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Case report

Modular junction fractures in a modern rotating-platform knee arthroplasty system

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ABSTRACT

In this series, we report the findings from four patients who presented with pain and mechanical symptoms after revision total knee arthroplasty with the DePuy Sigma TC3 RP prosthesis. Plain radiographs for each patient demonstrated failure of the femoral component at the modular junction of the femoral prosthesis. Retrieved implants at the time of surgery revealed fractures occurring exclusively at the femoral adapter bolt and the corresponding adapter. Retrieval analysis was performed on two of the four cases by visual light microscopy. Our findings suggest that the implants had suffered from fatigue fractures likely due to cyclic loading. This is the first case series to describe the failure mechanism and clinical scenarios contributing to failure of the femoral locking bolt and adapter sleeve in this prosthesis.

Introduction

The number of patients requiring revision total knee arthroplasty (TKA) continues to rise in the United States [1]. Modularity is a common feature among modern-day revision TKA systems. Modular metallic augments and customizable intramedullary stems allow for intraoperative customization, enhanced kinematics, and superior construct fixation [2]. When zonal fixation strategies are applied [3], modular stemmed components are used to bypass regions of deficient bone stock to obtain more favorable initial construct stability in zone 3, the diaphyseal region. More recently, porous titanium metaphyseal sleeves (DePuy, Warsaw, IN) have been used as a modular option in scenarios where the bone stock is inadequate [4]. The sleeves fit over an intramedullary stem that is mated to the femoral component by an adapter bolt, screw, and/or a taper junction. The sleeves function as prosthetic structural allografts for the metaphyseal region, enhancing load transfer and restoration of the joint line, while also possessing the potential for long-term biologic fixation [3,5]. Early and midterm results in the literature have been promising thus far, with failure rates as low as less than 1% reported by various institutions [4,6-9].

However, the risk of failure of modular junctions in primary and revision TKA systems are a known drawback of these constructs. The Exactech Optetrak (Gainesville, FL) [10], Insall-Burstein II Constrained Condylar design (Zimmer, Warsaw, IN) [11,12], and the Scorpio knee (Stryker, Mahwah, NJ) have all had documented failures observed at their modular junctions [13]. We recently reported a case of a spontaneous, catastrophic failure of the femoral adapter and femoral adapter bolt of an uncemented PFC Sigma Total Condylar III Rotating platform (TC3 RP) (DePuy, Warsaw, IN) [14]. Since this report, we have compiled data on a series of modular junction failures of the Sigma TC3 RP TKAs where metaphyseal sleeve augments had been used at two different institutions. The purpose of this study was to further describe the observed scenarios and potential mechanisms of failure of the TC3 revision TKA prosthesis.

We retrospectively reviewed the arthroplasty registries at two institutions from 2011 to present to identify any cases of mechanical failure of the TC3 RP revision knee arthroplasty. The operative reports, preoperative and postoperative radiographs, and medical records of any potential cases were thoroughly analyzed by the authors at their respective institution. All patients with a documented mechanical failure on both preoperative radiographs and the operative report were included in the analysis. Patients, who underwent a TC3 revision TKA, undergoing revision for infection,

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instability, loosening, or other causes were excluded from the study. The study was approved by each facility's institutional review board, and no external funding was received for the study. Under the institutional review board, patients have provided their consent to have information pertaining to their case published. Patient demographics, indications for index surgery, bone loss, time to revision surgery, and component sizing were all recorded. We then analyzed any components available from one institution's implant retrieval laboratory by light microscopy.

All four patients included in the report were male with an average body mass index (BMI) of 33 (range: 29-36) and an average age of 58 years (range: 50-64). They all presented with a chief complaint of pain without antecedent trauma and had an effusion. Three of the patients complained of mechanical symptoms, and one patient complained of instability. These failures were revised at an average of 52 months (range: 41-72) from the initial revision procedure. Preoperative radiographs demonstrated mechanical failure of the femoral component. Each patient had uncemented fixation of their femoral and tibial components, with cement use limited to the joint line. Intraoperatively, all four patients were found to have a broken femoral adapter bolt with a substantial amount of metal debris intraarticularly. No patient was found to have an infection at the time of revision surgery. In all patients, both the femoral and tibial metaphyseal sleeves were found to have been well fixed. After the revision surgery, all patients were doing well with their current implants, and none required a return to the operating room.

