It's worth cleaning – The examination of the female taper could identify a particular cause of trunnionosis at revision 16 years after total hip arthroplasty

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LIST OF ABBREVIATIONS

ARMD	adverse reaction to metal debris
MoM	metal-on-metal
THR	total hip replacement
CMM	coordinate measuring machine

ABSTRACT

Adverse reaction to metal debris (ARMD) is an issue in metal-on-metal (MoM) total hip replacements (THR). It mainly affects large-head MoM THR, whereas 28-32 mm MoM pairings are associated with low long-term revision rates. However, the bearing surface is not necessarily the only cause of metal debris. This report documents with advanced analysis of the retrievals a particular cause of trunnionosis in late failure of a small diameter MoM THR and illustrates the importance of cleaning of the taper when seating the head in THR. A 65-year-old patient was revised due to ARMD 16 years after small diameter MoM THR. Debridement and exchange of the inlay and the head had been performed through an anterior approach. While the cup and the outer surface of the head were accessible to direct analysis by an optical coordinate measuring machine, the female taper had to be analysed indirectly by measuring an imprint. Wear from the cup and the head was within expected low ranges. The analysis of the female taper identified bone fragments, which contributed to trunnionosis. Failure due to ARMD after MoM THR is not necessarily caused by the bearing, but can be due to trunnionosis. Bone fragments within the taper contact in this case highlight the importance of meticulous cleaning of the taper before seating the head, to avoid trunnionosis.

KEYWORDS

Trunnionosis, metal-on-metal, total hip replacement, THR, adverse reaction to metal debris, ARMD

RUNNING TITLE

Trunnionosis after total hip arthroplasty identified by examination of the female taper

1. INTRODUCTION

Failure of metal-on-metal (MoM) total hip replacements (THR) due to local adverse reactions to metal debris (ARMD) is a well-known issue.[1, 2] An additional reason for revision might be systemic toxicity of metal ions released from MoM THR, mainly with secondary neurologic, cardiac and immunologic disease.[3-5] Both issues lead to increased revision rates of THR with MoM bearings and might even be associated with an increased mortality.[6-8]

Increased revision rates are mainly associated with large diameter MoM THR.[7, 8] Small diameter (28 and 32 mm) MoM THR appear to have very low long-term revision rates.[8] However, ARMD after MoM THR is not necessarily caused by failure of the bearing. Trunnionosis, defined as wear and/or corrosion of the taper connection between the head and the stem in THR, can also be a source of metal particles.[2, 9-13]

We present observations made from a clinical case needing revision due to local ARMD 16 years after small diameter MoM THR. This case illustrates that the cause of failure is not always the most obvious, and provides insights useful in daily clinical routine and surgical practice. The technique required for proper analysis of the female taper (or bore) is presented, as it is neither commonly available nor commonly known. However, it may be considered to gain additional information when the male taper (or trunnion) is not available for direct examination.

2. PATIENTS AND METHODS

2.1 Case description

Bilateral THR was performed through a lateral approach on a 48-years old male, obese (197 cm, 125 kg, BMI 32,2 kg/m^2) patient, who suffered from symptomatic osteoarthritis of both hips.

Uncemented fixation with a small diameter MoM bearing had been chosen (Fitek cup, Metasul metal-polyethylene-sandwich inlay, 28 mm Metasul head with L/+4 mm taper, BEO stem; Zimmer Biomet, Winterthur, Switzerland). Postoperative recovery was uneventful, with a patient who had no complaints from his hips for over 10 years. Both implants caused leg lengthening of more than 10 mm, but as this was symmetrical, the patient had no associated complaints.

Approximately 14 years postoperatively, the patient started complaining of new onset hip pain on the right side, interpreted as an abductor tendinopathy at that time. Analgesia with NSAIDs and repeated series of physical therapy brought short-term improvement every time, but the hip complaints slowly increased over time. Two years later the patient presented again due to the pain in his right hip. Pain was located in the groin and increasing on flexion and abduction. Conventional radiographs (Fig. A) showed a well-oriented, uncemented THR without signs of loosening, but identified a soft tissue tumor around the joint. A computed tomography of the pelvis demonstrated an osteolysis in the posterior trochanter and a soft tissue tumor, located mainly anteriorly to the hip. Retrospectively, this soft tissue tumor was also identifiable on the radiographs performed 2 years earlier.

