Published in final edited form as:

J Arthroplasty. 2018 October ; 33(10): 3313–3319. doi:10.1016/j.arth.2018.05.020.

What Is the Incidence of Cobalt-Chromium Damage Modes on the Bearing Surface of Contemporary Femoral Component Designs for Total Knee Arthroplasty?

Christina M. Arnholt, MS¹, Daniel W. MacDonald, MS¹, Gregg R. Klein, MD², Harold E. Cates, MD³, Clare M. Rimnac, PhD⁴, Steven M. Kurtz, PhD^{1,5}, the Implant Research Center Writing Committee, Sevi Kocagoz, BS¹, and Antonia F. Chen, MD⁶

¹Implant Research Center, Drexel University, 3401 Market Street, Suite 345, Philadelphia, PA 19104

²Hartzband Center for Hip & Knee Replacement, Paramus, NJ;

³Tennessee Orthopedic Clinics, Knoxville, TN;

⁴Department of Mechanical and Aerospace Engineering and the Center for the Evaluation of Implant Performance, Case Western Reserve University, 10900 Euclid Ave., Cleveland, Ohio 44106

⁵Exponent, Inc., 3440 Market Street, Suite 600, Philadelphia, PA 19104

⁶Brigham and Women's Hospital, Department of Orthopaedics, Harvard Medical School, Boston, MA 02115

Abstract

Background—The purpose of this study was to determine the incidence of metal release in contemporary TKA and the patient-related factors associated with this release.

Methods—256 retrieved CoCr femoral components were collected through a multi-institutional orthopedic implant retrieval program (implanted: 1-15yrs). Implants were mainly revised for loosening (84/256), instability (62/256), and infection (46/256). Third body damage was assessed using a semi-quantitative scoring method. MECD was evaluated using digital optical microscopy. Radii of curvature were measured from representative components to calculate anterior-posterior and medial-lateral ratios. Femoral component surface roughness was measured using a white light interferometer. Using a multivariable linear model, associations between damage score, implant,

Corresponding author: Christina Arnholt, Implant Research Center Drexel University, 3401 Market St, Suite 345, Philadelphia, PA 19104, USA, cma64@drexel.edu phone: 215-571-4345.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

This work was performed at the Implant Research Center at Drexel University.

Each author certifies that the institution where the work was performed approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research. This document has not been submitted to any other journal.

and patient factors were tested. Spearman's r correlation tests were performed to determine the association between roughness measurements and damage score.

Results—Mild to severe damage was observed in 52% (134/256) of the components. In the multivariable linear model, A/P ratio ($\beta = -8.07$; $p < 0.001$), loosening ($\beta = -0.52$; $p = 0.006$) and patient weight ($\beta = 0.01$; $p = 0.007$) were associated with damage score. Suspected MECD damage was observed in 82% (209/256) of components. The R_a value ($p = 0.196$, $p = 0.002$), and R_q value ($p = 0.157$, $p = 0.012$) increased as the damage score increased.

Conclusions—The findings of this retrieval study support that similar damage mechanisms exist in contemporary and long-term TKA devices. Additionally, we observed associations between loosening, A/P conformity, and patient weight with increased surface damage.

Keywords

total knee arthroplasty; bearing surface damage; implant conformity; Cobalt-Chromium; Micro-scale electro-corrosion damage

Introduction

Metal debris and ions may be generated *in vivo* through adhesive/abrasive damage mechanisms [1, 2] and mechanically assisted crevice corrosion of taper junctions [3–5]. Microscopic evidence of surface damage has been observed on the bearing surfaces of retrieved CoCr total hip arthroplasty (THA) and total knee arthroplasty (TKA) components and was initially associated with an inflammatory cell induced corrosion mechanism [3, 6]. Since then, researchers have also suggested that the damage may alternatively be explained as damage from an electro-cautery device imparted at implantation and/or extraction of the device [7]. Given the uncertainty of the mechanism that generates this damage, we refer to these microscopic damage features of uncertain etiology as “microscale electro-corrosion damage (MECD).” Recently, on the bearing surfaces of TKA retrievals that were implanted for more than 15 years, we observed severe abrasion and scratching, mechanically-assisted crevice corrosion, and MECD [6]. However, as these findings were observed in historical knee designs (implanted before 1997) that may no longer be available clinically, the incidence of these damage modes in contemporary knee designs is currently unclear.

