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Original Article

# Trunnion Failure of the Recalled Low Friction Ion Treatment Cobalt Chromium Alloy Femoral Head

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### A R T I C L E I N F O

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### ABSTRACT

*Background:* Gross trunnion failure (GTF) is a rare complication in total hip arthroplasty (THA) reported across a range of manufacturers. Specific lots of the Stryker low friction ion treatment (LFIT) anatomic cobalt chromium alloy (CoCr) V40 femoral head were recalled in August 2016. In part, the recall was based out of concerns for disassociation of the femoral head from the stem and GTF.

*Methods:* We report on 28 patients (30 implants) with either GTF (n = 18) or head-neck taper corrosion (n = 12) of the LFIT CoCr femoral head and the Accolade titanium-molybdenum-zirconium-iron alloy femoral stems. All these cases were associated with adverse local tissue reactions requiring revision of the THA.

*Results:* In our series, a conservative estimate of the incidence of failure was 4.7% (n = 636 total implanted) at 8.0  $\pm$  1.4 years from the index procedure. Failures were associated with a high-offset 127° femoral stem neck angle and increased neck lengths; 43.3% (13 of 30) of the observed failures included implant sizes outside the voluntary recall (27.8% [5 of 18] of the GTF and 75.0% [8 of 12] of the taper corrosion cases). Serum cobalt and chromium levels were elevated (cobalt: 8.4  $\pm$  7.0 µg/mL; chromium: 3.4  $\pm$  3.3 µ/L; cobalt/chromium ratio: 3.7). The metal artifact reduction sequence magnetic resonance imaging demonstrated large cystic fluid collections typical with adverse local tissue reactions. During revision, a pseudotumor was observed in all cases. Pathology suggested a chronic inflammatory response. Impending GTF could be diagnosed based on aspiration of black synovial fluid and an oblique femoral head as compared with the neck taper on radiographs.

*Conclusion:* In our series of the recalled LFIT CoCr femoral head, the risk of impending GTF or head-neck taper corrosion should be considered as a potential diagnosis in a painful LFIT femoral head and Accolade titanium-molybdenum-zirconium-iron alloy THA with unknown etiology. Almost half of the failures we observed included sizes outside of the voluntary recall.

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\* Reprint requests: Kenneth L. Urish, MD, PhD, Bone and Joint Center, Magee Womens Hospital of the University of Pittsburgh Medical Center; Department of Orthopaedic Surgery, University of Pittsburgh, 300 Halket Street, Suite 1601, Pittsburgh, PA 15212. Cobalt chromium alloy (CoCr) has been the primary material used for femoral heads in modern day total hip arthroplasty (THA). Its material properties to resist wear and corrosion make it an ideal choice as a bearing surface. The overall longevity and survival of CoCr heads on cementless titanium alloy stems in prospective, registry, and retrospective studies is impressive at >80% with 15-25 years follow-up [1-3].

A potential disadvantage of CoCr femoral heads is increased concerns with adverse local tissue reactions (ALTR) from corrosion or wear debris at the trunnion interface. After its initial description in metal-on-metal bearing surfaces [4,5], ALTR has been associated, as a rare event, at the head-neck interface between a CoCr femoral 2

head and titanium femoral stem [6]. Clinical studies have reported ALTR association with head-neck taper corrosion [6,7] and with gross trunnion failure (GTF) [8]. A small series of cases involving GTF with the low friction ion treatment (LFIT) CoCr femoral head and the Accolade titanium-molybdenum-zirconium-iron alloy (TMZF) stem (Stryker Orthopaedics, Mahwah, NJ), as well as other designs, has also been reported [9,10].

The Stryker LFIT Anatomic CoCr V40 femoral head had a limited voluntary recall in August 2016. Recalled lots included femoral heads diameter and offsets of 36 + 5, 40 + 4, 40 + 8, 40 + 12, 44 + 4, 44 + 8, and 44 + 12 (head diameter, neck offset). Other remaining femoral head sizes have not been recalled. One of the reported hazards noted was disassociation of the femoral head-stem and GTF. There are limited data on the initial evaluation of these cases, on the ability to preoperatively plan for head-liner vs femoral stem revision, and on how to diagnose possible impending failure.