Figure A – Section of interest, showing the right hip, of the conventional anteroposterior radiographs of the pelvis of the initially 65 years old male patient. Contrast is impaired on all images due to the patient's corpulence. Preoperative osteoarthritis of the hip is visible in **1**. Cranial flattening of the femoral head due to wear is present, and the hip is laterally subluxated. The bone of the acetabulum and of the femoral head are in contact, with no more cartilage in between, which would be radiolucent. Osteophyte formation is visible both on the lateral femoral head, as well as on the acetabulum. The postoperative control radiography is shown in **2**. Note important leg lengthening, particularly the position of the lesser trochanter compared to the ischium, caused by the implant. The orientation of the cup is correct, both in inclination and anteversion. The inlay is a metal cup/polyethylene sandwich (Metasul 28 mm), the outer contour of the inner metal cup giving the cylindrical shape around the ball head. Radiographs 16 years postoperatively are shown in **3**. Black arrows mark the contours of a soft tissue tumour around the joint. No signs of loosening are visible, both around the cup as well as along the stem. Results at one year post-revision are shown in **4**. The soft tissue tumor is no longer visible. Note exchange of the inlay and of the head (now 36 mm mixed ceramics head with highly crosslinked polyethylene liner).

Aspiration of the hip joint showed dark grey fluid, macroscopically corresponding to marked metallosis. Automated cell count identified 11’832 leucocytes/µl among which 82.5% identified as polymorphonuclear neutrophil granulocytes. Prolonged microbiological cultures of the joint fluid remained sterile. Blood samples showed slightly increased cobalt levels (1.69 µg/l whole blood (28.6 nmol/l)), while chromium levels were normal.

These results were interpreted as an ARMD from a MoM THR, with formation of an inflammatory pseudotumor. The leucocyte count in the joint fluid was considered as falsely increased due to artefacts by metal particles. Because the cup and the stem were both well oriented and showed no signs of loosening, it was decided to perform a debridement of the soft tissue tumor and an exchange of the inlay and the head only. No revision of the stem was planned, despite the discussed possibility of causative trunnionosis.[2, 14, 15] Extraction of the stem would have required a transfemoral approach, whereas the patient's body weight and degree of physical activity contraindicated reconstruction with a modular stem. Furthermore, rehabilitation after an extended trochanteric osteotomy would have been far more complex.

Following an anterior approach to the hip, debridement of the soft tissue tumor and exchange of the inlay as well as the head (Durasul alpha, Biolox option 36 mm; Zimmer Biomet) was performed. Approximately 1'000 ml of partially fluid necrotic tissue could be removed. While the metal cup and the surface of the head showed no macroscopic damage, the taper showed severe corrosion and wear (Fig. B). Despite this finding, it was decided to stay with the initial plan, retaining the stem. A ceramic head with inner metal sleeve was chosen for reconstruction, instead of a CoCr head, as the softer titanium-aluminum-vanadium sleeve was expected to adapt better to the damaged male taper.[14, 15]