Case histories

Case 1

A 61-year-old male underwent revision of right TKA with the Sigma TC3 RP revision system with femoral and tibial metaphyseal sleeves after having failed his primary knee replacement due to a fractured tibial baseplate. Cement was used at the epiphyseal region of the femoral and tibial components, and the remainder of the construct was uncemented (Fig. 1). After living pain free for 3.5 years and returning to his usual activities, he returned with a 1-month history of mechanical complaints including clicking and catching. He denied a history of recent trauma. On examination, the patient weighed 143 kg and had a BMI of 35. He had a well-healed surgical incision and walked with an antalgic gait. A moderate effusion was present, and his range of motion (ROM) was limited by pain. He had neutral limb alignment, and there was no instability present on examination. Radiographic review demonstrated a fracture at the femoral adapter (Fig. 1). Aspiration and serologies were unremarkable. Given the clinical symptoms of pain and the radiographic findings of failure at the femoral adapter, the patient underwent revision 42 months after the index revision procedure.

At arthrotomy, a hematoma was evacuated from the joint. The femoral component was easily removed due to the fractured adapter bolt. The femoral sleeve was loose, and surface damage was also noted on the polyethylene component. The tibial component was well fixed and aligned. The femoral side was reconstructed with a TC3 femoral component with distal augments cemented into a press-fit femoral cone. The patient was subjected to partial weight-bearing for a 4-week period, postoperatively. At the most recent follow-up visit, 1 year after the operation, the patient was doing well. The patient returned to his premorbid level of activity without limitation. His most recent radiographs revealed well-fixed and aligned revision components (Fig. 1).

Case 2

A 56-year-old male underwent revision of a right TKA with the Sigma TC3 RP revision system with femoral and tibial metaphyseal sleeves for aseptic loosening of his primary components. Cement was used at the epiphyseal region of the femur and tibia, whereas the remainder of the components for the construct were press-fit. Postoperatively, the patient did well, as he was pain free and returned to his usual activities. Three years after his revision, the patient returned with a 2-week history of pain and inability to ambulate without walking aids. There was no history of recent trauma. On examination, the patient weighed 109 kg and had a BMI of 35. He had a well-healed surgical incision, and he walked with an antalgic gait. A tense effusion was present, and the remainder of his examination was limited by pain and guarding. Radiographs revealed fracture of the femoral adapter bolt (Fig. 2). Aspiration and serologies were unremarkable. Given the clinical symptoms of pain as well as the radiographic findings of failure at the femoral adapter, the patient underwent revision 41 months after the index revision procedure.

Intraoperatively, significant synovitis with metallic staining was encountered during exposure. The femoral component was noted