We report on 30 revisions associated with ALTR between the LFIT femoral head and the Accolade TMZF femoral stem. These revised implants involved femoral head sizes that are outside the recall. An additional mode of failure that is not listed as a potential hazard on the recall, head-neck taper corrosion, was included to investigate its potential association with the recall. The purpose of this report is to describe the presentation, diagnosis, and intraoperative findings of these cases, and report on our experience in diagnosing possible impending trunnion failure.

### Methods

### Study Population

After receiving institutional review board approval, we retrospectively reviewed 28 patients who underwent a THA with an LFIT femoral head and Accolade TMZF femoral stem that subsequently presented with GTF or head-neck taper corrosion and underwent revision arthroplasty (n = 30). Surgical revision was completed by one of 3 fellowship-trained arthroplasty surgeons from February 2012 to October 2016. Inclusion criteria included all patients identified with GTF or head-neck taper corrosion at the time of revision surgery. GTF was defined as all THA patients where the femoral head had disassociated from the femoral neck morse taper secondary to gross loss of material volume at the femoral neck trunnion interface [8]. Diagnosis was made with radiographs at presentation and confirmed during revision arthroplasty of the failed femoral stem. Head-neck taper corrosion was identified based on a combination of painful THA with elevated serum cobalt and chromium levels, evidence of ALTR on metal artifact reduction sequence (MARS) magnetic resonance imaging (MRI), and intraoperative observation of black corrosion debris on the trunnion interface. At the time of surgery, ALTR was judged to be present to some degree in all cases based on intraoperative observation. ALTR was defined clinically as the presence of fluid, necrotic soft-tissue destruction, "pseudotumor," and osteolysis [11,12]. The surface of capsular tissue was black in cases of GTF, consistent with metallic debris.

### Index Surgical Procedure

The initial index surgical procedure was between October 1999 and November 2007 using a cementless THA with a metal-onpolyethylene bearing surface. During this period, THA was performed using a single implant combination, a LFIT CoCr femoral head and an Accolade TMZF tapered wedge stem. All implants used a high-offset 127° femoral stem neck angle, a 36-mm diameter femoral head, and a range of femoral neck lengths of -5 (n = 2), +0(n = 4), +5 (n = 17), and +10 (n = 7). The implant was used during a period of 2.5 years by a single, fellowship-trained surgeon in our practice using a posterior approach, with the last implant placed in 2007. During this period, there were 636 Accolade TMZF femoral stems with LFIT CoCr femoral heads implanted at our institution.

### Surgical Revision

For patients diagnosed with GTF, surgical revision included removal of the femoral stem as the trunnion was severely damaged. A posterior approach was used, and a complete synovectomy was performed with removal of abnormal hypertrophic tissue. An extended trochanteric osteotomy was used in 3 cases to remove the stem, and in the remainder of cases, the stem could be removed with either flexible osteotomes or a variation of the "top-out" method for removal of femoral stems [13]. A modular revision femoral stem was used with a BIOLOX delta ceramic femoral head (CeramTec, Plochingen, Germany). In one case, the acetabular component needed to be revised as there was damage to the polyethylene liner locking mechanism from abrasion with the disassociated trunnion (case 5).

In cases involving head-neck taper corrosion, surgical revision included an exchange of the femoral head and polyethylene liner. The femoral stems and acetabular components were well fixed. A bovie scratch pad was used to remove the black corrosion precipitate from the stem taper. A titanium-alloy adapter sleeve with a BIOLOX OPTION delta ceramic femoral head (CeramTec, Plochingen, Germany) was inserted over the existing taper. This combination was selected out of concerns for an additional modular junction of a cobalt alloy and possible fracture of the ceramic head on a damaged taper [6,14].

### Statistical Analysis

Demographic characteristics of our sample participants were analyzed using univariate descriptive statistics. Means and standard deviations were calculated for approximately normally distributed variables; medians and interquartile ranges were computed for continuous variables with skewed distributions. Frequencies and percentages were determined for categorical variables, and double-tailed Fisher exact test was used to test for statistical significance in these cases.

#### Results

### Incidence and Presentation

In our series, the overall incidence of revision owing to GTF or ALTR and head-neck taper corrosion was conservatively estimated at 30 of 636 (4.7%). In the GTF group, 5 of 18 failures (27.8%) included head sizes not listed on the recall. In the head-neck taper corrosion group, 8 of 12 failures (75.0%) included head sizes not listed on the recall (Table 1). The difference in incidence between the GTF and taper corrosion groups was not significant (P = .06).