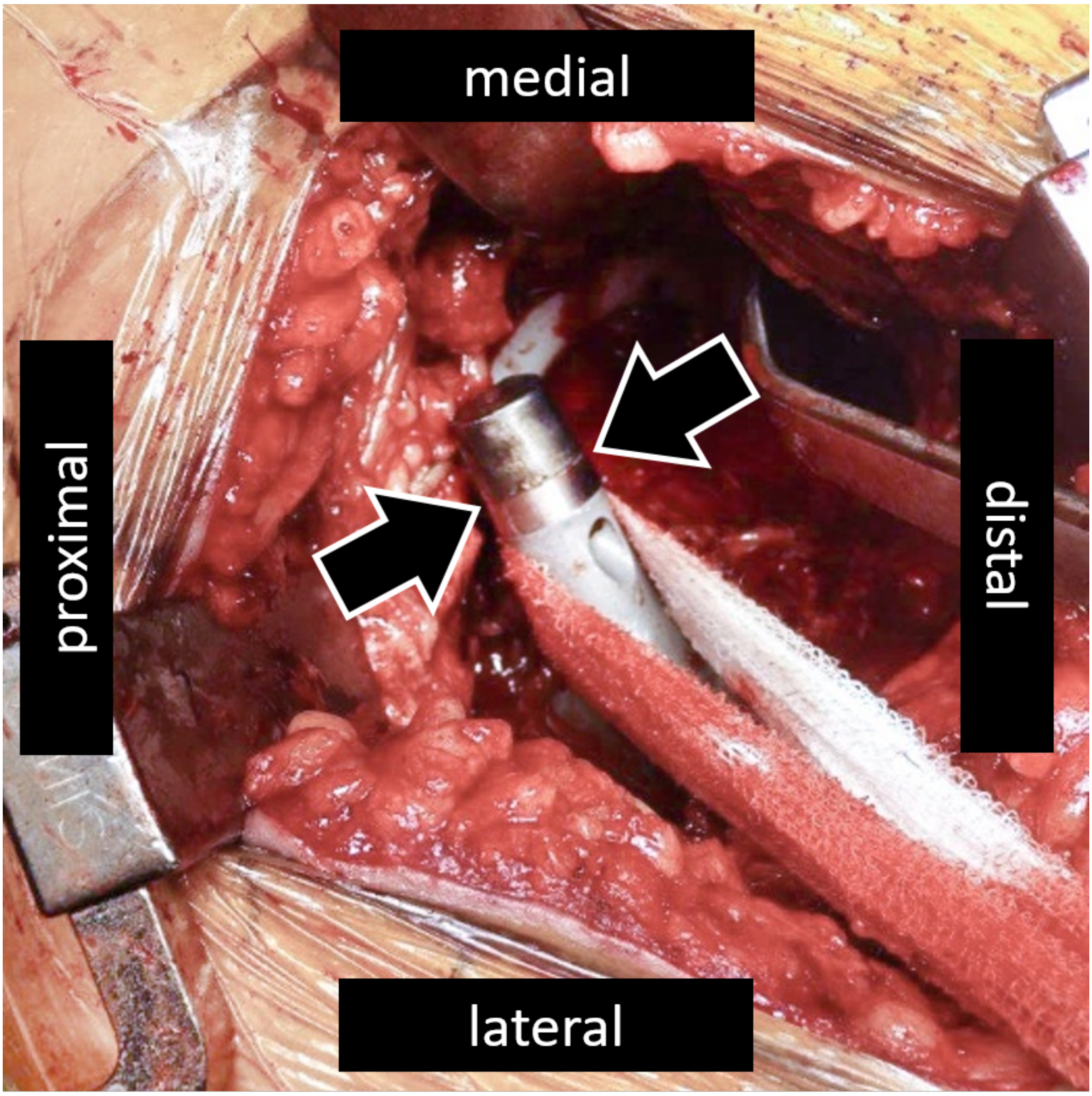

Figure B – Intraoperative view through an anterior approach to the hip. The semi-fluid necrotic tumor of ~1'000 ml already has been evacuated, the prosthesis is dislocated in external rotation, and the ball head component has been removed. The male taper had been cleaned as well as it is possible with wet gauze. The contact zone of the taper is corroded, well shown by dark discoloration compared to the non-affected distal part, as well as worn, with slight volume loss of the affected area, compared to the angle of the distal part of the taper. As the ball head had a L/+4 mm taper, the male taper was not entirely engaged. The contact zone on the distal taper is well identifiable.

Histology confirmed extensive necrosis in the samples from the pseudotumor, demarcated by a well-identifiable vital neocapsule (Fig. C). Within the rather thin-layered and mostly distended neocapsule, a macrophagic reaction was observed (Fig. C-2 and 3) demonstrating phagocytosis of golden-brown granules taking up Prussian blue stain (not shown), thus corresponding typically to hemosiderin. No metallic particles were identifiable. Microbiological workup with prolonged incubation of 14 days followed by subculture of the thioglycolate broth identified no microorganisms in any of the 5 tissue samples. The postoperative radiographs were inconspicuous and recovery was uneventful.

