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Delayed Dislocation Following Metal on Polyethylene Hip Replacement Due to "Silent" Trunnion Corrosion

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The study design was conceived and developed by NL, MRW, NVG, BAM, DSG and CPD. Data collection was performed by NL and MRW. Radiological analysis was performed by NL. All authors contributed to the analysis and interpretation of the data. NL, MRW and CPD drafted the manuscript. The final manuscript was edited by NL, MRW, NVG, BAM, DSG and CPD. The final manuscript was approved by NL, MRW, NVG, BAM, DSG and CPD.

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Abstract

We present a case series of metal on polyethylene total hip replacement (MoP THR) with delayed onset dislocation, associated with unrecognised adverse local tissue reaction to trunnion corrosion and pseudotumour formation. The diagnosis was not suspected in nine of the ten cases, despite the subspecialty nature of the unit at which they were treated. Instead, it was identified at the time of revision surgery, because of the intraoperative findings, subsequently confirmed by histological examination of the resected tissue. Preoperative assessment and culture results ruled out infection. A variety of treatment strategies were employed, including tumour resection and efforts to avoid recurrent dislocation. The rate of complications was high and included three deep infections, two cases with recurrent dislocation, and one recurrent pseudotumour. This series demonstrates that pseudotumour is an infrequent but important cause of delayed instability following MoP THR, and it is easy to overlook in the differential diagnosis, especially if the original implant alignment is less than optimal, leading to an assumption of component malalignment as the cause of the dislocation. Revision is complex, requiring resection of the pseudotumour and modification of the reconstruction. The risk of postoperative complication is high.

Introduction

Adverse local tissue reaction (ALTR) to metal debris around total hip replacement (THR), is a well-described phenomenon, with potentially severe deleterious consequences[1]. Metal-on-metal (MoM) bearings have been shown to create metal wear particles that lead to elevated serum metal ion levels following THR[2] and hip resurfacing[3]. The local host reaction can lead to pseudotumour formation. In the setting of a metal-on-polyethylene (MoP) THR, potential sources of metallosis are; corrosion between similar or dissimilar metals at modular interfaces[4-8]; full thickness polyethylene wear or liner dissociation, leading to unintended head-on-shell articulation; or impingement between the

femoral neck and acetabular rim[9]. In the latter two examples, the tissues are typically stained with a black metallic colour and the majority of the metallic debris is related to the softer titanium within the construct. This does not usually lead to ALTR.

Whilst ALTR in MoP THR has been described previously, the number of cases reported are few[4,5,10,11]. When pseudotumour formation occurs, patients can present with pain, weakness, dysfunction, and instability[2]. We present a single-centre case series of patients presenting with medium-term new onset instability of previously well functioning MoP THR. At the time of revision, the macroscopic appearance was consistent with pseudotumour formation secondary to trunnion corrosion (trunnionosis). This is an expanded series, with more detail and focus, of a smaller cohort included in a previous report from our centre[12]. The purpose of this outcome study and concise focus on delayed dislocation is; to identify factors that may raise the suspicion of this diagnosis, which in our experience was easy to miss; to measure in more detail the outcome of treatment; and to alert the orthopaedic surgical community to this infrequent but important cause of delayed onset dislocation.

Methods

Institutional Clinical Research Ethical Board approval was obtained. Using our departmental database, we identified 10 cases of pseudotumor found at revision surgery in MoP THR, with the main indication for revision being instability. The index operations were performed between 2006 and 2013. Seven cases had the index THR performed at our institution, and three cases were referred from other hospitals. One of the seven index cases performed at our institution was a revision from failed MoM THR to a MoP THR, and the remaining six were primary MoP THR.

Chart review was performed to identify demographic data, preoperative clinical findings, date of index surgery, time to revision surgery, index implants and trunnion geometry, preoperative

laboratory and radiological findings. Intraoperative findings, laboratory results, and relevant implant details were obtained. Postoperative clinical findings were recorded including the occurrence of complications. Radiological studies were reviewed for implant positioning and for the presence of radiological findings consistent with the presence of pseudotumour on pre-revision studies. Acetabular component positioning was measured using WebDi PACS system (v5.3.3, Philips Electronics) and analysed using the method described by Widmer[13], and refined by Liwa et al.[14]. Patient outcome scores were obtained (WOMAC, SF-12, Oxford Hip Score (OHS), UCLA Activity score).