Patients presented with either GTF or head-neck taper corrosion at 8.0  $\pm$  1.4 years (range, 4.7-9.6 years; median, 8.3 years) from surgery (Table 1). In the GTF group, patients were initially asymptomatic until an acute, severe hip pain, an inability to bear weight, and radiographs demonstrating implant failure. A group of patients (n = 5; 27.8%) had noticed an audible sound in their hip usually described as "clicking" within the month before presentation. Patients that presented with head-neck taper corrosion complained of a chronic hip pain (10 of 12). Overall, there was a statistically significant difference in demographics between both groups for body mass index (GTF mean:  $31.8 \pm 8.0 \text{ kg/m}^2$ , taper corrosion mean:

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Table	1
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Demographics, Patient, and Implant Characteristics.

Case	Failure Type	Age, Y	Gender	BMI, kg/m <sup>2</sup>	Time to Failure (Y)	Follow-up (Y)	Accolade Stem	Head Size	Neck Offset	Recalled
1	GTF	63	Male	28.2	9.6	1.2	127° Neck	36	(+) 5	Yes
2	GTF	66	Male	41.5	8.3	1.5	127° Neck	36	(+) 5	Yes
3	GTF	82	Male	25.6	9.3	1.8	127° Neck	36	(+) 5	Yes
4	GTF	50	Male	29.6	9.5	1.8	127° Neck	36	(+) 0	No
5	GTF	50	Female	53.6	8.8	1.8	127° Neck	36	(+) 10	No
6	GTF	65	Male	41.5	7.8	2.4	127° Neck	36	(+) 5	Yes
7	GTF	73	Male	28.6	7.9	2.9	127° Neck	36	(+) 10	No
8	GTF	79	Male	27.6	8.0	2.9	127° Neck	36	(+) 10	No
9	GTF	63	Male	25.8	7.6	3.5	127° Neck	36	(+) 5	Yes
10	GTF	65	Male	30.0	7.8	3.5	127° Neck	36	(+) 5	Yes
11	GTF	56	Female	27.4	6.3	3.7	127° Neck	36	(+) 5	Yes
12	GTF	69	Male	29.5	4.7	4.7	127° Neck	36	(+) 5	Yes
13	GTF	80	Male	22.7	11.0	0.3	127° Neck	36	(+) 10	No
14	GTF	80	Female	33.7	9.4	0.6	127° Neck	36	(+) 5	Yes
15	GTF	68	Female	31.9	9.0	0.7	127° Neck	36	(+) 5	Yes
16	GTF	82	Male	31.9	10.5	0.0	127° Neck	36	(+) 5	Yes
17	Impending GTF	89	Male	25.0	10.9	0.1	127° Neck	36	(+) 5	Yes
18	Impending GTF	76	Male	31.9	10.1	0.0	127° Neck	36	(+) 5	Yes
19	ALTR	68	Female	31.9	8.9	0.5	127° Neck	36	(+) 5	Yes
20	ALTR	82	Male	27.6	9.6	0.4	127° Neck	36	(-) 5	No
21	ALTR	59	Female	21.1	9.1	0.5	127° Neck	36	(+) 10	No
22	ALTR	72	Female	27.5	9.6	1.4	127° Neck	36	(+) 5	Yes
23	ALTR	61	Female	20.5	7.4	2.0	127° Neck	36	(+) 10	No
24	ALTR	75	Female	21.8	7.1	2.6	127° Neck	36	(+) 0	No
25	ALTR	80	Female	27.1	5.1	4.2	127° Neck	36	(+) 5	Yes
26	ALTR	88	Female	21.9	6.8	2.1	127° Neck	36	(+) 0	No
27	ALTR	60	Female	30.1	8.2	1.7	127° Neck	36	(+) 0	No
28	ALTR	73	Female	24.0	8.3	1.8	127° Neck	36	(–) 5	No
29	ALTR	70	Male	28.0	7.7	1.3	127° Neck	36	(+) 5	Yes
30	ALTR	74	Male	33.7	6.2	2.7	127° Neck	36	(+) 10	No

BMI, body mass index; GTF, gross trunnion failure; ALTR, adverse local tissue reaction associated with head-neck taper corrosion.

