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Case Report

Impending Trunnion Failure: An Uncommon Radiographic Presentation of Total Hip Arthroplasty Failure

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ABSTRACT

Trunnionosis is emerging as an early mode of failure in conventional metal-on-polyethylene total hip arthroplasty. It is defined as wear or corrosion at the trunnion, the taper at the femoral head-neck interface. Trunnion wear can result in a variety of negative sequelae and, in severe cases, necessitate revision arthroplasty. We describe a 64-year-old man with a metal-on-polyethylene total hip arthroplasty who presented with a sensation of clunking in the hip. Initial imaging and laboratory studies were inconclusive, and the decision was made to monitor. Two years later, trunnion wear was detected on radiographs, presenting as an abnormal alignment of the femoral neck relative to the femoral head. Several case reports and series describe catastrophic total hip arthroplasty failure due to trunnionosis. However, few describe the radiographic signs of wear at the trunnion before gross failure. This early presentation is important to recognize to minimize patient morbidity and aid surgical planning.

Introduction

Trunnionosis is an increasingly recognized complication of metal-on-polyethylene total hip arthroplasty (MoP THA), with current evidence describing it as present in up to 3% of THA revisions [1]. It is defined as wear and corrosion at the femoral head-neck interface, which can lead to a myriad of negative consequences, including release of metal ions, adverse local soft-tissue reactions (ALTRs), and frank failure of the hardware [2]. The cause of trunnionosis is multifactorial, with risk factors such as increased patient weight and activity level, the type of hardware components used, and the implantation method [3].

Detection of trunnion wear typically begins with clinical suspicion. Patients most commonly present with pain, frequently in the hip or groin, or symptoms of hip instability [4]. Initial workup consists of plain radiographs to rule out hardware failure, as well as laboratory studies, including erythrocyte sedimentation rate and C-reactive protein, to evaluate for infection [5]. Elevated serum metal ion levels (cobalt and chromium) can support the presence of trunnionosis and can ultimately cause systemic toxicity [3]. ALTR is a sequel of trunnionosis and other THA complications that result in the release of metal ions into the body. Magnetic resonance imaging (MRI) is the gold standard for detection of ALTR [6]. There are several case reports in the orthopedic literature of catastrophic trunnion failure, but few describe the radiographic findings of trunnion wear before gross head-neck dissociation.

Management is dependent on the clinical picture. For symptomatic patients with imaging or laboratory evidence of trunnion wear, revision should be considered [2]. If the femoral stem is well fixed and the taper damage is deemed sufficiently minimal, isolated exchange of only the femoral head component may be considered [5].

In this report, we describe the case of a man with a history of indeterminate symptoms and inconclusive studies related to his right THA, for whom the suspicion of trunnionosis and impending trunnion failure was raised based on radiographic findings. Informed consent for the writing and publication of this article was obtained from the patient.

Case history

A 64-year-old obese (body mass index: 36 kg/m^2) male presented for regular follow-up of his right THA. He had a primary

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right THA in December of 2002, with revision in January 2006 for aseptic loosening, both occurring at an outside institution. In April 2012, he had a second revision, using a Zimmer Biomet hip replacement system including an Arcos Modular Femoral Revision system with a titanium stem and size 40 + 9-mm neck length (Zimmer Biomet, Warsaw, IN) [7]. A femoral cortical strut allograft was used because of significant osteolysis that had led to this revision. Postoperative imaging showed proper alignment of the femoral head-neck junction without any acute complication (Fig. 1).

He recovered well from his second revision until a fall in 2018, after which he noted a clunking sensation in his right hip. He denied pain or feelings of instability and reported that he was able to complete his activities of daily living and work as a dairy farmer. With his history of 2 revisions, the minimal impact of his symptoms, and the physical nature of his job, he opted for accelerated follow-up in 6 months. At the 6-month follow-up appointment, his symptoms had persisted, but were unchanged. An MRI was performed 2 months later, which revealed a small, approximately 2 cm, nonspecific fluid collection within the right trochanteric bursa. There was no hip joint effusion, osteolysis, or pseudotumor. Serum metal ions were indeterminate; the chromium level was within normal limits, and the cobalt level was slightly elevated at 1.4 μg/L (normal ≤1). Based on these inconclusive study results, follow-up in 1 year was planned.