Adverse local tissue reactions (ALTRs) to metallic debris have been identified as a concern in metal on metal THA [8–11]. Recent studies have also investigated metal release in TKA [12–15]. Increased serum ion levels specifically cobalt and chromium have been observed in TKA patients as compared with patients without TKA components [16], leading some researchers to question the potential for biological reactions to metallic debris in TKA [14]. Reactions to metallic debris are rare in TKA [16]. However, symptoms of metal hypersensitivity in TKA patients can manifest as dermatitis or synovitis leading to implant failure [15]. This concern is further supported by observations of metallic particles in TKA periprosthetic tissues that were similar in size to particles found in THA periprosthetic tissue [17]. It is poorly understood which patient factors are associated with patient-specific reactions to metallic debris [18]. However, CoCr damage mechanisms on TKA femoral components could help explain how the debris is generated.

In the present study, we investigated the mechanisms of bearing surface damage of revised contemporary CoCr femoral components in TKA designs that are currently in clinical use. We asked (1) what is the prevalence of CoCr femoral component damage (third body damage and MECD) on the bearing surface of contemporary femoral components; (2) What patient factors and device factors, such as patient weight and conformity, are associated with CoCr femoral component damage? and (3) Are surface roughness parameters (R_a , R_q , R_{sk} , R_{ku}) correlated with the semiquantitative femoral component damage score used in this study?

Materials and Methods

Patient Demographics and Implant Characterization

Between 2000 and 2015, more than 3000 total knee replacement components were collected during revision surgery as part of an IRB-approved, multi-institutional (13 institutions) orthopedic implant retrieval program. The primary goal of this study was to elucidate the bearing surface damage occurring on contemporary CoCr femoral components currently in clinical use in the United States. Therefore, we restricted our study to four large orthopedic manufacturers based in the United States: Biomet (Warsaw, Indiana), Depuy (Warsaw, Indiana), Stryker (Mahwah, New Jersey), and Zimmer (Warsaw, Indiana [Zimmer and Biomet have subsequently merged]). We omitted other manufacturers due to insufficient sample size in our retrieval collection. Additionally, because we have previously reported on the damage mechanisms of historical designs (implanted before 1997), we restricted the scope of the current study to implants that were in situ between 1 and 15 years. Thus, CoCr femoral components were selected for this study based on the following inclusion criteria: the femoral components were *in vivo* between 1 and 15 years, and the component was one of eight contemporary designs (Depuy PFC, Stryker NRG, Stryker Scorpio, Stryker Triathlon, Zimmer-Biomet Maxim, Zimmer-Biomet NexGen, Zimmer-Biomet Persona, and Zimmer-Biomet Vanguard). This resulted in the identification of 293 TKA devices. After the devices were identified, implants were excluded due to missing or incomplete operative notes or if the polyethylene inserts were not received after revision. This resulted in a study cohort consisting of 256 femoral components, manufactured by 3 companies: DePuy Synthes (PFC (n=21)), Zimmer Biomet (Vanguard or Maxim (n=40), Persona (n=1), Nexgen (n=117)) and Stryker (NRG (n=8), Scorpio (n=28), Triathlon (n=41)).

Clinical information and operative reports were collected and utilized to ascertain the following specific patient factors: age at implantation, sex, weight, implantation time, and revision reason. The components in this study were implanted for an average of 5 ± 4 years (range: 1 to 15 years). Patients had an average age at insertion of 59 ± 10 years (range: 28 to 88 years) and an average an average weight of 210 ± 51 pounds (range: 411 to 112 lbs.). Fifty-eight percent of the patients were female (n=148). The devices were revised due to loosening (n=84, 33%), instability (n=62, 24%), infection (n=46, 18%), stiffness (n=16, 6%), pain (n=10, 4%), polyethylene wear (n=10, 4%), periprosthetic fracture (n=3, 1%), malalignment (n = 2, 1%), and other reasons (n = 23, 9%). Although not reported as a revision reason until recently, none of the devices were revised specifically for reactions to metal debris.

