Early Aseptic Loosening With a Precoated Low-Profile Tibial Component

A Case Series

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Abstract: Between March 2007 and December 2008, we performed 529 consecutive total knee arthroplasties in 460 patients with the Zimmer (Warsaw, IN) NexGen MIS Tibial Component using a minimally invasive approach. Eight knees in 8 patients (1.5%) were revised for early aseptic loosening of the tibial component despite normal initial postoperative radiographs. Several additional patients have concerning radiographic signs of pending failure. The mean time to revision was 17 months (range, 9-31 months). Intraoperatively, in all cases, more than 50% of the tibial tray was devoid of cement and factory-applied polymethylmethacrylate. Our experience with early aseptic loosening of this tibial component has led us to discontinue its use until the etiology of the high early failure rate is able to be determined. Keywords: total knee arthroplasty, aseptic loosening, minimally invasive, MIS Tibial Component, precoat.

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Minimally invasive total knee arthroplasty (TKA) has gained increasing popularity, with multiple studies reporting faster short-term recovery and improved pain relief in the early postoperative period [1-3]. Most minimally invasive methods rely on a modified surgical technique in which the majority of the procedure is performed with the knee in a relatively extended, as opposed to a hyperflexed, position. This consequently inhibits anterior translation of the tibia relative to the femur, necessitating implantation of the tibial component with the knee in extension. Implant manufacturers have developed specialized instruments and components to facilitate minimally invasive approaches to TKA. One such implant is the Zimmer (Warsaw, IN) NexGen MIS Tibial Component. This has been used by the senior author since 2005 and is designed to be used with the NexGen CR/CR-Flex and the NexGen LPS/LPS-Flex (Zimmer) knee systems. Its characteristics include a low-profile keel (<20 mm in length) and broad proximal fins designed to increase surface area and contact with the proximal tibial bone with the highest density, increasing resistance to bending moments, rotation, and liftoff. The all-titanium implant is also precoated with polymethylmethacrylate (PMMA) [4] (Fig. 1).

We have observed a concerning trend involving early failure from aseptic loosening of the NexGen MIS Tibial Component. This has occurred in several of our patients despite initial postoperative radiographs showing appropriate component sizing, position, and cement mantle. This case series serves to report these early failures while we continue to investigate this phenomenon in our patient population.

Materials and Methods

Between March 2007 and December 2008, the senior author performed 529 consecutive TKAs in 460 patients using the Zimmer NexGen MIS Tibial Component. All operations were performed using the NexGen knee system with cemented, modular, fixed-bearing, cruciate-retaining components and included the MIS Tibial Component. Surgery was performed under tourniquet for all subjects, using a 10-cm midline skin incision. The procedure was performed through a “minimally invasive approach” using either a subvastus or midvastus arthroscopy. The patella was subluxated laterally, and an intramedullary guide was used to cut the distal femur in 5° of valgus. The tibia was subluxated anteriorly, and the tibial plateau was cut perpendicular to its long axis using an intramedullary guide matching the patient’s anatomical...
posterior slope. The posterior cruciate ligament (PCL) and an accompanying bone block were preserved. The anterior and posterior condylar cuts along with the femoral chamfer cuts were then performed with the "4-in-1" cutting block. The patella was resurfaced in all knees. Immediately before cementing, the bony surfaces were cleaned with high-pressure, high-volume pulsatile lavage and then dried. Cement was then finger-packed to enhance cement penetration. Palacos (Zimmer) antibiotic-impregnated cement was used in all cases according to the Zimmer MIS Tibial Component cementing protocol[5]. Reinfusion drains were used in all knees.

From this cohort of 529 knees, we identified all patients who required revision of the tibial component for aseptic loosening. We reviewed the clinical, radiographic, and intraoperative findings during revision in each of these cases. Clinically, patients were evaluated for signs or symptoms of pain, instability, and infection. Radiographs from each patient’s initial postoperative clinical visit were assessed for alignment of the tibial and femoral components based on the Knee Society roentgenographic evaluation system[6]. In addition, the frontal and sagittal plane tibial alignment was measured in 412 well-functioning knees (without evidence of loosening) with available postoperative radiographs and was compared with the alignment in the failed group. Student t test was used to compare differences in mean alignment between the 2 groups.