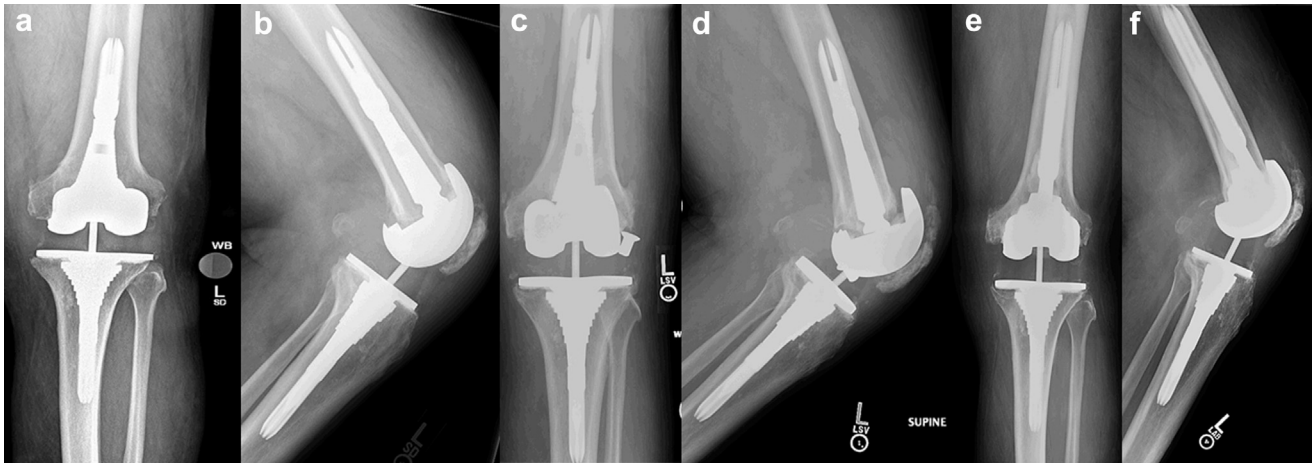

Figure 1. Anteroposterior (AP) (a) and lateral (b) radiographs obtained at revision surgery in 2014. Three and a half years later, the patient presented with onset of pain, and AP (c) and lateral (d) views confirmed fracture of the implant and taper disengagement from the metaphyseal stem. Note the lack of a maintained 90° relationship between the adapter and the femoral component on the lateral view. At the most recent follow-up visit, AP (e) and lateral (f) views demonstrate well-fixed and aligned components.

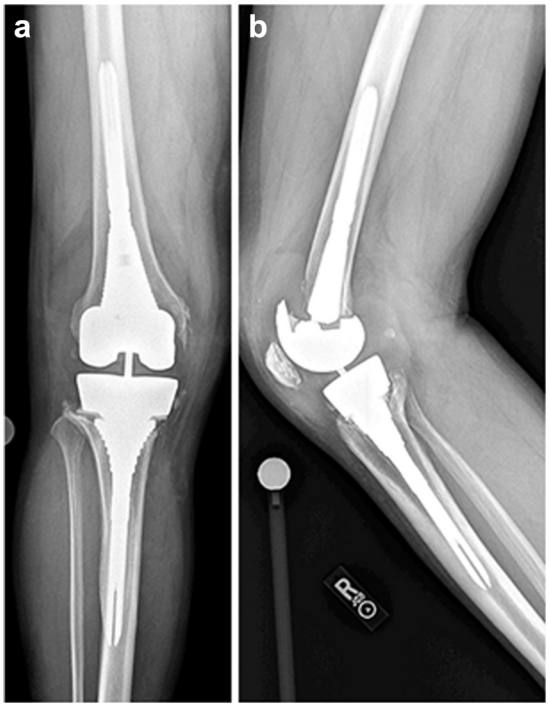

Figure 2. Anteroposterior (a) and lateral (b) views obtained 3 years after revision confirmed fracture of the implant at the adapter. Again, there is disruption of the 90° relationship between the adapter and the femoral component on the lateral view.

to have failed at the adapter bolt. The femoral sleeve was noted to be well fixed; therefore, an S-ROM hinged femoral component was press-fit to the well-fixed femoral sleeve. This allowed for a one-piece connection without any taper bolts. At the most recent follow-up visit, 1 year after operation, the patient was doing well and has returned to his premorbid level of activity without limitations. His most recent radiographs revealed well-fixed and aligned revision components.

Case 3

A 50-year-old male underwent revision TKA with the Sigma TC3 RP with femoral and tibial metaphyseal sleeves for aseptic loosening of his primary components. His postoperative course was unremarkable. After 4.5 years, the patient presented with complaints of pain and mechanical symptoms despite no recent history of trauma. On examination, the patient weighed 104 kg, and his BMI was 33. He had a well-healed surgical scar and was noted to have a moderate effusion. There was instability present, and although he was able to reach full extension, terminal flexion had decreased 20° from his prior assessment. Radiographs revealed dislodgement of the femoral component from the adapter bolt (Fig. 3). Aspiration and serologies were unremarkable for infection. The patient underwent revision 54 months after his index revision procedure. Intraoperatively, presence of substantial amount of metal debris was noted. The locking bolt had failed, and the femoral component was grossly loose. The metaphyseal sleeve was well fixed. Despite stable radiolucent lines on the serial radiographs underneath the baseplate, the tibial component was found to be well fixed. The knee was reconstructed with a fully cemented Zimmer Rotating Hinge Knee (RHK) system (Zimmer Biomet, Warsaw, IN). At the most recent follow-up visit, 2.5 years after operation, the patient was doing well and had returned to his premorbid level of activity without limitation.