Femoral Component Damage Score

Third body abrasive damage was assessed using a semi-quantitative scoring method, based on a modified version of the Hood polyethylene scoring method [19]. The bearing surface was described as the medial and lateral condyle regions, which were split into anterior and posterior areas creating a total of four quadrants [6]. Each quadrant was scored by trained investigators to describe the severity of damage. The primary damage that we observed and assessed included both deep and faint scratching that covered various amounts of the femoral condyles. Additionally, small localized areas of corrosion were included within the score to describe damage severity. Any damage believed to be the result of surgeon damage during removal was not included in the score. The distinction between *in-vivo* damage and surgeon removal damage was determined by looking at the damage scars. Damage that appeared to have occurred during implant removal showed evidence of sharp reflective edges, distinctive indentations, and possibly tool patterns. These were excluded from the damage score. The criteria for minimal damage was 0 to 1 surface scratches with no apparent corrosion. A mild score describes deep penetrating scratches on more than 10% of the affected area or very faint scratches on less than 50% of the area, or small localized corrosion. A moderate score describes deep penetrating scratches on more than 30% of the surface or faint parallel scratches on greater than 50% of the surface or corrosion on more than 30% of the surface. A severe score describes deep penetrating scratches or corrosion on greater than 50% of the assessed surface. (Table 1). Scores are presented as a summed total for the medial side (maximum score = 6), lateral side (maximum score = 6), and entire femoral component (maximum score = 12).

Implant Conformity Assessment

One representative component for both the femoral components and polyethylene inserts was chosen to assess the conformity of the different designs. Implant conformity was defined as the ratio of femoral condyle radius of curvature to the radius of curvature of the mating polyethylene insert [20]. This measure was calculated in both the anterior-posterior (A/P) plane and the medial-lateral (M/L) plane. The component radii ratio for A/P and M/L were calculated to represent the device in extension.

The polyethylene insert radii were measured using 3-dimensional (3D) reconstructions generated from microcomputed tomography imagery (resolution 74 μm). The 3D images were fitted with circles to match the curvature of the implant using commercial software (Analyze; Mayo Clinic, Rochester, MN, Figs. 1A and 1B). The radii of the CoCr femoral condyles were measured using digital photogrammetry. A photograph was taken of each example component conveying A/P and M/L positions with a calibrated ruler in the same plane (Figure 1 C and D). Circles were fitted to the femoral condyles. The radii were measured in open source software (GIMP 2.8.14) and then converted from pixel length to mm.

Microscale Electro-Corrosion Damage (MECD)

Identification of MECD on the component surface was conducted using a multistep process. Suspected areas of interest, consisting of small clouded regions, were initially screened using visual inspection at low magnification (Figure 2A). Three-dimensional features

consisting of circular craters with trailing regions, were determined to warrant further inspection using light microscopy (Keyence, Osaka, Japan) (Figure 2B). The suspected regions were then magnified to clarify MECD features such as pitting or circular craters with connective trailing regions using light microscopy (Figure 2C). Femoral components were inspected on the sides, bearing surface, anterior, and posterior of the device, Figure 3.

Surface Roughness Parameters

Surface roughness measurements of the femoral components were conducted using a white light interferometer (Zygo, NewView 6000, Middlefield, Connecticut). Each component was evaluated in three locations on the bearing surface. These three points were collected at the apex of the condyle in a straight line across from the medial to lateral side. One point in the center and one point at the medial and lateral side for each femoral condyle. The R_a (arithmetic average height parameter [21]) and R_q (standard deviation of the distribution of surface heights [21]) values were collected to describe the distribution of height deviations in the topography. Additionally, the skewness (R_{sk}) and kurtosis (R_{ku}) values were collected to describe the shape of the amplitude density function, revealing the distribution of peaks and valleys on the surface [21].

Statistical Analysis

Continuous variables within this study were tested for normality using Shapiro-Wilk test and determined to be non-normal. Therefore, we used nonparametric descriptive statistics. To describe the prevalence of observed femoral component damage score, the median $\pm$ interquartile range (IQR) and range were reported. A step-forward multivariable linear model was used to evaluate the role of femoral component surface damage in the context of implant (A/P conformity ratio and M/L conformity ratio) and patient factors (patient weight, implantation time, revision reason of infection, revision reason of loosening, revision reason of instability). Beta values were reported for this test to describe the effect size. Spearman's ρ correlation test was used to determine the correlations between measured surface roughness values (R_a , R_q , R_{sk} , R_{ku}) and the reported ordinal semi-quantitative femoral component damage score. For all tests, the alpha level was set to 0.05. Statistical analyses were performed using commercial statistical software (JMP 11.0, Cary, North Carolina and SPSS 24, Endicott, New York).

