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Complications - Other

Failure at the Tibial Cement–Implant Interface With the Use of High-Viscosity Cement in Total Knee Arthroplasty

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ABSTRACT

Background: Recent literature has shown debonding of the tibial implant–cement interface as a potential cause for implant loosening. The purpose of this case series is to report this phenomenon in a historically well-performing implant when used with high-viscosity cement (HVC).

Methods: Thirteen primary cemented Biomet Vanguard total knee arthroplasties were referred to 1 of 2 institutions with complaints of persistent pain after their index procedure. A radiographic and infectious work-up was completed for each patient. All 13 patients underwent a revision of the index surgery with intraoperative diagnosis of tibial component debonding at the implant–cement interface. HVC (Cobalt, DJO Surgical, Vista, CA and Depuy HVC; Depuy Inc, Warsaw, IN) was used in all index cases.

Results: The average time to revision surgery for the 13 patients was 2.7 ± 1.9 years from the index surgery. Laboratory infectious markers were within normal in most cases, and all intra-articular aspirations showed no bacterial, fungal, or anaerobic growth. Eleven of 13 patients showed no radiographic evidence of loosening; however, all cases demonstrated tibial component debonding intraoperatively.

Conclusion: Given our institution's experience and previously reported data demonstrating excellent survivorship with this total knee arthroplasty prosthesis, we propose that the early failures seen in this case series may be associated with the use of HVC cement. In the setting of a negative infectious work-up and no radiographic evidence to suggest loosening, the surgeon should consider debonding of the tibial component as a potential cause for persistent pain if HVC cement was used with this prosthetic design.

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In 2015, the number of total knee arthroplasties (TKAs) performed annually was at an all time high with a projected demand reaching upward of 2 million primary TKAs within the next 2 decades [1]. TKA is a highly effective and reliable treatment of degenerative joint disease, with survival rates of over 90% at 10–19 years of follow-up [2]. Furthermore, TKA is known to result in improvement in the patient's pain and satisfaction levels, quality of life, and function. However, despite the effectiveness of a TKA, implant failures and subsequent revisions can be quite problematic for the patient and the health care system as a whole. As the total

number of TKA increases, so too, will the number of associated complications. The number of revision TKAs is projected to grow by 601% from 2005 to 2030, which correlates with a significant number of patients who will be affected [3].

Failures of a TKA can be due to a variety of underlying issues, including infection, implant loosening, instability, and polyethylene wear. Infection ranks as one of the most common overall causes of revision TKA and is responsible for a large percentage of “early” revisions occurring within 2 years of the index procedure [4,5]. However, aseptic component loosening also poses a considerable problem, with recent investigations demonstrating aseptic loosening to be the most common cause of failure at greater than 2 years after the index procedure [6,7]. With the projected increase in revision TKAs, it remains critical to continue to analyze and study specific causes of failure to minimize potentially avoidable complications after TKA.

The Biomet Vanguard Complete Knee System prosthesis (Biomet Inc, Warsaw, IN) has been on the market in the United States for over 10 years and has demonstrated excellent survivorship.

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A recent investigation of 807 TKAs performed using the Vanguard prosthesis has reported 99% survivorship at 2 years and 98.6% survivorship at 6-year follow-up with revision for prosthesis-related reasons as the end point [8]. The type of bone cement used during this investigation was not reported. Our institution has previously reported on the use of the Biomet Vanguard prosthesis in 201 patients with a mean follow-up of 2.5 years with no instances of failure when performed using a non–high-viscosity bone cement [9].

High-viscosity cement (HVC) was introduced with proposed advantages being shorter mixing and waiting phases during polymerization, and longer working and hardening phases, which make it an attractive option for use in TKA [10]. Despite the known excellent survivorship of the Biomet Vanguard prosthesis, we have recently observed several early failures when used in combination with HVC cement, most frequently Cobalt cement (Formally Biomet Inc, Warsaw, IN, now DJO Surgical, Vista, CA). Specifically, all implants were revised for a diagnosis of implant–cement fixation failure and debonding at the tibial implant–cement interface.

