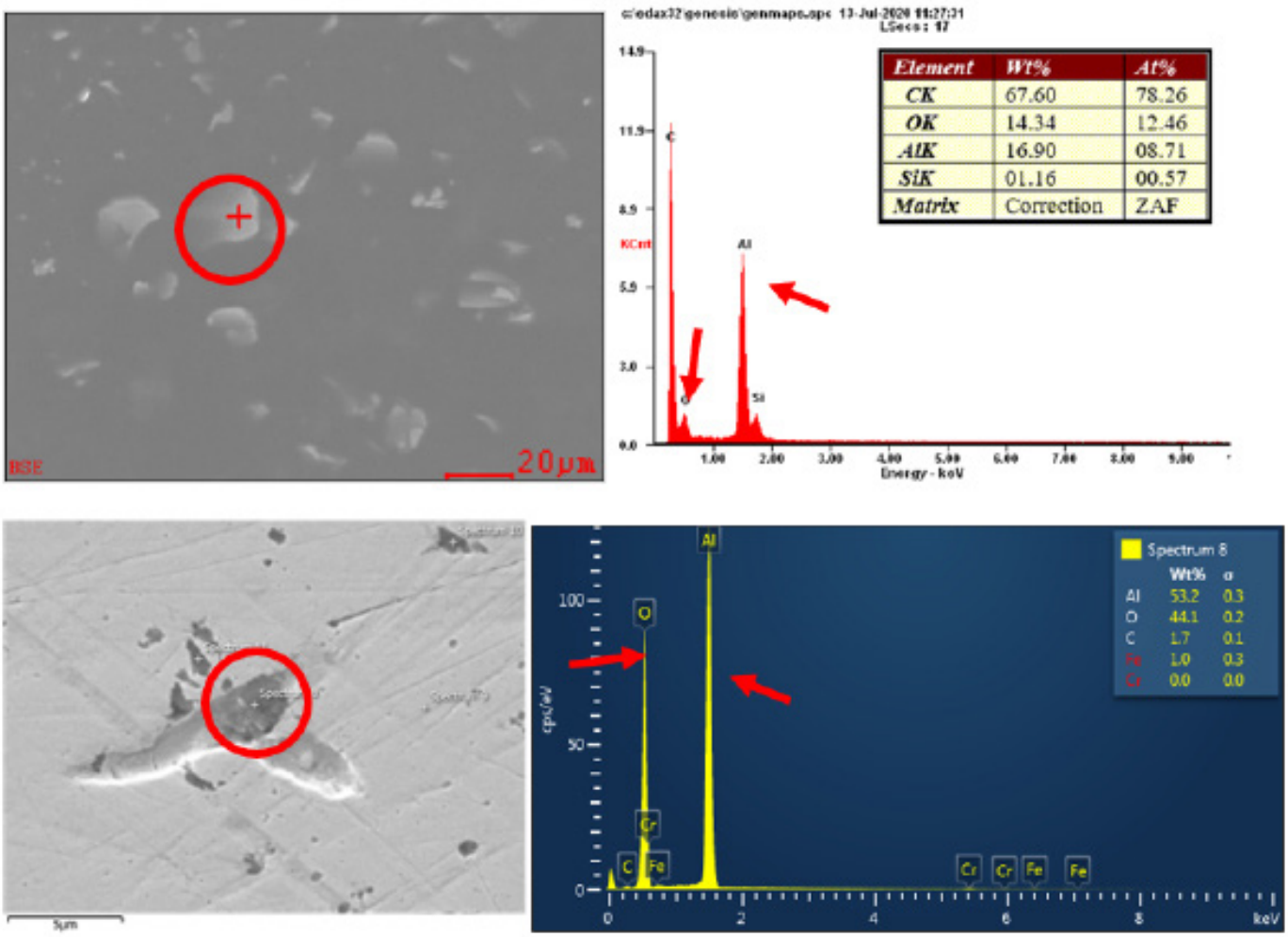

Figure 27
Comparison between exemplar Al_2O_3 slurry (top) and subject explant surface (bottom) with SEM images (left) and EDS results (right). Location of EDS analysis indicated by red circle. Aluminum (Al) and oxygen (O) EDS results are indicated by red arrows.

slurry; however, this was determined to be due to a number of factors. The smaller size of these particles resulted in the elemental readings from the carbon mounting tape to impact the overall results, making the sample appear as though it had more carbon than it actually did. In addition, Al_2O_3 was suspended in a hydrocarbon oil-based slurry that needed to be dried out in order to prevent damage to the SEM. The residue from these hydrocarbons more likely than not left behind a film of carbon on the particles and carbon tape, which further increased the carbon reading in the EDS spectra.

Additionally, the morphology of the particles on the explants were very similar to those found in the SiC powder and Al_2O_3 slurry. In the absence of alternative explanations for the presence of these imperfections, it was concluded the particles observed on the surface of the femoral heads were most likely SiC and Al_2O_3 left behind from the polishing process. Corroborating this conclusion, one of the deposed corporate representatives in these cases stated that it is foreseeable for at least 1-micron-sized SiC particle to be left behind on the surface of the devices.

