

Adverse Wear in MOM Hip-Arthroplasty Related to the Production of Metal Fragments at Impingement Sites

T. K. Donaldson¹, E. J. Smith², A. Koutalos³, A. John⁴, J. Y. Lazennec⁵, I. C. Clarke^{6*}

¹Empire Orthopedics, Colton, CA, USA

²Department of Orthopaedics, University of Bristol, Bristol, England

³Department of Orthopaedics, University Hospital of Larissa, Larissa, Greece

⁴Department of Orthopaedics, University of Cardiff and Vale NHS Trust, Wales, England

⁵Department of Orthopedic and Trauma Surgery, La Pitié-Salpêtrière Hospital, University of Paris, Paris, France

⁶Department of Orthopaedics, Loma Linda University Medical Center, Loma Linda, CA, USA

Email: thomas.donaldson100@gmail.com, evert@evertsmith.com, akoutmed@gmail.com, alunjohn@me.com, lazennec.jy@wanadoo.fr, *ithipgeek15@yahoo.com, ian.clarke@llu.edu

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Abstract

Metal on metal (MOM) bearings were reintroduced as resurfacing arthroplasty (RA) for the younger, more active patient and were later incorporated into total hip arthroplasty (THA). Early results were encouraging. However, recent publications identified adverse tissue responses to metal debris, such that the majority of MOM designs have been abandoned due to the increase in cobalt-chromium (CoCr) debris and associated metal ions. Reports of MOM THA cited risks that included acetabular cups with high-inclination angles, *i.e.* “edge-loading”, and “trunnionosis”. Hip impingement was also a cited risk in one MOM study, with “type-IV” wear noted to be a sliding/impaction type of wear, characterized by deep scratches. Sliding/impaction wear mechanisms produced at impingement are not well represented in current MOM literature. Therefore, our objective in this review was to consolidate evidence for impingement risks. We hypothesize that hip impingement and subluxation with metal-backed acetabular cups can trigger wear mechanisms that result in, 1) femoral-neck notching, 2) release of large metal particles, 3) production of uniquely large scratches, defined as “microgrooves” on heads and cups, 4) formation of “polar” and “basal” microgrooves precisely aligning with cup profiles during impingement, and 5) equatorial microgrooves relate to soft-tissue sites of impingement. Relevant risk scenarios were evaluated and included hip impingement in both sitting and standing postures, head subluxation, wear patterns defining *in-vivo* component positions, and evidence for circulating metal fragments. The study relied on map-

ping of wear patterns to deduce *in-vivo* positioning of devices and relied on surrogate femoral stems of the same brand to simulate neck-cup impingement. EOS imaging techniques were used to analyze functional-sitting and functional-standing postures and prove existence of hip impingement sites in patients. The study identified 8-risk scenarios for wear damage on MOM bearings. The microgrooves on femoral-heads crossing the main-wear area (polar) and non-wear regions (basal) aligned well with cup-rim profiles at impingement sites. This may represent the first description of such large scratches (40 - 300 μm wide) we termed microgrooves, that formed on femoral heads at sites representative of prosthetic impingement. As an abrasive wear process, similar to the formation of femoral-neck notches, these would have been acquired over millions of gait cycles. The pitting and linear microgrooves crossing the non-wear areas of heads (basal) represented the ingress sites of circulating metal particles. Similar microgrooves were evident in acetabular cups, also signifying 3rd-body abrasion by large metal particles. Hip impingement and head subluxation were implicated by the unequivocal evidence of 3rd-body abrasive wear as the triggering events producing large metal fragments. One caveat regarding retrieval studies is that such damage may be only representative of failed MOM devices. This study demonstrated that emerging technologies such as EOSTM x-ray analyses can reveal subtle changes in implant positioning using patient shifts in functional postures (sitting, standing, hyper-extension, etc.), and thereby assess impingement/subluxation risks in the clinical setting before failure occurs.

Keywords

Resurfacing Arthroplasty, MOM

1. Introduction

Large-diameter metal-on-metal (MOM) bearings were re-introduced as hip resurfacing arthroplasty (RA) concepts [1] [2] with the expectation that fluid-film lubrication regimes would be particularly beneficial in minimizing wear [1] [3]-[10]. Following a small but worrisome incidence of femoral-neck fractures [11] [12] [13] [14] [15] is a large diameter, MOM bearings were also incorporated into total hip arthroplasty (THA) intended for younger and more active patients. Early MOM studies appeared encouraging [1] [2] [14] [16] [17] [18] and related simulator studies demonstrated acceptable wear performance using 40 - 60 mm diameter MOM [19] [20] [21] [22] [23]. Unfortunately, initially good results with RA and THA were not maintained and the majority of MOM designs have now been abandoned due to excessive cobalt-chromium release (CoCr) debris and associated metal ions [24]-[33]. Commonly cited risks include cups positioned with higher inclination angles (“steep cups”) and taper corrosion with modular femoral heads (“trunnionosis”). Clinical and retrieval evidence has attributed adverse wear to “edge-loading” of acetabular cups, be-

lieved due to a combination of excessive lateral-inclination, and/or excessive anteversion [27] [29] [34] [35]. A 2nd commonly cited risk in THA retrievals has been corrosion between the modular femoral head and its femoral taper [36] [37]. Possibly, the use of 36 - 60 mm diameter heads adversely influenced the underlying corrosion dynamics [38].

Hip impingement was also cited as a common risk with McKee-Farrar type THA [39] [40] [41]. Howie *et al.* (2005) were able to determine component positioning *in-vivo* because the femoral stems were of monobloc design. They noted that cup-to-neck impingement sites demonstrated fatigue damage from sub-surface fractures, resulting in extrusion of large metal fragments. This was believed to represent a sliding/impaction type of wear mechanism. Such femoral-neck/stem impingement with acetabular cups was not surprising because the THA literature is replete with documentation of dislocations, liner impingements, rim fractures, ceramic chipping, neck notching, component disassociation and related black-staining of ceramic bearings [42]-[48]. Prevalence of THA impingement in retrieval studies has varied from 39% to 83% of cases [49] [50] [51] [52] [53]. The McKee-Farrar study also provided microscopic details of CoCr wear patterns. Four types were described; Type I-II wear patterns contained a background of randomly-oriented, fine scratches, with CoCr surfaces retaining their original reflective appearance. We would also note as typical strings of exposed carbides 5 - 10 μm size (**Figure 1**). Type III wear patterns had randomly-oriented scratches with a higher roughness that resulted in loss of reflective surface (**Figure 1(B)**). In contrast, type IV wear was characterized by deep, parallel scratches that created a 10-fold higher roughness due to scratches typically 40 - 100 μm wide with linearly-striated side-walls (**Figure 1(C)**). We depict here SEM observations of a deep scratch from Howie *et al.* (**Figure 1(D)**). Using white-light interferometry (WLI) we confirmed the presence of dramatically long scratches typically 100 μm wide and 2 - 4 μm deep (**Figure 2**) [40] [54] [55]. These we termed “microgrooves” (**Figure 1(C)**) to uniquely distinguish them from the fine, background scratches on CoCr surfaces (**Figure 1(A)**, **Figure 1 (B)**) and the “stripe wear” defects reported in ceramic retrievals [51] [56] [57].

In our THA study [54], pitting and microgrooves were detectable on all retrieved components (**Figure 1**), being more than 10-fold larger than typical background CoCr scratches and carbides. Microgrooves were identifiable by extreme lengths, raised lips and ranging 40 - 160 μm with conspicuous longitudinal striations (**Figure 1(C)**, **Figure 2**). These appeared very similar to type-IV scratches reported in the McKee-Farrar study (**Figure 1(D)**) [40]. Our assumption was that 100 μm wide scratches had been created by CoCr particles 100 μm or larger. However, we found no evidence to support the presence of large CoCr fragments. It is therefore significant that 96% of particles found embedded in the plastic liners of metal-on-polyethylene (MPE) retrievals were metallic, averaging 126 μm in size (ECD: equivalent circle diameter), and some even larger than 2.5