 $26.2 \pm 4.2 \text{ kg/m}^2$ ; P = .03). There was no statistical difference in age (GTF mean:  $67.3 \pm 10.4$  years, taper corrosion mean:  $73.2 \pm 9.9$  years; P = .13). In both groups, no infections were identified based on definition of the Musculoskeletal Infection Society criteria [15]. Of concern for falsely elevated automated nucleated synovial cell counts, manual cell counts were performed when necessary [16].

### Imaging

In the GTF group, radiographs demonstrated failure of the modular junction with a dissociation of the femoral head from the taper. A large radiolucent fluid collection from metal debris (Fig. 1A) was identified in 13 of the 18 cases (73.3%). Careful evaluation of previous radiographs collected before presentation did not demonstrate any obvious signs of impending trunnion failure. In a patient with bilateral GTF (case 3 and 7), the patient was seen as part of postoperative follow-up 1 month before presentation for failure on his opposite extremity. No obvious signs of impending failure could be seen on these radiographs. In a subset of 9 of 18 (50%) patients, small, not abnormal, amounts of a faint radiodensity around the hip capsule, similar to early heterotopic ossification, could be identified in the last set of normal radiographs before failure. MRI was collected in only 1 patient given the urgent need for revision. In this patient, a large fluid-filled cystic lesion typical for ALTR was present. In the head-neck taper corrosion group, MARS MRI demonstrated fluid collections of various size and cystic lesions.

### Metal Ion Levels

Serum cobalt (Co) and chromium (Cr) levels were elevated [17,18] (>4.5  $\mu$ g/L) in 80.0% (20 of 25) of patients tested preoperatively (Table 2). Mean cobalt levels were 8.9  $\pm$  8.2  $\mu$ g/L for GTF and 7.8  $\pm$  5.7  $\mu$ g/L for head-neck taper corrosion (P = .68). Mean chromium levels were  $4.4 \pm 3.3 \ \mu g/L$  for GTF and  $2.3 \pm 3.2 \ \mu g/L$  for head-neck taper corrosion (P = .11). Serum cobalt levels were elevated, typically more than chromium levels. The ratio of Co/Cr was 2.5 in the GTF group and 4.9 in the head-neck taper corrosion group, and these differences were statistically significant (P = .01).

Postoperative serum cobalt and chromium levels were measured in 15 patients. Serum cobalt and chromium levels as compared with preoperative levels were decreased in both groups. In the GTF group, 9 patients had a serum cobalt level of  $0.9 \pm 0.5 \mu g/L$  and serum chromium level of  $1.6 \pm 0.9 \mu g/L$  at a mean follow-up of  $0.9 \pm 0.4$  years. In the head-neck taper corrosion group, 6 patients had a serum cobalt level of  $0.9 \pm 0.7 \mu g/L$  at a mean follow-up of  $0.7 \pm 0.3$  years.

#### Intraoperative Findings

Intraoperative findings confirmed a diagnosis of ALTR. In cases involving GTF, incision in the deep fascia revealed a large collection of black synovial fluid and black, friable hypertrophic pseudotumor to varying degrees in all cases (Fig. 1B). There was a complete absence or damage to the abductors (Fig. 1C) and extensive erosion of the trunnion (Fig. 1D). In cases involving head-neck taper corrosion, incision in the deep fascia revealed a straw-colored or brown-gray fluid with hypertrophic synovial tissue. There was severe damage or absence of abductors. After removal of the head, there was a circumferential ring of black corrosion material around the femoral taper.

Tissue specimens were sent to pathology in 16 cases (11 GTF and 5 taper corrosions). A fibrous tissue surrounded by a chronic inflammatory infiltrate was observed with no acute inflammation. Description of the cellular infiltrate varied between each sample and included macrophages, granuloma, giant cells, histiocytes, and

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**Fig. 1.** Gross trunnion failure radiographic and intraoperative findings. (A) A large radiotranslucent fluid collection surrounded the proximal femur (arrows). Pieces of metallic debris were observed at the base of the fluid collection (double arrow) that were intraoperatively identified as pieces of the polyethylene liner locking mechanism. Note the appearance of the greater trochanter appearing with increased radiodensity in place of the normal bone. This increased radiodensity in the greater trochanter was fine metallic debris. (B) Opening of the fascia revealed friable black tissue with the absence of viable muscle tissue. (C) The greater trochanter (outlined with white line) was a thin cortical shell. Viable bone was replaced with a viscous black substance that had increased radiodensity as compared with bone as seen on radiographs. There were no abductors attached. (D) Direct examination of the trunnion after stem removal demonstrated severe erosion of the taper.

necrotic tissue. In cases of GTF, a foreign material consistent with the large amount of trunnion wear debris was also noted.

