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Standardizing terms for tribocorrosion-associated adverse local tissue reaction in total hip arthroplastv

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Introduction

Tribocorrosion is defined as "an irreversible transformation of material in tribological contact caused by simultaneous physicochemical and mechanical surface interactions" [1]. In other words, the discipline of tribocorrosion considers both the mechanical and electrochemical degradation of metallic materials in contact; the mechanical and electrochemical degradative processes for metal/ metal interfaces are synergistic and must be considered together to achieve a complete understanding of the potential sequelae [2]. Tribocorrosion-related failure of contemporary metal-onpolyethylene (MoP) total hip arthroplasty (THA) has been recognized for decades but recently appears to have become more common, more recognized, or both (Fig. 1). In addition, revision specifically for this problem is also more frequent [3,4] and is

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recognized to have poor outcomes [5-8], with over one-fourth of

patients experiencing serious complications including instability,

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ABSTRACT

Recognizing and adopting standardized terms for adverse local tissue reaction associated with tribocorrosion in total hip arthroplasty are essential for clear scientific discourse and clinical communication. Our goal was to develop terms that can be broadly applied to characterize the local tissue response to tribocorrosion debris, based on current evidence regarding the etiology of this failure mode and its consequences. The proposed standardized terms will improve the understanding and interpretation of analytical tests, advance diagnostic and treatment algorithms, and reduce confusion in research by maintaining consistent nomenclature.

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> infection, and chronic pain. Different terms are used to describe this mode of tribocorrosion failure, including both terms for the breakdown at the metal/metal modular junction itself and also terms referring to an individual's biological reaction to this malfunction.

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It is essential to standardize these terms to facilitate diagnosis, treatment, research, and interdisciplinary communication. To achieve this goal, particularly for purposes of uniform communication through peer-reviewed publication, Arthroplasty Today supports this project to identify terms that could be used consistently for tribocorrosion in MoP THA. When possible, the goal was to agree on uniform terms that could be applied to characterize (i) tribocorrosion failure mechanisms of the THA metal/metal modular junction and (ii) local biological reactions to tribocorrosion products produced from this failure.

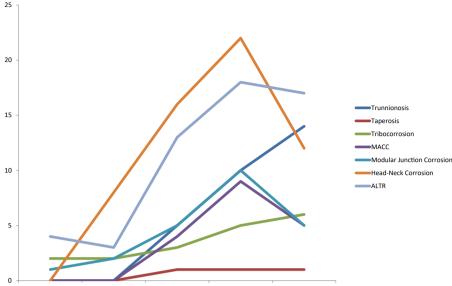
Problem statement

There is a lack of uniformity and specificity in the current terminology used to describe MoP THA failure due to in vivo tribocorrosion of metal/metal modular junctions and its biological consequences. The term "trunnionosis" is often used to describe a biological reaction, presumably inflammatory in nature, associated with the trunnion of the femoral component of a hip replacement.

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Jan 2010 - Dec 2011 Jan 2012 - Dec 2013 Jan 2014 - Dec 2015 Jan 2016 - Dec 2017 Jan 2018 - Dec 2019

Figure 1. Graph demonstrating general increase in keywords used as search terms for tribocorrosion-related adverse local tissue reaction usage over the last decade in PubMed. PubMed is a free search engine maintained by the United States National Library of Medicine at the National Institutes of Health that accesses the MEDLINE database for life sciences and biomedical topics.

This oversimplification is not particularly useful, and the presumption of an inflammatory response may be misleading. Another term commonly used to describe a patient's reaction to corrosive failure is "pseudotumor," and this too is poorly defined and misleading. Metallosis refers to macroscopic black or gray stained tissues. Aseptic lymphocyte-dominated vasculitis-associated lesion (ALVAL) is not a clinical diagnosis; however, it represents histological appearance of tissues characterized by lymphocyte infiltration and perivascular cuffing [9]. Fluid alone on an MRI may be interpreted as an adverse local tissue reaction (ALTR) [10,11], and systems to grade these MRI changes show only moderate agreement among reviewers [12]. A group of other such terms and test parameters, often adopted from research of failed metal-on-metal (MoM) hip arthroplasties, adds to confusion in this field (Table 1).

The lack of standard vocabularies describing this failure mode further interferes with comprehension of patients, clinicians, researchers, and readers of medical literature. Uncertainty is observed in oral presentations as well as publications on this topic. The impact on communication may significantly impede the understanding and treatment of this method of joint replacement malfunction.