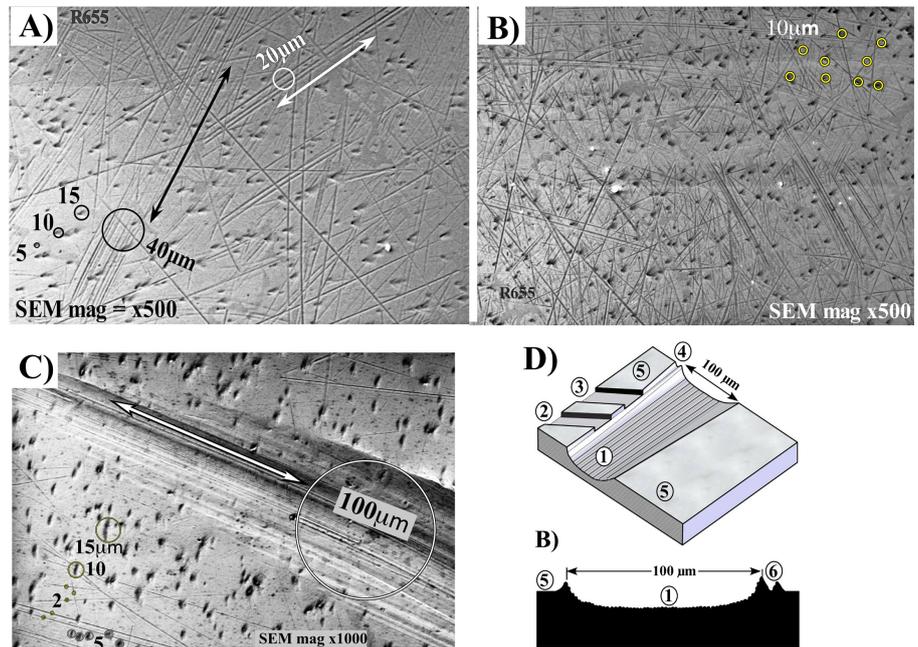


Figure 1. SEM image of Cor scratches and carbide inclusions (46 mm BHR head): (A) Type I-II wear, 5 - 15 μm scale markers indicate fine scratches, carbides and 20 - 40 μm parallel scratch formation: (B) Type-III wear, 10 μm scale markers; (C) Type-IV wear, “micro-groove” with striations (100 μm scale marker); (D) Type-IV scratch modeled on SEM image showing small scratches (#2-4) on CoCr surface (5) intersecting 100 μm microgroove (as in Howie *et al.*, **Figure 5**) [40].

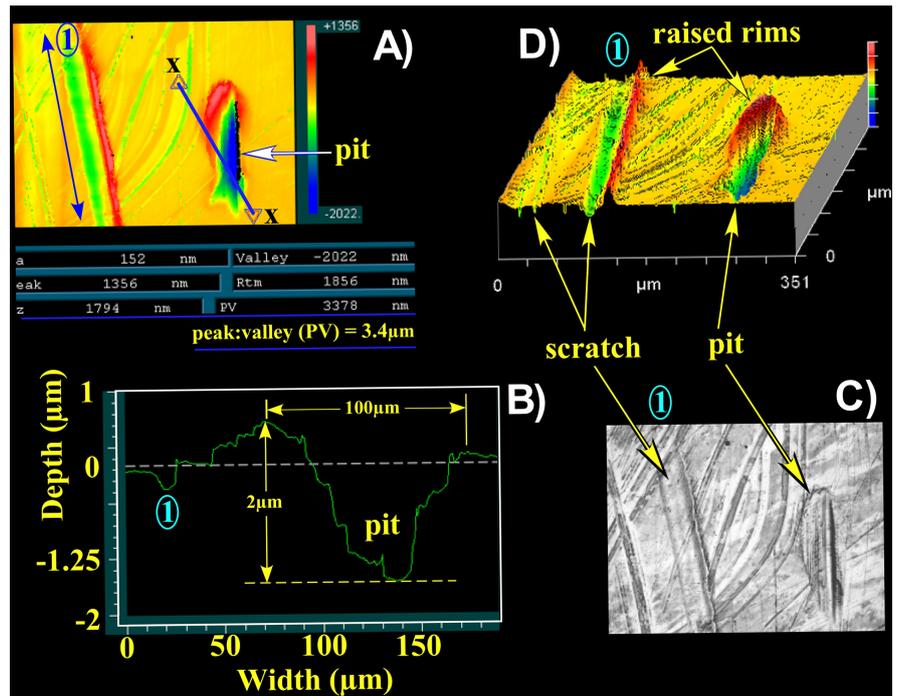


Figure 2. White light interferometer (WLI) images: fine scratches adjacent to large pit: (A) View of scratch (1) and profile trace (xx) crossing pit; (B) Cross-section of pit (xx) as traced in image-A; (C) Light-microscopy image (in image-A); (D) 3D-oblique view: raised lips around scratch and pit.

mm [46] [58]. The conceptual sliding/impaction/fatigue wear mechanisms that were described relative to THA impingement [40] are not represented in current literature espousing the risks of “steep-cups” and “trunnion corrosion”. Therefore, the objective of this study was to consolidate the available evidence for impingement/wear mechanisms, and to determine from this assemblage of information (Table 1), was this could be a clinically relevant risk scenario, or should it be rejected.

We formulated the following hypothesizes:

- 1) THA impingement can readily occur in either sitting or standing postures.
- 2) Neck notching is an impingement/abrasion process produced by the cup-rim over millions of cyclic hip motions.
- 3) Hip impingement and femoral-head subluxation release metal fragments into the joint space.
- 4) Ingress of metal particles into MOM bearings produces 3rd-body wear damage most evident in “non-wear” (basal) regions of femoral heads.
- 5) Cups positioned on basal and polar scratches (“microgrooves”) on femoral heads relate to sites of “simulated” prosthetic impingement.
- 6) Cups positioned along equatorial microgrooves do not represent sites of ‘simulated’ prosthetic impingement.
- 7) Head microgrooves are produced by abrasion over millions of cyclic hip motions due to a combination of, a) cup-rim cycling across head surface (2-body wear), and b) motion of entrapped metal particles (3rd-body wear).
- 8) Cup microgrooves represent 3rd-body wear by entrapped metal particles.

2. Hip Subluxation in Functional Standing and Sitting Postures

It is known that cup positions change depending on patient position (Figure 3). During sitting, the pelvis generally tilts posteriorly and both cup anteversion and inclination increase (Figure 4). Assessment of patient’s lateral or supine position during surgery does not eliminate the risk of impingement and subluxation,

Table 1. Evidence modules comparing impingement and wear damage in total hip arthroplasty (THA) and resurfacing arthroplasty (RA) [40] [54] [55].

###	Assemblage of MOM Wear Evidence	THA	RA
1	Hip subluxation in functional standing and sitting postures	yes	yes
2	Wear patterns defining <i>in-vivo</i> component positions	yes	yes
3	Notching mechanism in femoral necks	yes	-
4	Pits, microgrooves and plastically-deformed gouges	yes	yes
5	Cup positions defining femoral-neck impingements	yes	yes
6	Evidence of metal debris circulating in the hip joint	yes	yes
7	Demonstrating spino-pelvic/hip motions at impingement	yes	yes
8	Discussion of MOM wear mechanisms		

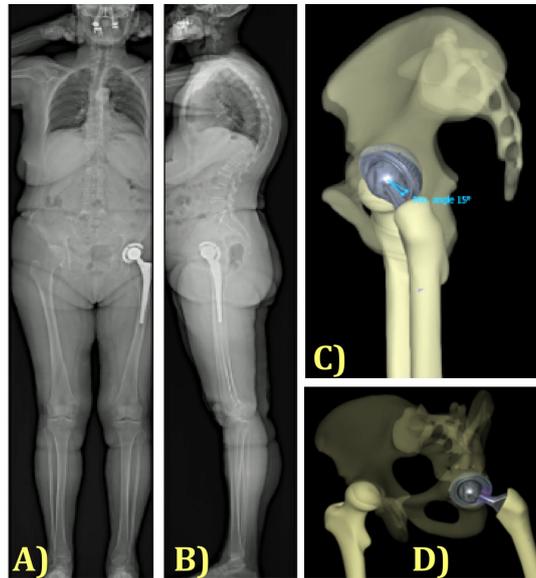


Figure 3. Standing EOS-radiographs with 3D-reconstructions showing 28 mm THA with anterior subluxation (left-hip, female patient): (A) EOS anterior view; (B) EOS lateral view; (C) femoral-neck on cup rim in lateral view; (D) Oblique view of femoral-neck impinging cup rim.

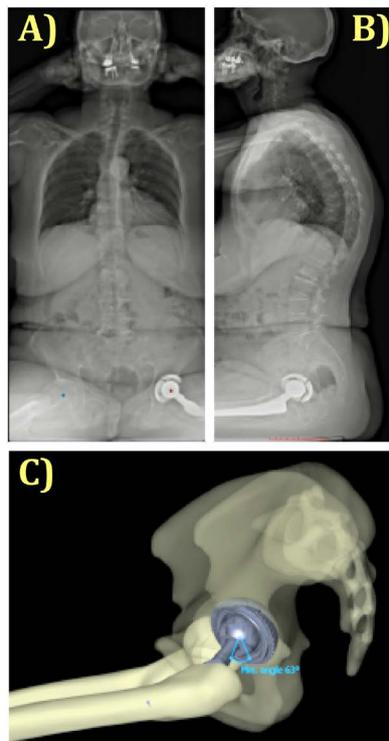


Figure 4. Sitting EOS-radiographs: (A) anterior view; (B) lateral view; (C) lateral view of 3D-reconstruction, no limitation to hip motion.

even if cup position is representative of the so-called “safe zone” [59]. The high rate of THA impingement [15] [22] [31] [45] [49] together with the fact that dislocation can occur when the cup is placed in the “safe zone” has demonstrat-

ed that hip impingement, subluxation and even dislocation can occur due to functional postural changes. The trial reduction intraoperatively cannot determine impingement risks in the patient's various functional postures. Moreover, the spino-pelvic mobility of each patient makes the functional position of the cup complex. [60] Patients with pelvic stiffness have less change in anteversion and inclination with sitting, *i.e.* the cup should be implanted in more inclination/anteversion to improve motion. The opposite is true in patients with a hypermobile pelvis, usually women. The cup needs to be placed in less inclination/anteversion because with sitting there will be larger than normal shifts in cup inclination/anteversion while risk of impingement or even dislocation increases [61]. In addition, the balance of the spine in the sagittal plane requires attention. Patients with unbalanced spines should 1) have sagittal deformity corrected before proceeding to THA, or 2) have cup placed in less anteversion because of the risk of posterior impingement with a retroverted pelvis and increased acetabular anteversion [62].