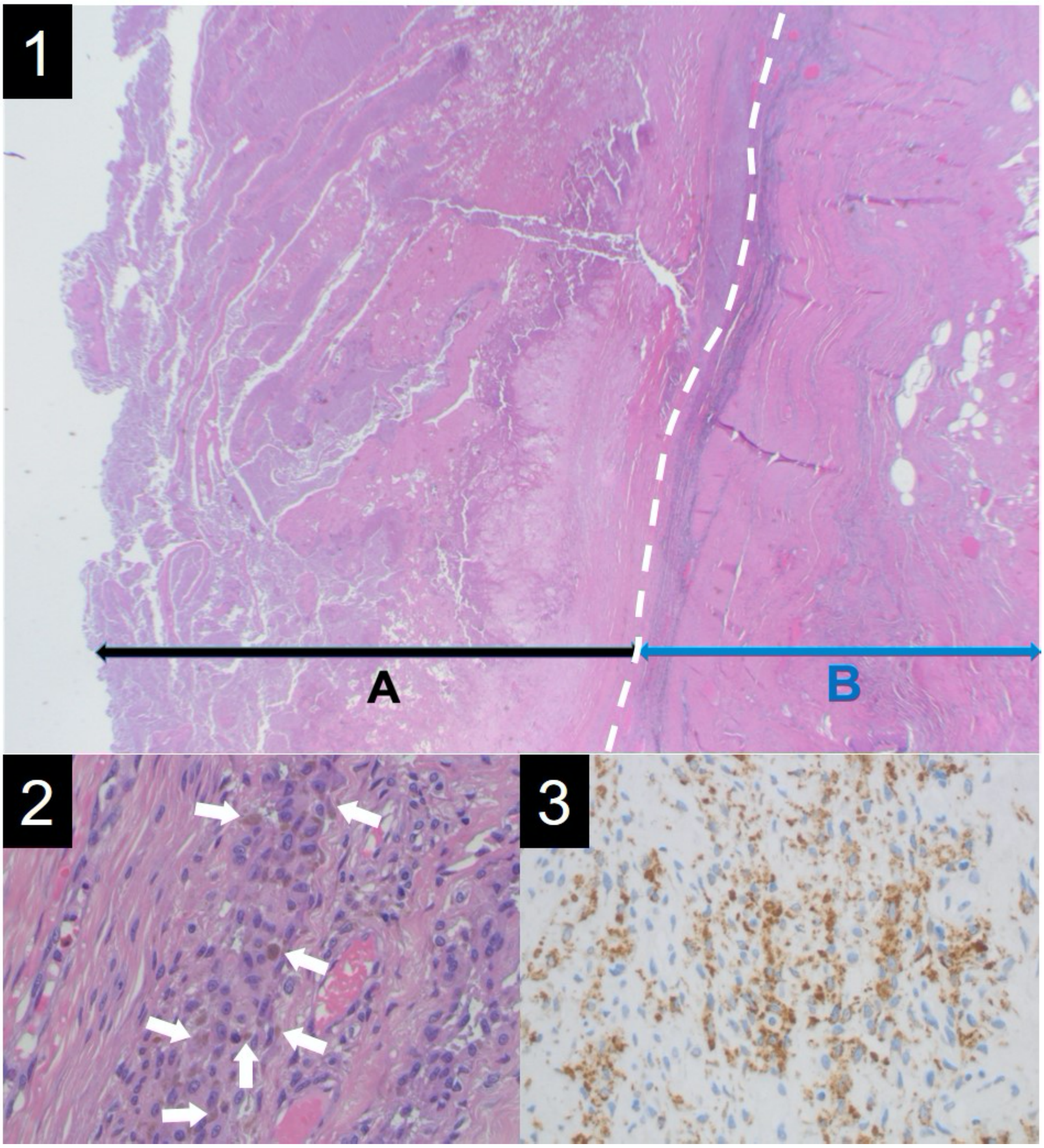

Figure C – Microphotographs of the histology of the periarticular neocapsule. **1:** Overview (hematoxylin eosin (HE) staining, magnification x12,5) showing an extensive necrosis of the innermost layer (area marked A), adjacent to a deeper layer of vital fibrous tissue (area marked B) comprising some adipocytes (at the right edge of the picture). The border between necrosis (A) and vital tissue (B) is demarcated by a macrophagic reaction (marked by a dashed white line). **2:** Higher magnification (HE, x400) of proliferated macrophages at the border of the necrotic tumor showing numerous intracytoplasmatic golden-brown granules (white arrows) corresponding to hemosiderin. **3:** CD68 immunohistochemistry (x400) with positive brown staining of macrophages.