To be specific in the scope of this project, we will focus on standard, contemporary THAs. These definitions will also have applicability to other metallic implants where there are metal/metal interfaces that have the potential to release debris via tribocorrosion mechanisms, eg, modular stem extensions in total knee replacement.

Table 1

Terms that may be confusing in current literature pertaining to adverse local tissue reaction (ALTR) in metal-on-polyethylene (MoP) total hip arthroplasty (THA).

Terms that are too general, misleading, or repetitive	Terms that are too specific and may be misleading if used out of context
 metallosis trunnionosis taperosis biocorrosion pseudotumor adverse reaction to	 aseptic lymphocyte-dominated
metal debris (ARMD)	vasculitis-associated lesions (ALVAL) galvanic corrosion

Proposed solution

We propose understanding in vivo tribocorrosion at modular metal/metal junctions of MoP THA in terms of 1) the underlying mechanism, mechanically assisted crevice corrosion (MACC) and 2) the patient's biological response, ALTR. Of note, having the former, MACC, does not imply that ALTR must be present, but tribocorrosion-related ALTR cannot be present without MACC in contemporary MoP THAs.

Mechanically assisted crevice corrosion

Retrieval and clinical studies have shown that both mixed-alloy (Ti-6Al-4V stems and Co-Cr-Mo heads) and similar-alloy (Co-Cr-Mo stems and Co-Cr-Mo heads, and Ti-6Al-4V stems and Ti-6Al-4V heads) couples sometimes demonstrate in vivo corrosion [3,4,13] (Fig. 2). There is some controversy as to whether this is more common in mixed-alloy settings [13,14], which highlights the need for additional research to clarify this finding because there may be bias introduced by evaluating only retrieved implants (retrievals are primarily failed total hips, and corrosion may contribute to a failure, without being recognized [15,16]). Furthermore, retrieval laboratories estimating prevalence of corrosion based on visual inspection may have poor accuracy for lower grades (Goldberg 1-2) [17]. It is important to know that not all modular hip replacements corrode [3,14,18], and in one sample of symptomatic THA patients with a contemporary titanium alloy stem and cobalt alloy femoral head, 51.1% of patients with symptoms had serum Co less than 1 ppb, at an average of 60.1 months after index THA [3]. A further cohort from the same institution demonstrated 60%-75% of all patients from a single year studied had a serum Co < 1 ppb 10 years postoperatively [19]. In addition, Levine and colleagues showed that well-functioning hips, followed over a 10-year span, also had serum metal levels less than 1 ppb. They did note, however, that serum Co levels increased over time for the subset of patients with hybrid Co-Cr-Mo stems and Co-Cr-Mo heads [14].

The corrosion process is thought to be the result of mechanicalelectrochemical interactions in the taper crevice. Metal implants all

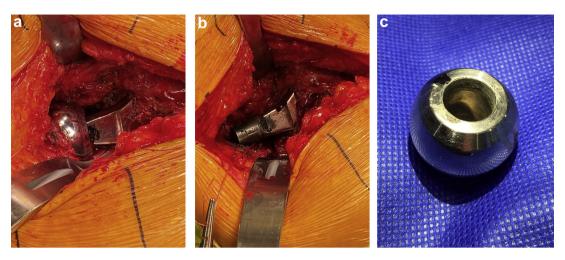


Figure 2. Mechanically assisted crevice corrosion (MACC) describes the underlying mechanism of significant tribocorrosion at the femoral trunnion-head bore junction, as seen in these clinical photographs: (a) dark material noted at base of junction of the head and trunnion in a failed metal-on-polyethylene (MoP) total hip arthroplasty (THA), (b) marked discoloration of trunnion after removal of femoral head, (c) marked discoloration of bore of femoral head with transfer of trunnion markings (so-called "stamping").

have passivation of their surface, a continuous, protective, oxide layer that protects against further oxidation and corrosion. In cases of MACC, the passivating oxide film disruption caused by fretting and the constrained crevice environment of the modular junction combine to cause changes in the fluid chemistry inside the taper (including decreases in pH and increases in chloride concentrations) [20]. Furthermore, the potential of the implant becomes significantly more negative, and this, in turn, causes the passive oxide layer which reforms to be thinner than the original film [21]. Loading of THAs during activities of daily living causes stress and possibly micromotion at the taper interface, leading to recurring disruption of the passive layer on the implant surface. The exposed metal substrate then spontaneously reoxidizes in vivo. This causes additional oxygen depletion in the fissure, thereby accelerating the process of crevice corrosion, including the release of metal ions and solid particles [22,23].