3. Wear Patterns Defining *In-Vivo* Component Positions

The key measure in retrieval analyses lies in discerning the in-vivo orientation of components. The prior study of McKee-Farrar THA had the advantage that the femoral components represented a monoblock design [40]. To determine in-vivo positioning of modular bearings, we utilized wear-pattern mapping developed from simulator studies [21] [63] [64]. This unique approach defined component wear-patterns using a combination of light microscopy, white light interferometry (WLI: NewView-600, ZygoInc, Tucson, AZ), and scanning electron microscopy (SEM: MA-15: Zeiss Inc., New York). Wear patterns on the retrieved components were stained red to illustrate main-wear zones for photography (**Figure 5**: MWZ, area of habitual wear) and also to delineate non-wear zones (**Figure 5** NWZ: region of incidental, non-wear) [54]. This was necessary for photography because the retrieved CoCr bearings retained their original, highly-reflective appearance. In addition, cup surfaces had to be taped to eliminate multiple images reflected from convex surfaces (see **Figure 24**) [21] [54].

Femoral heads were photographed in four orthogonal views and one polar view whereas cups were simply photographed en-face. Positioning of the narrow NWZ-margin (**Figure 5(A)**, B: S) defined the superior aspect of the femoral head and position of the habitual wear area (MWZ) in vivo. This we validated on THA received with heads fused to their femoral trunnions (**Figure 6**). To define the cup's in-vivo position, the typically eccentric position of its MWZ area was matched to that of the femoral MWZ. The sites of microgrooves visible to the naked eye on head and cup components were colored for photography (**Figure 5**, **Figure 6**: polar as blue, equatorial as green, basal as black).

4. Notching Mechanism in Femoral Necks

Howie *et al.* [40] noted that "femoral-neck on cup rim" impingement resulted in a fatigue-wear mechanism capable of releasing large CoCr particles. While the

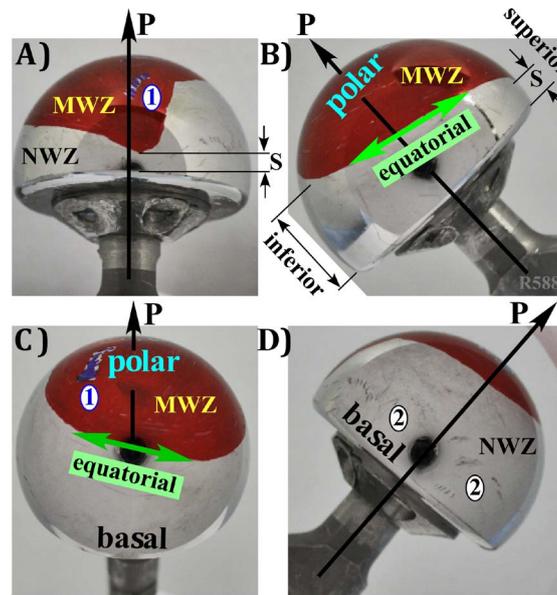


Figure 5. Main-wear zone (MWZ) on THA retrieval with head fused to trunnion (left hip, 50 mm Magnum THA) [65]. (A) View-1 superior region: narrow non-wear zone (S) and polar microgroove (1); (B) View-2 anterior: equatorial and polar landmarks; (C) View-3: basal, equatorial, and polar site with microgroove (1); (D) View-4 posterior: basal microgrooves.

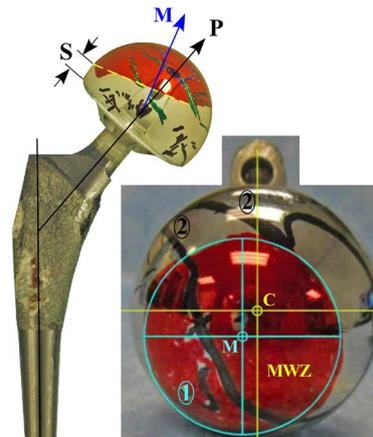


Figure 6. Wear pattern on fused-head (50 mm Magnum THA) illustrating position of NWZ narrow region (S) [65]. Inset shows polar axis (P), MWZ centroidal axis (M) and microgrooves, polar (1) and basal (2). MWZ area 2200 mm² represented 56% of hemispherical area (50 mm MOM).

authors did not share impingement evidence in this McKee-Farrar study, there are ample reports of femoral-neck notching and related risks [42] [43] [44] [48] [66]-[71]. There was no opportunity to check for circumferential neck-markings indicative of cup impingement because the majority of our MOM bearings were retrieved without mating femoral stems (Figures 7-9). While some cases could be related to multiple dislocations [66], the anatomy of these notches indicated an abrasive and/or fatigue-wear phenomena that occurred repetitively over millions of impingements (Figure 7). For example, the titanium femoral neck in

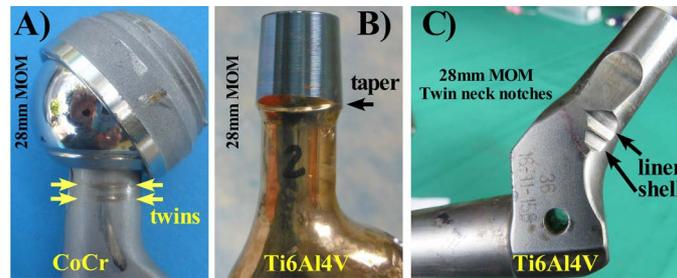


Figure 7. Cup rim impingement indicated by circumferential neck scratches, (A) twin defects on CoCr neck; (B) notch on Ti6Al4V trunion, and (C) two notches on Ti6Al4V neck.

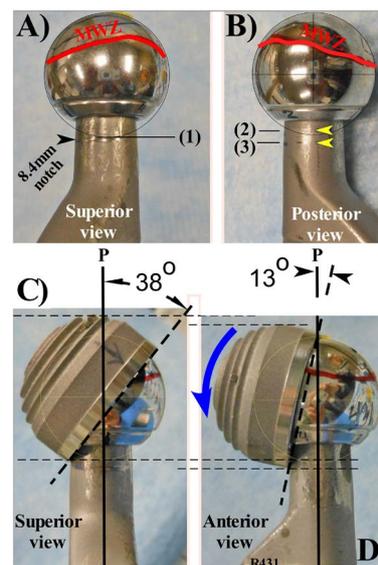


Figure 8. Impingement indicated by circumferential notches on femoral neck (28 mm Metasul THA): (A) notch (1) in superior femoral neck (female gymnast, squatting exercises); (B) twin notches (2, 3) in posterior neck; (C) cup rim contacting notch-3, posterior neck; (D) head subluxed, rim contacting notch-1 on superior neck.

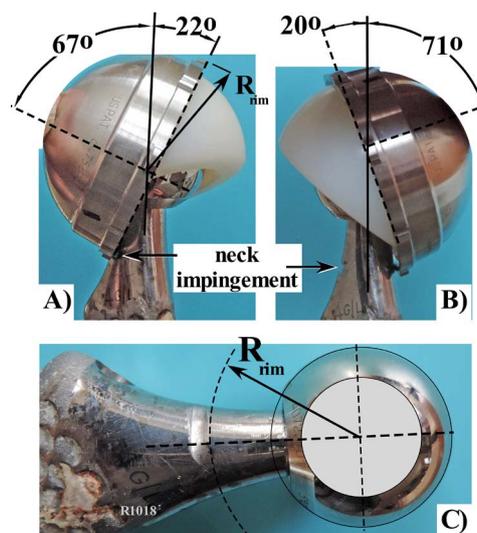


Figure 9. Metal-on-polyethylene THA with neck notch at impingement site.

our SROM case (**Figure 7(C)**) had two notches that exactly matched the rim profiles of the Pinnacle shell and CoCr liner [71]. This resembled a precision-machining process, unequivocal retrieval evidence that such neck-notching required millions of wear cycles to acquire. Some femoral necks demonstrated two and sometimes three notches (**Figure 7(A)**). Using geometric THA models, [43] we have shown that the proximal notch indicated the 1st impingement site (**Figure 7(A)**). For the more distal notch, the femoral head had to sublux to a more vertical position, relative to the polar axis (**Figure 8(B)**, **Figure 8(D)**). Such a mechanism, whereby the femoral neck was worn by repetitive oscillations of the cup rim, we defined by the acronym “NAR-damage” (**Table 2**). This was variable, from cosmetic scratches more typical on CoCr necks (**Figure 7(A)**) to deep notches found on Ti6Al4V necks (**Figure 7(B)**, **Figure 7(C)**). In this regard, it is notable that the majority of mating CoCr cups showed no comparable rim damage.