So far, now over three years after the revision, the patient remains free of pain and has a satisfactory joint function. Standard radiographs show no progression of osteolysis (Fig. A.4). The THR on the left side so far shows an uneventful follow-up.

2.2 Analysis of the retrieved components

After washing and sterilization of the retrievals, a 3D capture of the outside of the femoral head as well as of the inside of the cup was performed directly with the RedLux (RedLux Ltd, Southampton, United Kingdom) 3D optical non-contact coordinate measuring machine (CMM). This CMM provides data with a resolution of 20 nm.[10, 16] The analysis of the female taper could not be realized in a direct manner, as the optical sensor of the CMM is too large to fit into the bore. Thus, an imprint of the inner taper of the head was produced, using the Microset 202 replication silicone polymer (Micoset Products Ltd, Hincklex, United Kingdom), as described elsewhere.[16, 17] This technique reproduces textures with a resolution of 50-100 nm. For the analysis, 844'000 data points were acquired in a helical scan with 70 revolutions per mm axially and 720 data points per revolution. Reconstruction was then performed with the RedLux Artificial Hip Joint Profiler (RedLux Ltd, Southampton, United Kingdom).[10, 16, 17]

3. RESULTS

The analysis of the ball head showed total volumetric wear of 6.74 mm^3, which corresponds to 0.43 mm^3/year. The wear of the cup was similarly analyzed (1.53 mm^3 total volumetric wear, 0,0095 mm^3/year). Wear on both components was predominating in the superomedial main contact area (Fig. D).

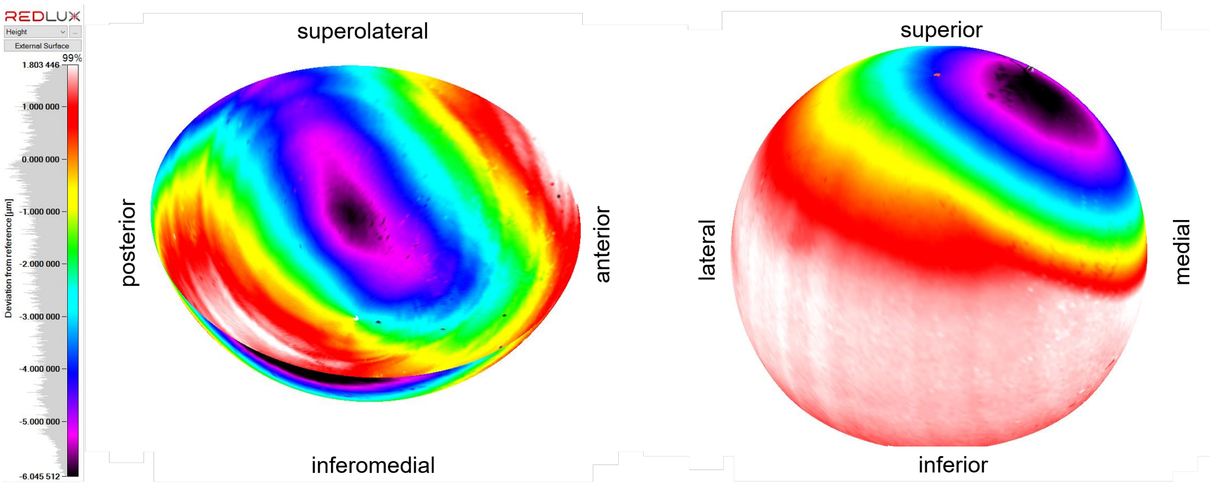

Figure D - Three-dimensional reconstruction from the data acquired by direct measurement by the RedLux CMM from the bearing surface of the cup (left) and the ball head (right). The measured inner diameter of the cup was 14.042 mm, and the outer diameter of the head 13.990 mm. The measured clearance between cup and ball head thus is 52 µm, corresponding closely to the 50 µm minimum diametral clearance specified by the manufacturer. Wear is mainly present at the superomedial contact point, as expected. Despite 16 years in situ, wear remains within some µm.