## Postsurgical Complications

In both groups, there was an increased incidence of postoperative instability after revision THA (30.0%; 9 of 30 cases). These patients required a constrained liner, and no further instability has occurred. Patients with instability had notable abductor damage at the time of surgery and in 5 cases had complete or near loss of the abductors. Postsurgical follow-up ranged from 0.1 to 4.7 years (2.6  $\pm$  1.1 years).

## Impending GTF

There were 2 cases of impending trunnion failure that were revised before failure (case 17 and 18). Radiographs demonstrated a slight oblique angle between the head-neck taper of the femoral

Preoperative Laboratory Findings

Table 2

F				
Case	Туре	Cobalt	Chromium	Co/Cr Ratio
1	GTF	3.6	2.3	1.6
2	GTF	6.2	3.7	1.7
3	GTF			
4	GTF			
5	GTF	5.2	5.0	1.0
6	GTF	7.0	4.1	1.7
7	GTF		3.5	
8	GTF			
9	GTF	33.8	9.8	3.4
10	GTF			
11	GTF	11.3	9.3	1.2
12	GTF	10.4	2.0	5.2
13	GTF	3.4	4.0	0.9
14	GTF	6.7	1.0	6.7
15	GTF	0.6	2.2	0.3
16	GTF	13.0	11.0	1.2
17	Impending GTF	7.3	1.6	4.6
18	Impending GTF	10.8	1.4	7.7
19	ALTR	13.0	11.0	1.2
20	ALTR	10.8	1.4	7.7
21	ALTR	4.9	1.3	3.8
22	ALTR	8.0	1.2	6.7
23	ALTR	5.2	1.2	4.3
24	ALTR	5.9	1.1	5.4
25	ALTR	22.8	6.5	3.5
26	ALTR	7.1	0.8	8.9
27	ALTR	0.7	0.2	3.5
28	ALTR	6.0	1.1	5.5
29	ALTR	3.8	1.1	3.5
30	ALTR	4.8	1.0	4.8

Co/Cr, cobalt/chromium; GTF, gross trunnion failure; ALTR, adverse local tissue reaction associated with head-neck taper corrosion.

stem. In case 17, there was a slight radiodensity around the hip capsule (Fig. 2A). Aspiration of the synovial fluid was black. MRI was unable to be obtained secondary to contraindications. Intraoperatively, after the femoral head was removed, there was a gross erosion of the proximal portion of the neck taper of approximately 20% (Fig. 2B).

# Discussion

A series of trunnion failures associated with the recalled LFIT CoCr femoral head implants are described, which at our institution was used with the Accolade TMZF femoral stem. Modes of failure included GTF or corrosion at the head-neck taper interface. Intraoperatively, we observed a spectrum of ALTR. Approximately one-half of the failures we observed included implant sizes outside of the August 2016 LFIT CoCr femoral head recall. Head-neck taper corrosion was not listed as a potential mode of failure as part of the recall. These 2 types of failure have been observed across a range of other manufacturers as a rare event [6-10,19-22].

In our series, 43% (13 of 30) of the failed trunnion included 36(-5), 36(+0), and 36(+10) femoral heads and were not part of the voluntary recall. Failures in implant sizes outside of the recall showed a trend of being skewed toward the taper corrosion group, but that association was at the borderline of statistical significance (P = .06). We cannot presently conclude, based on the limited sample size, whether there is statistically a higher incidence of taper corrosion cases outside the recall than in the GTF group. A larger sample size would be needed to further address this issue. When we consider the entire population of revisions in our series, almost all femoral head sizes  $\geq 36$  mm have reported failures. In another recent series of 5 cases of failed Accolade TMZF and LFIT femoral head, all the femoral head diameters and offsets reported were listed in the recall [9].