In all cases, at the time of revision surgery, macroscopic pseudotumour tissue was found expanding the capsule envelope, with or without disruption of that envelope (Figure 1.) Variable destruction of adjacent soft tissues was evident. Tissue from the pseudotumours was obtained for Hematoxylin and Eosin (H&E) staining, and was assessed by a subspecialised musculoskeletal pathologist (Figure 2.).

The femoral heads (all Cobalt/Chrome) were well fixed to the titanium trunnion, requiring forcible disimpaction. When disimpacted there was a black ring of debris and corrosion products staining the trunnion (male taper) and the internal aperture of the femoral head (female taper) (Figure 3). None had evidence of implant-on-implant impingement, or polyethylene wear significant enough to allow head-on-shell articulation, ruling these mechanisms out as a potential source of metal debris.

Statistical analysis of data was performed by departmental statistician using SAS v9.4. Comparative testing was precluded due to population size and lack of comparison group. Descriptive outocmes were illustrated using interquartile ranges, regardless of normality of distribution.

Results

Patient demographics are presented in Table 1. The femoral implants were of one combination: chrome-cobalt heads on a titanium stem. Modularity was confined to the head-neck junction with no neck modularity. For all cases the median diameter of the femoral head was 32mm (range 28-36; IQR 28-36), and the median offset was 0 mm (range -3.5–8; IQR 0-4). There were two manufacturers (Table 2).

Intermittent late onset pain, and a late onset feeling of instability or impending dislocation were the most common prodromata to full dislocation in six of the patients. Swelling or a mass was noted by one patient. Only one patient had a palpable mass. Three patients were noted to have a positive Trendelenburg sign and gait.

All patients had preoperative white cell count (WCC) performed, with a median of $6.6x10^9$/L (range 4.3-11.5; IQR 4.3-7.6). The neutrophil count was a median of $4.1x10^9$/L (range 2.4-7.3; IQR 4-6.4). Seven patients had a C-reactive protein performed, with a median of 2.3mg/L (range 0.6-6.6; IQR 1.6-4.7). Preoperative joint aspiration was done in only three patients because clinical and laboratory screening of other variables did not suggest infection. No aspiration grew bacteria on aerobic and anaerobic extended culture (14 days). The median aspirate WCC was $211x10^6$/L (range: 120-867). A polymorphonuclear (PMN) cell percentage was performed in two of the three cell counts performed and measured 75% and 77%. Serum cobalt and chromium ion levels were measured in one patient preoperatively, in which the possibility of an adverse reaction to metal was being entertained. The results were Cobalt 6.2µg/L and Chromium 1.2µg/L, (normal ranges: cobalt 0.03-0.4µg/L; chromium 0.1-0.2µg/L).

Preoperative radiographs were routinely performed, including antero-posterior (AP) pelvis, cross table lateral, and Judet views. Based on the AP view, anteversion and inclination measurements of the acetabular component were made (Figure 4)[15,16]. The median inclination was 44^0 (range 37-56;

IQR 42-46). The median anteversion was 16^0 (range 4-40; IQR 9-36). Six of the ten cases had inclination and anteversion values that fell within recommended ranges[15,16]. Review of the radiographs for evidence of pseudotumor formation revealed subtle lytic changes at the base of the greater trochanter in one patient. This was a retrospective observation. No acetabular radiolucent lines were observed.

Intraoperative findings: A posterolateral extensile surgical approach was used in all cases. A number of intraoperative findings alerted the surgical team as to the nature of the underlying diagnosis. There was abnormal thickening of the deep fascia in one, and a juxta-articular collection of non-purulent fluid was seen in others. The posterior capsule was commonly distended when it was found to be intact. In others it was substantially disrupted, leading to the collection of subfascial juxta-articular fluid found in those cases. There was an excess of intra-articular fluid when the capsule was still intact, usually turbid in appearance. The capsule was commonly patulous. It appeared thickened and hypovascular. It was lined by abnormal synovium, which was usually thickened and hypertrophic with occupation and distension of the joint cavity. These observations were consistent with our previous experience with ALTR. There was highly variable extension of the reaction into the surrounding soft tissues, including the abductors, vasti, tensor fascia lata, gluteus maximus and deep fascia. In five cases, where previous posterolateral approach was utilised, there was substantial avulsion of the abductors from the greater trochanter. In all ten patients, with disimpaction of the femoral head, a black skin of metal debris products was seen around the trunnion and internal aperture of the femoral head. The trunnion was cleaned with saline and a cautery scratch pad, and inspection showed the trunnion was free of macroscopic damage, allowing retention of the femoral stem. A minimum of three intraoperative tissue specimens were sent for culture in each case. No bacteria were isolated from aerobic and anaerobic culture extended up to 14 days of incubation. Joint fluid was not consistently sent for analysis because it is not the standard of care at our centre to do so. Synovial fluid or tissue metal ion measurement was not