At his follow-up appointment in 2019, the patient reported that the clunking had worsened and was now associated with a sensation of instability. On examination, he had clear clicking with gentle internal and external rotation of his hip. Antero-posterior radiograph of the right hip at this visit demonstrated an abnormal oblique angle at the femoral head-neck junction when compared with his initial postoperative radiographs (Fig. 2). These radiographic findings were concerning for trunnion wear.

Informed consent was obtained from the patient, and 2 weeks later, he underwent a third revision of his right THA, revealing marked trunnion damage, a half-thickness crevice in the femoral neck, and a loose femoral head (Fig. 3). The degree of trunnion erosion necessitated revision of the femoral stem, requiring extended trochanteric osteotomy, in addition to exchange for a ceramic femoral head. At his recent 7-month follow-up visit, he was noted to be ambulating well with minimal pain and without the need for assistance.

Discussion

There are many forces applied to the femoral head-neck junction in THA, and this can create conditions for corrosion to occur [5]. Galvanic corrosion is due to the electrical potential created between 2 dissimilar metals [8]. Damage has been shown to occur at

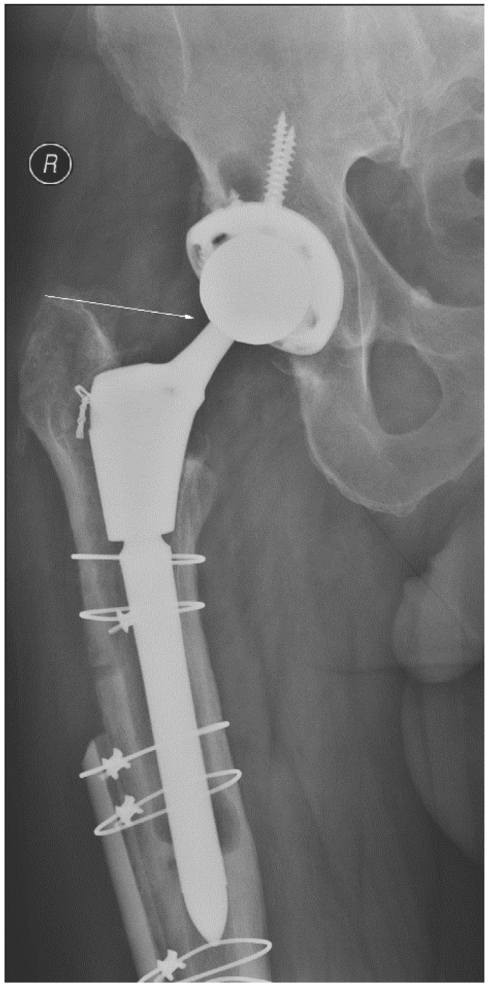

Figure 1. Antero-posterior hip radiograph of a 64-y-old male with metal-on-polyethylene total hip arthroplasty (THA) demonstrating symmetric positioning of the neck within the femoral head (arrow). This routine postoperative follow-up radiograph was obtained 2 mo after his second THA revision for aseptic loosening.

Figure 2. Antero-posterior hip radiograph of a 64-y-old male with 2 y of clunking, and a new-onset sensation of instability demonstrates an abnormal oblique angle between the head-neck taper of the femoral stem (arrow) concerning for trunnion damage and impending gross trunnion failure.

Figure 3. Explanted femoral stem demonstrating erosion of the proximal portion of the taper and a half-thickness crevice (arrows) in the femoral neck.

