Case series report: Early cement–implant interface fixation failure in total knee replacement

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Abstract

Background: Early failure in cemented total knee replacement (TKR) due to aseptic loosening is uncommon. A small number of early failures requiring revision were observed at one hospital due to observed cement–implant fixation failure. The purpose of this case series is to report and identify possible causes for these early failures.

Methods: Between May 2005 and December 2010, 3048 primary TKRs were performed over a five-year period of time by six surgeons. Two total knee systems were used during this period of time. Nine early failures were observed in eight patients. High viscosity cement (HVC) was used in all these cases.

Results: Aseptic loosening of the tibial component was observed in all nine early total knee failures. The high viscosity bone cement was noted to be non-adherent to the tibial trays at the time of revision surgery. HVC was used in all these cases.

Conclusions: Properties of HVC may contribute to make it more susceptible to early failure in a small number of TKRs. HVC in total hip replacement (THR) has been associated with cement micro-fractures, cement debris generation and early implant failure. The mechanical properties of HVC may similarly contribute to early failure at the cement–implant interface in a small percentage TKRs.

Published by Elsevier B.V.

1. Introduction

Cemented total knee replacement (TKR) is reported as a reliable successful surgical procedure as measured by pain relief, functional improvement and patient satisfaction [1–4]. Based upon this success and a growing number of surgical candidates with advanced arthritis of the knee, numbers of TKRs are projected to grow to more than two million procedures each year during the next couple of decades [5]. As the number of primary TKRs being performed each year increases, so will the number of revision TKRs, projected to grow by 601% from 2005 to 2030 [6].

With this projected increase of revision TKR, analysis and reporting of all failed TKRs are important to better identify and understand the specific causes of failure with a goal of minimizing adverse surgical outcomes and reducing the number of patients requiring revision. In a study by Fehring et al. [7], early TKR failure was defined as the need for revision within five years of the index procedure. Among the different mechanisms of early TKR failure, aseptic loosening occurred in eight of 279 patients, all requiring early revision. The exact cause or causes of these early aseptic loosening failures was not reported. A recent study by Arsoy et al. [8] identified failure of 25 TKRs out of 1337 primary cemented TKRs (1.9%), secondary to tibial component cement–implant interface de-bonding. Each of the 25 failed TKRs was revised for loosening and secondary boney subsidence resulting in implant varus and flexion. Twenty-two of the 25 failed TKRs occurred despite proper initial implant alignment with no correlation with limb alignment, individual component alignment or patient BMI. The same tibial implant was used in all cases and the failure mechanism was not identified. The authors did discontinue the use of this implant. A previous case report and a case series report also identified early aseptic loosening of TKRs with observed fixation failure and de-bonding at the tibial implant–cement interface [9,10].

Variable intrinsic bone cement properties as well as extrinsic differences from varying cement preparation and application techniques are among many factors that effect the strength and stability of the bone–cement–implant construct. Polymerization of bone cement progresses through four phases of bone cement use: a mixing phase, a waiting phase, a working phase and a hardening phase. Several bone cement properties, including porosity, can affect the behavior of bone cement as it progresses through these phases of polymerization. Higher viscosity cement (HVC) has relatively shorter mixing and waiting phases and longer working and hardening phases in comparison to lower viscosity cements. These known characteristics, make HVC attractive for TKR but
also known and less attractive is the diminished bone penetration of HVCs [11]. The surgeon must be aware of these intrinsic and extrinsic properties unique to different cement types and resulting differences in construct strength and stability effecting clinical TKR outcomes.

This TKR case series reports nine early failures all requiring revision. All nine failures were secondary to aseptic loosening with implant–cement fixation failure and de-bonding at the tibial implant–cement interface. This mechanism of failure was observed infrequently during a five-year period at one high volume TKR hospital among six experienced TKR surgeons using two TKR implant systems and three types of bone cement. The common variable identified among all these early failures was the use of HVCs prepared with vacuum mixing.

2. Methods

Institutional review board (IRB) approval was obtained to review all TKRs performed at one hospital from May 2005 to December 2010. A total of 3048 consecutive primary TKRs were performed during this time period by six experienced TKR surgeons. Two total knee systems were used: Smith and Nephew Genesis/Legion and Depuy P.F.C. Sigma Rotating Platform. All these TKRs were implanted using HVCs. Smartset-HV (Depuy) was used almost exclusively with a small percentage of TKRs performed with Palacos-R (Zimmer) cement.