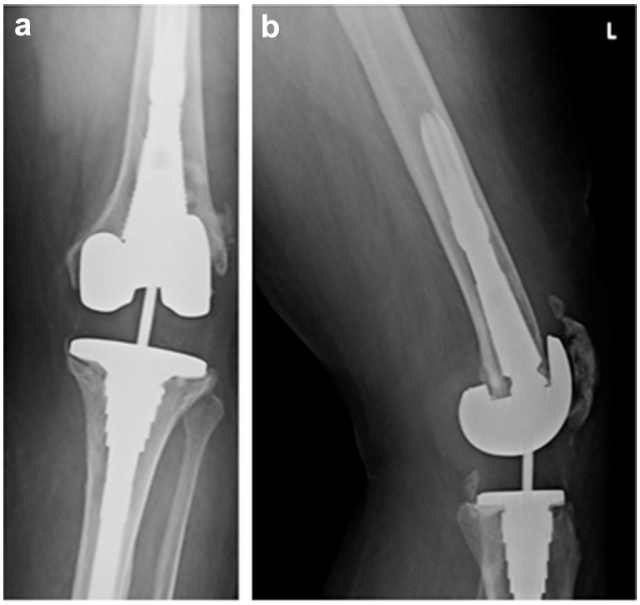

Figure 3. Anteroposterior (a) and lateral (b) views obtained 4.5 years after revision confirmed fracture of the implant at the adapter.

Case 4

A 64-year-old male underwent revision TKA with the Sigma TC3 RP with femoral and tibial metaphyseal sleeves for aseptic loosening of his primary components. Postoperatively, the patient did well as he was pain free and returned to his usual activities. After 6 years, the patient presented with complaints of pain without mechanical symptoms. There was no recent history of trauma. On examination, he weighed 96 kg, and his BMI was 29. He had a well-healed surgical scar and was also noted to have a moderate effusion. There was no instability present, and although a ROM of 0°-130° was noted from a previous examination, his current ROM was 5°-90°. Radiographs revealed fracture of the femoral construct at the level of the adapter bolt (Fig. 4). Aspiration and serologies were unremarkable for infection. The patient underwent revision 72 months after his index revision procedure. Intraoperatively, substantial amount of metal debris was found (Fig. 5). The metaphyseal sleeve was well fixed and was removed with a long pencil-tip burr. The tibial component was well fixed, and we trialed with a new femoral component distalizing the joint line with augments which had good stability throughout the ROM. The femoral reconstruction was completed with the TC3 system cemented into a press-fit metaphyseal cone. The tibial component that was well fixed and aligned was left in place. His postoperative course was uncomplicated, and no postoperative restrictions were placed on the patient. At the most recent follow-up visit, 1 year after operation, the patient was doing well as he had returned to his premorbid level of activity without limitation.

Biomechanical analysis

Two of the four retrievals in this report were cleaned and analyzed by light microscopy to determine the reason for failure (Figure 6; A: Case 2; B: Case 1). Both implants show evidence of a fatigue fracture due to cyclic loading. For the implant corresponding with case 2 discussed previously, clamshell marks propagate across the surface medially leading to the ultimate fracture point located at the medial edge of the bolt (Fig. 6a). The fracture surface for case 1 was not distinctly defined but portrays the implants'

Figure 4. Anteroposterior (a) and lateral (b) views obtained 6 years after revision confirmed fracture of the implant at the adapter bolt. The fractured bolt is seen in the joint space on both views.

ultimate failure at the medial edge (Fig. 6b). The boxes of both the femoral components were burnished and dull, indicative of motion at the surface where the bolt attaches to the femoral component (Figs. 6c and d). Both polyethylene components were severely pitted and scratched and had mild evidence of embedded debris. The posts had visible deformation anteriorly (Figs. 6e and f). Not all implants were assessed as two were removed at an outside institution and were not sent to the biomechanics department.