There are many factors involved in THA impingement and certainly head:neck ratios and range of motion are important with many retrieval studies featuring 28 mm THA (**Figure 7**). Nevertheless, THA designs optimized for range of motion can also impinge and produce neck notches (**Figure 9**).

5. Pits, Microgrooves and Plastically-Deformed Gouges

There was unequivocal evidence of large pits in all retrieved MOM bearings (**Figure 10(A)**). The basal head areas (non-wear zone) in particular provided the most dramatic evidence. This was likely because basal regions represent the first sites of ingress for circulating metal particles [49] [58] and such damage was not mitigated by habitual wear during patient’s normal activities (**Figure 5**, **Figure 6**: non-wear zone). Strings of surface pits were characterized by 100 - 300 µm width, smooth entry points, longitudinal striations indicating direction of travel, and lips raised towards the point of egress (**Figure 10(B)**). WLI imaging showed that pits typically varied 3 - 10 µm in depth (**Figure 11**, **Figure 12**). The pits presented partly as a ploughing action that raised scratch lips above the surface (plastic deformation) and partly abrasive action (releasing CoCr debris). For

Table 2. Wear damage observed on retrieved MOM bearings.

###	Acronym	Details of Wear Mechanism	Type	THA	RSA
1	NAR	Femoral neck abrasion by cup rim	Abrasion, deformation	yes	no
2	3CO	3rd body wear by CoCr debris	Abrasion	yes	yes
3	FHG	Femoral head gouges	Plastic deformation	yes	-
4	2CR	2-body damage to head by cup rim	Abrasion, deformation	yes	yes
5	3CR	Entrapped particles (3rd body)	Abrasion	yes	yes
6	3TI	3rd body wear by Ti6Al4V debris	Abrasion	yes	-
7	TTL	Titanium contamination	Metal transfer	yes	-
8	2OR	Surgical damage	Abrasion, metal transfer	yes	-

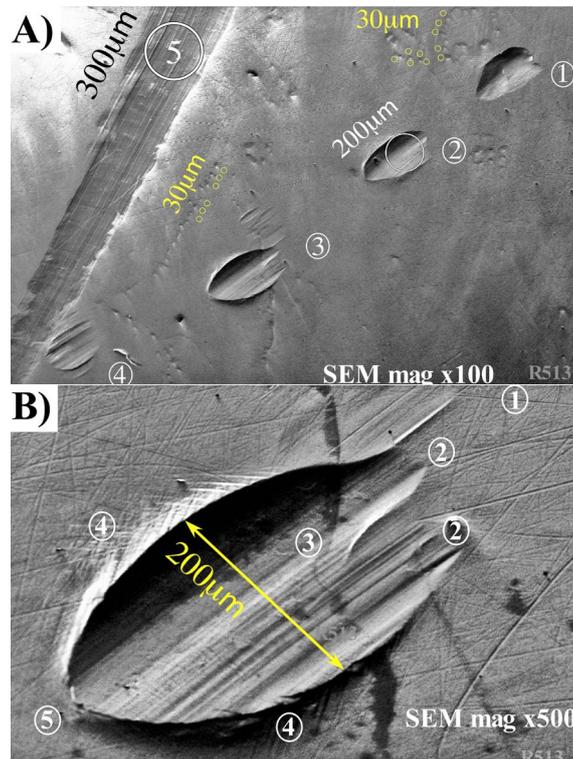


Figure 10. SEM image of string of pits in basal head (38 mm M2a): (A) 200 µm pits (#1-4) juxtaposed to 300 µm microgroove (5), 30 µm circles indicate carbides; (B) SEM image of pit defect, (1) fine CoCr scratches, (2) entry point of particle, (3) longitudinal striations, (4) plastic deformation in defect lips/shoulders, and (5) exit terminus.

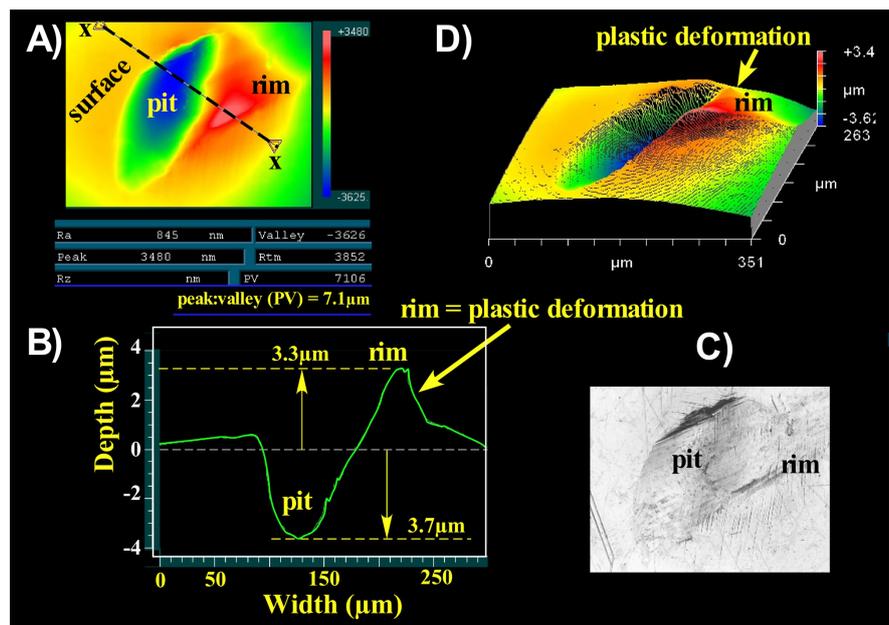


Figure 11. Imaging of pit in basal head area following repetitive sub-clinical subluxations (RSS) and 2 dislocations (complex case, 65-year old rheumatoid patient, 44 mm Magnum) [72] [73]. (A) profile line across pit and elevated lip; (B) Cross-sectional view 100µm defect (valley 3.7 µm, plastically-deformed lip 3.3 µm); (C) Light microscopy image (in image-A); (D) WLI oblique view of plastically-deformed lip and shoulder.

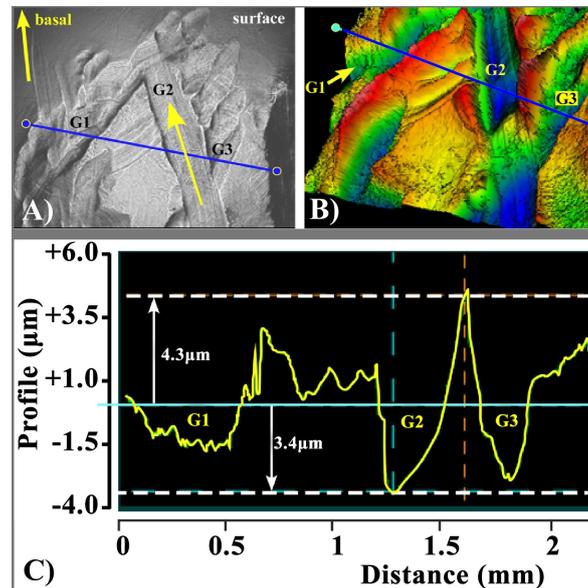


Figure 12. Extensive damage in basal head (dislocating case, **Figure 11**): (A) SEM image of multiple pits and microgrooves (G1-3) oriented in polar direction; (B) Corresponding WLI image showing profile trace.

discussion purposes, pits will be defined as a 3rd-body abrasive-wear mechanism, using acronym “3CO-damage” as the descriptor. However, it is to be noted that we were unable to find any evidence of CoCr fragments or CoCr smears representing transfer onto bearing surfaces.

All retrieved MOM bearings revealed microgrooves from 40 to over 100 µm wide with raised lips and linearly-striated sidewalls (**Figure 13**) [54]. Depending on location, these were defined as basal, polar or equatorial microgrooves (**Figure 5**). Our retrieval study may be the 1st to confirm such “type IV” wear as described in the McKee-Farrar study [40]. In addition, the microgroove characteristics, *i.e.* 100 µm width, longitudinal striations, and plastically-deformed lips (**Figure 13**, **Figure 14**) appeared very similar to the large pits (**Figure 10**, **Figure 11**) and both will also be considered representative of 3rd-body abrasive wear by large CoCr particles (**Table 2**: 3CO).

Surface “gouges” were described in a retrieval study of large diameter MOM. Gouges ranged up to 1.5 mm length, 25 - 75 µm width, and 0.25 - 1 µm depth [74]. These were observed on the majority of retrievals and lacked longitudinal striations typical of microgrooves. The authors attributed the gouges on heads to impaction by the cup rims, *i.e.* a plastic deformation mechanism [74]. Our SEM analysis revealed similar arrays of parallel gouges and surrounding slip bands (**Figure 15**). These were shallow depressions 1 - 3 mm long, showing extensive plastic flow onto surrounding surfaces (**Figure 16**). For discussion purposes, we shall term femoral-head gouging by the acronym “FHG-damage”.

