# Severe Adverse Local Tissue Reactions Associated with Gross Trunnion Failure of THRs with a Beta Titanium Femoral Component

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## Introduction

There have been increased reports of gross taper failure (GTF) of Stryker Accolade Ti-12Mo-6Zr-2Fe (TMZF or beta titanium) femoral components with detailed analyses of the femoral trunnion.[1,2] However, little has been reported on the chemical composition of the wear/corrosion debris and the nature of the resulting cellular reaction of the joint tissues broadly identified as adverse local tissue reaction (ALTR).

**The purpose of this study was to analyze the damage features on both head and stem surfaces, the resulting implant debris, and tissue reaction associated with gross trunnion failure of beta titanium alloy femoral components coupled with a CoCrMo femoral head.**

## Materials and Methods

**Table 1. Components Studied**

| Case | Time *in Situ* (yrs.) | Femoral Stem | Modular Head | Presentation to Surgeon | Findings at Surgery | Tissue Available |
|---|---|---|---|---|---|---|
| #1<br>71 yr. old male | 9 | Size 3.5, 124 mm long<br>Neck length: 35 mm<br>Offset: 39 mm | CoCrMo<br>40 mm<br>-4 mm | • Left hip pain, with increasing groin pain for a year<br>• Patient noted shortening of left leg<br>• Significant changes on x-ray | • Extensive metal debris with black tissue<br>• Taper and trunnion were significantly eroded and the remaining femoral component was engaged with head, in an exceptionally loose fashion<br>• Lytic reaction around femoral component | No |
| #2<br>66 yr. old male | 8.5 | Size 5.5, 133 mm long<br>Neck length: 37 mm<br>Offset: 45 mm | CoCrMo<br>44 mm<br>+0 mm | • Pain<br>• Elevated serum metal levels | • Extensive metal debris with black tissue<br>• Catastrophic failure of trunnion<br>• Stem well-fixed | Yes |

**Evaluation Methods:**

- Characterization of the damage features on the tapers was conducted using a scanning electron microscope (SEM) with energy dispersive x-ray spectroscopy (EDS).
- Head taper surfaces were measured with an optical coordinate measuring machine (CMM) (OrthoLux, RedLux) using a replica method as previously described.[3]
- Histologic sections were analyzed using EDS, Fourier Transform Infrared Spectroscopy Imaging (FTIR-I) and micro-Raman spectroscopy.

## Results

### Damage Features

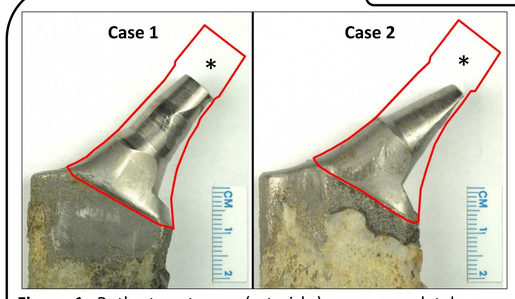


**Figure 1.** Both stem tapers (asterisks) were completely worn away due to abrasion resulting in at least 5,000 mm$^3$ material volumetric loss for each component. The total material loss, however, was even greater as much of the femoral necks were also severely worn (red outlines), giving both femoral necks the previously described characteristic "bird beak" appearance[2].

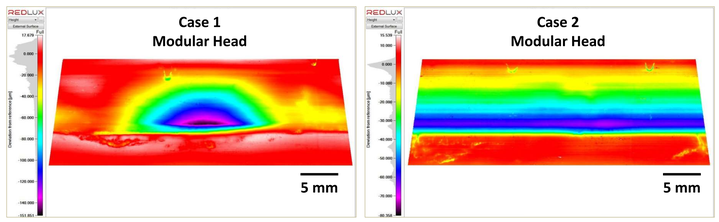


**Figure 2.** "Unwrapped" head taper surfaces generated by optical CMM data. Case 1 showed the deepest wear (blue-purple-black) was concentrated to one side. Case 2 demonstrated wear depths (blue-purple-black) increasing superior to distal.

***Volumetric Material Loss within Head Taper***
*Case 1: 12.86 mm$^3$*
*Case 2: 11.24 mm$^3$*

***Damage Modes Observed within Head Tapers***
*Fretting, fretting corrosion, material transfer, and pitting*

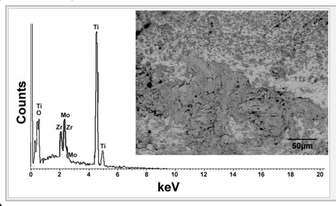


**Figure 3.** SEM/EDS analysis of the modular head tapers revealed that material transfer of the TiMoZr-alloy covered the entire head taper surfaces. **Inset:** Backscattered SEM image (x350) of head taper from Case 1. Dark-gray material is the transferred TiMoZr-alloy from femoral stem.