We have observed patterns that may help predict impending implant failure associated with the implant, imaging, and laboratory values. From an implant perspective, failure has an association with high-offset 127° neck angle femoral stems and increased femoral neck offset. In 2 cases, impending GTF was diagnosed based on radiographs that demonstrated a slight oblique angle between the femoral head and neck taper. In other cases, a faint radiodensity around the hip capsule, similar to a small amount of early heterotopic ossification, has been observed. MRI findings appeared similar to those associated with ALTR, including fluid collections and the development of cystic lesions [23]. We observed elevated serum metal ion levels and a preferential elevated cobalt level as compared with chromium level in both the head-neck taper corrosion and GTF groups. Similar to ALTR associated with other pathologies, all these methods, imaging, serum metal ion levels, and symptoms are important but are not independent diagnostic tools [24]. These observations have allowed us to diagnose impending GTF before the femoral head disassociates from the neck taper.

We have been able to differentiate between impending GTF and head-neck taper corrosion in this combination of femoral head and stem by aspiration of fluid under image guidance using a simple colorimetric assay. Black synovial fluid is associated with wear at the trunnion interface and the need to replace the entire stem at



Fig. 2. Impending gross trunnion failure radiographic and intraoperative findings. (A) Radiographs show radiodensities around the hip capsule (white arrow heads) and a slight oblique angle of the femoral head-neck taper (black arrow). (B) Direct examination of the trunnion demonstrated erosion of the proximal portion of the taper.

the time of revision. Brown, light gray, or straw-colored synovial fluid, with or without turbidity, has been associated with headneck taper corrosion and no gross damage to the trunnion. In these cases, an exchange of the modular head and liner was required at the time of revision. In both types of failure, we recommend the use of a ceramic femoral head with a titanium sleeve. This colorimetric test may aid in preoperative planning by differentiating between failure from head-neck taper corrosion and impending GTF and determining if the femoral stem may need to be revised from trunnion damage before failure.

ALTR was defined in our study as heterogeneous cellular infiltrate with the presence of corrosion products in the periprosthetic tissue. This was observed in all cases sent to pathology. We are unable to assess if this occurred from the cobalt, chromium, or titanium; however, all 3 metals likely had elevated levels in the tissue given the wear from the titanium trunnion and the elevated serum cobalt and chromium levels. Other groups have observed that ALTR can encompass a range of histologic patterns depending on the involved implant [25]. We would anticipate a similar pattern here. Secondary to ALTR, we observed abductor damage with a range from minimal abductor loss to complete absence of abductors. Abductor damage appeared to be similar to other corrosion scenarios where ALTR has been observed [26,27]. We have approached this issue with a standard strategy [28]. Hip stability is optimized intraoperatively using length, offset, stem version, and minimizing any sources of impingement. If repeated episodes of instability occur and no obvious etiology can be identified, we have been using a constrained liner for additional stability.

The etiology of GTF is unknown. One possibility, supported by visual observation at the time of revision, includes abrasive wear of a loose taper trunnion inside the female taper of the femoral head. Another possible mechanism includes failure representing the end stage of mechanically assisted crevice corrosion at an initially well-fixed modular junction. Gradual material loss at the taper junction in mechanically assisted crevice corrosion could lead to late loosening of the taper, and a progressively loose junction would allow continued abrasive wear. Retrieval analyses of the explanted components, beyond the scope of the present study, may provide insight into the mechanism of GTF in these cases.

There are limitations to this study. First, this is a retrospective study of an unexpected problem limiting our ability to have complete follow-up of the entire patient cohort in our practice that received LFIT femoral heads and Accolade TMZF stems. We are unable to report on demographic, implant, and laboratory values of patients that did not have any issues with implant failure. We observed these failures were associated with increased offset stems and femoral neck offsets. The ability to compare outcomes in a group of patients that did not have failure would strengthen the validity of this observation. Second, there was an observational bias associated with our study. After an initial series of GTF, we more actively screened for possible or impending implant failure using MARS MRI and serum metal ion levels. This may have increased the overall number of failures detected secondary to head-neck taper corrosion. Finally, a single surgeon performed all index surgeries. We were unable to assess the role of surgical technique in trunnion failure. The technique used to impact the femoral head onto the trunnion has been postulated to play a role in trunnion corrosion [9]. We cannot comment on this; however, the identical technique was used on other femoral stems used before and after this implant in our practice. We have not observed similar levels of failure in these other stems.