Results

Surface damage indicative of mild to severe third body damage (cumulative femoral damage score = 4) was observed in 52% (n=134) of the examined femoral components (observed as either shallow or deep scratching). Seventy-nine percent (n=203) of the cohort had mild to severe damage (cumulative femoral component damage score = 1) on the posterior portion of the femoral component. Seventy percent (n=181) of the cohort had mild to severe damage (cumulative femoral component damage score = 1) on the bearing region of the femoral component. Two percent of the cohort (n=6) had severe damage (cumulative femoral component damage score = 12) on the bearing region of the femoral component. Additionally, two different types of scratches were observed: erratic scratching: small scratches without any clear direction, and directional plowing scratches which presented as

longer, parallel lines in a specific direction (typically, the anterior posterior direction, Figure 4). We did not observe a difference in third body damage scores between the medial and lateral condyles of the femoral condyle.

In the multivariable linear model, the A/P ratio, presence of loosening, and patient weight were all associated with the femoral component damage score, Table 2. A/P ratio was associated with femoral component damage score ($\beta = -8.07$; $p < 0.001$), where a 10% increase in A/P ratio was estimated to decrease the femoral component damage score by 0.81. The mean A/P ratio was 0.69 ± 0.12 (range: 0.40 to 1.14) and the mean M/L ratio was 0.60 ± 0.17 (range: 0.20 to 0.86). Loosening was also associated with damage scores ($\beta = -0.52$; $p = 0.006$), where patients with loosening had a femoral component total damage score that was 0.5 points lower than patients without loosening. Finally, patient weight was associated with femoral component total damage score ($\beta = 0.01$; $p = 0.007$), where an increase of 1 lb in patient weight was associated with 0.01 point increase in femoral component damage score. Implantation time ($\beta = 0.04$; $p = 0.45$), MECD ($\beta = -0.18$; $p = 0.48$), M/L ratio ($\beta = -0.56$; $p = 0.63$), instability ($\beta = 0.42$; $p = 0.059$), and implant infection ($\beta = -0.15$; $p = 0.54$) were not predictive factors for cumulative femoral component damage score, Table 2.

MECD was observed in 82% ($n=209$) of the cohort. This phenomenon was observed in 14% ($n=35$) of the components on the posterior of devices, 75% ($n=193$) of the components on the anterior of devices, 40% ($n=103$) of the components on a side surface of the devices, and 36% ($n=91$) of the components on the bearing surface of the device. The presence of MECD was not correlated with any implant or patient factors.

The median roughness average (R_a) value was $0.07 \mu\text{m}$ (interquartile range (IQR) = $0.03\mu\text{m}$), and the median root mean squared (R_q) value was $0.10 \mu\text{m}$ (IQR = $0.04 \mu\text{m}$). The median skewness (R_{sk}) value was $-0.77 \mu\text{m}$ (IQR = $1.7\mu\text{m}$) and the median kurtosis (R_{ku}) value was $49.84\mu\text{m}$ (IQR = $68.3 \mu\text{m}$). The R_a value ($p=0.196$; $p=0.002$; figure 5), and R_q value ($p=0.157$; $p=0.012$; figure 6) increased as the femoral component damage score increased. However, the R_{ku} value ($p= -0.154$; $p=0.014$) decreased as the femoral component damage score increased. The skewness (R_{sk}) values were not correlated with the femoral component damage score ($p=0.084$; $p=0.18$).

Discussion

In some patients, the presence of metallic debris in total joint arthroplasty has been associated with metal toxicity [22], dermatitis [22, 23], hypersensitivity [24, 25] and synovitis [26]. Implant loosening has also been associated with increased exposure to metallic and other debris [1, 27, 28]. The purpose of this study was to report the prevalence of damage on the bearing surface in contemporary CoCr TKA components. The incidence of third body damage on the bearing surface of the femoral component was found to be associated with decreased A/P ratio. The incidence of third body damage was also found to be associated with increased implant loosening and increased patient weight. MECD was observed in 82% of the cohort. Mild to severe third body damage (cumulative femoral damage score 4) was observed in 52% ($n=134$) of the examined femoral components.

However, the prevalence of MECD was not associated with any implant or patient factors. Finally, the roughness average (R_a), and root mean squared (R_q) were positively correlated with femoral component damage score. These results indicate that the as the damage increased the measured surface roughness increased.

