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# Implant Interface Debonding After Total Knee Arthroplasty: A New Cause for Concern?

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ABSTRACT

*Background:* Aseptic loosening has long been an associated etiology for revision total knee arthroplasty (TKA).
*Methods:* This case series investigates commonalities between 9 patients who underwent revision TKA and were found to have complete debonding at the cement-implant interface of a femoral and/or tibial component within the past 2 years.
*Results:* Only 3 preoperative radiographs were indicative of aseptic loosening, and all patients had an infectious etiology ruled out.
*Conclusions:* This case series and other similar reports suggest that there may be a growing concern for debonding as a modern form of aseptic loosening. Further research through American Joint Replacement Registry and other national databases will need to be conducted to better understand if this is truly a new cause for concern after TKA and how it may be best prevented.


## Introduction

Total knee arthroplasty (TKA) is one of the most frequently performed orthopaedic procedures currently performed worldwide. Implant technology continues to evolve with the goal of increasing survivorship, with a recent study demonstrating a 96.1% and 89.7% survivorship at 10 and 20 years, respectively [1]. It is estimated that about 20% of TKA revisions are due to mechanical aseptic loosening [2]. Although there are many etiologies and factors that can lead to mechanical loosening, one specific cause that has recently drawn more attention is debonding of the tibial, femoral, or both components at the cement-implant interface [3].

When such debonding occurs, it can lead to persistent knee pain, recurrent effusion, and subsequent component migration, which may require partial or complete revision surgery. This type of mechanical debonding may be difficult to diagnose as radiographs often do not show clear evidence of aseptic loosening and migration can be a late finding [4]. Other case series looking at similar implant failures suggested the cement type (high-viscosity cement [HVC]) may be a risk factor for debonding [5,6]. Furthermore, the cement technique, surface coating, and implant design may play a role in the ability of components to maintain stability within a given cement mantle. More attention needs to be paid and more research needs to be carried out to further investigate this recent trend of cement-component debonding. This case series presents 9 patients who required revision surgery and were found to have aseptic loosening secondary to component-cement interface debonding.

## Clinical presentation

We identified 9 consecutive patients (of 175 revision TKAs during the study period, 5%) who on TKA revision were found to have complete cement-implant interface debonding of the tibial, femoral, or both components, from December 2017 to September 2019. A detailed single-surgeon retrospective review of these patients was performed, including medical records, hospital charts, and radiographs. All sources were analyzed in an attempt to better understand the implant debonding etiology mode of failure.

The 9 patients underwent TKA revision surgery for diagnoses outlined in Table 1. Intraoperatively, all patients were found to have

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**Table 1**
Preoperative diagnoses with preoperative and postoperative TKA component findings.

| Patient | Preoperative diagnosis | Loose component(s) on preoperative radiograph[a] | Debonded component(s) intraoperatively |
|---|---|---|---|
| 1 | Failed TKA due to aseptic loosening and stiffness | None | Tibial and femoral |
| 2 | Failed TKA due to flexion contracture and arthrofibrosis | None | Tibial and femoral |
| 3 | Failed TKA due to instability and patella DJD | None | Tibial and femoral |
| 4 | Failed TKA due to knee instability, worsening recurvatum, and VMO defect | None | Tibial and femoral |
| 5 | Failed TKA due to patella fracture nonunion | None | Tibial and femoral |
| 6 | Failed TKA due to aseptic loosening | None | Tibial |
| 7 | Failed TKA due to stiffness and instability | Tibial | Tibial |
| 8 | Failed TKA due to aseptic loosening | Tibial | Tibial |
| 9 | Failed TKA due to aseptic loosening | Femoral | Femoral |

DJD, degenerative joint disease.
[a] Only one patient met diagnostic criteria of aseptic loosening. The other 2 were suspected based on imaging but did not meet official diagnostic criteria.

complete cement-implant debonding of one or more components from their previous primary TKA. Four of the 9 patients were male, and the cohort had an average age at time of revision of 67.8 years with a range of 51 to 75 years. The average body mass index for all 9 patients was 32.0 kg/m$^2$ with a range of 23.3 to 43.8. Before revision, the average Knee injury and Osteoarthritis Outcome Score Junior (KOOS JR) of the knee undergoing revision was 49.31 with a range of 42.8 to 59.38. Most notably, the average time to revision was 2.6 years with a range of 1.3 to 4.75 years.