6. Cup Positions Defining Femoral-Neck Impingements

Our study of modular MOM retrievals may be unique in that head and cup

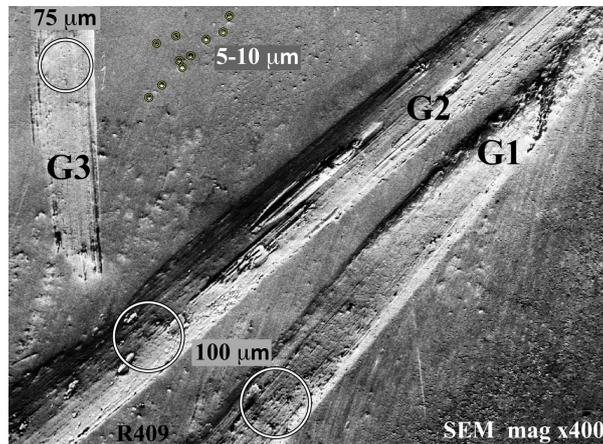


Figure 13. SEM image of twin 100 μm microgrooves (G1, 2) intersected by 70 μm microgroove (G3). Note 5 - 10 μm carbides dwarfed by microgroove size.

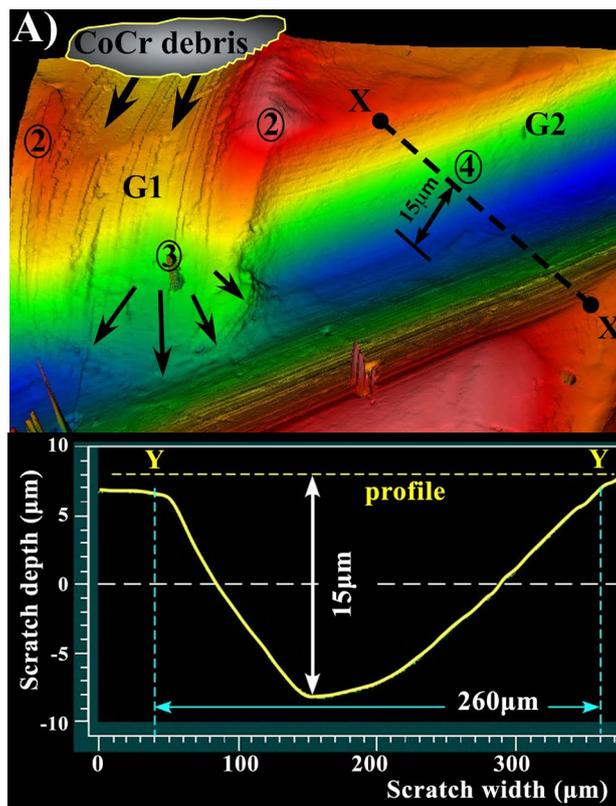


Figure 14. WLI image of 100 μm microgroove (G1) intersecting microgroove (G2) with profile track (xx): (A) Hypothetical metal fragment sketched on microgroove-G1 indicating ploughing direction (arrows) and longitudinal striations, plastic deformation of side-walls (2) and avalanche-like flow of CoCr matrix (3); (B) Cross-sectional profile (xx) of microgroove (G2: 260 μm wide, 15 μm deep).

wear-patterns were mapped to discern how each component was positioned in vivo (Figure 5, Figure 6) [54]. In consequence, it was possible to map the locations of microgrooves with reference to likely neck-on-cup impingement sites (Figure 8, Figure 9). Polar microgrooves crossed the main-wear zone (Figure 5:

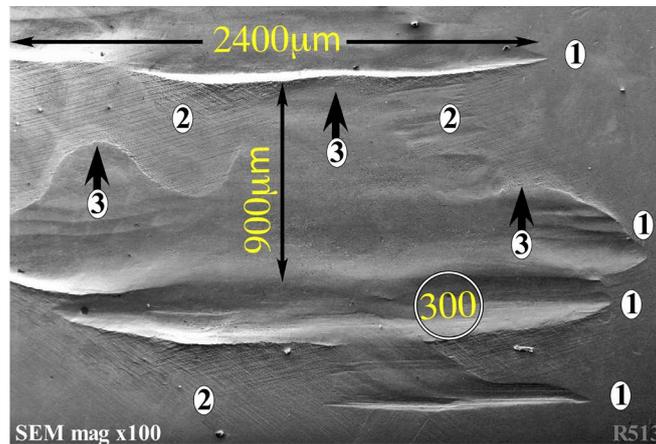


Figure 15. Gouges formed by plastic deformation in basal head (38 mm M2a): (1) parallel surface defects; (2) slip planes; (3) plastic-deformation.

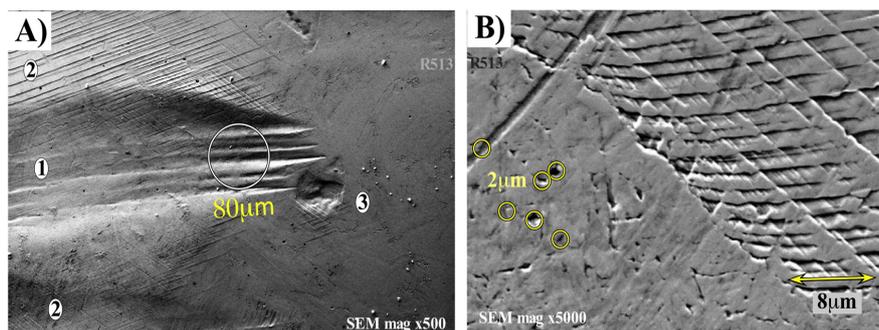


Figure 16. Damaged basal head (38 mm M2a). (A) Large defect (1) and pit (3) surrounded by slip bands (2); (B) Higher magnification of slip bands.

MWZ) and were oriented in a radial direction. Basal microgrooves crossed the non-wear zone (Figure 5: NWZ) and were oriented somewhat radially-oblique. In contrast, equatorial microgrooves tended to align in the transition zone around MWZ-boundaries, their orientation being conspicuously different from basal and polar types. A commonality for all microgrooves was scratch-widths that could span hundreds of microns with raised lips and conspicuous longitudinal striations of sidewalls (Figures 10-14).

The majority of our modular THA bearings were retrieved without mating femoral stems. We therefore used femoral-stem surrogates from inventory when studying likely angles of cup-impingement (Figure 8(C)). The major finding in impingement simulations was that rim-profiles of cups overlaid the basal and polar microgrooves marked on RA and THA heads (Figure 8(C), Figure 8(D), Figure 17). The microgrooves were not always continuous, sometimes obscured by a layer of protein contaminants [63]. Nevertheless, there was generally enough evidence of multiple scratches tracking from base of head into the polar regions of main-wear zone (Figure 6). Some retrievals demonstrated several basal-polar pairings, indicative of multiple impingement sites (Figure 17) [73]. It was noted that equatorial microgrooves around the main-wear zone boundaries

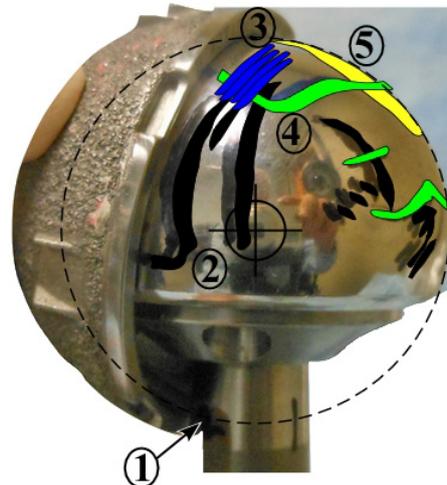


Figure 17. Retrieved head (44mm Magnum) positioned on surrogate femoral stem with impingement on cup rim (1), rim juxtaposed to basal (2: black) and polar (3: blue) microgrooves. Equatorial microgrooves (4: green) and degraded protein layer (5: yellow) as indicated.

were less predictable, could vary from short to considerable length, and were generally not at locations associated with prosthetic impingement (**Figure 18**).

Our comparisons of both THA and RA femoral components showed essentially similar patterns of microgrooves. The natural bony necks retained with RA femoral shells reduced head: neck ratios and limited the available range of motion [75]. Our microgroove evidence in RA cases revealed that patients routinely compensated by head subluxation [55]. The quandary was in deducing what abrasive wear mechanism formed such large microgrooves in RA and THA bearings? Was it the cup rim or the entrained metal particles? The former would represent Mode-2 wear as described by McKellop *et al.* [76] and the latter would represent Mode-3. For discussion purposes, microgrooves produced by the cup rim or entrained metal debris will be differentiated by the acronyms 2CR-damage and 3CR-damage (**Table 2**).