The analysis of the imprint identified 2 localized defects on the female taper (Fig. E). No reliable determination of volumetric loss was possible, as not enough undamaged taper was available for adequate referencing, due to important imprinting from the trunnion as well as due to material loss in the contact area, and as in this design the female taper stops short above the contact zone, with the contact-free clearance above being a cylindrical bore not usable as reference, due to software limitations. The defect of the softer male taper, made of titanium alloy, was macroscopically more pronounced (Fig. B) than the one identified on the firmer CoCr counterpart of the head. However, this could not be further quantified, as the stem had not been revised.

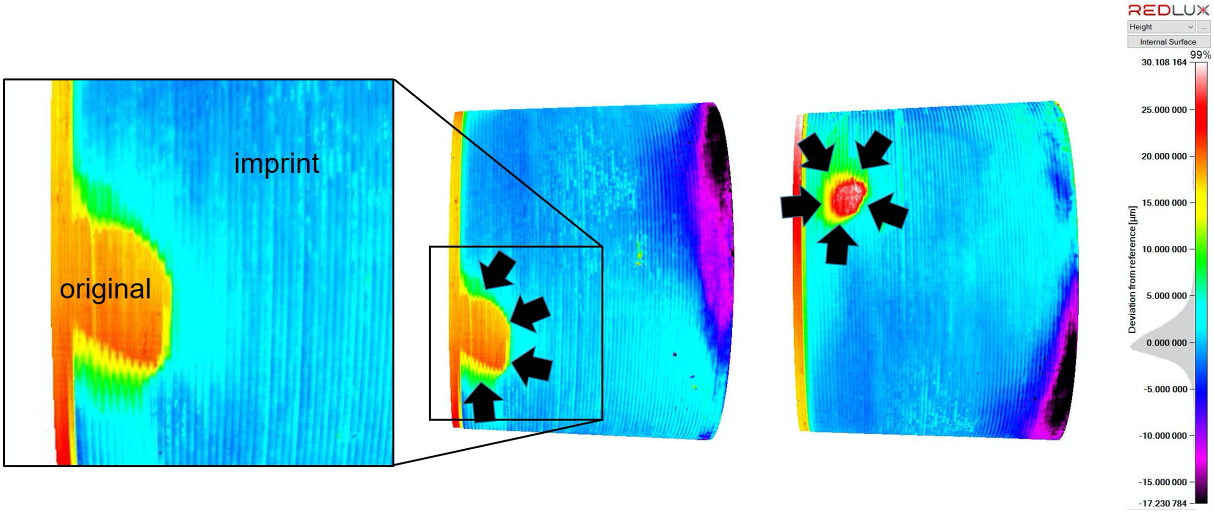

Figure E – Three-dimensional reconstruction from the data acquired by the RedLux CMM from the Microset 202 imprint of the female taper. The taper angle measured at 5.668° is very close to the specifications of the manufacturer, ranging 5°29'00" to 5°46'30" (5.483° - 5.775°) for CoCr-head female taper, illustrating the high degree of data fitting. Both views show opposite sides of the taper. The red/orange stripe at the tip of the taper corresponds to the native taper outside of the contact zone. The rest of the bore, corresponding to the clearance above the contact zone, is cylindrical in this design, and could not be used for referencing. A magnification is provided (black square on the left) to show the difference in the surface pattern between the manufacturing marks on the female taper, visible in the red/orange areas, compared to imprinting on the rest of the contact zone, showing a wider spacing corresponding to the pattern on the male taper. Two localized defects (marked by black arrows) are identifiable, appearing as positive relief on the imprint. Note that the scale is larger than in Fig. D by an order of magnitude. As the component fixation was uncemented, and as both the cup and the stem had no coating such as hydroxyapatite, bone fragments most probably caused these defects. No other material hard enough to indent the CoCr alloy of the head was present. Interposed bone fragments are known to weaken a taper assembly and to contribute to trunnion failure.

4. DISCUSSION

The patient reported on required revision of his small-diameter MoM THR 16 years postoperatively due to local ARMD, where trunnionosis played an essential role. While both ARMD and trunnionosis are known issues in hip arthroplasty,[1, 2, 7-12, 14, 15] the distinctive features of this case is the identification of the cause of trunnionosis by sole measurement of an imprint of the female taper. This technique allowed evaluation of the wear of the taper despite the fact that the stem had not been revised. The trunnion could only be photo-documented intraoperatively since it was not available for any direct measurements. Secondly, bone fragments interposed within the taper connection contributed to the failure.[2] This failure might have been avoidable by better surgical technique at the primary operation, even if the revision had to be performed more than 10 years postoperatively. This long delay until relevant trunnionosis and ARMD developed speaks in favour of the quality and tolerance of the taper connection of this specific stem and ball head.