As SiC and Al_2O_3 particles were from polishing slurries intended to remove material to smooth out the surface of the implant, the manufacturer's failure to completely remove these abrasive particles following polishing triggered an unnecessary and avoidable increase in wear. Due to this increased abrasive wear, small metal particles — and thus cobalt and chromium ions — would be released that can result in the local death of tissues and the formation of pseudotumors.

A 2008 journal article entitled "Characterization of the Running-in Period in Total Hip Resurfacing Arthroplasty: An in Vivo and in Vitro Metal Ion Analysis" discussed

third-body wear caused by hard polishing-agent particles remaining on a device surface during testing. "Other possible causes for the delayed running-in period are aluminum oxide and silicon oxide-filled pits and scratches originating from these pits. These compounds are used as polishing agents during manufacturing. Residua of these very hard compounds may become incorporated into the surface and could later be released during simulation, thus causing third-body wear. This would explain the abrasive scratches originating from these pits. It is, however, questionable whether these particles are released exactly after 300,000 cycles."[52]

In this study, these hard, polishing-agent particles were embedded in the surface of the device. SEM analysis of the device surface after testing showed scratches originating from pits (**Figure 28**). Based on this evidence, it is reasonable to conclude that the Al_2O_3 and SiC particles were, in fact, residua left over from polishing of the hip implants and caused the large gashes observed on the devices.

An email from the manufacturer explicitly refers to the presence of polishing compounds as being causative in increased third-body wear, and that a "…high content of aluminum oxide and silicon oxide in these pits suggested the presence of residua from the polishing agent."

Not only does this provide more evidence for the aforementioned conclusion that these silicone and carbon-rich particles were polishing compounds, but it also goes to show that the manufacturer was aware of the potential for polishing agents to be left behind on their devices — and that such particles would more likely than not increase the experienced wear.

The authors' team was unable to quantify the number of embedded particles in these femoral heads due to the lack of necessary equipment. However, this proved to be unnecessary for their work as the sheer magnitude of embedded particles was sufficient to demonstrate the sheer magnitude polishing debris left behind. Future work by retrieval analysts should attempt to quantify the amount of polishing compounds left behind on devices and determine their influence on the wear of hip replacement devices.

Further SEM/EDS analysis was conducted on the taper sleeves, acetabular cups, and metal liners. On at least eight of the 11 devices available for analysis, the taper sleeves were unable to be removed from their respective modular head. As a result, SEM/EDS of the taper's surface and interior was impossible because there was not an angle the authors could position the embedded taper that would allow for proper SEM. For these cases, the team opted to utilize the SEM/EDS results of previously inspected tapers and relate the observations from these other devices to the devices where taper analysis was impossible. As shown in **Figures 29** and **30**, biological products and chromium-rich corrosion debris were observed on the taper sleeves, distinct from the underlying CoCrMo alloy.

Analysis of the metal liners revealed similar SiC particles to those found on the heads. A coating of iron and nickel was observed on the surface of these liners, likely

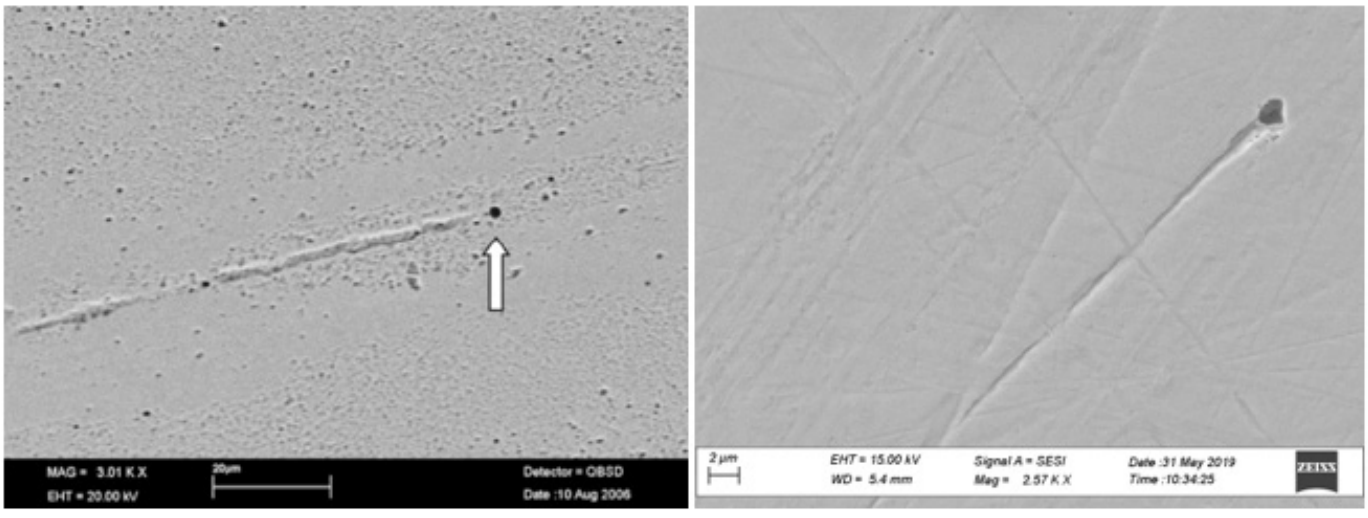

Figure 28

SEM image showing a figure from a study with "scratch originating from alumina filled pit ([white] arrow)" (left) and SEM image from the subject modular S&N femoral head with a similar scratch or furrow adjacent to the pit (right), which exhibited high levels of aluminum (Al) and oxygen (O) consistent with aluminum oxide (Al_2O_3), another polishing agent used during the polishing step of manufacturing.

left behind by biological debris (**Figure 31**).