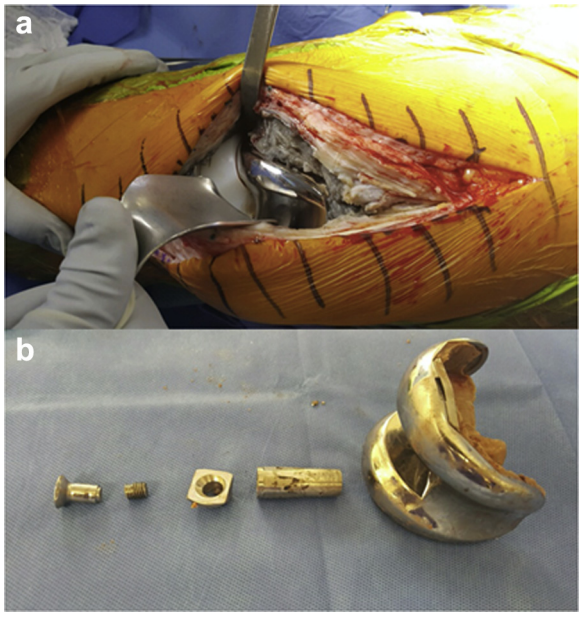

Figure 5. Intraoperative photograph demonstrating significant synovitis, presence of metal debris, and femoral component loosening (a). Intraoperative photograph of retrieved components, note the fractured adapter bolt and femoral adapter (b).

Discussion

Challenging scenarios are often encountered in revision procedures where bone stock is inadequate and fixation options are limited. Porous titanium metaphyseal sleeves are a contemporary modular alternative for challenging cases with compromised bone stock. Although this system provides many surgical advantages and has demonstrated a good track record in the short term [4,6-9], there are concerns with the modular femoral junction [14]. In this series of 4 patients, we found that mechanical failure of the PFC Sigma TC3 RP system with metaphyseal sleeves occurred exclusively at the femoral adapter bolt and the adapter sites. Although one published case report has reported this problem in the literature [14], this is the first case series to describe the failure mechanism and certain clinical scenarios contributing to failure of the femoral locking bolt and adapter sleeve in this prosthesis.

Although modular components provide many benefits, the potential for failure remains a concern. Failure in conjunction with corrosion, fretting, and dissimilar metal coupling has been studied in depth in the arthroplasty literature [15,16]. In particular, catastrophic failures of modular components in revision TKA systems have been previously reported. Issack et al [10] reported fatigue fracture at the taper lock of a modular stemmed femoral implant in a revision TKA. In the Scorpio knee system (Stryker, Mahwah, NJ), cases have been reported in which the threaded bolt had dissembled from the femoral component due to loose implant fixation [13]. Lim et al [12] reported on a series of patients with failed TC3 components, where 2 cases of dissociated bolts were noted to be free-floating in the intercondylar joint space. Although these bolts had not fractured, the mechanism for disassembly was reportedly due to femoral component loosening giving rise to eccentric loads throughout the system, ultimately yielding increased motion at the modular interfaces. Sandiford et al [17] reported three cases in which failure of modular rotating-hinge prostheses occurred due to fracture of the femoral stem at the stem-condylar junction. In this report, they highlight the role played by the constrained prostheses in transmitting excessive loads to the stem at the modular junction, particularly in scenarios where metaphyseal bone stock is deficient, metaphyseal support is not incorporated, and the diaphysis is heavily relied upon [17].

In all four patients, failure occurred at the femoral locking bolt securing the component to the metaphyseal sleeve and between 3 and 5 years after their index revision surgery. Although the epiphyseal surface of the femoral components was cemented, this prosthesis relies on biological fixation with bony ongrowth to the metaphyseal sleeves, with the stem acting as a deep post to transmit forces from weaker, compromised metaphyseal bone to the diaphysis. We hypothesize that stress shielding of the metaphyseal surface of the femur is the result of this biologic fixation, likely resulting in weakening of the cement-prosthesis interface. With continuous cyclic loading, the femoral locking bolt is the weakest biomechanical link in the system and can fail over time. This form of cantilever bending is a known failure mechanism of certain diaphyseal fitting stems after total hip arthroplasty. Without proximal metaphyseal ongrowth, several smaller diameter stems have been reported to fail. All patients in our series were male and younger (age range: 50-64 years). The failure of the locking bolt and adapter in these patients in this patient population is likely due to their higher preoperative activity level than most patients undergoing