The tibial and femoral components were divided into 7 zones, and interface lucencies were graded according to the method of Ewald[6]. Serial radiographs were evaluated for progressive interface lucencies and subsidence. During revision surgery, intraoperative inspection of the femoral and patellar components was performed to assess for evidence of loosening and wear; and the PCL was tested for competence. The proximal tibia was inspected for osteolysis, fracture, and remaining cement. The explanted tibial components were evaluated for structural damage, wear, and remaining cement. In all cases, absence of infection was determined with intraoperative synovial fluid cell count, synovial tissue frozen section, and aerobic and anaerobic bacterial cultures.

**Results**

**Clinical Results**

Eight knees in 8 patients (1.5%) of 529 TKAs were revised for early aseptic loosening of the tibial component. There were 5 women and 3 men. The mean age at index arthroplasty was 61 years (range, 56-73 years). The primary diagnosis was osteoarthritis in all cases. The mean time from index arthroplasty to revision was 17 months (range, 9-31 months). All patients had pain that was exacerbated by weight-bearing and that first presented at a mean follow-up of 11 months (range, 4-15 months). All patients had a pain-free interval after their index arthroplasty. Physical examination...
consistently revealed knee effusions, and 2 of the 8 patients had complaints of subjective knee instability.

**Radiographic Results**

Postoperative radiographs revealed femoral components to be in an average of 4.1° of valgus (range, 1.5°-6.4° of valgus) in the coronal plane and 0.2° of extension (range, 1.4° of flexion to 2.4° of extension) in the sagittal plane. This was similar to the femoral alignment in the well-functioning group. There was no difference in alignment of the tibial components in the group of failed knees and the group of well-functioning knees. Tibial components were in an average of 1.3° of varus (range, 0.7°-2.0° of varus) in the coronal plane in failed knees vs 0.77° of varus (range, 4.9° of varus to 5.1° of valgus) in well-functioning knees ($P = .95$). Posterior tibial slope averaged 7.2° (range, 1°-11.6°) in failed knees vs 6.8° (range, 1.9°-13.8°) in well-functioning knees ($P = .98$).

The lateral view of the femoral component was divided into 7 zones for evaluation of interface lucencies. No lucencies were observed around any of the femoral components. The tibial component was divided into 7 zones on the anteroposterior view and 3 zones on the lateral view. On the initial postoperative radiographs, no radiolucencies were identified around any tibial component. Radioluencies first appeared at a mean of 12 months (range, 3-26 months). Radioluencies appeared most commonly in zones 1 and 2 (corresponding to the medial and lateral aspects of the tibial plateau, respectively). Seven of 8 patients had lucencies in both of these zones. Five of 8 patients had radioluencies in zones 5 and 6 (corresponding to the area under the keel). On the lateral view, radioluencies were most commonly seen in zones 1 and 3 (corresponding to the area under the anterior lip and keel of the component, respectively) (Fig. 2). It is notable that many of the patients with radioluencies first noted along the medial and lateral plateau did not have pain at the time they were initially observed radiographically. However, with longer follow-up, patients developed pain with weight-bearing and effusions. Radiographs obtained when patients became symptomatic routinely demonstrated posterior subsidence of the tibial component (Fig. 3).

Result of intraoperative infection workup was negative in all cases. The mean synovial fluid white blood cell count was 1468 (range, 253-3700), with a mean of 12% polymorphonuclear cells (range, 2%-25%). Intraoperative frozen section of synovial tissue was negative for acute inflammation in all cases. In addition, intraoperative cultures were negative in all patients. The femoral

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**Fig. 3.** Thirteen-month postoperative radiographs of the same patient shown in Fig. 2. On the A/P view, there are subsidence and a continuous radiolucency around the entire prosthesis. On the lateral view, the prosthesis has subsided posteriorly. The patient began experiencing significant pain 2 months before these radiographs.

**Fig. 4.** (Left) Explanted tibial component. The medial half of the tibial tray is completely devoid of cement, whereas the cement on the lateral aspect of the tray remains well adherent. Note the complete absence of precoat PMMA. (Right) Another explanted tibial component. The medial aspect of the tibial tray, which was largely devoid of cement, also demonstrated complete absence of the factory-applied PMMA precoat. The arrow marks the only remaining area of precoat.
and patellar components remained well fixed in all knees, and there was no evidence of macroscopic polyethylene wear. In all cases, the tibial component was grossly loose; and the backside of the implant demonstrated that at least half of the tibial tray (usually medially) was devoid of cement (Fig. 4). The remaining cement on the tibial plateau remained well adherent. In all cases, the portion of the tibial tray devoid of cement also demonstrated complete absence of the factory-applied PMMA precoat (Fig. 4). Significant osteolysis was frequently observed along the posterior tibial plateau and in the footprint of the fins. The PCL remained intact and competent in all patients, and an isolated tibial revision with a stemmed component was successfully performed in all knees (Fig. 5).