Eleven TKRs in 10 patients were identified with early aseptic loosening and failure requiring revision. All 11 had tibial implant–cement interface failure and de-bonding with secondary implant loosening. All 11 revised patients were contacted by telephone for inclusion in the study. Two patients declined to participate citing displeasure with their outcome as a reason for refusal to participate. This case series report analyzed the remaining nine TKR failures in eight patients. Seven failures occurred in patients with Depuy P.F.C. Sigma Rotating Platform TKR and two in patients with Smith and Nephew Genesis/Legion TKR. The tibial implants in both systems were roughened grit-blasted titanium surfaces for bone cement–implant fixation. The nine failures were implanted with three types of HVC: four with Smartset-HV; three with Smartset-HVC (Gentamicin) and two with Palacos-R.

All TKRs were performed with similar surgical techniques with a standard medial para-patellar exposure. All femoral cuts were anatomically based with 5°–6° of valgus with neutral flexion and rotation. All tibial cuts were also anatomically based perpendicular to the long tibial axis with 3°–5° of posterior slope and neutral rotation. All cases utilized similar HVC cement techniques. The HVC was brought into the OR with an OR temperatures less than 70° prior to beginning the TKR. In all cases the HVC was mixed prior to implantation with a vacuum cement mixing system. After mixing, soft HVC was independently applied evenly to dry implant surfaces and finger packed into dried open metaphyseal bone surfaces. The cement covered implants were then impacted into the cement covered bone surfaces until the implant rested at the level of the bone cut. Using the appropriate size trial polyethylene spacer, the freshly cemented TKRs were then positioned in full knee extension. The knee was kept in this position without knee motion until unused cement was hard and polymerized as tested by the surgeon.

All patients had a routine three-week post-op office visit with a standardized post-op evaluation including x-rays followed by three month and one year examinations. Serial examinations and x-rays were obtained as these patients reported unexpected symptoms to detect implant/cement/bone radiolucency and/or implant subsidence. All symptomatic patients were evaluated for deep surgical site infection with TKR joint fluid aspiration and analysis as well as blood studies including WBC with differential, ESR and CRP.

At the time of revision surgery intraoperative assessments included evaluation of TKR stability, polyethylene wear, implant structural damage, implant component loosening and cement mantle failure with or without cement debris. Cement–bone and cement–implant interfaces were inspected for evidence of de-bonding and secondary loosening of the tibial, femoral and patellar components. Seven of eight patients had negative cultures taken at the time of revision surgery.

3. Results

A total of 3048 primary TKRs were performed at one hospital by six surgeons from May 2005 to December 2010. Eleven of these TKRs were revised for early aseptic loosening of the tibial component (0.36%). All were observed to have de-bonding and loosening at the tibial implant–cement interface. Two patients declined participation in the IRB approved study, leaving nine TKRs in eight patients for analysis. Four were males and four were females. The body mass index (BMI) of these patients ranged from 27.3 to 43.7. All primary TKRs were performed for osteoarthritis. The mean age of these eight patients at the time of revision was 58.6 years (range 50–75 years). Table 1 is a summary of clinical and demographic data for each patient as well as the dates of the initial and revision surgeries.

Post-operative radiographs of the nine failed TKRs were evaluated to determine initial alignment of the femoral and tibial components. The femoral component was determined to be an average of 4.6° of valgus (range, 1.5° to 7.9°) and 0.8° flexion (range, 4.0° to 11.1° of extension). Tibial components were found to be an average of 0.08° of varus (range, 2.0° of varus to 1.3° of valgus) with an average of 3.8° of posterior slope (range, 1.8° to 7.3°). No outliers (>2° of varus/valgus) in knee alignment were identified among failed TKRs including standing full leg radiographs.

At the time of the index primary TKR, one patient developed erythema of the distal incision in initial post-operative period. Oral antibiotics were ordered but never taken by the patient and the erythema resolved spontaneously. There were no other post-operative wound complications.