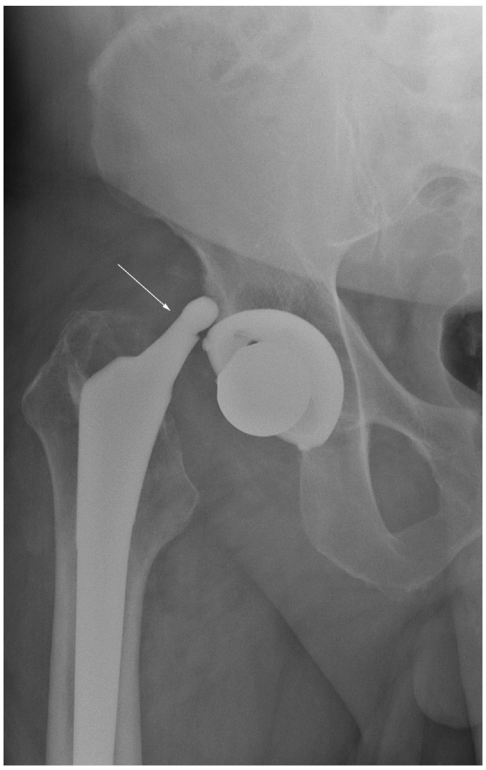

Figure 4. Antero-posterior hip radiograph of a 47-y-old male (different patient than the case report) with acute-onset right hip pain after sitting in a chair demonstrates gross trunnion failure with complete dissociation of the femoral head from the neck at the taper and notching of the trunnion (arrow). Black synovial fluid was aspirated from the joint before revision surgery. This case illustrates a potential complication of trunnion wear leading to catastrophic trunnion failure.

higher rates in implants that use a cobalt-chromium head vs those with a ceramic head paired with a titanium trunnion, supporting galvanic corrosion as a contributing factor to wear at the trunnion [9]. Trunnion corrosion levels have also been shown to be higher in metal-on-metal implants than those in MoP implants, indicating that the overall choice for hardware can affect this process [10]. The primary mechanism that has been described is mechanically assisted crevice corrosion (MACC), which occurs secondary to micromotion destroying the superficial passivation layer, allowing oxidation of the metal alloy beneath and acidification of the fluid surrounding the taper [3]. A recent cohort study found the incidence of MACC to be 3.2% in patients with MoP implants, reinforcing that MACC plays a role in the development of trunnionosis [11]. However, this cohort received hardware from a different manufacturer from our patient, and these results may not be directly applicable.

Release of metal ions into the body from corrosion can lead to a variety of soft-tissue reactions, commonly referred to as ALTR. These reactions can include periarticular soft-tissue destruction, including necrosis of the hip capsule and abductor muscles, and formation of fluid collections and pseudotumors [6]. ALTR requires targeted investigation, typically with MRI, as its presentation often lacks radiographic findings [12]. Recognition, however, is critical as an extended time interval between presentation and surgery is associated with more significant soft-tissue damage [3]. It is also noteworthy that revision procedures for those with ALTR are associated with more serious complications due to the tissue damage [13].

Many risk factors for trunnionosis have been described. The largest category pertains to the hardware. Larger diameter femoral heads (>32 mm) have recently increased in popularity. A larger head increases the jump distance, provides for a more favorable head-to-neck ratio, and therefore affords greater stability [4]. However, several studies have shown that a larger femoral head increases the risk of corrosion, potentially through increased micromotion and stress on the trunnion-taper junction [12]. This causation is not clear though, as other studies have not found any association of femoral head size and corrosion [2]. Certain properties of the trunnion, including increased flexibility, shorter length, smaller diameter, and wider taper angle, have all been shown to be associated with higher rates of trunnionosis [14]. Patient characteristics also play a role, with increased body mass index, in vivo time, and activity level all implicated in its development [4]. Finally, implantation technique may also contribute to the development of trunnion wear. Thorough cleaning of the trunnion and greater impaction force at the time of head assembly are both associated with a decreased risk of trunnionosis [15].