The objectives of this investigation are to report on a series of early failures due to debonding at the tibial implant–cement interface with the use of HVC in an implant design previously reported to have excellent survivorship and to describe the clinical and radiographic features associated with such failures.

Materials and Methods

Institutional review board approval was obtained to review all revision TKAs with a preoperative diagnosis of persistent pain or debonding and/or failure of the tibial component of a primary Biomet Vanguard prosthesis performed at 2 institutions from August 2013 to December 2015. A total of 13 revision TKA cases in 13 patients were identified, all with a postoperative diagnosis of tibial component debonding at the tibial implant–cement interface. All index TKAs were performed at outside hospital systems by multiple surgeons and referred to one of 2 institutions for further evaluation. HVC was not used for TKAs at either of the institutions in which the revision TKA was performed. Revision TKAs were performed by 4 experienced, fellowship-trained arthroplasty surgeons at 2 institutions. Data for each of these cases were collected prospectively with analyses performed retrospectively.

Patient demographic data, including age, gender, and body mass index, were collected from each institution's joint arthroplasty repository. Each patients' prerevision symptoms including the presence of pain, instability, and stiffness were reviewed. All patients received prerevision standing anteroposterior knee, lateral knee, and merchant radiographs, which were analyzed for the presence of radiolucent lines suggestive of aseptic loosening as previously described by Gejo et al [11]. Furthermore, measurements of coronal tibial and femoral component alignment relative to each, respective anatomic axis were performed, along with each patient's prerevision femorotibial alignment. For convention, a negative value was considered varus and a positive value valgus. Six patients had preoperative hip–knee–ankle radiographs from which the overall, mechanical lower extremity alignment, and femoral and tibial component alignments relative to each, respective mechanical axis was performed.

All patients received a prerevision erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) level, with a knee aspiration performed at each surgeon's discretion based on the laboratory results. Furthermore, additional imaging modalities including a bone scan to evaluate for infection or component loosening or computed tomography scan to evaluate for component malrotation were performed at the surgeon's discretion. The results of these studies were collected and reviewed.

At the time of each revision surgery, intraoperative assessments were performed to assess for stability, polyethylene wear, implant damage, and implant loosening. Each revision TKA included in this series demonstrated a grossly loose tibial component with debonding from the implant–cement interface, which entailed a separation of the tibial baseplate from the cement mantle. The tibial cement mantle remained intact and adhered to the underlying tibial bone. The implant type and bone cement used during the index TKA was confirmed after review of the index surgery's operative report. Continuous variables are reported as the mean and standard deviation.

Results

All patients underwent their primary TKA for a diagnosis of osteoarthritis (9 right and 4 left) and received a revision of their femoral and tibial components at the time of their revision TKA.

There were 6 males and 7 females in the study with the mean age at the time of the revision surgery of 62.4 ± 9.7 years (range, 49–84 years), and a mean body mass index of 32.1 ± 8.8 kg/m² (Table 1). The average time from the index surgery to the revision surgery for the 13 patients was 2.7 ± 1.9 years.

The predominant presenting symptom was persistent pain after the index TKA procedure. Twelve of 13 patients specifically noted the absence of pain relief from their index TKA, whereas 2 noted persistent stiffness and 5 noted instability.

The CRP and ESR rates (normal ranges <10 mg/L and between 0–29 mm/h, respectively) varied but were mainly low and within normal ranges. Two patients had a preoperative ESR that was above normal limits (57 mm/h and 45 mm/h, respectively), but CRP levels were within normal limits (0.9 mg/L and 0.6 mg/L, respectively). Each of these patients had a prerevision aspiration that was negative for any bacterial, fungal, or anaerobic growth. One patient had a CRP level of 121 mg/L, but normal ESR (14 mm/h) and received 2 prerevision aspirations that were both negative for bacterial, fungal, or anaerobic growth with low cell counts of 64 and 270 cells/ μ L and low percentages of neutrophils (2% and 47%, respectively). Five other patients with a normal ESR and CRP received prerevision aspirations that were also negative for growth with correlative low cell counts and neutrophil percentages.