We observed a series of modular junction failures of the LFIT femoral head and Accolade TMZF stem. Approximately one-half of the failures were observed outside the voluntary recall of Stryker LFIT femoral head size and offsets. Although there is limited evidence, these events seem to be associated with increased offset stems and femoral heads. Serum metal ion levels, radiographs, and MARS MRI should be obtained as part of the initial evaluation and can be used to help predict impending trunnion failure. Black synovial fluid from a hip aspiration appears to be associated with impending GTF requiring a complete revision of the femoral stem as compared with a femoral head and liner exchange, allowing appropriate preoperative planning. Based on this experience, we have changed our clinical practice from using CoCr femoral heads to ceramic heads based on the lower risk of corrosion and metal release [29,30], which should theoretically mitigate ALTR issues in the future.

#### References

- [1] Kolb A, Grubl A, Schneckener CD, Chiari C, Kaider A, Lass R, et al. Cementless total hip arthroplasty with the rectangular titanium Zweymuller stem: a concise follow-up, at a minimum of twenty years, of previous reports. J Bone Joint Surg Am 2012;94:1681–4.
- [2] Corten K, Bourne RB, Charron KD, Au K, Rorabeck CH. Comparison of total hip arthroplasty performed with and without cement: a randomized trial. A concise follow-up, at twenty years, of previous reports. J Bone Joint Surg Am 2011;93:1335–8.
- [3] Makela KT, Eskelinen A, Pulkkinen P, Paavolainen P, Remes V. Total hip arthroplasty for primary osteoarthritis in patients fifty-five years of age or older. An analysis of the Finnish arthroplasty registry. J Bone Joint Surg Am 2008;90:2160-70.
- [4] Kwon YM, Thomas P, Summer B, Pandit H, Taylor A, Beard D, et al. Lymphocyte proliferation responses in patients with pseudotumors following metalon-metal hip resurfacing arthroplasty. J Orthop Res 2010;28:444–50.
- [5] Clayton RA, Beggs I, Salter DM, Grant MH, Patton JT, Porter DE. Inflammatory pseudotumor associated with femoral nerve palsy following metal-on-metal resurfacing of the hip. A case report. J Bone Joint Surg Am 2008;90:1988–93.
- [6] Cooper HJ, Della Valle CJ, Berger RA, Tetreault M, Paprosky WG, Sporer SM, et al. Corrosion at the head-neck taper as a cause for adverse local tissue reactions after total hip arthroplasty. J Bone Joint Surg Am 2012;94:1655–61.
- [7] McGrory BJ, MacKenzie J, Babikian G. A high prevalence of corrosion at the head-neck taper with contemporary Zimmer non-cemented femoral hip components. J Arthroplasty 2015;30:1265–8.
- [8] Banerjee S, Cherian JJ, Bono JV, Kurtz SM, Geesink R, Meneghini RM, et al. Gross trunnion failure after primary total hip arthroplasty. J Arthroplasty 2015;30:641–8.
- [9] Matsen Ko L, Chen AF, Deirmengian GK, Hozack WJ, Sharkey PF. Catastrophic femoral head-stem trunnion dissociation secondary to corrosion. J Bone Joint Surg Am 2016;98:1400–4.
- [10] Spanyer J, Hines J, Beaumont CM, Yerasimides J. Catastrophic femoral neck failure after THA with the Accolade((R)) I stem in three patients. Clin Orthop Relat Res 2016;474:1333–8.
- [11] Engh Jr CA, Ho H, Engh CA. Metal-on-metal hip arthroplasty: does early clinical outcome justify the chance of an adverse local tissue reaction? Clin Orthop Relat Res 2010;468:406–12.
- [12] Jacobs JJ, Cooper HJ, Urban RM, Wixson RL, Della Valle CJ. What do we know about taper corrosion in total hip arthroplasty? J Arthroplasty 2014;29: 668–9.
- [13] Kwon YM, Antoci Jr V, Eisemon E, Tsai TY, Yan Y, Liow MH. "Top-Out" removal of well-fixed dual-taper femoral stems: surgical technique and radiographic risk factors. J Arthroplasty 2016;31:2843–9.
- [14] Pulliam IT, Trousdale RT. Fracture of a ceramic femoral head after a revision operation. A case report. J Bone Joint Surg Am 1997;79:118–21.
- [15] Parvizi J, Zmistowski B, Berbari EF, Bauer TW, Springer BD, Della Valle CJ, et al. New definition for periprosthetic joint infection: from the Workgroup of the Musculoskeletal Infection Society. Clin Orthop Relat Res 2011;469:2992–4.
- [16] Yi PH, Cross MB, Moric M, Levine BR, Sporer SM, Paprosky WG, et al. Do serologic and synovial tests help diagnose infection in revision hip arthroplasty with metal-on-metal bearings or corrosion? Clin Orthop Relat Res 2015;473:498–505.
- [17] Griffin WL. Metal ion levels: how can they help us? J Arthroplasty 2014;29: 659–60.
- [18] Hart AJ, Sabah SA, Bandi AS, Maggiore P, Tarassoli P, Sampson B, et al. Sensitivity and specificity of blood cobalt and chromium metal ions for predicting failure of metal-on-metal hip replacement. J Bone Joint Surg Br 2011;93:1308–13.
- [19] Pande K, Leong JF, Lo NN. Spontaneous dissociation of anatomic medullary locking A Plus (AML A Plus) femoral component at the head-neck interface. J orthopaedic case Rep 2015;5:48–50.
- [20] Kusaba A, Katsui M, Hakuta N, Tsuchida M, Maeda A, Kondo S. Catastrophic stem taper wear in ceramic on polyethylene bearing couple: a case report. J long-term effects Med Implants 2014;24:185–8.
- [21] Mann MA, Tanzer D, Tanzer M. Severe metal-induced osteolysis many years after unipolar hip endoprosthesis. Clin Orthop Relat Res 2013;471:2078–82.