7. Evidence of Metal Debris Circulating in the Hip Joint

SEM analysis demonstrated basal scratches that resembled 100 μm wide microgrooves, except they lacked typical longitudinal striations (**Figure 19**). WLI imaging frequently revealed multiple parallel tracks that represented metal transfer of 1 μm thickness with 3 - 5 μm peak heights (**Figure 20**). SEM analysis (**Figure 21(A)**) and energy dispersive spectroscopy imaging revealed predominantly elemental titanium (Ti) tracking along CoCr surfaces (**Figure 21**). SEM analysis also revealed longitudinal surface striations exiting some transfer layers. These tracks were therefore considered microgrooves coated by a layer of titanium transfer. Clinical studies of MOM THA have demonstrated that high concentrations of Ti-ions correlated with femoral-neck notching noted in revised Ti6Al4V stems [77]. This unequivocal evidence of metal transfer proved existence of large

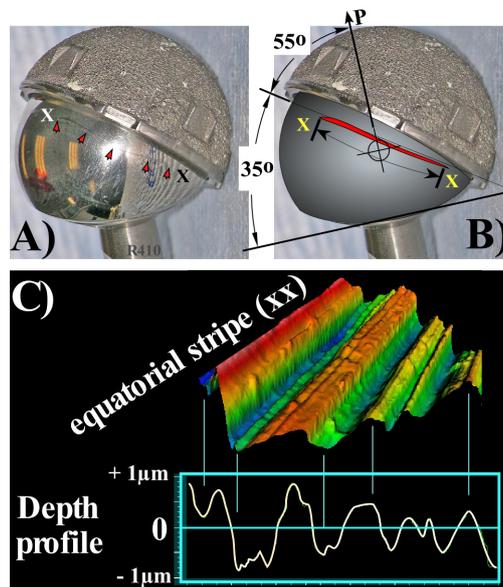


Figure 18. Same worked example (Figure 17) showing cup rim juxtaposed to equatorial microgroove: (A) Visual of long microgroove (red arrowhead track-xx); (B) Cartoon depicting microgroove > 40 mm length oriented 55° to polar axis (P); (C) WLI profile showing longitudinal striations (2 μm peak-to-valley).

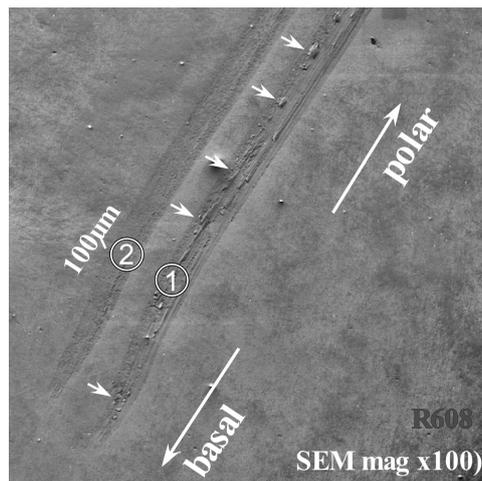


Figure 19. SEM image of twin 100 μm microgrooves extending from base of head in polar direction (47 mm ASR XL). Metal transfer (arrows) shown obscuring any longitudinal striations.

circulating Ti6Al4V fragments, which in turn implicated Ti6Al4V-component impingement (Figure 7(B), Figure 7(C)). This SEM evidence was a significant finding because we could not prove the existence of circulating CoCr fragments or CoCr-transfer. The quandary here was in deducing did the Ti6Al4V particles actually damage the CoCr surface *i.e.* created microgrooves, or did they just form a transfer layer that coated pre-existing microgrooves? For discussion purposes, microgrooves produced by abrading Ti6Al4V particles will be termed 3TI-damage and titanium transfer will be termed TTL-damage (Table 2).

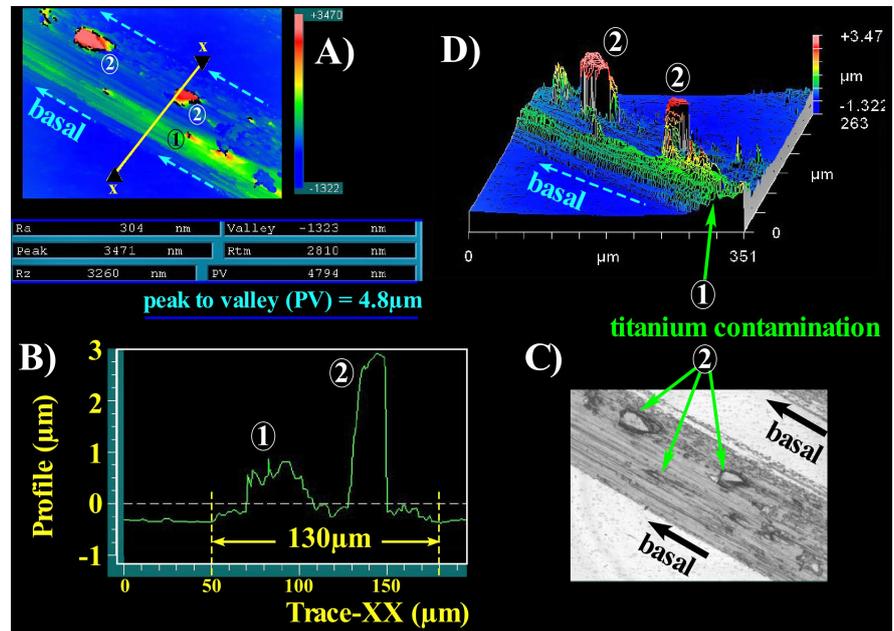


Figure 20. WLI images of twin 100 μm tracks with metal transfer (36 mm Pinnacle): (A) Profile trace indicated across transfer peak; (B) Profile of metal transfer, 1 - 4.8 μm thick; (C) Light microscopy (in image-A); (D) 3D oblique view of metal transfer (presumed titanium).

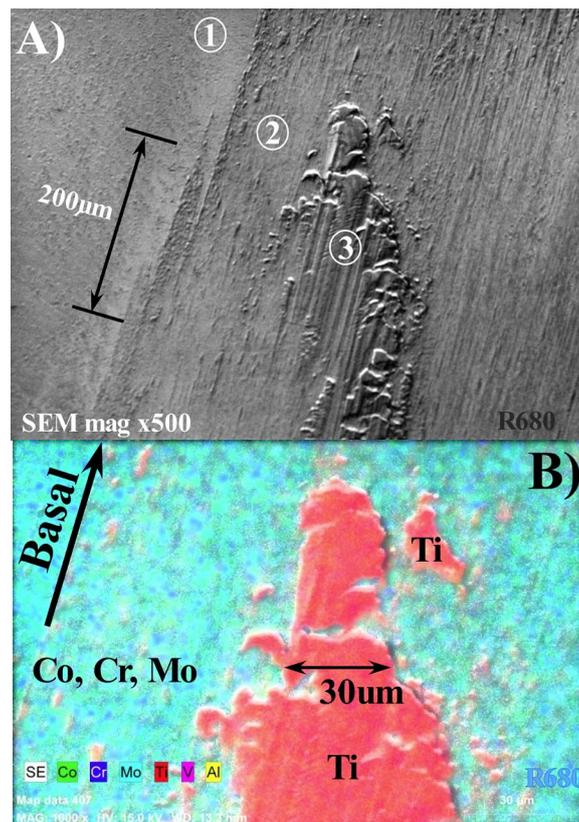


Figure 21. Images of basal microgroove in Figure 20 showing metal transfer: (A) CoCr surface (1) with exposed carbides, (2) metal transfer layer, and (3) metal peaks; (B) Energy dispersive spectroscopy (EDS): titanium smear track crossing CoCr surface.

8. EOS Demonstration of Spino-Pelvic/Hip Motions at Impingement Sites

EOS imaging with 3D-reconstructions in standing and sitting positions provided details of cup functional inclination and anteversion. Knowing femoral anteversion, the important combined anteversion could be determined. EOS images in the functional-standing position of our 1st example show a cup with 40° inclination but excessive 48° anteversion (**Figure 22(A)**). With 34° of femoral anteversion, this hip demonstrated 82° combined-anteversion. Shifting from functional-standing posture (**Figure 22(B-1)**) into hyperextension (**Figure 22(B-2)**) determined available range of motion. The cup impingement site was demonstrated by 3D-reconstruction (**Figure 22(C)**). This patient's 15° extension ability in functional-standing position proved insufficient (**Figure 22(D)**) and patient could sense anterior subluxation of the head approaching within 5° of impingement site (**Figure 22(B-2)**). However, in functional-sitting posture, the pelvic tilt increased slightly to 25° thereby providing a 5° increase in cup anteversion. With 58° cup inclination in sitting posture, this hip had 63° of motion before impingement. Thus, EOS imaging demonstrated no limitation in functional-sitting.