Prerevision radiographs demonstrated the absence of radiolucent lines in 11 of 13 anteroposterior knee radiographs. One patient demonstrated a radiolucent line just medial to the keel of the tibial component and one patient demonstrated a complete, radiolucent line across the entire surface of the tibial component. Ten of 13 patients demonstrated the absence of radiolucent lines of the tibial component on the lateral radiograph. Three patients demonstrated

Table 1
Patient Demographics.

Case	Age	Gender	Laterality	Time Between Surgeries (y)	Height (m)	Weight (kg)	BMI (kg/m ²)
1	55	F	Right	2	1.70	86.8	30
2	62	M	Right	4	1.83	84.5	25
3	59	M	Right	3	1.73	87.3	29
4	71	F	Right	1.5	1.60	67.3	26
5	49	F	Right	3	1.70	115	40
6	64	M	Left	2	1.83	79.8	24
7	62	M	Left	2	1.70	105	36
8	54	F	Right	1	1.10	112	47
9	84	F	Left	8	1.80	70.5	20.9
10	56	F	Right	3	1.65	114	42
11	58	F	Left	0.5	1.64	58.3	22
12	60	F	Right	4	1.56	120.8	44
13	77	M	Right	1.3	1.68	87.4	31

F, female; M, male.

a radiolucent line anterior to the keel of the tibial component on the lateral radiograph. Six patients received a nuclear imaging bone scan to evaluate for component loosening or infection, with all results being negative for definitive signs of component loosening. One bone scan did demonstrate increased nonspecific inflammation surrounding the knee, but no definitive component loosening. A computed tomography scan was performed in one patient to evaluate for axial component rotation and was negative for component malrotation or fracture.

The mean coronal tibial component anatomic alignment was $-1.7^\circ \pm 2.5^\circ$ (range -6.5° to 1°) and tibial component mechanical alignment was $-2.0^\circ \pm 2.7^\circ$ (range -6.0° to 2°). Based on the tibial component anatomic alignment, 2 patients had a varus alignment of $>3^\circ$, whereas 11 patients had a component alignment within 3° of neutral. The mean coronal femoral component anatomic alignment was $5.9^\circ \pm 4.5^\circ$ (range -2.9° to 13°) and femoral component mechanical alignment was $0.1^\circ \pm 4.4^\circ$ (range -6.3° to 7°). Three femoral components had a coronal anatomic alignment of $>7^\circ$ of valgus. The mean femorotibial alignment was $4.7^\circ \pm 4.6^\circ$ (range -1.2° to 9.9°) and mean hip–knee–ankle alignment was $-1.1^\circ \pm 5.6^\circ$ (range -5.0° to 8.4°). Assuming a neutral femorotibial alignment to be within 2° and 7° of valgus, 2 patients had an overall valgus alignment, 2 patients had an overall varus alignment, and 9 patients were in a neutral alignment.

Of the 13 Vanguard TKAs undergoing revision in this series, 8 were cruciate-retaining and 5 were posterior-stabilized design. At the time of revision, all patients had a grossly loose tibial component that could easily be lifted off of the cement mantle during intraoperative assessment (Fig. 1). The cement mantle remained fixed to the underlying bone (Fig. 1B). As noted in Figure 1C, the tibial baseplate was removed without any trace of cobalt cement adherence to the underside of the tibial component. Twelve patients had their index TKA performed with the use of cobalt HVC cement, whereas 1 patient received a HVC cement manufactured by Depuy Inc (Warsaw, IN). One patient had a cementless femoral component that demonstrated fibrous ingrowth at the time of surgery. Twelve had cemented femoral components with 4 demonstrating debonding at the implant–cement interface and 2 demonstrating loosening at the bone–cement interface.