The results of the authors' SEM and EDS analysis provide further corroboration of these observations. It is more likely than not that the presence of not only the polishing compounds' residue contributed to the increased wear and corrosion of the device, which, in turn, resulted in increased presence of metal ions and the ensuing metallosis in the recipients.

Analysis of Taper Crevice Debris

In order to provide insight into the nature of the corrosion debris observed on the head and taper of one of the explants at issue, a piece of carbon tape, typically utilized for affixing smaller samples for SEM analysis, was utilized to extract corrosion particulate from the interior surface of the taper sleeve (**Figure 32**). While there is no specific ASTM standard for debris removal methodology, the use of carbon tape for nondestructively removing corrosion products and residue for observation is a common practice in materials science applications in a wide range of industries.

SEM and EDS analysis of the recovered corrosion debris revealed the presence of chromium, molybdenum, titanium, and oxygen (**Figures 33** through **35**).

These results held some similarities to the wear debris previously observed during EDS of the taper sleeves.

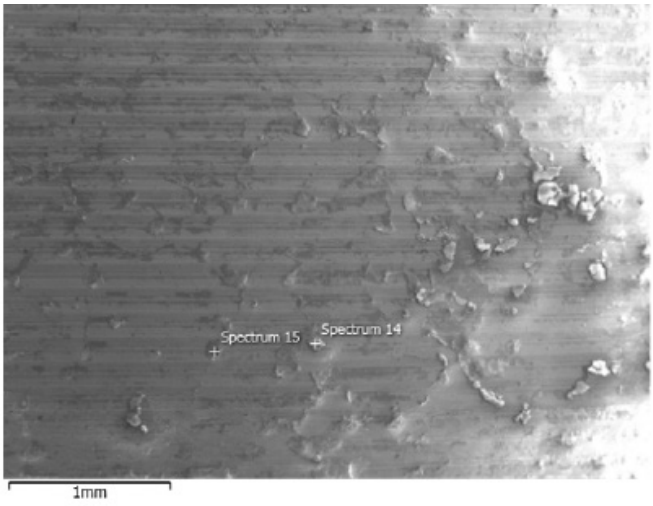

Figure 30
SEM and EDS results from one of the tapers available for such analysis. These images show macroscopically visible particles containing chromium, carbon, and oxygen.