EOS images in the functional-standing position of the 2nd example showed a cup with 40° inclination and 35° anteversion (**Figure 23(A)**). Including 15° of femoral anteversion, this hip demonstrated 50° of combined anteversion. This patient's standing posture showed 37° motion available before neck-on-cup posterior impingement for extension testing. Thus, EOS imaging demonstrated no significant limitation in functional-standing. However, in functional-sitting position (**Figure 23(B)**), this patient had only 22° of flexion arc. This hip impinged

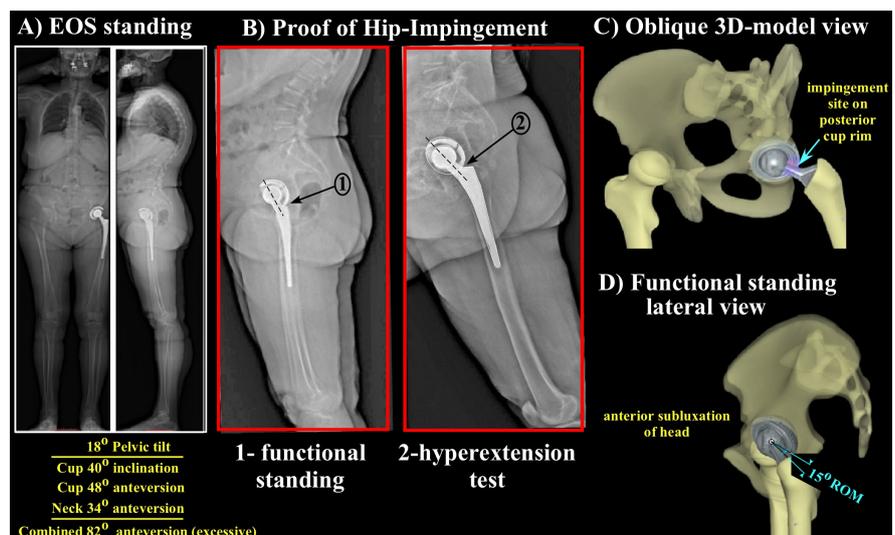


Figure 22. EOS-reconstructions with cup-impingement site in functional-standing: (A) frontal and lateral images in functional-standing posture; (B) functional standing (1) and impingement revealed in extension-test (2); (C) Oblique 3D-reconstruction, femoral neck close to posterior cup rim; (D) Lateral reconstruction, 15° arc before neck impinged posteriorly.

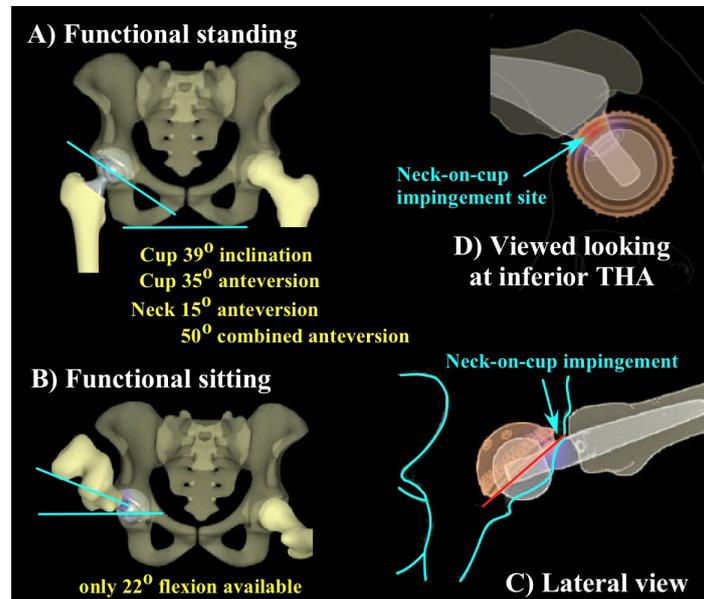


Figure 23. EOS-reconstructions with cup-impingement site in functional-standing: (A) frontal and lateral images in functional-standing posture; (B) functional standing (1) and impingement revealed in extension-test (2); (C) Oblique 3D-reconstruction, femoral neck close to posterior cup rim; (D) Lateral reconstruction, 15° arc before neck impinged posteriorly.

and subluxed, as demonstrated in the corresponding lateral (**Figure 23(C)**) and inferior views (**Figure 23(D)**).

9. Discussion of MOM Wear Concepts

As part of our analysis of large diameter MOM retrievals, we defined eight potential types of damage (**Table 2**). The unequivocal evidence of circumferentially-notched femoral-necks (**Figures 7-9**) represented, 1) NAR-damage (**Table 2**) that could only have occurred over millions of gait cycles, and 2) notches that unequivocally defined sites of prosthetic-impingement (**Figure 8(C)**, **Figure 9**). We recognize that a loose and migrating metal cup could also produce damage in failing hip-procedures. However, it would be difficult to conceive that loose cups, patients suffering from multiple dislocations [71], or even inadvertent damage during surgery, could produce such neck notching. Thus, our conclusion was that neck notches represented abrasion by the cup rim, an unintended consequence representative of 2-body abrasion, thus confirming our 2nd hypothesis.

Impingement has been a frequently-raised concern in McKee-Farrar studies [28] [39] [40] [41] [78]. Our current focus on impingement in modular MOM bearings was based on wear analysis of the “fixed-head” McKee-Farrar design [40]. Howie *et al.* described “impingement marks” in nine of 29 THA and noted extrusion of metal fragments due to sub-surface fatigue. However, in our opinion, their landmark finding lay in the description of “type-IV” wear patterns. These were described as deep and parallel wear tracks that spanned approx-

imately 100 μm width on highly-reflective head surfaces. Ours may be the first to confirm this type-IV wear evidence. We found ample evidence of 100 μm wide scratches (and larger) and similar sized pitting. We termed these type-IV scratches as “microgrooves”. The microgrooves were significantly larger than anything described in current MOM literature and dwarfed the scale of exposed carbide formations frequently attributed to scratch formations (**Figure 1**, **Figure 10**, **Figure 13**, **Figure 21(A)**) [28] [78]. Microgroove characteristics included long curvilinear tracks, raised lips (evidence of plastic deformation), and longitudinal striations (evidence of ploughing/abrasion). Salient observations made from this review of microgroove formations included;

- 1) Curvilinear microgrooves crossing the main-wear zones in polar areas of femoral heads had to be forming repeatedly, otherwise they would have been eradicated by the hip’s normal and routine wear process.

- 2) Neck-on-cup prosthetic impingement (NAR-damage) appeared to be the sole mechanism that could produce observed consistency in siting of basal/polar microgrooves. This was supportive of hypothesis-5.

- 3) The variability of equatorial microgrooves around the periphery of main-wear zones was not related to prosthetic-impingement sites. Most likely these microgrooves represented impingement with soft-tissues, a possible confirmation of hypothesis-6.

- 4) The large pits and linear microgrooves crossing basal head areas appeared an enigma, since these were designated “non-wear” regions. However, as others have described, these areas would represent the ingress sites of circulating metal particles [46] [79]. As noted, these were not areas of normal head-wear and therefore basal surfaces were well preserved, confirming hypothesis-4.

- 5) Cup microgrooves could only have been formed by circulating metal particles, and therefore represented 3rd-body abrasive wear, confirming hypothesis-8.

- 6) The circular shape of femoral wear-patterns (**Figure 6**) was not duplicated in cups. The cup wear-patterns were mostly eccentrically positioned around arcs of cup rim (**Figure 24**).

- 7) Large arcs of cup wear represent “edge-loading” may be representative of head subluxation or sub-optimal cup positioning.

What we did not find was any evidence of tracks that would have represented transfer of CoCr debris. We had to infer the existence of CoCr particles from pit and scratch morphologies (**Figure 2**, **Figures 10-12**, **Figure 14**) that revealed raised lips (plastic-deformation) and linear striations (abrasion). These features represented the classic signature of 3rd body abrasion by hard particles. Nevertheless, our SEM/EDS analyses did confirm layers of Ti6Al4V contamination smeared over similar-sized microgrooves (**Table 2**: TTL damage). Titanium transfer onto head microgrooves was also commented on in a previous SEM study (see Band *et al.*, figs. 6.38, 6.39) [80]. These authors speculated that Ti-transfer could have originated from debris released from ingrowth-surfaces. However, in THA devices with Ti6Al4V-shells or Ti6Al4V-stems, titanium

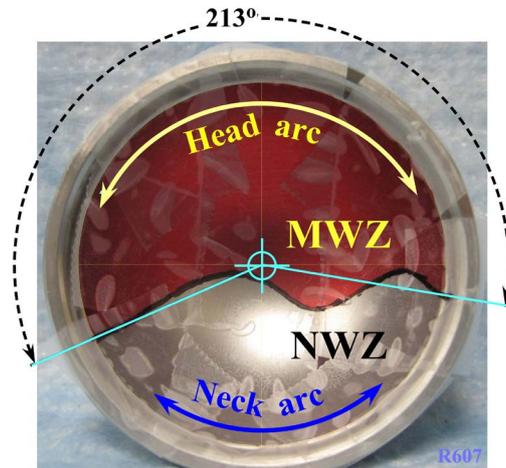


Figure 24. Position of main-wear zone (MWZ) representative of superior quadrant in retrieved cup (46.5 mm ASR). Cup rim-wear produced by subluxing head extends around large arc (213°) while femoral neck rotated against contra-rim (neck arc).

particles could equally originate from prosthetic impingement (**Figure 7**, **Figure 8**). The Ti-ion concentrations detected in vivo [81] and titanium smears on CoCr retrievals represented unequivocal evidence of 1) prosthetic impingement on Ti6Al4V components, 2) release of Ti6Al4V particles, 3) ingress of circulating Ti6Al4V particles into MOM bearings, thereby forming 4) Ti6Al4V transfer layers that resembled microgrooves. We demonstrated in the laboratory setting that introduction of both Ti6Al4V and CoCr particles produced microgrooves in CoCr surfaces (**Table 2**: 3CO, 3TI) and provoked adverse wear in simulator tests [82] [83]. This accumulation of evidence therefore is supportive of our 3rd hypothesis that hip impingement and head subluxation represent major risks for release of large metal fragments.