Wear can be measured on retrieved arthroplasty components by CMM. The majority of available CMM are mechanical, with a resolution limited to approximately 1 µm.[1, 18] However, after initial run-in, wear on small diameter MoM THR bearings might be in this particular range, or just little above such values.[18, 19] Non-contact 3D optical CMM are particularly useful in the analysis of such retrievals, as they might offer a much better resolution (e.g. 20 nm with the RedLux CMM).[10, 16] While the bearing surface of the cup and of the ball head, as well as the male taper from the stem are accessible to direct measurements, the female taper within the ball head is too small to accommodate the detector of most CMM. Adequate measurement by mechanical CMM is rarely reported.[20, 21] Indirect measurements of an imprint is an alternative always feasible. This technique induces a certain loss of resolution, but it could be validated to be accurate to within 0.22 mm^3 volume loss of the taper.[16, 17] A higher number of data points collected by 3D optical CMM, compared to mechanical CMM, allows enhanced visualisation of surface details and any deviations from the original taper surface.[17, 20] As illustrated in Fig. E, the pattern from the manufacturing marks on the original taper surface may well be differentiated from the imprinting visible in the contact area. Our case highlights the benefits of the additional resolution of the surface reproduction provided by this technique.

The analysis of the bearing surfaces showed wear on both components, the ball head as well as on the cup, corresponding to the values observed on other retrievals of the same brand and revised for other reasons than ARMD.[18, 19] Predicted volumetric wear would be 8.23 mm^3, considering run-in and time in vivo,[19] a value very close to the measured total volumetric wear of 8.27 mm^3. As usual, slightly more wear was present on the head than on the cup.[18] Overall, wear was less pronounced on the bearing surfaces than on the taper connection, by an order of magnitude regarding linear wear (Fig. D and E). The male taper showed severe corrosion and wear (Fig. B).[22] The analysis of the female taper identified two particles within the taper connection (Fig. E). As no bone cement or ceramic coating, such as hydroxyapatite, was present in this THR, only bone fragments could be hard enough to cause an imprint into the cobalt chromium alloy of the head. The defect of the softer titanium alloy male taper (Fig. B) was macroscopically more pronounced than the one identified on the firmer counterpart of the head (Fig. E). The picture shows the trunnion after cleaning with wet gauze. No brushing with harder materials should be performed, as this would not only remove corrosion products, but would also cause further damage to the taper.[23]

The pseudotumor around the joint was mainly fluid and composed of acellular necrosis, as confirmed by histopathology. Only the neocapsule showed vital fibrous tissue (Fig. C). Large necrotic reactions are usual in trunnionosis, whereas lymphoplasmocytic infiltrates are more commonly seen as reactions to wear particles from the bearing surfaces.[1, 10-12, 24, 25] No wear particles were identifiable on optical microscopy, the macrophagic reaction present within the neocapsule showing inclusions corresponding typically to hemosiderin, resulting probably from microhemorrhages. While wear was also present and measurable on the bearing surfaces, the wear volume corresponds to expectations in revision for other causes, together with the tissue reaction present indicate trunnionosis as principal cause of the ARMD. Nevertheless, submicroscopic wear and corrosion particles may be present. Further typisation by electron beam microscopy might be indicative of their origin, as being either from the bearing surfaces or from any taper connection.[24, 25] However, electron beam microscopy is not available in clinical routine, routine embedding of samples in paraffin would need time-consuming re-embedding in epoxy resins with a notable risk a loss of the structure of the tissues, and the final yield of such a work-up might well be disappointing, considering the rather low density of phagocyted particles and products (Fig. C-2). While trunnionosis may not be proven as cause of failure, as the MoM pairing is a confounding factor, considering all observations together, it may still, in our opinion, be considered as determining.