Discussion

The Vanguard knee prosthesis has shown excellent component survivorship, and to our knowledge, a high rate of early implant failures has not been reported [6]. Prior investigations have shown survival rates of over 90% at up to 19 years with the use of a cemented metal-backed stemmed tibial tray; thus, the recent presentation of a series of patients with tibial component debonding is a significant concern. All TKAs performed in this case

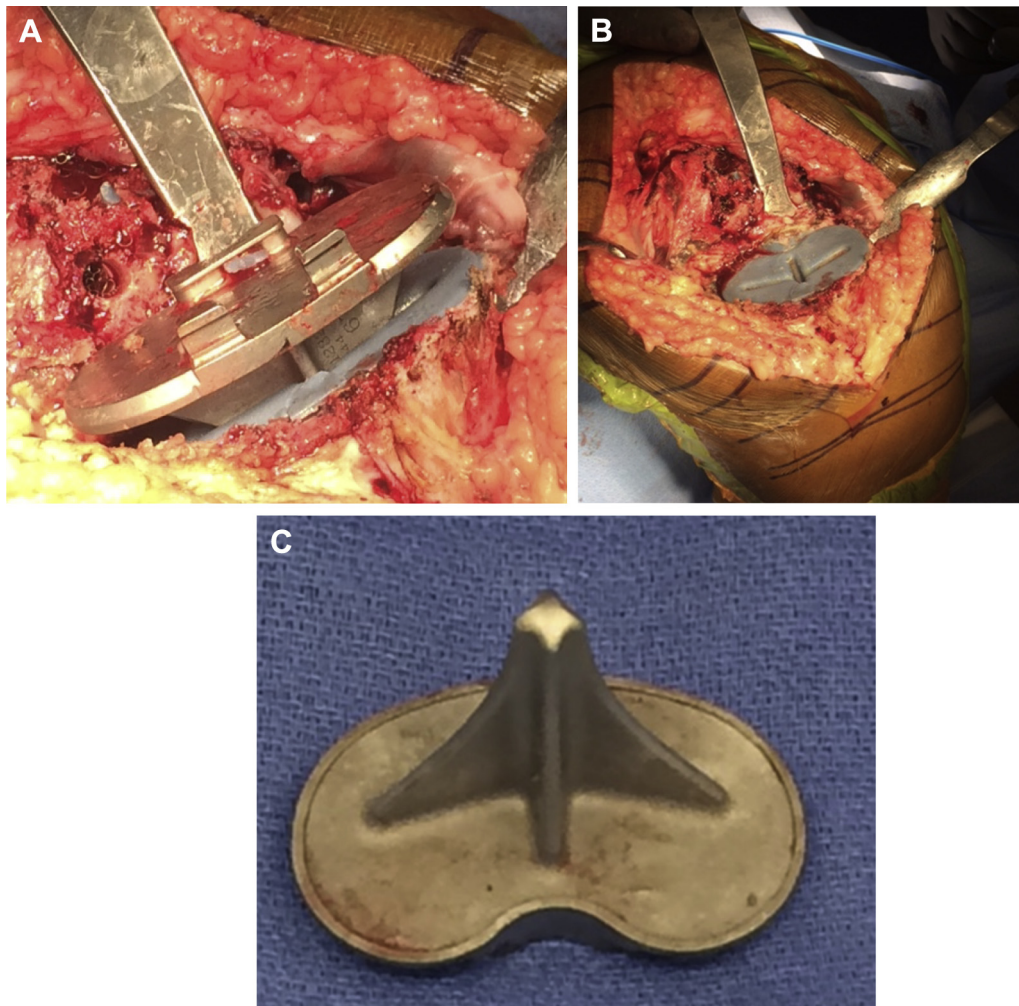


Fig. 1. (A) Tibial baseplate being elevated off of the tibial surface and the cobalt cement mantle. (B). Intraoperative image of the proximal tibia with the remaining intact cobalt cement–bone interface. (C) Extracted tibial baseplate at the time of revision surgery. The component demonstrates no adherence of cement to underside of the tray.