All symptomatic patients presented similarly to the office or emergency room with a new onset of knee pain after an initial pain-free interval following their TKR surgery. This pain was perceived by the authors to be in excess of what is normally observed in the post-operative period. The average time between the index procedure and the onset of new knee pain was 23 months (range, 2–67 months). On physical examination each patient was noted to have a trace to moderate effusion prior to revision surgery. All had a range of motion from better than 10° of flexion to more than 120° of flexion. A review of serial radiographs taken post-operatively was performed on each failed TKR. Patients initially developed some relative radiolucency adjacent to the cement–bone interface in the proximal tibia, often without clear evidence of cement–implant radiolucency. As symptoms continued radiolucency at the cement–implant interface developed on average 26.8 months after surgery (range, 4 to 65 months). In two cases there was loosening and varus subsidence of the tibial implant. In eight of nine cases, knee pain preceded radiographic evidence of loosening with radiographic changes appearing on average 6.7 months after the onset of pain (range 1 to 22 months). In one failure there was subsidence of the tibial tray two months prior to the onset of pain. There were no radiographic signs of loosening observed of the femoral or patellar components in these patients. Fig. 1 is a standing AP of the bilateral knees of a patient taken two months prior to the onset of knee pain, which demonstrates osteopenia of the mediolateral tibial plateau and radiolucently at the lateral tibial implant–cement interface without gross implant failure. Twenty-two months after the onset of knee pain this patient developed tibial–cement implant interface failure. Fig. 2 is a standing AP of the bilateral lower extremities of the same patient, demonstrating appropriate AP alignment, taken four years after the index procedure and one month prior to revision.

All patients had a sterile TKR joint fluid aspiration performed prior to revision. Revision operative cultures were all negative among the eight of the nine cases cultured during the revision. All cultures were processed for five days. The average white blood cell count on aspirated fluid was 1434. The ESR and CRP were normal to slightly elevated in all cases. Intraoperative evaluation of the failed nine TKRs revealed gross loosening and fixation failure of the tibial implant–cement interface in all cases. In all cases there was observed nearly complete absence of cement adherence to the tibial tray at the time of implant removal. The cement–bone interface was observed to be intact except for the two cases in which there was tibial implant varus subsidence. Four of the nine failed TKRs had isolated loosening of tibial implant only at the time of revision surgery. The remaining five had additional loosening of either the femoral

### Table 1
Patient summary of demographic and clinical data.

<table>
<thead>
<tr>
<th>Case</th>
<th>Age (time of revision)</th>
<th>Sex</th>
<th>BMI</th>
<th>Laterality</th>
<th>Index procedure</th>
<th>Revision surgery</th>
<th>Time to revision (months)</th>
</tr>
</thead>
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<tr>
<td>1</td>
<td>59</td>
<td>M</td>
<td>29.6</td>
<td>Right</td>
<td>5/12/2005</td>
<td>8/27/2010</td>
<td>63</td>
</tr>
<tr>
<td>2</td>
<td>59</td>
<td>M</td>
<td>29.6</td>
<td>Left</td>
<td>5/12/2005</td>
<td>12/10/2010</td>
<td>70</td>
</tr>
<tr>
<td>3</td>
<td>75</td>
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<td>Right</td>
<td>2/28/2006</td>
<td>8/30/2010</td>
<td>54</td>
</tr>
<tr>
<td>4</td>
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<td>M</td>
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<td>Right</td>
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<td>2/26/2010</td>
<td>9</td>
</tr>
<tr>
<td>5</td>
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<td>Left</td>
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</tr>
<tr>
<td>6</td>
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<td>10/8/2008</td>
<td>3/17/2010</td>
<td>17</td>
</tr>
<tr>
<td>7</td>
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<td>F</td>
<td>43.6</td>
<td>Right</td>
<td>10/3/2006</td>
<td>6/24/2008</td>
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<tr>
<td>8</td>
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<td>Left</td>
<td>2/23/2009</td>
<td>2/20/2010</td>
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</tr>
</tbody>
</table>
implant, patellar implant, or both at the time of revision. In these cases, the patellar and femoral components were similarly found to be almost completely devoid of adherent cement. These observed findings were all consistent with failure of fixation or de-bonding at the cement–implant interface.

In none of these cases was significant polyethylene wear or debris found. Some synovitis and cement debris was observed. Fig. 3 is an intraoperative photo taken at the time of revision showing the lack of cement adherence to the tibial tray. Fig. 4 shows the intact cement at the proximal tibia.