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- [22] Talmo CT, Sharp KG, Malinowska M, Bono JV, Ward DM, LaReau J. Spontaneous modular femoral head dissociation complicating total hip arthroplasty. Orthopedics 2014;37:e592–5.
- [23] Hauptfleisch J, Pandit H, Grammatopoulos G, Gill HS, Murray DW, Ostlere S. A MRI classification of periprosthetic soft tissue masses (pseudotumours) associated with metal-on-metal resurfacing hip arthroplasty. Skeletal Radiol 2012;41:149–55.
- [24] Kwon YM, Lombardi AV, Jacobs JJ, Fehring TK, Lewis CG, Cabanela ME. Risk stratification algorithm for management of patients with metal-on-metal hip arthroplasty: consensus statement of the American Association of Hip and Knee Surgeons, the American Academy of Orthopaedic Surgeons, and the Hip Society. J Bone Joint Surg Am 2014;96:e4.
- [25] Ricciardi BF, Nocon AA, Jerabek SA, Wilner G, Kaplowitz E, Goldring SR, et al. Histopathological characterization of corrosion product associated adverse local tissue reaction in hip implants: a study of 285 cases. BMC Clin Pathol 2016;16:3.
- [26] Nodzo SR, Esposito CI, Potter HG, Ranawat CS, Wright TM, Padgett DE. MRI, retrieval analysis, and histologic evaluation of adverse local tissue reaction in metal-on-polyethylene total hip arthroplasty. J Arthroplasty 2017;32: 1647–53.
- [27] Liow MH, Urish KL, Preffer FI, Nielson GP, Kwon YM. Metal ion levels are not correlated with histopathology of adverse local tissue reactions in taper corrosion of total hip arthroplasty. J Arthroplasty 2016;31:1797–802.
- [28] Wera GD, Ting NT, Moric M, Paprosky WG, Sporer SM, Della Valle CJ. Classification and management of the unstable total hip arthroplasty. J Arthroplasty 2012;27:710–5.
- [29] Kocagoz SB, Underwood RJ, MacDonald DW, Gilbert JL, Kurtz SM. Ceramic heads decrease metal release caused by head-taper fretting and corrosion. Clin Orthop Relat Res 2016;474:985–94.
- [30] Kurtz SM, Kocagoz SB, Hanzlik JA, Underwood RJ, Gilbert JL, MacDonald DW, et al. Do ceramic femoral heads reduce taper fretting corrosion in hip arthroplasty? A retrieval study. Clin Orthop Relat Res 2013;471:3270–82.