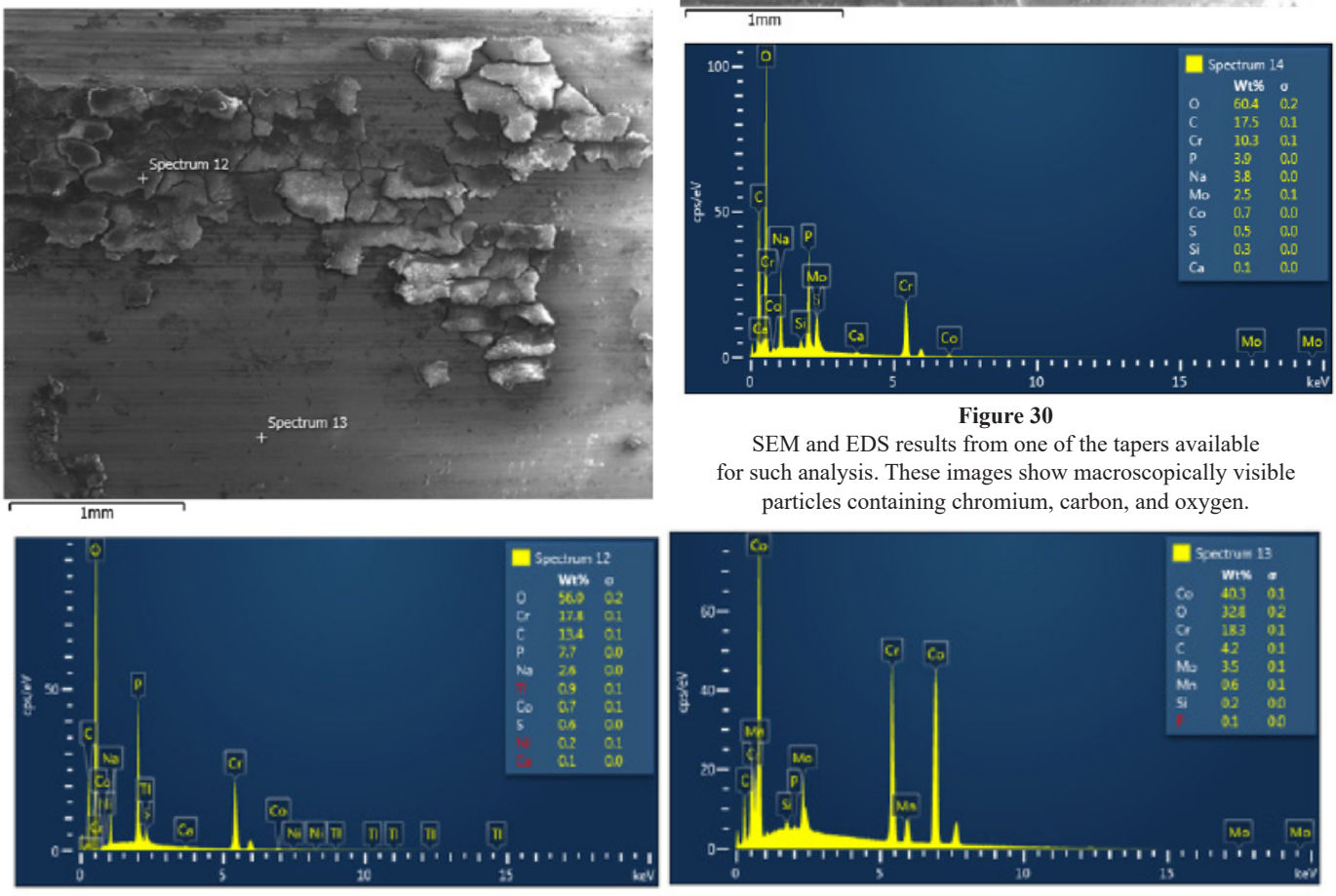

Figure 29
SEM and EDS results from one of the tapers available for such analysis. These images show the presence of chromium and oxygen-rich debris distinct from the base alloy.

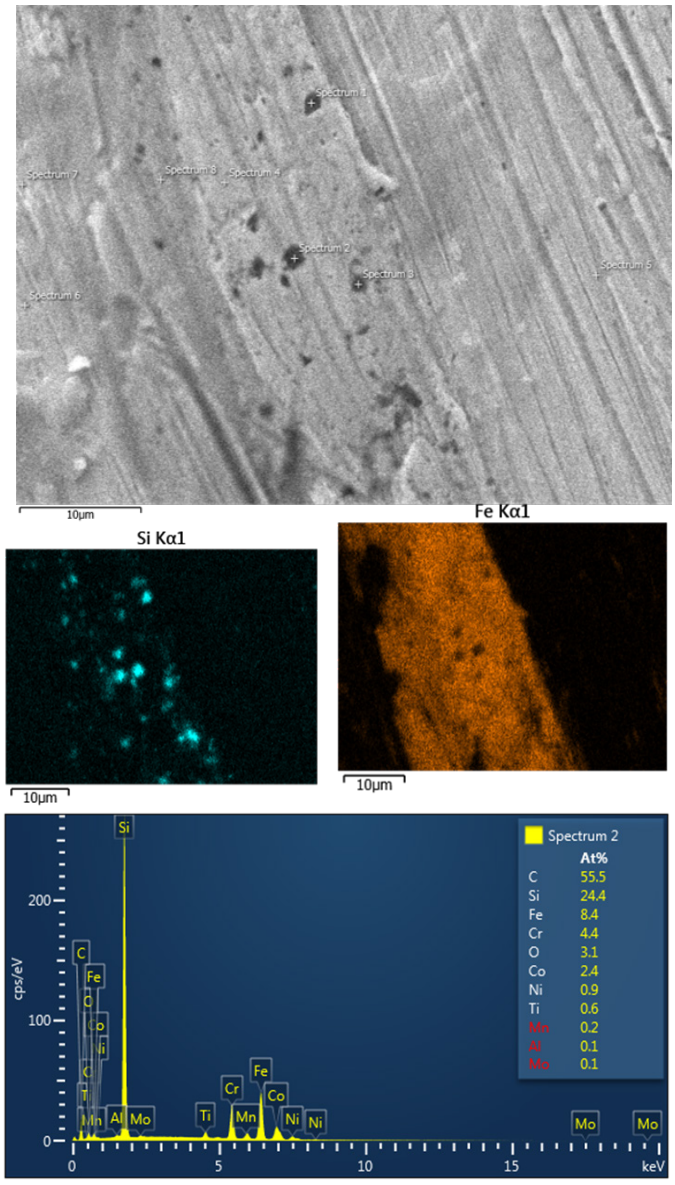

Figure 31
SEM and EDS of a metal liner, showing embedded SiC particle and biological products.

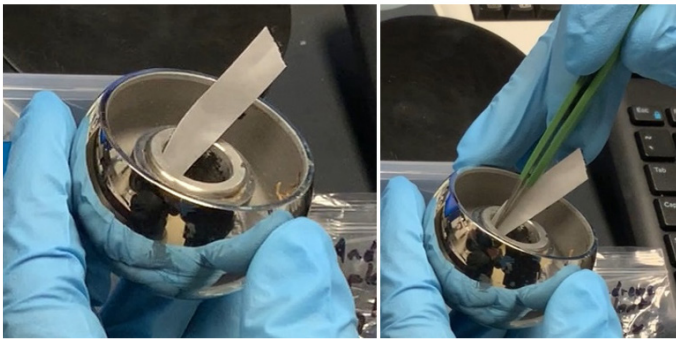

Figure 32
Images showing the process utilized to extract corrosion debris from the interior surface of the taper sleeve.