There were limitations to this study. First, the extent of third body damage was analyzed using a semi-quantitative method. Similar methods have been used to characterize other phenomena, mainly polyethylene knee insert damage [19] and mechanically assisted taper corrosion in THA [5] and TKA [3]. Although these methods do not provide measured volumetric material loss from these surfaces, it has been demonstrated in taper corrosion that the perceived damage within a particular area graded with a semi-quantitative scoring method was correlated with the measured volume of material released [29]. The methods utilized to identify MECD were visually qualitative with the use of light microscopy and 3D microscopy at increasing levels of magnification. Although we could observe this damage, the mechanism by which the surface damage was created was not determined. Inflammatory cell induced corrosion damage which we have renamed as MECD to reflect the current theory for the damage mechanism, has previously been identified using energy-dispersive X-ray spectroscopy. This method was a final confirmation step to determine the presence of iron and other elements indicative of biological material [3, 30]. However, both the composition of the incurred damage of electro-cautery devices and biological material containing iron making it difficult to differentiate the source of the damage. Another limitation in this study was that each component included within this cohort was retrieved at revision surgery. This restricted the cohort to only represent a population of implants that have by definition, failed clinically. However, in the absence of alternative methods, analysis of retrieved components remains the primary method for studying *in vivo* performance of arthroplasties. Lastly, the components selected for this study were restricted to eight different designs from three major manufacturers. The results from this study should not be extrapolated to describe other implant designs not included in this study such as hinged knee designs.

Mild to severe third body damage (cumulative femoral damage score 4) was observed in 52% (n=134) of the examined femoral components. Third body damage present in CoCr femoral components has been reported in a long-term CoCr TKA cohort, 98% of the cohort had evidence of third body damage on the bearing surface [6]. However, it is still considered unknown how material could be removed from a CoCr femoral component that articulates against a polyethylene insert. An in vitro simulator study performed by Kretzer et al. [31] controlled the bearings within the simulator, so that metallic debris present in the wear testing fluid was likely from the TKA device tested; a high volume of metallic debris from the device was found. This study reported both polyethylene (7.28 ± 0.27 mg), and metallic (1.63 ± 0.28 mg for cobalt, 0.47 ± 0.06 mg for chromium, 0.42 ± 0.06 mg for molybdenum and 1.28 ± 0.14 mg for titanium) particle volumes with 12% of the weight of the damage products being metallic [31]. It is suspected that this damage could be due to carbides removed from the bulk alloy [31], as no third body particles were introduced. With regards to the studied TKA components from this study, a similar mechanism could be responsible for the third body scratching on the bearing surface. Additionally, the third body scratching on the bearing surface could be resulting from third body particles.

A recently appreciated damage mechanism, MECD has been increasingly reported as either a product of micro electro-cautery device [7], or damage due to cellular attack of the implant surface, previously reported as ICIC (inflammatory cell induced corrosion) damage [3]. Evidence of suspected ICIC damage has been increasingly reported in both retrieved THA and TKA [3, 6, 30]. However, a study by Campbell et al. [7] showed that similar morphologies could be produced using an electro-cautery device. This device is used during the implantation and extraction of orthopedic joint arthroplasty components. Using the following techniques: dotting, dragging, and hovering with a unipolar electro-cautery machine, Campbell et al. [7] reproduced the cellular tracks and circular features similar in shape and size to the previously reported ICIC damage mechanism. Currently, it is unclear how to distinguish between the two mechanisms making it difficult to clarify the cause of damage on implant retrievals.

Third body damage of the bearing surface was correlated with the following implant factors: the A/P conformity ratio, implant loosening, as well as the patient factor of weight. In a matched cohort including 19 pairs, Cottrell et al. [20] reported that changes in the M/L ratio had a larger effect on the stresses experienced by the components. The study observed Exactech Optetrak, and Zimmer IBPS-II TKA designs, focusing on the damage observed in the polymer insert. The increased M/L conformity resulted in a larger contact area and thus reduced contact stresses [20]. The observed increase in implant loosening resulting in decreased femoral component damage was not consistent with previous observations of implant loosening correlating with increased implant debris [1, 27, 28]. It is currently unclear whether the loosening observed in this study was related to debris (metallic, polyethylene, or cement), mechanical factors, a combination thereof, or currently unidentified factors.

Increased roughness average (R_a), and root mean square (R_q) was observed with increased cumulative femoral component surface damage scores, while the skewness (R_{sk}) and kurtosis (R_{ku}) were not correlated with the damage score. Historically, roughness values have been used to describe the performance of polyethylene inserts, tibial trays, and femoral components in TKA by describing the increased roughness of the surface to indicate implant damage and possible debris [32–36]. The R_a and R_q values are amplitude parameters that describe an increase in peak height and valley depth on a surface [21]. The observed correlation between femoral component surface damage scores and roughness values is indicative of increased surface scratching. These results support the hypothesis that bearing surface damage can be accurately described by semi-quantitative damage scoring.