A wide range of signs and symptoms have been described for trunnionosis. Most commonly patients experience hip, thigh, or buttock pain [1]. Painless, unstable hips have also been described as presenting signs, particularly in the setting of marked periarticular tissue destruction [1]. Other, less common, signs include a palpable mass secondary to pseudotumor formation, gait alterations such as limping or Trendelenburg pattern, and unilateral leg swelling [3]. It is also important to note that patients may be asymptomatic [12].

Laboratory studies are recommended as part of the workup. Infection should be ruled out early on, typically beginning with an erythrocyte sedimentation rate and C-reactive protein, followed by joint aspiration if these values are elevated [16]. Cellular and metal debris can alter automated cell counts, so it is necessary to obtain a manual cell count to accurately interpret the study [1]. Joint aspiration often yields black synovial fluid in the setting of trunnion damage but may be brown, light gray, or straw colored in the setting of head-neck taper corrosion without gross damage to the trunnion [17]. Serum metal ions, specifically chromium (Cr) and

cobalt (Co), are often elevated, and higher Co-Cr ratios (>5) have been shown to be suggestive of trunnionosis specifically [3]. Exact cutoffs for cobalt values that should prompt concern have not yet been established for trunnionosis but have been suggested as >1.0 ng/mL for ALTR [18]. Our patient's cobalt of 1.4 ng/mL is outside of the normal range for our laboratory (<1.0 ng/mL) and meets suspicion for ALTR by Fillingham's guidelines, supporting an underlying corrosive process [18]. Elevations in serum titanium have been suggested as a possible marker of impending THA failure in patients with titanium hardware [19]. However, clinically significant reference ranges for titanium levels have not yet been clearly established, and significant elevation in titanium levels have been shown to be present up to 10 years out from initial implantation [20,21]. Titanium levels were not checked for the patient in this case report but may have been abnormal as the femoral component was titanium. This also may explain why the serum Co and Cr were not elevated.

Imaging plays a major role in the workup of possible trunnionosis. Plain radiographs, both antero-posterior and cross-table lateral views of the pelvis, are recommended as part of the initial evaluation to assess hardware positioning and screen for alternate diagnoses [12]. Often, actionable findings are not seen on radiographs, even if corrosion is occurring [1]. MRI, aided by metal artifact reduction sequences or 3D multispectral imaging sequences, is the gold standard to look for ALTR as it can provide visualization of the tissue surrounding the implant [22]. Concerning findings can include intraarticular and extraarticular fluid collections, soft-tissue masses or pseudotumors, and thickening or expansion of the synovium, all of which can indicate the presence of ALTR [23]. Ultrasound has been shown to be an acceptable alternative for patients that have contraindications to MRI [22].

While radiographs are consistently recommended for initial workup, their role in detection of trunnion wear has not been well described. Review of the literature on trunnionosis from the past 5 years revealed 10 case reports and 8 case series for a total of 73 cases described. Of these, 24 cases had no radiographic findings of trunnionosis [17,24-28]. Almost two-third of the cases had complete dissociation, gross trunnion failure, or femoral neck fracture evident on a radiograph [17,25,26,29-39]. Figure 4 represents this more common radiographic presentation of gross trunnion failure seen at the same medical center as the patient in our case report. Finally, 8 cases in the orthopedic literature had evidence of misalignment at the femoral head-neck junction on radiograph, similar to the case described in this report [17,25,38,40]. Interestingly, one case series reported small foci of faint radiodensity around the hip capsule, similar to early heterotopic ossification, in half of the patients who ultimately went on to gross trunnion failure [17].

As trunnion wear is a less common complication in THA, recommendations for when surgical revision is indicated are varied [5]. Generally, if symptoms are present and trunnionosis or ALTR is confirmed with imaging and laboratory studies, revision should be considered [1]. For most cases, a well-fixed stem with minimal trunnion corrosion can be left in place. However, if trunnion damage is severe and its connection with the head will be unstable, the entire femoral stem may need to be replaced [1]. Exchange of the femoral head with a ceramic model is typically advised, as a ceramic head is inert and will decrease the risk for future corrosion. The ceramic head may be paired with a titanium adaptor sleeve to minimize the risk of future head fracture [5].