possible because we did not suspect the diagnosis before operation and therefore did not have Institutional Ethics Board approval or patient consent to do so, nor was the research team on standby to receive the samples.

Histology: Representative tissue was sent for histology in all cases. Histological examination by a subspecialized musculoskeletal pathologist included assessment for the presence of neutrophils, macrophages, chronic inflammatory cells (lymphocytes, plasma cells and lymphoid follicles), eosinophils, multinucleated giant cells, necrosis, the pattern of necrotic debris surrounded by histiocytes, granulomatous inflamed tissue, metal particles, bone chips, and aseptic lymphocytic vasculitis-associated lesions (ALVAL); features characteristic of the MoM implant-associated pseudotumours[17,18]. In every case the findings were diagnostic of adverse local tissue reaction to metal.

Reconstruction: All trunnions were free from macroscopic damage following cleaning and therefore the stems were retained. Acetabular revision, to some degree, was performed in all cases. Five of ten cases were treated with liner exchange and retention of the original well-ingrown shell. Two of these five, had liner exchange to accommodate an increased femoral head diameter. One of the five had a constrained liner implanted, and the remaining two had Trident® acetabular components into which Modular Dual Mobility (MDM) ® (Stryker, Mahwah, NJ) components, were implanted. Of the other five cases, the acetabular components were revised to larger outer diameter components, with two patients having Trabecular Metal ™ revision acetabular components (Zimmer, Warsaw, IN.) and large diameter femoral heads. Two underwent revision to an Anatomic Dual Mobility® acetabulum (Stryker, Mahwah, NJ), and one had revision to a Tritanium® acetabular component with a MDM® liner (Stryker, Mahwah, NJ).

Femoral heads were revised in all cases. Eight of the ten cases were revised to delta ceramic femoral heads, with a titanium adaptor sleeve in seven. A chrome-cobalt head was used in the remaining two. Our management of the femoral head during revision for pseudotumour was in evolution over the duration these cases were treated. Today it is our standard practice to use a delta ceramic head and titanium adaptor sleeve if the stem is retained.

Complications: Six of the ten cases suffered a major complication, requiring unexpected readmission and further surgery at a mean of 4 months (range:1-10). There were three periprosthetic infections, of which two required two-stage revision with a PROSTALAC (DePuy Synthes, Warsaw, IN) articulating spacer between stages (Group G β-haemolytic *Streptococcus*, and methicillin-resistant Staphylococcus *epidermidis*). One case with an acute infection (within four weeks of revision) with *Staphylococcus lugdunensis* was successfully treated with radical debridement, modular exchange and prolonged intravenous antibiotic therapy.

Two patients suffered from recurrent dislocation, both requiring re-revision to resolve. The first case was noticed at initial revision to have significant abductor muscle destruction and was treated with a revision to an ADM acetabular reconstruction. Recurrent dislocation of the ADM femoral articulation occurred and the patient was revised to a Trabecular Metal Modular cup (Zimmer, Warsaw, IN) and a Trilogy Constrained Liner (Zimmer, Warsaw, IN). The second case, also noticed to have no posterior capsule and significant damage to the abductor muscles, requiring reattachment, was initially revised to a larger diameter femoral head (40mm). After recurrent dislocation, the patient was again revised (using a previously retained Trilogy acetabular component) to a constrained liner.

One patient had recurrence of a symptomatic pseudotumor. The first revision was to a MDM articulation within a retained well-fixed Trident acetabulum. The internal femoral head used was a 28mm cobalt-chrome device. The ceramic head with a titanium adaptor sleeve was not available at

that time. Ten months following initial revision, the patient underwent further revision, debulking of the recurred pseudotumour, and revision of the acetabulum to a larger Tritanium (Stryker, Mahwah, NJ) shell and constrained liner, with a ceramic femoral head and titanium adaptor sleeve. This case illustrates the evolution of our current treatment.