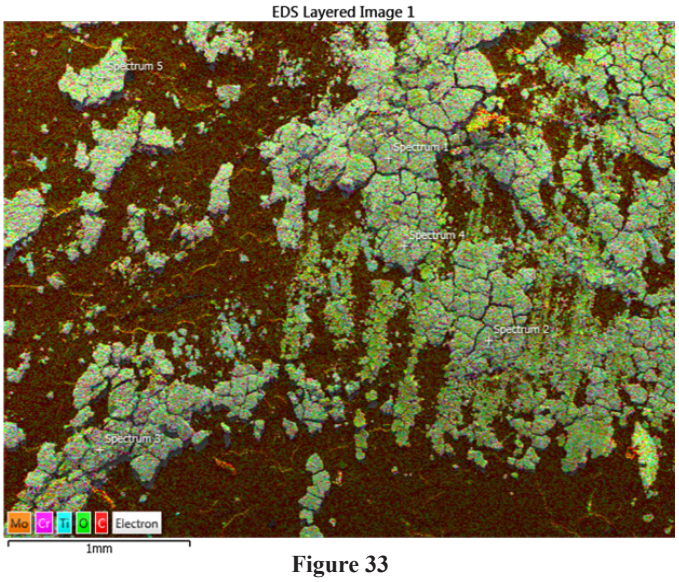

Figure 33
EDS map of the debris collected from the interior surface of the subject taper sleeve.

Based on the EDS maps and percent weight of these elements at various analysis points, it was concluded that, on a more-likely-than-not basis, the debris recovered from the interior surface of this taper sleeve primarily consisted of chromium, molybdenum, and titanium corrosion products produced as a result of MACC.

A number of research papers (as well as the manufacturer's internal testing) found that the taper junction preferentially releases cobalt ions and that chromium is left behind on the taper, producing the chromium-rich debris such as that observed on the debris in the conducted test[53,54]. A 2014 study titled "Influence of Implant Design on Blood Metal Ion Concentrations in Metal-on-Metal Total Hip Replacement Patients" postulates that the main source of metal ion debris in patients suffering from metallosis in modular THA devices is from the modular taper junction, given that the blood cobalt concentrations of these patients were nearly twice those of chromium concentration[55]. This is supported by the manufacturer's own internal testing, which concluded that high Co/Cr ion ratios indicate that "…the magnitude of wear from the bearing area is considerably less than that from the taper area."

Based upon the results of the conducted test, as well as the information presented in the aforementioned research, the chromium-rich debris along with the elevated levels of cobalt ions found in the blood of the recipients of the devices indicate that, within a reasonable degree of scientific and engineering probability, the majority of wear particulate and metal ions found in their body originated