series used HVC cement, which we hypothesize creates a unique situation with a previously well-performing implant in which the tibial component fails to adhere to the cement interface. Likely, there are many nuances of the surgeon's cementation technique during surgery including the timing of cementing, the way in which the cement is applied, and whether the cement is adhered to the components or not, which all may lead to issues with implant loosening [12–14]. Our case series suggests that the failures may be associated with the use of HVC given that at our institution we have not seen instances of tibial debonding when the same implant design was used with a non-HVC. In a review of our institutional registry of 277 TKAs implanted using the Biomet Vanguard prosthesis and a non-HVC with a minimum of 2-year follow-up, we found no instances of aseptic loosening or tibial component debonding. Therefore, we are concerned that the use of a HVC with the Vanguard prosthesis may potentially lead to tibial component debonding and early aseptic failure.

This study has several limitations that must be recognized. First, it is a retrospective study and thus we are unable to determine causation of failures and can only suggest associations. Second, as all of the index TKAs were performed at outside institutions by multiple surgeons, we cannot comment on the specific technique used during cementation, nor can we report the actual incidence of tibial component debonding when using HVC with the Vanguard prosthesis. Specific details such as the mixing technique of the cement or the cementing technique of the surgeons performing the index procedures are not known, and thus technique may play a role in early failure more so than the use of specific cement. However, given that this is a previously unreported mode of failure using this implant design and HVC, we believe that our case series still presents important findings and raises significant concerns.

HVC and non-HVC have different inherent properties that may lead to alterations in how the cement performs in a TKA. Rey et al evaluated cement intrusion depth between HVC and non-HVC under varying injection pressures in a bovine cancellous model. They found that the intrusion depth of the non-HVC was almost double that of the HVC at all pressures tested [15]. In addition to the intrusion depth varying between these types of cement, Jasty et al showed the mean pore size and total porosity to be superior in the non-HVC group in comparison to the HVC [16]. These 3 differences may play a significant role in the bone–cement and cement–implant interfaces and potentially contribute to varying rates of early aseptic loosening.

Unfortunately, this phenomenon has been reported elsewhere. Recently Foran et al [17] published a case series outlining loosening of the tibial component and cement interface of 8 patients, using the Zimmer, NexGen TKA (Zimmer Inc, Warsaw, IN). The cement in this case series was also HVC (Palacos-R + G; Zimmer Inc). Although the authors only suggested that the HVC could have played a role in the aseptic loosening seen, the mechanism of loosening was not fully understood.

Another recent case report by Hazelwood et al evaluated over 3048 TKAs over a 5-year period in which 11 TKAs were revised for early aseptic loosening (0.36%) [7]. They found the tibial component to be loose and show debonding at the implant–cement interface in patients who received HVC, including Smartset-HV (Depuy Inc, Warsaw, IN) and Palacos-R cement. The surgeons discontinued use of the HVC and returned to using the lower viscosity cement, Simplex P (Stryker Inc, Mahwah, NJ), in which no cases of cement–implant debonding have been observed.

In our case series, all TKAs demonstrated debonding at the tibial baseplate–cement interface, but without disruption of the cement–bone interface. The patients in our series predominantly complained of persistent pain after the index procedure, and work-ups for infection were consistently negative. Arsoy et al [18] reported 25 cases of tibial component debonding of the NexGen LPS 3° tibial tray over an 11-year period and noted a characteristic radiographic finding of the tibial component falling into varus and flexion. Unfortunately, in our case series, most cases demonstrated tibial components that were in acceptable alignment, without definitive radiographic signs of component loosening. Furthermore, when performed, advanced imaging studies failed to provide further insight into the cause of persistent pain. Therefore, based on the results of this case series, we propose that in the setting of a cemented Vanguard prosthesis implanted with HVC, the surgeon should be aware of potential debonding of the tibial component as the reason for persistent pain after a patient's index procedure. Although aseptic loosening after TKA can clearly be multifactorial, our past success with this prosthesis and the recent failures reported in this case series makes us concerned that use of the Vanguard prosthesis with cobalt cement may increase the risk of early aseptic loosening, specifically tibial component debonding at the implant–cement interface.