On presentation, 8 of the 9 patients had a three-view radiograph series (anterposterior, lateral, and merchant) of the affected knee and one had a four-view series (AP, lateral, merchant, and skiers) reviewed and compared with prior and preoperative (when available) radiographs. In addition to the serial radiographs, 2 patients also underwent technetium-99 triple-phase bone scintigraphy and another patient underwent both magnetic resonance imaging and computed tomography. Thorough evaluation of the plain radiographs looking at radiolucent lines and implant migration on serial radiographs revealed that 3 of the patients showed some minor signs of aseptic loosening, with only one patient (#8) meeting diagnostic criteria (>2 mm of radiolucency) [7] (Table 1). The other 6 patients did not show signs of loosening on their office radiographs and were revised for various etiologies (Table 1). Of note, 2 patients who did not show signs of aseptic loosening on preoperative radiographs were found to have signs of component loosening on technetium-99 triple-phase bone scintigraphy including asymmetrical hyperemia and increased uptake along component margins. These patients were then classified as suspicious for aseptic loosening. All 8 preoperative mechanical axis radiographs before revision were found to be normal or neutral. On physical examination, there was an absence of a joint effusion in 2 of the patients, whereas the other 7 were noted to have a mild to moderate effusion. Two patients were also noted to have significant varus-valgus laxity. Preoperative serum markers for infection were negative and were ultimately confirmed with an intraoperative synovial fluid and histological analysis of a representative frozen section, tissue sample (Table 2). The primary TKA implants were from a variety of different manufacturers (Table 3).

On removal of the polyethylene liner, one or more of the previous TKA components were grossly loose in all 9 patients. Five patients were found to have both tibial and femoral component debonding, 3 patients had only tibial component debonding, and one patient had only femoral-component debonding (Table 1). In each case, there was complete debonding observed between the component and the cement interface. Each component was removed with minimal manual manipulation, requiring no intraoperative tools or equipment. Furthermore, the components were completely free of any attached cement and the cement mantle remained in continuity on the respective femur or tibia (Figs. 1 and 2). There were no intraoperative complications reported during the 9 revision surgeries.

The most recent KOOS JR score recorded for 8 of the 9 patients was an average of 60.50 with a range of 39.62 to 91.97. One patient's KOOS JR scores were not taken at follow-ups. The average increase from preoperative KOOS JR scores to the most recent postoperative scores was 10.63. The average time to the most recent follow-up is 8.55 months with a range of 3 months to 15 months. At the most recent visits, all patients had 3-view radiographs (AP, lateral, and merchant) assessed and they were all negative for any signs of wear, loosening, or radiolucent lines. Of note, one patient whose revision was for a flexion contracture and arthrofibrosis had a recurrence of his flexion contracture. At 6 weeks postoperatively, he underwent a manipulation under anesthesia, which temporarily relived the contracture; however, at his most recent follow-up (3 months), he still had the contracture of 16-20 degrees (believed to be related to an undiagnosed neurological condition with Parkinsonian traits). Another patient who was revised due to knee instability with known vastus medialis obliquus (VMO) and

**Table 2**
Infectious disease markers.

| Patient | ESR (mm/hr) | CRP (mg/dL) | Intraoperative cell counts | Intraoperative frozen section |
|---|---|---|---|---|
| 1 | 29 | 5.4 | WBC 731 PMN 47% | Negative for infection |
| 2 | 9 | 0.5 | WBC 78 PMN 10% | Negative for infection |
| 3 | 16 | <.5 | WBC 189 PMN 13% | Negative for infection |
| 4 | 34 | <.5 | WBC 80 PMN 16% | Negative for infection |
| 5 | 8 | 0.5 | WBC 193 PMN 32% | Negative for infection |
| 6 | 18 | 1.1 | WBC 1150 PMN 58% | Negative for infection |
| 7 | 11 | 1.1 | WBC 374 PMN 51% | Negative for infection |
| 8 | 48 | 4 | WBC 1148 PMN 22% | Negative for infection |
| 9 | 4 | <.3 | WBC 381 PMN 38% | Negative for infection |
| Average | 19.7 | 1.5 | WBC 480 PMN 32% | - |

CRP, C-reactive protein; ESR, erythrocyte sedimentation rate; PMN, polymorphonuclear leukocyte; WBC, white blood count.

**Table 3**
Failed TKA components.

| Patient | Components removed |
|---|---|
| 1 | Global Medacta Knee (GMK) Sphere, Medacta, Switzerland |
| 2 | Global Medacta Knee (GMK) Sphere, Medacta, Switzerland |
| 3 | Global Medacta Knee (GMK) Sphere, Medacta, Switzerland |
| 4 | Global Medacta Knee (GMK) Sphere, Medacta, Switzerland |
| 5 | Global Medacta Knee (GMK) Sphere, Medacta, Switzerland |
| 6 | Zimmer Biomet Persona, Zimmer Biomet, Warsaw, IN |
| 7 | Zimmer Biomet Persona, Zimmer Biomet, Warsaw, IN |
| 8 | Attune Knee System, DePuy Orthopaedics, Warsaw, IN |
| 9 | Zimmer Biomet Persona, Zimmer Biomet, Warsaw, IN |

quadriceps deficit has experienced recurrent patella subluxation because of continued weakness and partial quadriceps tear (she is slated for upcoming allograft reconstruction of the extensor mechanism). Otherwise, all other patients are recovering as expected, with an average increase in the KOOS JR score of 9.3 at 6-week follow-up and 10.63 at the most recent follow-up (average 8.55 months). Excluding the 2 patients mentioned previously, at the most recent follow-up, the average range of motion was 115 degrees, which is improved from the preoperative average range of motion of 99 degrees.