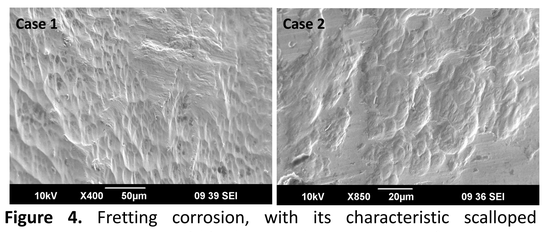


**Figure 4.** Fretting corrosion, with its characteristic scalloped appearance was seen within the modular head tapers of both cases.

### Implant Debris Analysis

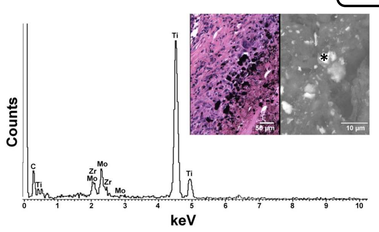


**Figure 5.** SEM/EDS analysis identified the dense, black particles in the pseudocapsule of Case 2 as TMZF alloy wear particles. **Left inset:** H&E, x200; **Right inset:** Backscattered SEM, x2000, the asterisk marks the 3.4 µm particle analyzed for the spectrum.

**Black Particles in Tissue**

- *Identified by SEM/EDS analysis as either Ti-oxide or particles of Ti, Mo and Zr, indicating TMZF alloy debris*
- *Micro-Raman identified the rutile phase of Ti-oxide*

**Fine Birefringent Particles**

- *Seen within macrophages adjacent to the fibrin exudate under polarized light microscopy*
- *Confirmed as polyethylene by FTIR-I by strong characteristic absorbance signals at 2850 cm$^{-1}$.*

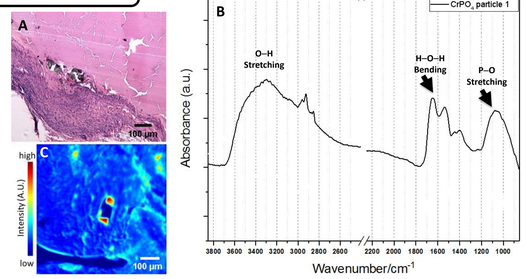


**Figure 6.** The presence of $CrPO_4$ particles within the necrotic regions **(A, H&E, x40)** was confirmed by FTIR-I with characteristic peaks on the infrared spectra **(B, arrows)** and chemical image **(C)** plotted at 1080-1030 cm$^{-1}$.

### Tissue Response

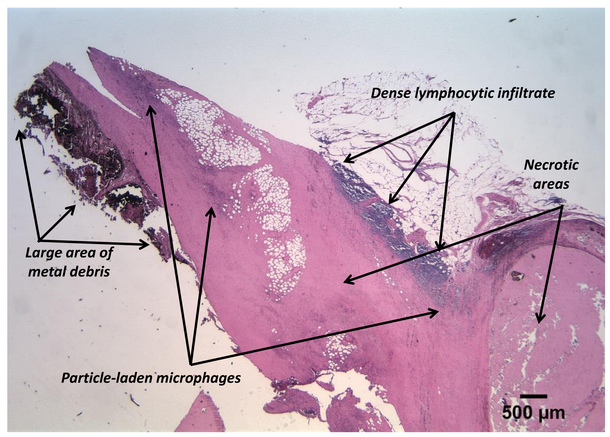


**Figure 7.** Low power photomicrograph illustrating the mixed inflammatory pattern seen in the pseudocapsule of Case 2, with both a marked presence of lymphocytes and particle-laden macrophages adjacent to large areas of necrotic tissue (H&E, x13)