Over the last decade, several implant designs have been recalled because of metal-on-metal complications and modular junction corrosion [41-43]. In 2016, specific lots of the Stryker low-friction ion treatment anatomic cobalt chromium alloy V40 femoral head (Stryker, Kalamazoo, MI) were recalled because of concerns for femoral head-stem dissociation and gross trunnion failure [44].

Of note, the sequence of events cannot be determined retrospectively for this case. It is possible the patient's fall resulted in disengagement of the head, resulting in macromotion and notching in the femoral neck. Hence, trunnionosis or MACC may be the result of the head disengagement rather than the cause. Regardless, trunnion wear remains a clinically significant finding, whether it is the cause or the effect of head disengagement, and the radiographic findings are an important indication of impending trunnion failure.

Trunnionosis has been well documented and investigated within the orthopedic literature, yet its inclusion in the radiology literature has been somewhat limited, with focus primarily centered on the role of MRI in identification of ALTR. While radiographs are indicated as part of the initial workup, there are minimal available data describing how early trunnionosis may present. Most case reports or series describe gross failure of the trunnion necessitating immediate surgical intervention. It would be beneficial for both the patient and surgeon if trunnion damage could be recognized before catastrophic failure and revision could be scheduled in an elective, rather than urgent, manner. Our case, in addition to the other small number of cases identified in the orthopedic literature, is an example of a more subtle, yet concerning radiographic finding that can facilitate intervention before the development of significant morbidity to the patient. Surveillance for, and recognition of, these early findings of abnormal obliquity at the femoral head-neck taper indicating trunnion damage is important to the clinical care of THA patients. Further investigation of the incidence of misalignment, as well as other potential early radiographic signs, is needed as this may identify patients who may require further workup with MRI or surgical intervention.

Summary

Trunnionosis is a serious complication of THA. It can result in hip pain and instability and, if not detected early, frank failure of the hardware. Our patient exemplifies the challenge of diagnosing trunnionosis. This process initially went undetected, presenting only with vague symptoms and inconclusive signs on MRI and laboratory studies, until finally femoral head-neck misalignment was noted on radiograph. Awareness of how trunnion damage can present radiographically may improve outcomes for patients and surgeons alike.

Conflict of interest

C. French is a American Institute of Ultrasound in Medicine Musculoskeletal Executive Planning Committee Officer. C. M. Davis is a member of the AAOS Central Program Committee.

References

[1] Sultan AA, Cantrell WA, Khlopas A, et al. Evidence-based management of trunnionosis in metal-on-polyethylene total hip arthroplasty: a systematic review. J Arthroplasty 2018;33(10):3343.
[2] Mistry JB, Chughtai M, Elmallah RK, et al. Trunnionosis in total hip arthroplasty: a review. J Orthop Traumatol 2016;17(1):1.
[3] Weiser MC, Lavernia CJ. Trunnionosis in total hip arthroplasty. J Bone Joint Surg Am 2017;99(17):1489.
[4] Jennings JM, Dennis DA, Yang CC. Corrosion of the head-neck junction after total hip arthroplasty. J Am Acad Orthop Surg 2016;24(6):349.
[5] Lanting B, Naudie DDR, McCalden RW. Clinical impact of trunnion wear after total hip arthroplasty. JBJS Rev 2016;4(8).
[6] Padgett DE, Su EP, Wright TM, Burge AJ, Potter HG. How useful is magnetic resonance imaging in evaluating adverse local tissue reaction? J Arthroplasty 2020;35(6S):S63.
[7] Dyreborg K, Petersen MM, Balle SS, Kjersgaard AG, Solgaard S. Observational study of a new modular femoral revision system. World J Orthop 2020;11(3):167.