ARMD is one of the major issues with MoM THR, leading to the increased revision rates observed with this type of bearing.[1, 7, 8] However, small diameter Metasul MoM THR (28 and 32 mm diameter) show excellent long-term results, and are still recognized nowadays as being among the best solutions in hip arthroplasty regarding wear and long-term revision rates.[8, 18] Interestingly, large diameter MoM THR made of Metasul (marketed under the brand name Durom by Zimmer Biomet) are not available anymore, as they appeared to be associated with increased long-term revision rates. Large diameter MoM appeared to cause an unexpected overload of the head-neck taper junction, with metal debris induced failure due to trunnionosis.[9, 10, 26] Another possible explanation of this discrepancy of results might also be differences in lubrication of the bearing surfaces by joint fluid depending on head sizes.[27]

As illustrated by the current case, taper failure may also affect small diameter THR. The stability of a taper connection depends mainly on frictional forces at the interface.[2] This depends on the taper angle, given by the implant design chosen, the static friction coefficient, which is related to surface properties of the taper connection, and the assembly force.[2, 26, 28-30] Two factors are of the utmost importance for the surgeon. The taper has to be cleaned and dried before seating the head, as interposition of soft tissues or even wetting of the surfaces greatly weakens the connection.[2, 29, 31-33] Just leaving the surface of the taper wet may critically reduce the coefficient of friction.[30, 32] The relation between disassembly force and coefficient of friction is not linear, but if it drops to 0.05, the taper does not hold anymore.[2, 26, 29] Under ideal conditions, the coefficient of friction is approximately 0.2.[2, 29, 34] Interposition of soft tissues literally greases the interface, respectively causes incongruences, with consecutive weakening of the connection.[31-33] In this case, two hard particles could be identified, which reasonably can only be bone fragments, as no other material present in this THR is hard enough to indent metal. Interposed hard particles hinder proper alignment of the pairing tapers, further reducing the strength of the connection. The other important factor in taper connections is the impaction force. Two blows, axially aligned with the taper are recommended, with a strength of approximately 6'000 N or more.[2, 28, 35-37] This takes into account the fact that the femur gives way under the blow, contrary to the setting of mechanical tests with dynamometers fixed on hard surfaces, and that the impactor dissipates 20% or more of the impaction force.[38, 39] Larger heads cause greater torque on the taper connection, and thus require greater assembly forces for initial stability.[26] Greater impaction forces are also required to ensure rotational stability around the axis of the taper, which is a more probable failure mode than axial disconnection.[28]

In case of trunnionosis, well-fixed stems do not necessarily require revision. In a series of 73 retrievals with more than 10 years follow-up after taper corrosion diagnosed at head and liner revision with retaining of the stem, only 8% had been revised in the interval and all of these for other causes, even when severe corrosion was present.[40] Corrosion and wear have to be assessed thoroughly. To the best of our knowledge, no recommendations are available regarding tolerance of wear and deformation of the male taper. In this case, a ceramic head with a titanium-aluminum-vanadium alloy inner sleeve (Biolox Option, CeramTec, Plochingen, Germany) had been chosen, expecting this material to better adapt to the deformation of the trunnion (Fig. B) compared to harder cobalt-chromium alloys.[14, 15]

Our patient has been free of complaints since revision of his THR more than three years ago. Considering that this patient has a high degree of activity, corresponding to 2 to 3 million steps per year, a number of cyclic loads required to reach the endurance limit would already been reached, particularly as his heavier weight represents higher than usual loads.[41, 42] Following this reasoning, later failure is not to be expected. Obviously, every option has mechanical limitations, and stem revision might be necessary if wear and deformation of the trunnion are too critical to ensure stability of a new ball head.

Overall, trunnionosis due to interposition of residual particles within the taper connection might well be an underreported issue in THR. Meticulous cleaning of the taper before seating the head may reduce its incidence. Some degrees of ARMD, as well as corrosion and wear of the taper, might well be overlooked at revision. If the stem is revised, the head usually is not disconnected, and thus the taper is not inspected. In case of sole revision of the ball head, advanced techniques, as reported here, are required to quantify wear of the taper, but this is routinely neither available nor necessary. Detailed analysis of any failure after THR might identify specific and avoidable causes. Ten-year revision rates under 5% should be aimed for after THR.[43] Considering revision rates for infection and dislocation, which are not in direct relation to technical specificities of the implants, aseptic failures should not simply be accepted as such, as probably the largest potential for reduction of revisions is to be found among this group of failures. Each case should be analysed in detail, in order to optimize future patient care.

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