Following re–revision surgery, no further dislocations or recurrence of pseudotumour had occurred at latest follow-up. Two of three infections were successfully treated, the third patient is waiting to undergo second stage implantation of their two-stage revision.

Patient Outcome Scores: Clinical outcomes were assessed using the OHS, WOMAC, SF-12, and UCLA Activity Scale questionnaires. The median results of OHS, WOMAC global, SF-12 PCS and MCS, and UCLA were: 32 (range 16-45; IQR 28-44); 45 (range 3-66; IQR 32-58); 34 (range 28-56; IQR 31-43); 43 (range 34-65; IQR 38-56); 4 (range 2-5; IQR 2-4). The normalised scores, where applicable, (100 best, 0 worst) are presented in Table 2.

Discussion

Pseudotumour formation is a well-documented sequelae of increased metal ions[1-3], and is a severe manifestation of adverse local tissue reactions (ALTR). With pseudotumour formation and development of an inflammatory response, significant soft tissue damage can ensue. ALTR is most commonly described in MoM THR but also occurs in MoP THR[4,5,10,11] and even modular hemiarthroplasty[19]. The presented series describes significant ALTR and secondary pseudotumour formation in a cohort of MoP THR patients. In some cases the soft tissue destruction was significant enough to create defects in, or substantial disruption of, the posterior capsule, compromising its role as a stabiliser of the hip. Five of the ten cases had abductor muscle destruction, a further contributor to the delayed occurrence of dislocation. It is possible that the mass effect of the pseudotumour not only leads to distension and reduced function of the static soft tissue stabilisers of the hip, but has

an intra-articular mass effect as well, leading to soft tissue impingement in flexion combined with internal rotation, leading to leverage dislocation.

Component positioning could be a further contributing factor to late onset instability but in this series, six of the ten cases had acetabular components that fell within recommended ranges[15,16]. This highlights the possibility of instability occurring in MoP THR with pseudotumour formation, even when components are appropriately implanted.

The development of pseudotumours usually occurs over a period of years following index surgery[20]. The pattern of presentation in this series is consistent with this because the time from index surgery to revision was just under six years (mean 57 months). This contrasts with revision for early instability in MOP THR, which is usually required within 6 months of index surgery[21]. Clinicians should be cognizant that the late presentation of instability following index surgery in a previously stable THR, raises the possibility of an underlying pathology, such as ALTR secondary to trunnion corrosion.

Another key finding in this series was the 'silent' nature of the trunnion corrosion. Only five patients had preoperative pain, six reported symptoms consistent with subluxation and only one patient had swelling. These symptoms are not specific for pseudotumour/trunnionosis or instability making the diagnosis difficult to appreciate. The covert nature of the underlying pathology prompted more comprehensive investigation in only one patient, in that instance the case with unexplained pertrochanteric swelling.

Preoperative investigations were found to be non-contributory with normal WCC, neutrophil count, C-reactive protein, and ESR. Only one patient had preoperative serum cobalt and chromium ion levels measured, both were elevated, x15 and x6 times base values respectively. The cobalt-

chromium ratio was also preferentially reversed. Arthrocentesis was only helpful to rule out periprosthetic infection in the few cases where the laboratory investigation introduced that possibility. Preoperative radiological examination demonstrated a small lytic defect within the greater trochanter in one patient and six patients had fine calcific changes in the periarticular tissue, not typical of heterotopic ossification. These features did not assist us in identifying the underlying diagnosis. In cases of delayed dislocation we would recommend ultrasound or metal-artifact reduction sequence magnetic resonance imaging (MARS-MRI)[22] to rule out pseudotumour formation or soft tissue destruction secondary to trunnionosis is suspected.