The unique finding in our simulated “femoral-neck/cup-rim” impingements was that cup rims invariably followed tracks of basal and polar microgrooves (**Figure 8(C)**, **Figure 17**, **Figure 18**), confirming hypothesis-5. Two possibilities were that, 1) cyclic loading by the cup rim produced plastic deformation represented by gouge defects (**Table 2**: FHG-damage) [74] or 2) cyclic abrasive motion produced microgrooves (**Table 2**: 2CR-damage). It was equally possible that circulating metal fragments trapped under the cup rim moved with it, their ploughing action producing microgrooves (**Table 2**: 3CR-damage). The similar morphology of large pits (**Figures 10-12**) and microgrooves (**Figure 13** & **Figure 14**) favored 3rd-body wear (**Table 2**: 3CR). This was supported by evidence of cup microgrooves, wherein the only possibility was abrasion by circulating metal particles. Also compelling in an unrelated study was retrieval evidence of metal particles (126 μm avg. size) embedded in polyethylene cup surfaces [58]. Such correlations appeared very supportive of a 3rd-body wear hypothesis. Nevertheless, the evidence of microgrooves of considerable length aligned with cup-rim profiles was also suggestive of 2-body abrasion (**Table 2**: 2CR). Thus, hypothesis-7 appears satisfactory, that head microgrooves represent 2-body and

3-body wear mechanisms created by the cup rim during millions of hip impingements.

There was ample evidence of plastic-deformation in modular CoCr bearings. The raised side-walls of microgrooves and the presence of slip bands on scratch shoulders attested to plastic-flow in damaged CoCr surfaces. Intersections of crossing microgrooves provided further evidence of cold-flow (**Figure 14**). Larger gouges surrounded by arrays of slip bands represented evidence of plastically-deformed defects [74]. These we also found and could be attributable to indents made by an impinging cup rim (**Table 2: 2CR**) or damage produced during revision surgery (**Table 2: 2OR**). Either way, we were not impressed that these were as common or consistently present as the 100 μm microgroove formations. Therefore, we support our overriding 3rd-body wear scenario, that impingement and head subluxation trigger the release of metal fragments. These metal particles will readily circulate in the hip during patient gait and ingress between moving bearings [46] [49] [84]. There is also the added risk with highly-inclined and highly-anteverted cups. Such patients are likely to have more frequent and more adverse THA impingement episodes than normal.

The concept of hip impingement occurring without the patient's awareness we termed a repetitive sub-clinical subluxation (RSS) phenomenon [73] [85]. An appropriately-positioned acetabular cup will reduce the risk of the metal acetabular shell impinging on a metal femoral-neck (**Table 2: NAR-damage**). However, with hip impingement and subluxation there remains the risk of the femoral head being damaged. It is to be noted that laboratory simulations of steeply-inclined cups [20] [64] did not produce black lubricants or the adverse MOM wear described clinically. In contrast, introduction of metal particles in each ¼-million cycle interval of our MOM debris studies immediately turned the yellow lubricants black [83]. Therefore, we find our overriding scenario of 3rd-body wear supported, that hip impingement and head subluxation release metal fragments that trigger the advent of adverse wear in MOM bearings.

It is conceivable that even one hip impingement could have 3rd-body wear implications over ensuing millions of gait cycles. Metal particles can readily circulate in the hip during patient gait and ingress between moving bearing surfaces [46] [49] [84]. From theoretical considerations, large-diameter MOM bearings in motion may develop lubricating films of 7 - 30 nm thickness [4]. However, such proteinaceous layers would offer no protection to the ingress of metal particles some 3000-times larger. It is noted that contemporary debris descriptions in MOM simulator and retrieval studies [8] [19] [86] ascribed only nanometer size to CoCr particles. It is to be noted that the life cycle of large CoCr fragments hundreds of microns in size disintegrating and ionizing in hip-joints remains virtually unknown. Thus, it is our hypothesis that "hard-on-hard" bearings represented a particularly harsh environment for circulating metal particles. We postulated [54] that disintegration of one 100 μm size CoCr fragment could produce 8000 particles of nanometer size and that such fine debris likely

represented the “self-polishing” mechanism attributed to MOM bearings [8] [39] [41] [87] [88]. In contrast, THA designs with metal-on-polyethylene (MPE) bearings have a soft surface that can readily absorb 3rd-body debris including large metal particles [49] [84]. Thus, the accumulating evidence is persuasive that it is the production of large metal fragments that triggers adverse wear. This we would consider proof that, unlike more forgiving MPE bearings, MOM bearings are extremely sensitive to the ingress of metal debris.

The limitations of this study are common to other retrieval studies. Components were seldom received with any markings to indicate position at revision surgery. Thus, we relied on mapping of wear-patterns to deduce *in-vivo* positioning. Retrieval of femoral stems proved to be an infrequent occurrence in these 2nd generation MOM designs. Hence, we lacked evidence of femoral impingement. We also had to rely on surrogate femoral stems of the same brand for neck-cup impingement studies such that the equivalent size neck/femoral stem would simulate the original device. In addition, these data relate only to failed MOM bearings. The visual and microscopic evidence of large pits and polar microgrooves persisting in habitual wear patterns (main-wear zones) denoted repetitive and consistent episodes of hip impingement and subluxation in these retrievals. However, we have no knowledge of whether such wear mechanisms either contributed directly to the failures, or would be present in more successful cases.

Hip impingement and subluxation of the femoral head are key concepts in understanding “normal” functioning of THA and predicting the risk of adverse conditions. In the activities of daily living, patients are continually implementing a succession of standing and sitting postures. The roles of 1) hyperextension, and 2) combined flexion and rotation, reflect the importance and recognition of “critical contact zones” occurring between femoral neck and rim of the acetabular cup. Our EOS studies showed that THA impingement and head subluxation can be demonstrated in patient’s functional postures, notably standing, full extension and sitting, and can be present even when the cup is positioned in the “safe zone”. [60] [89] EOS results confirmed our 1st hypothesis and this was regardless of whether THA designs had 28 mm heads (**Figure 8(C)**) or larger (**Figure 9**). These EOS observations supporting the analysis of retrieved MOM bearings can now be carried into clinical studies of THA devices to discern which patients have normal function and which risk impingement, subluxation and dislocation.

10. Conclusion

By consolidating the impingement/wear evidence from retrieved MOM bearings, 8-risk scenarios were identified. Neck/cup impingement has been confirmed by 1) circumferential scratches and notches on femoral stems, and 2) microgrooves dominating specific locations on femoral heads. In basal and polar regions of the femoral head, these represented sites of prosthetic impingement.

In equatorial regions of the femoral head, we hypothesize that these represented impingement sites with soft-tissues. This retrieval evidence demonstrates that the rim of an impinging CoCr cup can result in abrasive damage on the femoral head (2CR: 2-body wear; 3CR, 3rd-body wear) as well as femoral-neck notching (**Table 2**: NAR, 3rd body wear). In this regard, we were surprised to find that such self-evident impingement damage on MOM bearings, as first described by Howie *et al.* [40] apparently has received no attention over the past 13 years. This applies to some metal-backed polyethylene cups (**Figure 9**) as well as CoCr cup designs. It is noted that metal-backed cup designs offer the surgeon many options. Nevertheless, the National Joint Registries have shown that cemented polyethylene cups have consistently better clinical outcomes than non-cemented cups, *i.e.* the metal-backed cups have not been as forgiving [26] [90]. EOS imaging and associated 3D-reconstructions will also aid our understanding of the retrieval data and better conceptualizing of optimal component positioning in patients with differing complexities of spino-pelvic mobility. In turn, EOS imaging of implant positioning in the clinical setting will offer an improved diagnosis with respect to patient's functional postures and help determine risk of failure.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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Listing of Abbreviations

2CR: 2-body wear on head (by cup rim)
3CR: 3rd-body wear on head (entrapped metal particles)
2OR: 2-body defects created during surgery (instruments, head dislocation)
3CO: 3rd-body wear by CoCr particle
3TI: 3rd-body wear by Ti6Al4V particle
COC: ceramic-on-ceramic hip bearing
CoCr: cobalt chromium alloy
ECD: algorithm utilizing equivalent circle diameter
EDS: Energy dispersive spectroscopy
EOS: EOS® system for low-dose 3D imaging of patients
FHG: femoral-head gouges (plastic deformation)
MOM: metal-on-metal hip bearing
MPE: metal-on-polyethylene hip bearing
MWZ: main-wear zone (area of normal, habitual wear)
NAR: femoral-neck abrasion by cup rim
NWZ: non-wear zone (area of infrequent or non-wear)
RA: resurfacing arthroplasty
SEM: scanning electron microscopy
THA: total hip arthroplasty
Ti6Al4V: titanium alloy
TTL: Titanium transfer layer
WLI: white-light interferometry