## Discussion

Given the relatively uncommon occurrence of cement-implant interface debonding, it is difficult to identify the exact causes for this type of aseptic loosening. This cohort of patients all had a range of clinical presentations with variable radiographic findings. Interestingly, several independent companies manufactured these implants, and it does not appear to be isolated to a single supplier. This implies that implant debonding is likely multifactorial and not isolated to a single implant design. Unfortunately, we were not able to confirm the cement type or specific surgical techniques in prepping the cement and implants used during the primary surgery in all cases, but it did appear to be a mix of both HVC and low-viscosity formulations. Although complete debonding is uncommon, there are a handful of past studies and case reports that have investigated analogous circumstances. Similar to this case series, previous studies have not been able to determine an exact etiology for the debonding. A range of possible hypotheses has been postulated including using HVC during the TKA, the specific cement application technique, and even the implant design [3–6,8–11]. The majority of these studies were published in the last 5 years and are not necessarily related to polyethylene wear (which may be a late factor in debonding cases).

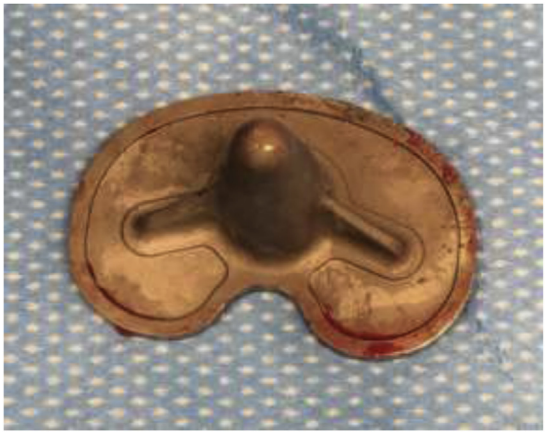

**Figure 1.** Intraoperatively removed debonded tibial component.

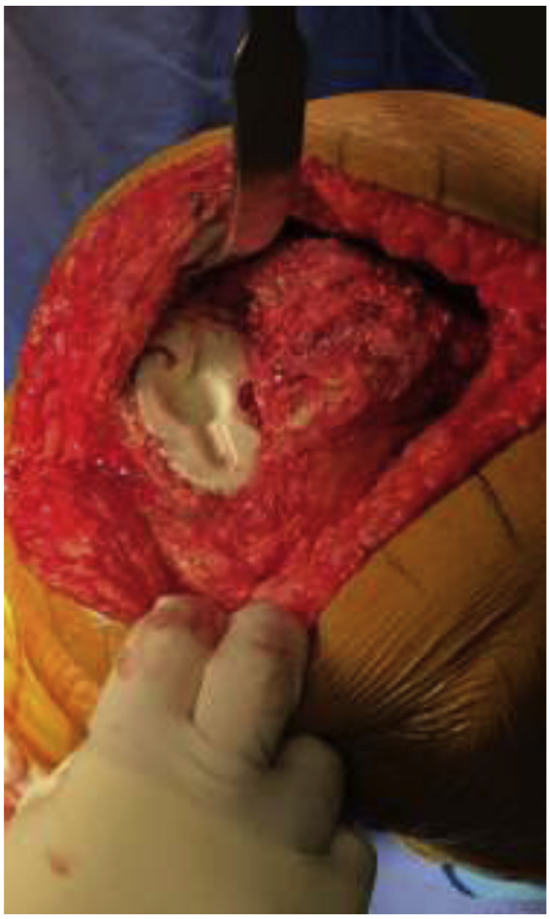

**Figure 2.** Fully debonded tibial component in vivo.

Past studies have linked certain implants as potential risk factors for implant-cement interface debonding in TKA [3,4,8]. For example, one retrieval analysis study of low-contact-stress mobile-bearing TKA found a negative correlation between the cement mantle thickness rates of debonding. They also noted the low tibial-surface roughness and lack of a keeled stem may have contributed to the early debonding failure [3]. These reports have been helpful in identifying specific component design features that may be more prone to debonding, but there is not enough evidence or numbers to prove a certain style of implant has a higher incidence of debonding than any others. In addition, there are so many variables, cement types, cementation techniques, patient factors, and implant designs (coating, locking mechanism, keel/peg length, etc…) that it is difficult to pin this phenomenon on a specific etiology [10–12]. In the future, it may be worthwhile to perform a finite-element analysis to control for the various potential causes for debonding failures. Given the numerous possible variables, further research with large registry data is needed.