Fretting involves more severe mechanical damage to the metal surface. Deep-surface asperities form beyond the passive layer and consequently provide further sequestered electrochemical environments for pitting corrosion. Once fretting starts, the corrosion processes may continue in the absence of loading [17]. Some retrieved tapers show evidence of etching and grain egression (a mechanism of fatigue-crack initiation) at these interfaces, suggesting macroscopic movement [24]. Furthermore, corrosion at the interface may lead to instability and macromotion, making them further susceptible to abrasive wear [17,24,25], although this may be prosthesis specific [16].

This process is referred to as MACC and we propose that this term be used to describe the underlying mechanism of significant tribocorrosion at the femoral trunnion-head bore junction, the femoral neck-stem junction in modular neck devices, the metal acetabular liner-shell junction, and other metal/metal modular connections (Table 2). The discoloration and debris are likely a combination of tribocorrosion mechanisms and may or may not lead to discoloration of the surrounding tissues or joint fluid. Ideally, retrieval analysis with a coordinate measuring machine to assess material loss due to corrosion could confirm with certainty the diagnosis of MACC [26].

The products of tribocorrosion generated from MACC vary in size from <1 to 500 micrometers [27]. Most particulate debris is <5 micrometers in size and plate shaped, irrespective of the material combination used [27,28]. The most abundant particles produced are chromium orthophosphate (CrPO4) and mixed oxides; but chlorides of chromium, molybdenum, and titanium (Ti) are also common [27]. The biological response to these corrosion products is similar to that produced by MoM bearing surface debris [4] but there is evidence suggesting that tribocorrosion products may be more biologically active and highly necrotizing [29], possibly as a result of higher concentrations of ionized metal and chemokines [29,30].

MACC is therefore associated with elevated intra-articular Co levels (greater than 100 ppb [29,31,32]) and through diffusion, phagocytosis, and other means—serum, whole blood, cerebrospinal fluid, urine, and solid organ levels are also elevated. Peripheral metal levels in MACC are significantly lower than in the tissues directly around the implant because of dilutional effects, renal excretion, and possibly necrosis of joint tissues impeding diffusion

Table 2

Proposed terminology and criteria for terms referring to triobocorrosion-related findings in contemporary total hip replacement (THA) including mechanically assisted crevice corrosion (MACC) and adverse local tissue reaction (ALTR).

Terminology	Criteria
MACC	Retrieved femoral head with evidence of tribocorrosion damage (Goldberg grade 2 or higher)
ALTR (one or more of these)	1. Osteolysis on radiographs and no evidence of infection or wear in patients with cross-linked polyethylene when there is concomitant evidence of MACC either by direct observation intraoperatively or by findings of elevated blood cobalt levels.
	 Cross-sectional imaging (MARS-MRI; ultrasound or CT scan when MRI is contraindicated or MARS not available) demonstrating abnormal tissue reactions involving surrounding muscle and/or bone and cystic lesion(s) surrounding the hip when there is concomitant evidence of MACC either by direct observation intraoperatively or by findings of elevated blood cobalt levels. Intraoperative finding of osteolysis, devitalized tissue, bone necrosis, muscle necrosis, tendon detachment, capsule dehiscence, capsular thickening, cystic lesion(s), excessive fluid collection(s), and soft tissue masses when there is concomitant evidence of MACC by direct observation intraoperatively. These gross findings may be present with or without metal staining of the tissues. Histopathology from biopsy or from a revision with dense infiltrates of perivascular lymphocytes (ALVAL) and/or areas of tissue necrosis when there is concomitant evidence of
	MACC either by direct observation intraoperatively or by findings of elevated blood cobalt levels.

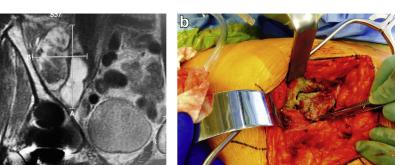


Figure 3. A significant local biological reaction noted in a high proportion of cases of MACC is referred to as an adverse local tissue reaction (ALTR), as is exemplified by (a) a periarticular mass noted on metal artifact reduction sequence (MARS) magnetic resonance imaging (MRI) in this patient with elevated serum cobalt (Co) and chromium (Cr) levels and new-onset hip symptoms and (b) a clinical photograph of a different patient with an MOP THA, progressive hip weakness, and a pathological local biological reaction attributed to MACC.