In summary, this study reported the incidence of *in vivo* damage mechanisms on the bearing surface of contemporary total knee CoCr femoral components. Mild to severe third body damage (cumulative femoral damage score 4) was observed in 52% (n=134) of the examined femoral components. We observed a correlation between third body damage and implant loosening, patient weight, and A/P conformity ratio. These results describe how patient factors, as well as implant design features, can impact the implant bearing surface damage. Additionally, through the observed correlations with surface roughness values and the semi-quantitative scoring method, we have also shown that the extent of implant damage on the bearing surface of a femoral device can reasonably be assessed using visual scoring

methods. Future research will be useful to better understand how *in vivo* damage mechanisms in TKA are associated with implant debris generated *in vivo*.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

This study was supported, in part, by NIH/NIAMS R01 AR47904. Institutional support has been received from Stryker, Zimmer Biomet, InVivo, Stelkast, Wright Medical Technology, Ceramtec, Celanese, Simplify Medical, and Ferring Pharmaceuticals.

References

1. Bartel DL, Bicknell V, Wright T. The effect of conformity, thickness, and material on stresses in ultra-high molecular weight components for total joint replacement. *The Journal of Bone & Joint Surgery*. 1986; 68(7):1041. [PubMed: 3745241]
2. White SE, Whiteside LA, McCarthy DS, Anthony M, Poggie RA. Simulated knee wear with cobalt chromium and oxidized zirconium knee femoral components. *Clinical orthopaedics and related research*. 1994; 309:176.
3. Arnholt CM, MacDonald DW, Tohfafarosh M, Gilbert JL, Rimnac CM, Kurtz SM, Klein G, Mont MA, Parvizi J, Cates HE. Mechanically assisted taper corrosion in modular TKA. *The Journal of arthroplasty*. 2014; 29(9):205. [PubMed: 24996586]
4. Kurtz SM, Kocagöz SB, Hanzlik JA, Underwood RJ, Gilbert JL, MacDonald DW, Lee G-C, Mont MA, Kraay MJ, Klein GR. Do ceramic femoral heads reduce taper fretting corrosion in hip arthroplasty? A retrieval study. *Clinical Orthopaedics and Related Research*®. 2013; 471(10):3270. [PubMed: 23761174]
5. Goldberg JR, Gilbert JL, Jacobs JJ, Bauer TW, Paprosky W, Leurgans S. A multicenter retrieval study of the taper interfaces of modular hip prostheses. *Clinical orthopaedics and related research*. 2002; 401:149.
6. Arnholt CM, MacDonald DW, Malkani AL, Klein GR, Rimnac CM, Kurtz SM, Committee IRCW. Corrosion Damage and Wear Mechanisms in Long-Term Retrieved CoCr Femoral Components for Total Knee Arthroplasty. *The Journal of Arthroplasty*. 2016
7. Campbell P, Yuan N, Luck J, Courpron P, Park S. Re-examining the concept of inflammatory cell-induced corrosion. *Bone Joint J*. 2017; 99(SUPP 3):57.
8. Campbell PA, Kung MS, Hsu AR, Jacobs JJ. Do retrieval analysis and blood metal measurements contribute to our understanding of adverse local tissue reactions? *Clinical Orthopaedics and Related Research*®. 2014; 472(12):3718. [PubMed: 25160942]
9. Cooper HJ, Urban RM, Wixson RL, Meneghini RM, Jacobs JJ. Adverse local tissue reaction arising from corrosion at the femoral neck-body junction in a dual-taper stem with a cobalt-chromium modular neck. *J Bone Joint Surg Am*. 2013; 95(10):865. [PubMed: 23677352]
10. Engh CA, Ho H. Metal-on-metal hip arthroplasty: does early clinical outcome justify the chance of an adverse local tissue reaction? *Clinical Orthopaedics and Related Research*®. 2010; 468(2):406. [PubMed: 19727991]
11. Fricka KB, Ho H, Peace WJ, Engh CA. Metal-on-metal local tissue reaction is associated with corrosion of the head taper junction. *The Journal of arthroplasty*. 2012; 27(8):26. [PubMed: 22554728]
12. Innocenti M, Carulli C, Matassi F, Carossino AM, Brandi ML, Civinini R. Total knee arthroplasty in patients with hypersensitivity to metals. *International orthopaedics*. 2014; 38(2):329. [PubMed: 24389947]
13. Münch HJ, Jacobsen SS, Olesen JT, Menné T, Søballe K, Johansen JD, Thyssen JP. The association between metal allergy, total knee arthroplasty, and revision: study based on the Danish Knee Arthroplasty Register. *Acta orthopaedica*. 2015; 86(3):378. [PubMed: 25582229]