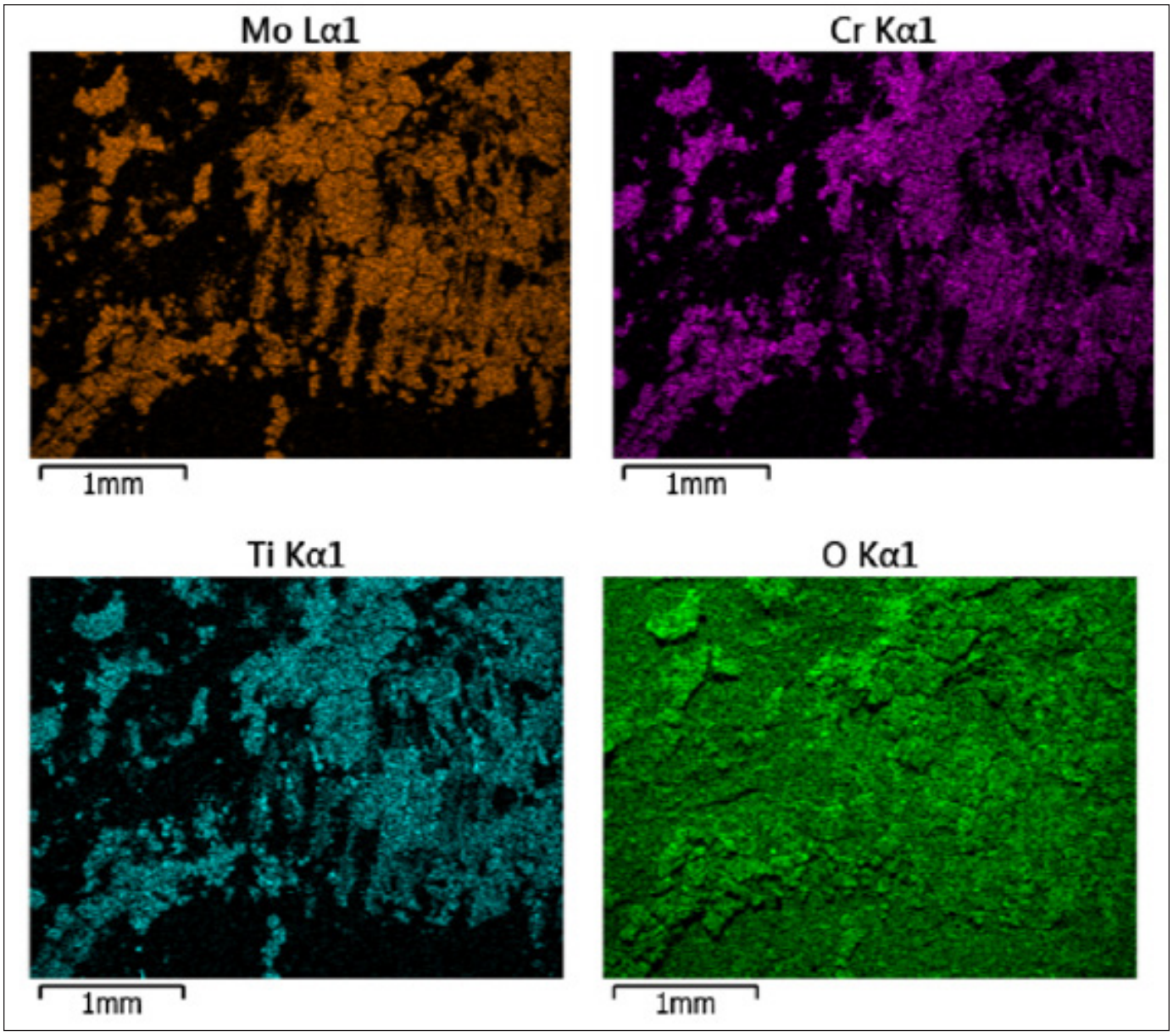

Figure 34
EDS maps of individual elements from the debris collected from the interior surface of the subject taper sleeve.

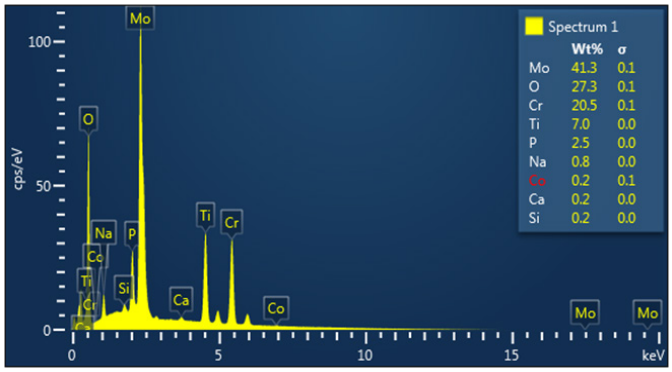

Figure 35
EDS results from the debris collected from the interior surface of the subject taper sleeve.

from the taper interfaces.

Inappropriate Material Combinations

The taper sleeve utilized in the subject device was noted to have been manufactured using low-carbon CoCr-Mo, while the femoral heads were manufactured using high-carbon, as-cast CoCrMo. The subject femoral stem was manufactured using a titanium alloy (Ti6Al4V). According to a wear study conducted by the manufacturer that explores "the wear characteristics of various cobalt-chromium (Co-Cr) alloy combinations," low-carbon Co-Cr alloys exhibited the highest rate of wear out of the alloys amongst the materials tested (**Figure 36**). Since the taper

sleeve was being manufactured from this vulnerable alloy, one can expect any tribocorrosion and fretting wear at the modular interface to be greater than it would have been had a different alloy been selected for use in the taper sleeve.

In addition, the wear rate of the low-carbon CoCrMo would be exacerbated by the differential hardness between the mated materials (low-carbon CoCrMo taper sleeve mated with the high-carbon CoCrMo femoral head and titanium femoral stem). Since micromotion occurs at both of these modular junctions, the use of low-carbon CoCrMo at this junction would result in additional wear.

Galvanic corrosion is a type of corrosion that occurs when two dissimilar metals are in contact (a couple) with each other, creating an electrochemical reaction that can accelerate the corrosion commensurate with the electropotential difference between the metals. The combination of CoCrMo and Ti at the modular interface between the taper and stem creates a "galvanic couple" resting in accelerated corrosion at this interface.

A number of research papers have shown that when the passive oxide layers for CoCrMo and Ti6Al4V are maintained, mating of these two materials results in negligible galvanic current. However, the removal of these passive oxide layers due to wear and the prevention of their reformation can cause the galvanic corrosion to become a significant issue[56,57,58.]

While the individual mechanics of the galvanic coupling among the different phases and corrosion particulate of these material are rather complex, a general understanding of the corrosion behavior can be determined using the open circuit potential (also known as equilibrium or corrosion potential) and the placement of the materials on the galvanic series. Based on these principles, it is found that for the unpassivated coupling of CoCrMo and Ti6al4v, CoCrMo will act as the "anode" in the couple and experience preferential dissolution[59,60].

Convex/Concave	Convex Wear	Concave Wear	Total Wear
As-cast/As-cast	4.1 ± 4.0	65 ± 45	69.1 ± 49.0
S.T. cast/S.T. cast	37 ± 31	114 ± 34	150 ± 51
S.T. cast/As-cast	3.1 ± 0.7	102 ± 12	105.1 ± 12.7
Low carbon/Low carbon	471 ± 51	187± 28	658 ± 77
Low carbon/S.T. cast	470 ± 54	29 ± 5	499 ± 57
High carbon/High carbon	69 ± 60	85 ± 74	154 ±134
High carbon/S.T. cast	86 ± 81	68 ± 40	154 ± 121
High carbon/As-cast	0	0.02	0.02

Figure 36
Experimental results for Co-Cr alloy average weight loss (mg) and standard deviation after 250,000 cycles with 100±50µm diametral clearance with low carbon Co-Cr alloy results highlighted by the red box.