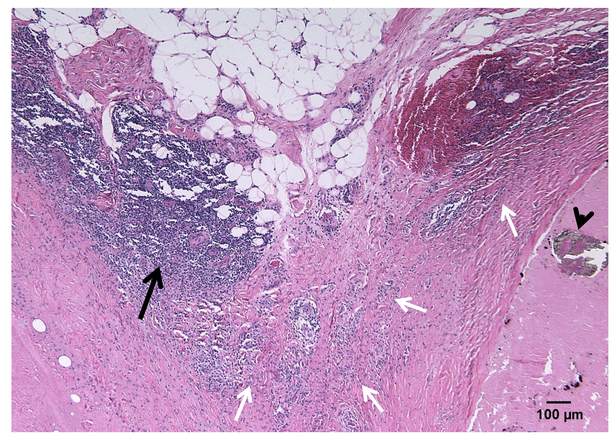


**Figure 8.** Higher power of an area of the mixed inflammatory pattern seen in Figure 7. The dense lymphocyte region is indicated by the black arrow. The macrophage-rich area (white arrows) also contains foreign body giant cells. A large translucent green $CrPO_4$ particle (arrow head) is seen in the necrotic area (H&E, x50).

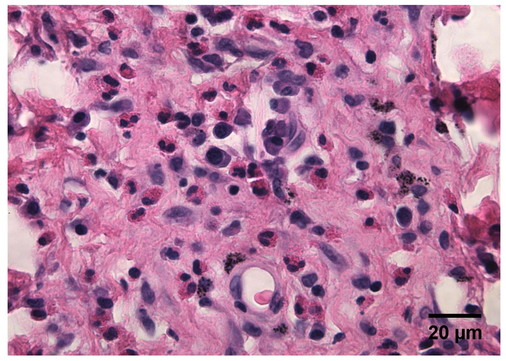


**Figure 9.** Plasmacytes and eosinophils were also observed among the lymphocytes (H&E, x600).

***Implant Debris In the Pseudocapsule***

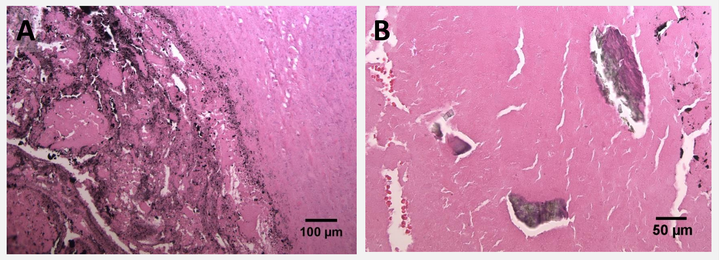


**Figure 10. A:** A large accumulation of dense, black particles was seen within the fibrin exudate that covered the synovial surface (H&E, x100). **B:** Within the necrotic areas, multiple translucent green particles were observed (H&E, x200).

## Discussion

- The severe tissue reaction with a **mixed inflammatory pattern** seen in this study was due to both the **corrosion** at the head-neck junction **and the gross taper failure** at the stem.
- **The intense lymphocytic infiltrate with widespread necrosis was characteristic of previously reported ALTRs associated with severe taper corrosion** of contemporary metal-on-poly modular femoral components.[4]
- Both femoral heads exhibited corrosion features indicative of damage modes such as fretting, fretting corrosion, material transfer, and pitting. In Case 1, damage was concentrated to one side where the trunnion was apparently rubbing against the surface. In Case 2 it appeared that the head eventually started to rotate on the severely damaged and sharpened trunnion leading to a uniform radial damage pattern. **As the head taper surfaces were entirely coated with TMZF material transfer, it was unlikely that corrosion took place at this stage.**
- However, the presence of **$CrPO_4$ clearly indicates that at an earlier stage corrosion of the CoCrMo surface took place leading to the characteristic histopathological pattern of a lymphocyte dominated ALTR to corrosion products.**
- **The strong macrophage response appeared to be primarily related to the extensive Ti-debris**. Interestingly, the majority of particles were in the **rutile oxide form**, indicating that the initial TMZF debris was chemically altered despite its chemical stability, likely due to repeated mechanical transfer to the head surface and subsequent detachment.
- Previous work suggests that GTF is initially triggered by fretting eventually leading to an abrasive wear mechanism[1,2]. **Our study shows that corrosion on the head side contributed initially to the overall damage and tissue reaction, but became secondary as abrasive wear of the Ti-alloy began to dominate the damage process.**

**References:**
[1]Morlock et al, J Arthrop 2018, doi: 10.1016/j.arth.2018.07.017; [2]Martin AJ et al, J Othop Res 2018, doi: 10.1002/jor.24107; [3]Cook RB et al, ASTM STP1591:362, 2015; [4]Hall DJ et al ASTM STP1591:410, 2015.

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