[31]. Of note, serum Co levels are disproportionately greater than Cr in MACC (4-5:1) in both intra-articular and systemic measurements. Cr is less soluble than Co and can precipitate as CrPO4 (chromium orthophosphate) or other species. Therefore, the concentration of Cr is less in the bloodstream and is more persistent in the local tissues.

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Adverse local tissue reaction

ALTRs are pathological local biological tissue reactions that occur in direct approximation to a MoP hip joint that has significant tribocorrosion (Fig. 3). Reactions may include osteolysis, bone necrosis, muscle necrosis, tendon necrosis with or without detachment, capsular necrosis with or without dehiscence, capsular thickening, cystic lesion(s), excessive fluid collection(s), ALVAL, and soft tissue masses [10,11,33-37]. Many of these features are seen in variable amounts in cases of ALTR and it is not clear why some lesions show a predominance of one feature over the others. Although these reactions originate locally, they may extend into the surrounding tissues, local lymph system, muscular planes, and may even cause obstructive vascular or neurological compromise [8,38,39]. The cause of ALTR is most likely multifactorial and both local Co toxicity [29,31,32] and a delayed-type hypersensitivity-like immune response (aseptic lymphocyte-dominated vasculitisassociated lesion or ALVAL) may be operative [35]. Furthermore, the adaptive immune response or hypersensitivity may play an important role in the pathogenesis of these ALTRs in a subset of patients, but current diagnostic tools for metal hypersensitivity have yet to be clinically validated [40]. Patients with an ALTR may or may not be symptomatic [19].

A significant local biological reaction noted in a high proportion of cases of MACC (49% on initial presentation in one study [3]) is best referred to as an ALTR and we propose that this term is used to describe all cases of pathological local biological reaction attributed to MACC. A serum Co of >1 ppb has been shown to be associated with both tribocorrosion and associated ALTR [34,37]. It is acknowledged that MRI abnormalities may not be significant in patients without MACC [10], but such findings are likely to be important in patients with MACC [3,19].

Future direction and long-term focus

We hope that this proposed general terminology be used in clinical practice, research publications, and other communications when describing tribocorrosion damage and its local biological sequelae associated with MoP THA with metal/metal modular junctions. Furthermore, we recommend that world registries, including the American Joint Replacement Registry, refine diagnostic codes (both primary and secondary) adopting these criteria for MACC and ALTR relating to THA failures and revisions. Such codes could also be added as a set of supplementary codes for the 10th revision of the International Statistical Classification of Diseases and Related Health Problems.

Recommendations

We propose that clinicians, researchers, and authors describe the mechanism of in vivo tribocorrosion at metal/metal modular junctions of THA using the term MACC, and patient's local biological response using the term ALTR. We want to reiterate that all hip implants do not demonstrate MACC and that an ALTR appears to occur at presentation in only some cases of MACC.

Conflict of interest

Brian J. McGrory, MD, MS, reports royalties from Innomed, Inc., Smith & Nephew, Inc.; Speakers bureau/paid presentations and paid consultant for Smith & Nephew, Inc. Joshua J. Jacobs, MD, Paid consultant for Consultant, Zimmer Biomet, Stock for Hyalex; Research support Medtronic, Nuvasive; Royalties, financial or material support Secretary of the Board of Trustees, Journal of Bone and Joint Surgery; Medical/Orthopaedic publications editorial/ governing board Secretary of the Board of Trustees, Journal of Bone and Joint Surgery; Board member/committee appointments for a society President, The Hip Society; Vice President, American Board of Orthopaedic Surgery; Treasurer, Orthopaedic Research and Education Foundation. Young-Min Kwon, MD, PhD, Institutional Research support as a Principal Investigator from the following companies – Smith & Nephew, Zimmer Biomet, Stryker, Corentec; Yale Fillingham, MD, Paid consultant for Johnson & Johnson, Medacta; Stock Muvr Labs, Inc.; Board member/committee appointments for a society AAOS, EBVQ Committee Member and AAHKS, YAG Committee Member.

For full disclosure statements refer to https://doi.org/10.1016/j. artd.2020.01.008

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