According to the manufacturer's documentation, they knew that the passivation layer was what made the coupling of CoCrMo and Ti6al4v somewhat acceptable. The corrosion resistance provided by this passive oxide layer made the galvanic potential between the coupled metals a rather insignificant factor due to their overall low corrosion. However, as the passive oxide layers on the CoCr and Ti alloys utilized in the head/taper sleeve and taper sleeve/stem connections were abraded due to micromotion at these interfaces, the galvanic current between these two interfaces greatly increased. Despite this knowledge, the manufacturer made no attempt to alter the design of its devices.

The effect of this galvanic coupling can be seen from the revision rates in registries and literature. A recent meta-analysis of modular THA implants concluded that modular connection of CoCrMo and Ti6Al4V had an excessively high failure rate in comparison with other material connections, and, as such, CoCr necks should be abandoned in favor of purely Ti6Al4V connections[61].

ISO 21534:2007 "Non-Active Surgical Implants — Joint Replacement Implants — Particular Requirements" states in Annex B that a combination of cobalt chromium (CoCr) and titanium (Ti) is not an acceptable material combination for articulating surfaces of implants[62]. As previously mentioned, the motion associated with the articulating nature of the components results in the progressive breakdown of the oxide layer, which, in turn, results in the creation of small metal debris particles as well as exposure of fresh metal to continue this oxidation/wear cycle. Therefore, since the "motion" associated with the articulation mechanism is of concern within the spirit of ISO 21534:2007, even micromotion can result in the same phenomenon as described above, thereby creating micron and sub-micron-sized debris in the process.

The above observation regarding creation of micron and sub-micron sized metal particle debris as a result of micromotion at tapered junctions was also made by multiple employees of the manufacturer. One of these employees stated that "…all modern tapers, independent of design, have some degree of micromotion that, in my opinion, makes a taper a junction between articulating surfaces." Therefore, based on the above observations,

the micromotion between the CoCr sleeve and Ti taper would also break down the passive oxide layer between the surfaces and result in the accelerated corrosion of this junction. Therefore, the combination of CoCr and Ti at the taper junction in the devices at issue would have been unacceptable according to ISO 21534:2007.

Testing Performed by the Manufacturer

Prior to the revision of the implanted devices studied in this paper, a number of similar MoM devices produced by other manufacturers were noted to have been recalled due to high failure rates as defined by the degree of metal ion release. A number of manufacturers with similar MoM THA implants were noted to have experienced five- to seven-year failure rates ranging from 12% to 50.4%[63]. As was shown in documents provided by the manufacturer, the manufacturer of the devices at issue knew that its products were similar to these recalled implants.

Review of provided discovery documents also revealed that the manufacturer previously conducted in-vitro (simulated) testing via "hip simulators" in order to accelerate the wear experienced by the device over its useful life in an attempt to assess its long-term wear resistance. However, while such tests utilized a typical hip simulator to accelerate the wear process, the test components were immersed in a solution of simulated body fluid (pH 7). As a result, the corrosion environment to which the devices were subjected was not accelerated like the in-vivo wear was, and thus failed to provide an accurate long-term tribocorrosion environment.

As accelerated wear tests are intended to reproduce the equivalent of many years of wear in a short amount of time, by failing to combine the wear tests with a similarly accelerated corrosion environment, their testing resulted in misleading information regarding the resistance of these devices to tribocorrosion. Had the manufacturer combined accelerated corrosion and wear tests, this would have more accurately simulated the environment the THA implants would be subjected to and would have shown the manufacturer that its modular devices presented an unreasonable risk of corrosion and exposure to metal-ion to recipients of the device.

It was also revealed that the manufacturer had previously conducted accelerated corrosion tests as early as 2004 to reproduce the "imprinting" corrosion marks observed on some of its devices. The solution utilized for this test was an "acidified ringers solution" with a pH of 1. This solution properly provides an accelerated environment consistent with the manufacturer's knowledge that the in-vivo pH of this crevice environment was approximately 3.5 or lower. In addition, research by the manufacturer and by the scientific community as far back as the early 1990s found that the crevice environment of these modular devices was acidified by the creation of hydrochloric acid due to the migration of chloride ions into the crevice environment[37,59].

The "acidified ringers solution" with a pH of 1 would have been able to properly simulate not only the natural environment of the human body, but also reproduce the long-term effects the hydrochloric acid crevice environment would have on MACC in a significantly shorter time period. Although this method was able to properly reproduce said imprinting marks, the manufacturer did not utilize this accelerated corrosion test (or a modified version of it) in combination with its typical accelerated wear tests. They also made no attempt to utilize this method or combine a variation of it with their mechanical wear tests for any of their pre-clinical studies for the devices at issue.

The manufacturer knew — or should have known — that this accelerated corrosion/wear environment would allow its in-vitro tests to simulate the conditions of the human body more accurately[64]. In addition, the results of these tests were not submitted to the FDA during the manufacturer's attempts to get regulatory approval for the subject device combination, although this test would have been more in line with the "worst-case" scenario the FDA requires for these applications.