14. Mitchelson AJ, Wilson CJ, Mihalko WM, Grupp TM, Manning BT, Dennis DA, Goodman SB, Tzeng TH, Vasdev S, Saleh KJ. Biomaterial hypersensitivity: is it real? Supportive evidence and approach considerations for metal allergic patients following total knee arthroplasty. *BioMed research international*. 2015; 2015
15. Lachiewicz PF, Watters TS, Jacobs JJ. Metal Hypersensitivity and Total Knee Arthroplasty. *Journal of the American Academy of Orthopaedic Surgeons*. 2016; 24(2):106. [PubMed: 26752739]
16. Luetzner J, Krummenauer F, Lengel AM, Ziegler J, Witzleb W-C. Serum metal ion exposure after total knee arthroplasty. *Clinical orthopaedics and related research*. 2007; 461:136. [PubMed: 17438467]
17. La Budde JK, Orosz JF, Bonfiglio TA, Pellegrini VD. Particulate titanium and cobalt-chrome metallic debris in failed total knee arthroplasty: a quantitative histologic analysis. *The Journal of arthroplasty*. 1994; 9(3):291. [PubMed: 8077978]
18. Posada OM, Tate RJ, Meek R, Grant MH. In Vitro Analyses of the Toxicity, Immunological, and Gene Expression Effects of Cobalt-Chromium Alloy Wear Debris and Co Ions Derived from Metal-on-Metal Hip Implants. *Lubricants*. 2015; 3(3):539.
19. Hood RW, Wright TM, Burstein AH. Retrieval analysis of total knee prostheses: a method and its application to 48 total condylar prostheses. *Journal of biomedical materials research*. 1983; 17(5): 829. [PubMed: 6619179]
20. Cottrell JM, Townsend E, Lipman J, Sculco TP, Wright TM. Bearing surface design changes affect contact patterns in total knee arthroplasty. *Clinical orthopaedics and related research*. 2007; 464:127. [PubMed: 18062045]
21. Gadelmawla E, Koura M, Maksoud T, Elewa I, Soliman H. Roughness parameters. *Journal of Materials Processing Technology*. 2002; 123(1):133.
22. Wapner KL. Implications of metallic corrosion in total knee arthroplasty. *Clinical orthopaedics and related research*. 1991; 271:12.
23. Gao X, He R-x, Yan S-g, Wu L-d. Dermatitis associated with chromium following total knee arthroplasty. *The Journal of Arthroplasty*. 2011; 26(4):665. e13.
24. Elves M, Wilson J, Scales J, Kemp HB. Incidence of metal sensitivity in patients with total joint replacements. *BMJ*. 1975; 4(5993):376. [PubMed: 1192079]
25. Bergschmidt P, Bader R, Mittelmeier W. Metal hypersensitivity in total knee arthroplasty: revision surgery using a ceramic femoral component—a case report. *The Knee*. 2012; 19(2):144. [PubMed: 21292491]
26. Romesburg JW, Wasserman PL, Schoppe CH. Metallosis and metal-induced synovitis following total knee arthroplasty: review of radiographic and CT findings. *Journal of radiology case reports*. 2010; 4(9):7.
27. Liu T-K, Liu S-H, Chang C-H, Yang R-S. Concentration of metal elements in the blood and urine in the patients with cementless total knee arthroplasty. *The Tohoku journal of experimental medicine*. 1998; 185(4):253. [PubMed: 9865472]
28. Evans EM, Freeman M, Miller A, Vernon-Roberts B. Metal sensitivity as a cause of bone necrosis and loosening of the prosthesis in total joint replacement. *Journal of Bone & Joint Surgery, British Volume*. 1974; 56(4):626.
29. Kocagoz SB, Underwood RJ, MacDonald DW, Gilbert JL, Kurtz SM. Ceramic heads decrease metal release caused by head-taper fretting and corrosion. *Clinical Orthopaedics and Related Research®*. 2016; 474(4):985. [PubMed: 26847452]
30. Di Laura A, Hothi HS, Meswania JM, Whittaker RK, de Villiers D, Zustin J, Blunn GW, Skinner JA, Hart AJ. Clinical relevance of corrosion patterns attributed to inflammatory cell-induced corrosion: A retrieval study. *Journal of Biomedical Materials Research Part B: Applied Biomaterials*. 2015
31. Kretzer JP, Reinders J, Sonntag R, Hagmann S, Streit M, Jeager S, Moradi B. Wear in total knee arthroplasty—just a question of polyethylene? *International orthopaedics*. 2014; 38(2):335. [PubMed: 24218115]
32. Chapman-Sheath P, Cain S, Bruce W, Chung W, Walsh W. Surface roughness of the proximal and distal bearing surface of mobile bearing total knee prostheses. *The Journal of arthroplasty*. 2002; 17(6):713. [PubMed: 12216024]