**Discussion**

Aseptic tibial loosening was historically the most common cause of failure in early designs of semi-constrained cemented TKA [7-9], with rates of tibial loosening reported to be as high as 10% in short- to midterm follow-up. However, with advances in prosthetic design, instrumentation, surgical experience, and cementation techniques, the incidence of component loosening in stemmed designs has markedly decreased [10].

The published results of other tibial designs commonly used in minimally invasive TKA have also been encouraging. The cumulative rate of tibial aseptic loosening of Zimmer’s NexGen and Miller Galante I and II 4-pegged designs was only 2 (0.33%) of 612 [11-14] with medium- to long-term follow-up (Table 1). However, substantially higher (and earlier) rates of aseptic loosening have been reported for the NexGen MIS Tibial Component as well as a similarly designed tibial component manufactured by Smith and Nephew (Memphis, TN). The cumulative rate of tibial aseptic loosening in 2 recent studies was 30 (5.6%) of 533 with short-term follow-up (Table 1). In the current case series, the 1.5% rate of aseptic loosening was higher than that of the 4-pegged designs but lower than that reported by Weeden and Ogden [15] and Anderson and Anderson [16]. It is remarkable to note the early follow-up interval over which our failures occurred. In our series, the 8 revisions were performed at a mean of 17 months (range, 9-31 months). These revisions were preceded by signs of failure at a mean of 11 months (range, 4-15 months).

The cause of the early aseptic loosening observed in this series as well as the above series is uncertain, although several explanations may be offered. We emphasize that all proposed etiologies of these failures remain speculative and recognize the need to collect more data before definitive assertions of causation. One

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>No. of Knees</th>
<th>Knee Design</th>
<th>Mean F/U, y (Range)</th>
<th>Aseptic Loosening Rate</th>
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<tr>
<td>Barrington et al [11]</td>
<td>2009</td>
<td>87</td>
<td>Zimmer NexGen Precoat</td>
<td>11.1 (10-12)</td>
<td>1/87 (1.1%)</td>
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<td></td>
<td></td>
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<td>Pegged Tibial Plate</td>
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<td>Zimmer NexGen Precoat</td>
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<td></td>
<td></td>
<td></td>
<td>Pegged Tibial Plate</td>
<td>5.9 (5-7)</td>
<td>0/141 (0%)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Zimmer Pegged Tibial Plate</td>
<td>11 (8-15) MG I;</td>
<td>0/289 (0%)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>(MG I, MG II)</td>
<td>9 (8-10) MG II</td>
<td></td>
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<td></td>
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<td></td>
<td>Zimmer Pegged Tibial Plate</td>
<td>10.5 (8-13)</td>
<td>1/95 (1.1%)</td>
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<td></td>
<td></td>
<td>Plate (MG I, MG II)</td>
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<td>Berger et al [13]</td>
<td>2001</td>
<td>289</td>
<td>Zimmer NexGen MIS</td>
<td>2.6 (1.2-3.8)</td>
<td>21/403 (5.2%)</td>
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<td>Miller and Pettygrow [14]</td>
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<td>95</td>
<td>Tibial Component</td>
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<td>Weeden and Ogden [15]</td>
<td>2010</td>
<td>403</td>
<td>Zimmer NexGen MIS</td>
<td>2.6 (1.2-3.8)</td>
<td>21/403 (5.2%)</td>
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<td>130</td>
<td>Tibial Component</td>
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<td>Zimmer NexGen MIS Tibial</td>
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<td>Component + Smith and N/A</td>
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<td></td>
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<td>N/A;</td>
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<td>0.9 (0.6-1.25)</td>
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With medium- to long-term follow-up, there was a low rate of aseptic loosening in the 4-pegged design (unshaded rows). However, a marked increase in the rate of aseptic loosening was reported in the short-keeled design, even with short-term follow-up (shaded rows). F/U indicates follow-up; MG, Miller Galante; N/A, not available. Time to revision is shown.
possibility is that the minimally invasive surgical technique contributed to the loosening. With the technique used, the tibial component is sized and then cemented with the knee in extension because, with the small incision, it is difficult to fully translate the tibia anterior to the femur in the flexed position. As such, achieving full visualization of the posterior and lateral aspects of the tibia is more difficult than in more standard approaches. Nevertheless, we do feel that the exposure gained with the minimally invasive technique is adequate to ensure placement of an appropriately sized tibial tray that achieves circumferential cortical contact on the proximal tibia and allows for a complete and adequate cement mantle. Another possibility is that minimal incisions may lead to component malalignment, which may lead to early loosening. However, none of the failed tibial components in our series were placed in greater than 3° of varus; and none of the femoral components were malpositioned.