[8] Bedard NA, Burnett RA, DeMik DE, Gao Y, Liu SS, Callaghan JJ. Are trends in total hip arthroplasty bearing surface continuing to change? 2007-2015 usage in a large database cohort. J Arthroplasty 2017;32(12):3777.
[9] Rowan FE, Wach A, Wright TM, Padgett DE. The onset of fretting at the head-stem connection in hip arthroplasty is affected by head material and trunnion design under simulated corrosion conditions. J Orthop Res 2018;36(6):1630.
[10] Lanting BA, Teeter MG, Howard JL, MacDonald SJ, Van Citters DW. Metal-on-metal compared with metal-on-polyethylene: the effect on trunnion corrosion in total hip arthroplasty. J Arthroplasty 2017;32(8):2574.
[11] Hussey DK, McGrory BJ. Ten-year cross-sectional study of mechanically assisted crevice corrosion in 1352 consecutive patients with metal-on-polyethylene total hip arthroplasty. J Arthroplasty 2017;32(8):2546.
[12] Wawrose RA, Urish KL. Diagnosis and management of adverse reactions to metal debris. Oper Tech Orthop 2019;29(3):100732.
[13] Waterson HB, Whitehouse MR, Greidanus NV, Garbuz DS, Masri BA, Duncan CP. Revision for adverse local tissue reaction following metal-on-polyethylene total hip arthroplasty is associated with a high risk of early major complications. Bone Joint J 2018;100-B(6):720.
[14] Berstock JR, Whitehouse MR, Duncan CP. Trunnion corrosion: what surgeons need to know in 2018. Bone Joint J 2018;100-B(1 Supple A):44.
[15] Rieker CB, Wahl P. What the surgeon can do to reduce the risk of trunnionosis in hip arthroplasty: recommendations from the literature. Materials (Basel) 2020;13(8):1950.
[16] Erivan R, Villatte G, Ollivier M, Paprosky WG. Painful hip arthroplasty: what should we find? Diagnostic approach and results. J Arthroplasty 2019;34(8):1802.
[17] Urish KL, Hamlin BR, Plakseychuk AY, et al. Trunnion failure of the recalled LFIT cobalt chromium alloy femoral head. J Arthroplasty 2017;32(9):2857.
[18] Fillingham YA, Della Valle CJ, Bohl DD, et al. Serum metal levels for diagnosis of adverse local tissue reactions secondary to corrosion in metal-on-polyethylene total hip arthroplasty. J Arthroplasty 2017;32(9S):S272.
[19] McAlister IP, Abdel MP. Elevated serum titanium level as a marker for failure in a titanium modular fluted tapered stem. Orthopedics 2016;39(4):e768.
[20] Levine BR, Hsu AR, Skipor AK, et al. Ten-year outcome of serum metal ion levels after primary total hip arthroplasty: a concise follow-up of a previous report. J Bone Joint Surg Am 2013;95(6):512.
[21] Yao JJ, Lewallen EA, Thaler R, et al. Challenges in the measurement and interpretation of serum titanium concentrations. Biol trace Elem Res 2020;196(1):1.
[22] Nam D, Barrack RL, Potter HG. What are the advantages and disadvantages of imaging modalities to diagnose wear-related corrosion problems? Clin Orthop Relat Res 2014;472(12):3665.
[23] Morozov PP, Sana M, McGrory BJ, Farraher SW, Abrahams TG. Comparison of pre-revision magnetic resonance imaging and operative findings in mechanically assisted crevice corrosion in symptomatic metal-on-polyethylene total hip arthroplasties. J Arthroplasty 2017;32(8):2535.
[24] Lachiewicz PF, O'Dell JA. Trunnion corrosion in metal-on-polyethylene hip arthroplasty: a simple diagnosis and treatment? Bone Joint J 2018;100-B(7):898.
[25] Banerjee S, Cherian JJ, Bono JV, et al. Gross trunnion failure after primary total hip arthroplasty. J Arthroplasty 2015;30(4):641.