The associated soft tissue destruction in this entity can be extensive. The destruction of the static and dynamic stabilizers of the joint creates the potential for instability, which must be addressed with the reconstructive strategy. Our treatment strategy, which evolved during this cohort, initially utilised large femoral heads in four cases (>32mm), next dual mobility articulations in five, and a constrained liner in one case. One of the large head cases suffered recurrent instability requiring revision to a constrained liner. Revision of two of the dual mobility articulations was required for other reasons (infection and recurrent pseudotumour) and these were both revised to constrained liners. Extensive soft tissue destruction may also impact on postoperative pain and function, as may the incidence of major complications. Five patients had soft tissue destruction to the point where a portion or all of the hip abductor insertion required attempted repair. Patient outcome scores were found to be fair, regardless of the measurement tool used, and comparable to other studies for revision for pseudotumour[23], MoM revision cases[24-26], and revision for instability in MoP THR[21].

Pseudotumour formation in MoP THR requires a high degree of suspicion to detect and can present with instability alone. When the time between index surgery and presentation of dislocation is extended, surgeons should be aware that soft tissue destruction and mass effects could be

contributing factors and this may be secondary to pseudotumour formation in cases of ALTR even in MoP THR.

The standard preoperative work up of revision cases including haematology, serum biochemistry, microbiology, and plain radiography do not appear to be of use in screening for or detecting pseudotumours in this context, hence we recommend cross sectional imaging (ultrasound and MARS-MRI according to local service provision), and serum metal ion levels for assessment. While it is well established that elevated serum metal ions are not diagnostic of pseudotumours, and lower levels do not rule it out[27], the presence of elevated levels and reversal of the usual chrome-cobalt ratio would serve to alert the surgeon to the presence of an adverse local tissue reaction, even in MoP arthroplasty.

When faced with a pseudotumour in the operating room, the ability to compensate for soft tissue defects and secondary instability is critical. Large head dual mobility constructs and constrained devices are often required to achieve stability. Furthermore, because these patients may have become sensitised to chrome and/or cobalt it is now our routine practice to use a delta ceramic head with a titanium sleeve. Revision of these cases is associated with a high incidence of complications and the likelihood of compromised outcomes in pain relief and function. This is important information to share with the patient before the revision procedure.

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Tables

Table 1: Patient demographics (All values expressed as mean (range))

Age (years)	66 (53-78)
Gender (Male : Female)	4 : 6
Height (meters)	1.67 (153-187)
Weight (kilograms)	84 (51-120)
BMI (kg / m^2)	30 (22-42)
Time from index to revision surgery (months)	57 (36-84)
Time to follow up from revision (months)	19 (8-31)
Number of dislocations	2.5 (1-6)

Table 2. Index Surgery Implants.

Component	Zimmer	Stryker
Femoral Stem	M/L Taper™ (n=7)	Accolade™(n=3)
Femoral Taper	12/14, 5^0 38' (n=7)	V40™, 5^0 40' (n=3)
Acetabulum	Trilogy™(n=6) Continuum™ (n=1)	Trident™ (n=3)
Acetabular Liner	Longevity™(n=7)	X3™(n=3)
Femoral Head	Versys™ CoCr 32mm diameter n=3 36mm diameter n=4	Vitallium™ CoCr 28mm diameter n=2 32mm diameter n=1

Table 3. Postoperative Clinical Outcome Scores

Outcome Tool	Median Raw Score (range; IQR)	Median Normalised Score (range; IQR)
Oxford Hip Score (0-48, worst -best)	32 (range; 16-45, IQR; 28-44)	58 (range; 31-92, IQR; 33 – 66)
WOMAC – Pain (0-20, best-worst)	7 (range; 1-15, IQR; 1 – 13)	65 (range; 25-95, IQR; 35 – 95)
WOMAC- Stiffness (0-8, best –worst)	4 (range; 0-6, IQR; 2 – 5)	50 (range; 25-100, IQR; 38 -75)
WOMAC-Function (0-68, best –worst)	35 (range; 2-45, IQR; 29 – 43)	49 (range; 34-97, IQR; 37 – 57)
WOMAC- Global (0-96, best –worst)	45 (range; 3-66, IQR; 32-58);	53 (range; 31-97, IQR; 40 – 67)
SF-12- PCS	34 (range; 28-56, IQR; 31-43)	
SF-12 – MCS	43 (range; 34-65, IQR; 38-56)	
UCLA Activity Scale (1-10, worst to best)	4 (range; 2-5, IQR; 2-4)	