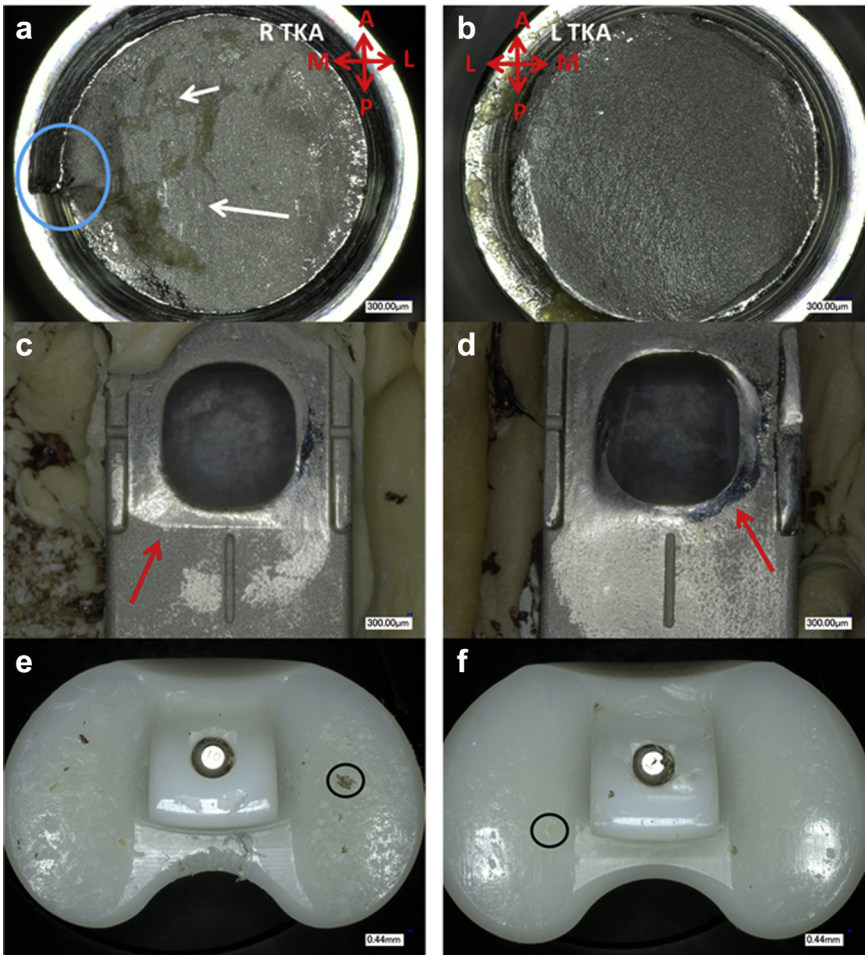

Figure 6. Two implants were retrieved and reviewed under light microscopy to assess reasons for failure. Two cases are shown including images of the fractured adapter bolt (a, b), femoral component (c, d), and the polyethylene tibial insert (e, f). The femoral adapter bolt has evidence of clamshell marks, indicated by the white arrows, leading to the ultimate failure point shown in the blue circle. The red arrows indicate burnished regions of the cobalt chromium alloy femoral component, likely from motion at the adapter bolt interface. The polyethylene tibial components were moderately to severely worn with heavy pitting and scratching. Embedded debris is circled in black.

revision TKA. In this series of patients, we failed to find any correlation between BMI or component sizing and failure of the TC3 revision TKA prosthesis.

There are several limitations to our study. We were unable to report the overall incidence of this unique complication. Although several thousand revision TKA procedures were performed during the study period at both institutions, we cannot identify how many were revisions of Depuy Sigma TC3 RP TKA prostheses. Without a control group and a small sample size of patients, we are also not able to perform any hypothesis testing to analyze our data. The findings reported in this small series of patients are relatively uncommon. However, we do believe it is important to highlight these occurrences and begin to define the circumstances in which they may occur. This report has further described the failure region and mechanism of the Sigma TC3 RP metaphyseal sleeve construct, ultimately providing a starting place for future investigation into the matter. Discussion of such cases is beneficial not only to surgeons who are involved in the management of complex cases but also to joint registries that are charged with surveilling these implants.

Summary

Obtaining durable fixation and an optimally aligned knee is often a challenge in revision TKA. Modular metaphyseal sleeve and stem components in the PFC Sigma TC3 RP system enhance the surgeon's ability to achieve these goals. Although the RP TC3 has had excellent results thus far to address metaphyseal bone loss in revision TKAs, fracture of the femoral locking bolt and adapter has become a cause for failure unique to this prosthesis. Surgeons should be aware of this complication and consider it as a potential etiology for patients presenting with pain with the TC3 prosthesis, particularly in younger, active male patients between 3 and 5 years from their revision surgery.

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