33. Puloski SK, McCalden RW, MacDonald SJ, Bourne RB, Rorabeck CH. Surface analysis of posterior stabilized femoral components used in total knee arthroplasty. *The Journal of arthroplasty*. 2003; 18(7):822. [PubMed: 14566734]
34. Que L, Topoleski L, Parks NL. Surface roughness of retrieved CoCrMo alloy femoral components from PCA artificial total knee joints. *Journal of biomedical materials research*. 2000; 53(1):111. [PubMed: 10634960]
35. Oonishi H, Ueno M, Kim SC, Oonishi H, Iwamoto M, Kyomoto M. Ceramic versus cobalt-chrome femoral components; wear of polyethylene insert in total knee prosthesis. *The Journal of arthroplasty*. 2009; 24(3):374. [PubMed: 18524533]
36. McGloughlin TM, Kavanagh A. Wear of ultra-high molecular weight polyethylene (UHMWPE) in total knee prostheses: a review of key influences. *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine*. 2000; 214(4):349.

Figure 1.

A circle was fitted to the dominant radii of the femoral component and polymer insert using a digital camera and calibrated ruler or a μ CT scan with digital software respectively. Radii measurements of (A) anterior-posterior plane and (B) medial-lateral plane of the polyethylene inserts. Radii measurements of the (C) anterior-posterior and (D) medial-lateral planes of the femoral condyle.

Figure 2. Description of the process for identification of MECD on femoral condyle surfaces. Initially suspected spot (A), having a confined and cloudy appearance. Low magnification light microscopy revealing suspected MECD features (B). Higher magnification revealing crater-like features consistent with MECD (C).

Figure 3. Silhouette of femoral component with four regions inspected for MECD. The posterior, anterior, side, and bearing surface of the femoral component were inspected for each component within the cohort.

Figure 4.

Images describing the range of damage modes referred to in the scoring system. A and B: Score of 3 represented deeper scratches effecting dominant regions of the device, highly damaged area indicated by red arrows. C: Score of 2 described moderate damage with deeper scratches affecting a broader area of the device, deep scratches indicated by red arrows. D: Score of 1 showed mild damage with slight scratching, on smaller regions of the device. Red arrows indicate affected area. E: A score of 0 represented minimum to no damage.

Figure 5.

The relationship between cumulative femoral component damage score and R_a surface roughness parameter. As the R_a increases there is an increase in component femoral damage score, $p=0.001$.

Figure 6.

The relationship between cumulative femoral component damage score and R_q surface roughness parameter. As the R_q increases, there is an increase in component femoral damage score, $p=0.003$.

Table 1

Description of femoral component damage scoring method criteria.

Damage	Score	Criteria
Minimal	0	Surface Scratches: 0 to 1 surface scratches with minimal coverage Corrosion: No apparent corrosion
Mild	1	Surface Scratches: Deep penetrating scratches on more than 10% of surface, or very faint parallel scratching with less than 50% area coverage OR Corrosion: Small and localized
Moderate	2	Surface Scratches: Deep penetrating scratches on more than 30% of surface, or faint parallel scratching with larger than 50% area coverage OR Corrosion: More than 30% of the surface area
Severe	3	Surface Scratches: Deep penetrating scratches on the majority (>50%) of the surface OR Corrosion: More than 50% of the surface area

Table 2

Predictive and nonpredictive factors for increased cumulative femoral component damage score.

Predictive Factors	β value	p value
A/P ratio	-8.07	p<0.001
Implant loosening	-0.52	p=0.006
Patient weight	0.01	p=0.007
Nonpredictive factors	β value	p values
Implantation time	0.04	p=0.45
MECD	-0.18	p=0.48
Conformity M/L Ratio	-0.56	p=0.63
Implant Instability	0.42	p=0.06
Patient Infection	-0.15	p=0.54