Poor cement technique may also have contributed to the failures in this series. All knees were cemented with Palacos R+G bone cement (Zimmer) according to manufacturer recommendations. This included vacuum mixing and finger packing of the tibial plateau including into the punched-out keel section. In all cases, sclerotic tibial bone was predrilled with a 2.5-mm drill for improved cement interdigitation. Of note, Zimmer released a memo in July 2009 detailing proper cement technique for the MIS Tibial Component. It emphasized that “cement must be applied within the tibial medullary canal as well [as] on the proximal tibial surface, under the tibial plate and around the keel [5].” Even before this directive, this type of cement technique was used in all of our knees.

It is possible that some factors inherent to Palacos cement may have contributed to the loosening, although this is speculative. We were unable to identify any literature demonstrating decreased fixation strength of Palacos cement in terms of adherence to a PMMA precoat or the bone interface as compared with other bone cements.

Another possibility could be unfavorable design features of the tibial component. Although the MIS tibial tray was thoroughly tested before market release and found to be equivalent to the traditional NexGen Stemmed Tibial Plate [4], these results may not be applicable when in vivo phenomena are considered. It is possible that the geometry of this component may lead to unfavorable stress shielding in vivo and weakening of the underlying bone, thereby increasing susceptibility to bone loss and osteolysis. Intraoperatively, there was significant osteolysis consistently present along the posterior tibial plateau and along the track of the fins. The significance of this pattern remains unclear.

Another variable that may influence fixation is the precoated PMMA surface. The rationale behind PMMA precoating is to enhance bonding of the cement-implant interface. Biomechanical studies have shown that precoated surfaces demonstrate improved adhesion and fatigue resistance in simulated conditions as compared with uncoated surfaces [17,18]. However, the clinical results of precoated femoral components in total hip arthroplasty have demonstrated inferior results in some designs [19-21]. Although we are aware of no literature describing the clinical outcomes of precoated tibial designs, one may speculate that implant design features may contribute to unexpectedly inferior clinical outcomes in knee arthroplasty components as well. Mann and Bhashyam [22] suggested that a precoated implant surface may be more susceptible to debonding under tensile loading. The intraoperative findings raise concerns about the cement-implant interface that warrant further investigation. In all cases, the tibial component was grossly loose; and the backside of the implant demonstrated that 50% of the tibial tray (usually medially) was void of cement, whereas the cement on the contralateral aspect of the tray remained well bonded (Fig. 4). The corresponding bone along the medial tibial plateau had well-fixed retained cement. In all cases, the medial aspect of the tibial tray, which was void of cement, also demonstrated complete loss of the factory-applied PMMA precoat (Fig. 4). It is unclear whether this pattern of retained cement and precoated PMMA loss was a consequence of the mode of failure (ie, shear forces on the loosening implant leading to secondary loss of precoat) or a primary failure and separation of the precoated surface.

We reiterate that the etiology of tibial loosening observed in these patients is uncertain. The senior author began using the MIS Tibial Component in...
August 2005. In fact, between August 2005 and March 2007—the period before which we noted a high rate of aseptic loosening—the senior author performed 274 TKAs using the MIS Tibial Component. Although we are aware of only one failure due to aseptic loosening during this period, the clinical follow-up during this interval is incomplete; and further data collection is ongoing. We are in the process of reviewing this cohort and calling patients back for follow-up. Given the limited scope of this case series, presently we can only assert that a concerning trend of early aseptic loosening of this implant has been observed. A more rigorous clinical and radiographic review is under way in an effort to more fully elucidate the true prevalence of this phenomenon as well as to shed light on possible causes. In the meantime, we have identified several additional concerning radiographs showing significant lucencies that are currently asymptomatic (Fig. 6). The significance of these radiographs is unclear; but given the observations of the failures in the current series, we are carefully monitoring these patients for progression.

Our experience with early aseptic loosening of the Zimmer MIS Tibial Component has led us to discontinue its use, and we recommend discontinued use of this product in primary TKA until the etiology of the high early failure rate of this implant is able to be determined. Prospective studies comparing the results of the Zimmer MIS Tibial Component using conventional and minimally invasive exposures as well as comparing fixation with different types of bone cement are warranted.

**References**