References

- Kurtz S, Ong K, Lau E, et al. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. *J Bone Joint Surg Am* 2007;89(4):780.
- Abdeen AR, Collen SR, Vince KG. Fifteen-year to 19-year follow-up of the Insall-Burstein-1 total knee arthroplasty. *J Arthroplasty* 2010;25(2):173.
- Bozic KJ, Kurtz SM, Lau E, et al. The epidemiology of revision total knee arthroplasty in the United States. *Clinorthoprelat Res* 2010;468:45.
- Sharkey PF, Hozack WJ, Rothman RH, et al. Why are total knee arthroplasties failing today? *Clinorthoprelat Res* 2002;404:7.
- Fehring TK, Odum S, Griffin WL, et al. Early Failures in total knee arthroplasty. *Clinorthoprelat Res* 2001;392:315.
- Schroer WC, Berend KR, Lombardi AV, et al. Why are total knee arthroplasties failing today? Etiology of total knee revision in 2010 and 2011. *J Arthroplasty* 2013;28(8 Suppl):116.
- Piedade SR, Pinaroli A, Servien E. Revision after early aseptic failures in primary total knee arthroplasty. *Knee Surg Sports Traumatolarthrosc* 2009;17(3):248.
- Kievit AJ, Schafroth MU, Blankevoort L, et al. Early experience with the Vanguard complete total knee system: 2–7 years of follow-up and risk factors for revision. *J Arthroplasty* 2014;29:348.
- Nam D, Park A, Stambough JB, et al. The Mark Coventry award: custom cutting guides do not improve total knee arthroplasty clinical outcomes at 2 years followup. *Clin Orthop Relat Res* 2016;474(1):40.
- Hazelwood KJ, O'Rourke M, Stamos VP, et al. Case series report: early cement-implant interface fixation failure in total knee replacement. *Knee* 2015;22:424.
- Gejo R, Akizuki S, Takizawa T. Fixation of the NexGen HA-TCP-coated cementless, screwless total knee arthroplasty: comparison with conventional cementless total knee arthroplasty of the same type. *J Arthroplasty* 2002;17(4):449.
- Dunne NJ, Orr JF. Influence of mixing techniques on the physical properties of bone cement. *Biomaterials* 2001;22(13):1819.
- Graham J, Pruitt L, Ries M, et al. Fracture and fatigue properties of acrylic bone cement; the effects of mixing method, sterilization technique, and molecular weight. *J Arthroplasty* 2000;15(8):1028.
- Lewis G, Mladsi S. Effect of sterilization method on properties of Palacos R acrylic bone cement. *Biomaterials* 1998;19:117.
- Rey Jr RM, Paiement GD, McGann WM, et al. A study of intrusion characteristics of low viscosity cement simplex-P and palacos cements in a bovine cancellous bone model. *Clin Orthop Relat Res* 1987;215:272.
- Jasty M, Davies JP, O'Connor DO, et al. Porosity of various preparations of acrylic bone cements. *Clin Orthop Relat Res* 1990;259:122.
- Foran JR, Whited BW, Sporer SM. Early aseptic loosening with a precoated low-profile tibial component. A case series. *J Arthroplasty* 2011;26(8):1445.
- Arsoy D, Pagnano MW, Lewallen DG, et al. Aseptic tibial debonding as a cause of early failure in a modern total knee arthroplasty design. *Clinorthoprelat Res* 2013;471:94.