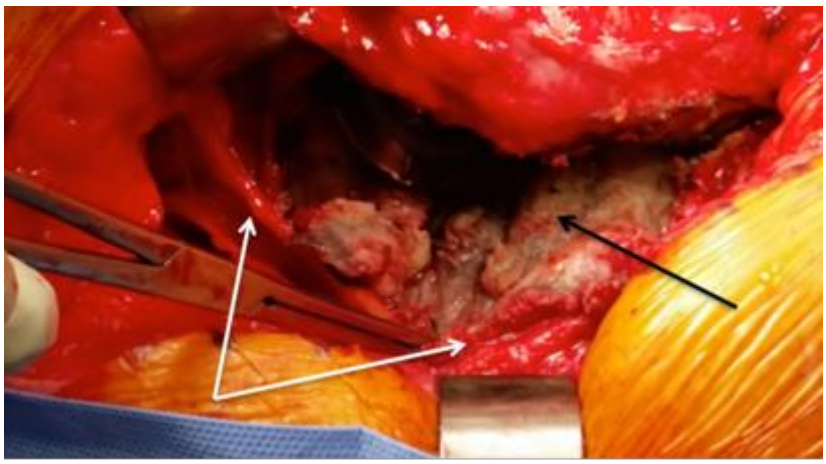
Figure Legends.

Figure 1. Intraoperative photograph demonstrating the pseudotumour (black arrow), which has caused expansion and laxity of the posterior capsule (white arrow).

Figure 2. Histology slide revealing pink hyalinised necrotic material (black arrow) rimmed by purple lymphohistiocytic infiltrate (white arrow) typical of adverse local tissue reaction.

Figure 3. Intraoperative photograph demonstrating trunnionosis with a rim of black metal debris (white arrows) around the trunnion and internal aperture of femoral head.

Figure 4. Scatter graph of acetabular component position. For each case, acetabular anteversion and inclination (degrees) is displayed. The shaded area represents ideal anteversion and inclination ranges (14,15).



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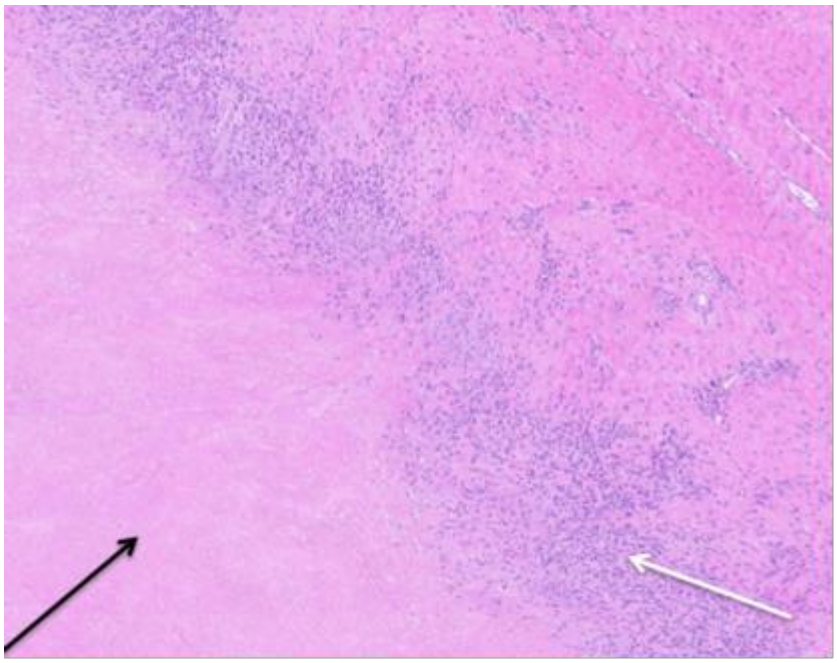

Figure 2: Histology slide revealing pink hyalinised necrotic material (black arrow) rimmed by purple lymphohistiocytic infiltrate (white arrow) typical of adverse local tissue reaction.