[26] Bechtel C, Abraham JA. Femoral head-stem dissociation secondary to severe trunnion corrosion. International Congress for Joint Reconstruction; 2016. https://icjr.net/articles/femoral-head-stem-dissociation-secondary-to-severe-trunnion-corrosion. [Accessed 23 June 2020].
[27] Moskal J, Stover M. Mechanically assisted crevice corrosion of the head-neck taper in a large head metal-on-metal total hip arthroplasty. Arthroplasty Today 2015;1(4):103.
[28] Shulman RM, Zywiel MG, Gandhi R, Davey JR, Salonen DC. Trunnionosis: the latest culprit in adverse reactions to metal debris following hip arthroplasty. Skeletal Radiol 2015;44(3):433.
[29] Jagadale V. A case report and literature review to aid in the management of trunnion failure in hip arthroplasty patients: can trunnionosis and prosthetic joint infection Co-exist? Cureus 2019;11(8):e5544.
[30] Wood TJ, Alzahrani M, Langohr D, et al. Catastrophic femoral head trunnion dissociation: a case series with surface wear analysis. Hip Int 2019;29(5):NP1.
[31] Runner RP, Bellamy JL, Roberson JR. Gross trunnion failure of a cobalt-chromium femoral head on a titanium stem at midterm follow-up: a report of 3 cases. JBJS Case Connect 2016;6(4):e96.
[32] Bolarinwa SA, Martino JM, Moskal JT, Wolfe MW, Shuler TE. Gross trunnion failure after a metal-on-polyethylene total hip arthroplasty leading to dissociation at the femoral head-trunnion interface. Arthroplasty Today 2019;5(1):5.
[33] 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(16):1400.
[34] Spanyer J, Hines J, Beaumont CM, Yerasimides J. Catastrophic femoral neck failure after THA with the Accolade(®) I stem in three patients. Clin Orthop Relat Res 2016;474(5):1333.
[35] Patel NN, Guild III GN, Erens GA. Femoral head-trunnion dissociation in metal-on-polyethylene total hip arthroplasty - a unique case report. Reconstr Rev 2017;7(4).
[36] Shamshoon S, Thornley P, de Beer J. Profound trunnion wear resulting in femoral head-neck dissociation in total hip arthroplasty. Case Rep Orthop 2018;2018.
[37] Parker SJ, Khan W, Mellor S. Late Nontraumatic dissociation of the femoral head and trunnion in a total hip arthroplasty. Case Rep Orthop 2015:2015.
[38] Raju S, Chinnakkannu K, Puttaswamy MK, Phillips MJ. Trunnion corrosion in metal-on-polyethylene total hip arthroplasty: a case series. J Am Acad Orthop Surg 2017;25(2):133.
[39] Fahey EJ, Pomeroy E, Rowan FE. Acute trunnion failure of a TMZF alloy stem with large diameter femoral heads. J Orthop 2020;20:17.
[40] Hunter AM, Hsu A, Shah A, Naranje SM. A case example and literature review of catastrophic wear before catastrophic failure: identification of trunnionosis and metallosis in metal-on-polyethylene hip arthroplasty prior to frank failure or fracture. Eur J Orthop Surg Traumatol 2019;29(3):711.
[41] US Food and Drug Administration. Class 2 device recall ABG II modular hip stem. Silver Spring, MD: US Food and Drug Administration; 2012.
[42] US Food and Drug Administration. Class 2 device recall DEPUY ASR XL ACETABULAR CUP SYSTEM. Silver Spring, MD: US Food and Drug Administration; 2011.
[43] US Food and Drug Administration. Class 2 device recall rejuvenate modular stems. Silver Spring, MD: US Food and Drug Administration; 2012.
[44] US Food and Drug Administration. Class 2 device recall stryker LFIT anatomic V40 femoral head. Silver Spring, MD: US Food and Drug Administration; 2016.