By the time lawsuits regarding metal poisoning from their THA devices began in 2013, the manufacturer used the aforementioned accelerated corrosion test on the modular femoral head and modular taper. When it did, the tests reproduced the severe imprinting they had observed for years on explant (i.e., the implants that have been removed from a recipient) retrievals. In addition, the material loss observed at the modular interfaces far exceeded the amounts observed in previous studies. Had the manufacturer performed this combined accelerated wear/corrosion testing in its pre-clinical trials, it would have seen the susceptibility of its modular devices to tribocorrosion and realized that the modular implants were not safe enough to be placed on the market.

Off-Label Use

In addition, a number of these incidents were noted to involve off-label combinations of the manufacturer's components (i.e., physicians legally utilizing them in

combinations that had not been specifically approved by the FDA).

The 510(k) applications submitted by the manufacturer to the FDA to gain clearance for the device combinations utilized in the cases at issue to be utilized in THA operations were rejected by the FDA because the manufacturer was unable to provide appropriate clinical data for the safety and effectiveness of these device combinations. Ultimately, the FDA granted clearance for the acetabular cup in the device combination at issue to be utilized in resurfacing operation and clearance for the modular head and taper to be utilized to hemiarthroplasty procedures.

Despite this, the surgeon training, device labels, as well as marketing and promotional materials presented the device combinations at issue as FDA-cleared THA systems, despite neither device being cleared for such operations. In addition, the manufacturer's sales representatives were routinely bringing the modular femoral head and sleeves into THA procedures, even when the doctor did not request those parts (as was done in a number of the cases investigated in this paper).

Summary

Modular metal-on-metal THA implants exhibit excessive failure rates, mostly associated with the release of hazardous metal ions into the recipient's body. These ions, resulting from the wear and corrosion of the implant's CoCrMo alloy, can result in damage or death of local tissue, loosening of nearby implants, development of pseudotumors, and other adverse consequences.

Modular interfaces, such as the junction between the femoral head/taper sleeve and/or the femoral stem/taper sleeve, experience "micromotion" that can destroy the metal's protective passive oxide layer at these interfaces, leading to the occurrence of MACC and fretting wear. This combined action of wear and corrosion mechanisms at the modular interfaces creates a positive feedback loop that exponentially increases material loss. The manufacturer knew of its modular MoM THAs' susceptibility to MACC but failed to properly guard against it or seek alternative designs

SEM and EDS analysis of the subject femoral head showed surface imperfections and embedded surface particles containing an inhomogeneous elemental makeup inconsistent with the nominal surface topography of the base material surface. A comparison of the elemental make-up, as well as size and geometry, of the imperfections/debris discovered on the surface of the subject explant with particles in a polishing compound utilized by the manufacturer, concluded that the discovered surface imperfections/debris were silicon carbide (SiC) and aluminum oxide (Al_2O_3) particles left behind from the polishing process. The presence of these particles accelerated the wear on bearing surface, increasing the number of metal ions released into the bodies of the recipients.

SEM/EDS of the taper sleeves as well as examination of corrosion debris extracted from the taper of one of the devices identified chromium-rich corrosion debris. The presence of these chromium-rich deposits combined with the high ratio of cobalt to chromium ions in this individual's blood, coincides with previous findings that elevated levels of cobalt are indicative that the taper junction is the main source of metal ion release in these individuals. Similar signs of chromium-rich debris along with the elevated levels of cobalt ions found the blood of all the recipients indicate that — within a reasonable degree of scientific and engineering probability — the majority of wear particulate and metal ions originated from the taper interfaces.

The taper sleeve of the subject device was manufactured from low-carbon CoCrMo, which has been shown to exhibit relatively poor wear resistance. Coupling of this low-carbon CoCrMo taper with a Ti6Al4V femoral stem results in increased wear characteristics due to the materials' differential hardness. In addition, the use of dissimilar materials created a galvanic couple that further increased the corrosion and wear at the sleeve-stem interface.

Review of provided documents revealed that the manufacturer performed pre-clinical testing on the device at issue. Such testing involved the use of a hip simulator to accelerate the wear experienced by the device in order to assess its long-term wear resistance. However, by not creating conditions that would also accelerate the experienced corrosion, the performed testing failed to properly simulate the tribocorrosion (coupled effect of corrosion and wear) environment to which the device would be subjected during the device's useful life.

By failing to perform coupled accelerated corrosion and accelerated wear testing, the manufacturer failed to properly simulate the environment of the human body and provided misleading information regarding the performance of its modular MoM THA system. The manufacturer had previously conducted accelerated corrosion tests to reproduce characteristics observed on retrieved

devices, yet failed to implement this more accurate condition into its wear tests.

Conclusion

It is the authors' hope that the information and methodology discussed in this paper can be utilized as an outline for expert witnesses in cases involving the failure of MoM and modular THA implants as the number of lawsuits for these devices continues to increase. The team's findings also raise questions related to the quality of testing performed by manufacturers and the knowledge they had regarding the dangers their devices presented. It is the opinion of the authors that disasters similar to the mass recall of MoM hips in the early 2010s are likely to occur in the future should such negligent testing and product marketing be allowed to continue without consequence.

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