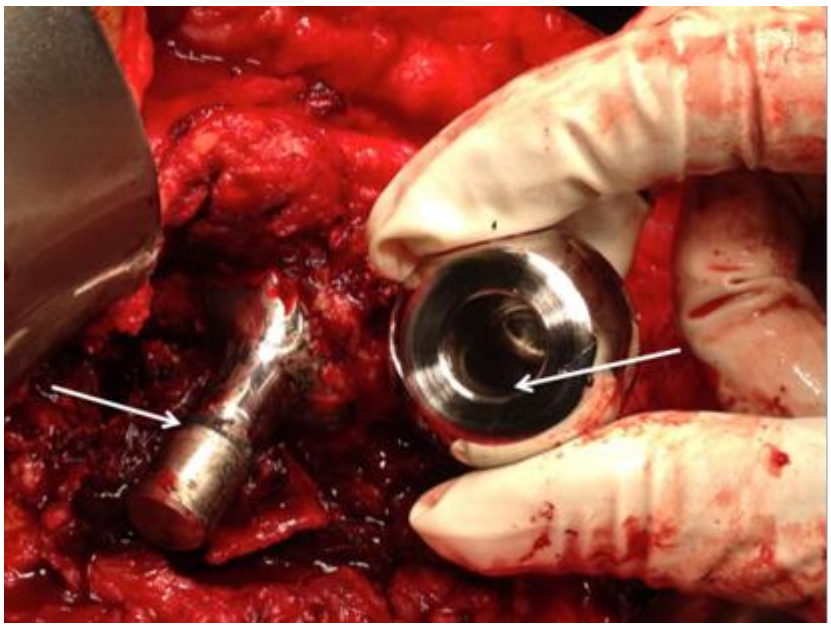

Figure 3: Intraoperative photograph demonstrating trunnionosis with a rim of black metal debris (white arrows) around the trunnion and internal aperture of femoral head.

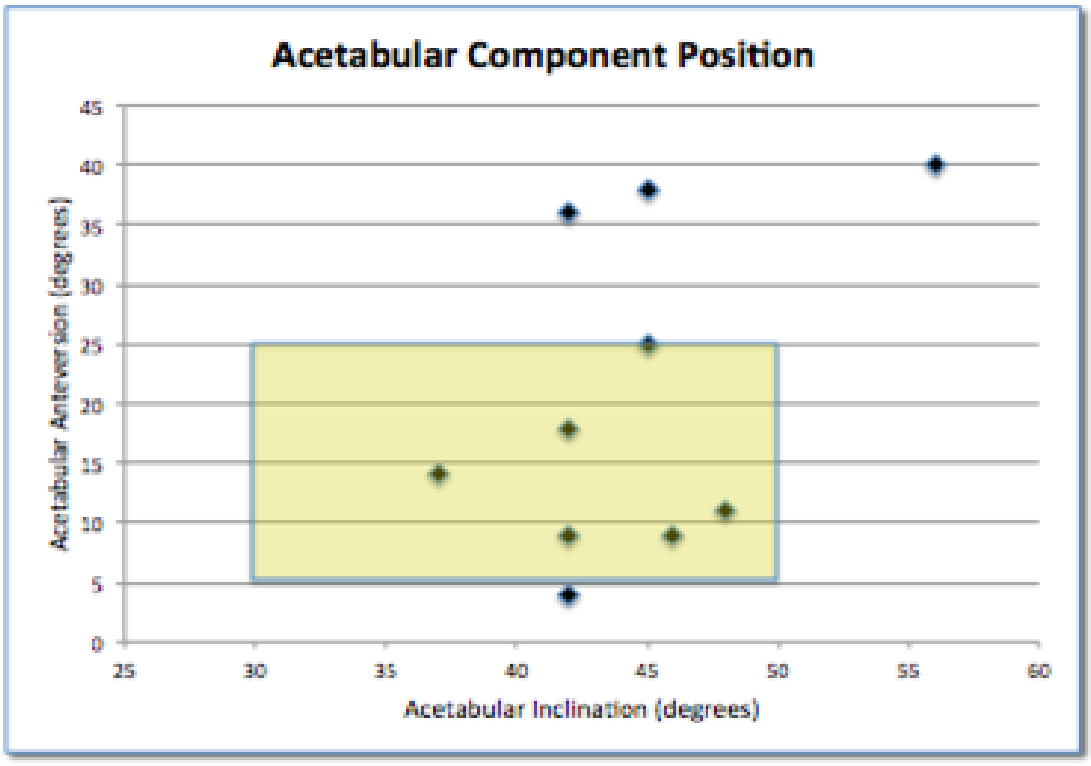

Figure 4: Scatter graph of acetabular component position. For each case, acetabular anteversion and inclination (degrees) is displayed. The shaded area represents ideal anteversion and inclination ranges.