Operative technique and postoperative alignment should also be considered as possible contributors to implant-cement interface failure. Most of the past reports of debonding have alluded to operative technique as a possible factor. Given that our cohort of patients each had their TKA performed by a different surgeon at different facilities, it is hard to ascertain specific techniques that may contribute to this type of TKA failure; thus, we are unable to further comment on this aspect. In the current literature, compelling data on what aspects of the surgical technique may be

contributing to this type of debonding are lacking and further investigation is needed. However, it has been suggested that a major contributor of associated aseptic loosening in TKA is postoperative limb alignment [13]. However, 2 studies investigating debonding found this type of debonding in well-aligned knees [3,4]. Similarly, in our cohort, alignment was normal or neutral on preoperative axis radiographs before revision. Of note, 2 of the patients were shown to have significant varus-valgus laxity preoperatively (before revision), possibly contributing to recurrent effusions, polyethylene wear, and abnormal forces on their implants, which could have been a factor in their implant failure. This further demonstrates that while alignment and postoperative stability may be a factor in some patients, no single aspect can be implicated as the sole cause of debonding. Further investigation, at the registry level, should be carried out to further investigate what role postoperative alignment may have on debonding.

This study does have some limitations. As a retrospective case series review of patients from one surgeon, the scope is limited to cases that were discovered intraoperatively at this time. Pain after TKA is not an uncommon presentation; therefore, other cases that did not undergo revision may also be affected by similar cement-implant interface debonding. Because the patients for this study were identified intraoperatively during their revision, little is known beyond the original operative report of how the cement and implants were prepared and inserted into place. Further studies should look at the cementing technique in TKA and its role in potential implant-cement interface debonding. In addition, specific design features and commonalities need to be vetted between the implants to determine if there are factors that can be attributed to this mode of failure.

Strengths of this report include the fact that although all the revisions were performed by one surgeon, not all of the primary TKAs were from the same institution or performed by the same surgeon. This helps rule out site- or surgeon-specific techniques or procedures that might predispose implants to this kind of failure. In addition, past reports have primarily only shown tibial component debonding; however, our case series also features multiple cases with both tibial and femoral cement-implant interface debonding. This emphasizes the fact that intraoperatively all components must be thoroughly assessed regardless of the preoperative radiographs.

What is most troublesome is the early need for revision (with modern-generation implant designs) that is common between past reports and ours. In 2 similar studies, the average time to revision was 2.7 years and 2.75 years, which is very close to our average time to revision of 2.6 years [5,6]. This early need for revision is drastically earlier than the normal timeline for anticipated longevity of TKA implants [14]. It is not uncommon to see excellent survivorship for TKA out to 15 years now and these early failures, although not a cause for panic, should raise a red flag for some further investigation [15].

## Summary

In this study, 9 patients presented with knee pain after primary TKA with or without instability. On preoperative evaluation, only 3 of the patients showed some signs of component loosening on the radiograph, with only one actually meeting criteria for aseptic loosening (>2 mm of radiolucency) and 2 others with a positive technetium-99 triple-phase bone scintigraphy scan indicative of loosening. On revision, all 9 patients were noted to have cement-component interface debonding of one or more of their components. Five of the cases were completely unexpected as there were no signs of radiographic loosening preoperatively, and the patients were indicated for an alternative etiology for the revision procedure. The most concerning revelation is the early timeframe of failure in modern implants that were recently introduced to the market (all implants were the latest generation from the manufacturer). Further research is necessary to determine if these were anomalous cases associated with the particular cement fixation or patient factor or if an impending trend is to be expected. Large database reviews through American Joint Replacement Registry and national registries may help identify these trends and shed some light on whether debonding is a true cause for concern with modern-day implants.

## Conflict of interests

B.R. Levine is a paid consultant for Link Orthopaedics, McGraw-Hill, Merete, and Exactech, Inc, receives royalties, financial, or material support from Human kinetics and SLACK Incorporated, is a member of the editorial or governing board of the *Arthroplasty Today*, *Journal of Arthroplasty*, and *Orthopaedics*, and is a board or committee member of the AAOS and American Association of Hip and Knee Surgeons; all other authors declare no potential conflicts of interest. As Deputy Editor of *Arthroplasty Today*, he was recused from the editorial process for this manuscript, which has undergone blinded peer review.

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