Prior to May 2005 a lower viscosity cement, Simplex P (Stryker), had been used by the same surgeons using the same TKR implant systems. Since identification of this early cement–implant fixation failure mode in December 2010, the surgeons returned to the use of a lower viscosity cement, Simplex P (Stryker) in January 2011. Although a comprehensive review of these cases was not performed, no similar TKR failures at the cement–implant interface have been seen at this institution with the use of lower viscosity cement, Simplex P (Stryker) prior to or following the study period reported.

4. Discussion

Approximately three percent of primary TKRs require revision [5]. Infection and polyethylene wear are the most common historical causes for reported TKR failure [5,12]. Early TKR failure has been defined as failure within two to five years of the index procedure [7,12]. Historically, aseptic tibial implant loosening at the bone–cement interface was an observed cause of failure with semiconstrained TKR implant designs [13]. Modes of early failure in a more recent series of 279 TKRs identified infection, instability, patellofemoral complications, polyethylene wear with secondary osteolysis and aseptic loosening as most frequent causes of failure [7]. Of those mechanisms, aseptic loosening was the least common cause (three percent). The causes of early aseptic loosening were not discussed.

A case report by Cheng et al., described early aseptic loosening of the tibial component after TKR with observed de-bonding between the tibial component and cement mantle and an intact cement–bone interface [9]. The cemented surface of the tibial baseplate had abrasive markings consistent with rotation at the cement–implant interface. The femoral component was not loose at the time of revision, but some small osteolytic defects of the femoral cement mantle were observed. The authors concluded that metal and polymethyl–methacrylate (PMMA) debris was produced from de-bonding of the tibial cement–implant interface leading to some observed focal osteolysis. The type of cement used in this case was not reported.

A more recent single surgeon case series reported early failure in eight TKRs with an observed similar tibial implant–cement fixation failure mechanism [10]. The mean time to revision among 529 single system (Zimmer, Next Gen) TKRs was 17 months. Palacos–R + G (HVC) cement was used for implant fixation in all cases. At the time of revision in all cases minimal polyethylene wear was found and the femoral and patellar implants remained well fixed. The tibial implant in each case was grossly loose and at least 50% of the tibia implant surface was devoid of adherent cement. The authors proposed several possible causes for these early aseptic failures including: minimally invasive surgical technique, poor cementing technique, tibial implant design deficiency and fixation failure of the precoated PMMA tibial implant surface. In addition the authors speculated that “factors inherent to Palacos (HVC) cement may have contributed to the loosening.”

This series reports aseptic failure of nine TKRs with failure mechanism identical to the above case series. In all cases, there was fixation failure at the cement–implant interface with an intact cement–bone interface in all cases in which there was no tibial implant subsidence. This mode of aseptic loosening and failure in this large consecutive series was not frequent – 11/3048 (0.36%) – but presented similarly in all cases. The exact cause for the fixation failure or de-bonding at the cement–implant interface is not known but HVC prepared with vacuum mixing is a common variable identified in this series. Unique properties
Several total hip replacement (THR) studies report adverse effects of cement viscosity on the cement–bone interface increasing implant fixation failures in THR. A biomechanical study evaluated push-out strength of implanted femoral components using different cement types. Femoral components cemented with low-viscosity cement required a greater force to dislodge the prosthesis [14]. Low-viscosity cement had increased depth of cement penetration as compared to high-viscosity cement. A cadaveric femur study found better bone penetration and a greater cement implant interface shear-strength with low-viscosity cement as compared to high-viscosity cement [15]. Varying effects of cement viscosities on stability of the Exeter femoral implant have been evaluated by measured component subsidence [16]. No statistically significant differences in subsidence of the femoral component were observed in 41 cemented THRs using low-viscosity or high-viscosity cement. However, two acetabular components in the high-viscosity group had to be revised due to aseptic loosening.

Less has been published regarding effects of lower versus higher viscosity cements in TKR. A study of 79 TKRs in 72 patients compared the penetration depth of medium vs. higher viscosity cement as measured on post-operative radiographs [17]. Cement penetration depth in the tibial plateau was significantly decreased with the use of the higher viscosity cement. The authors speculated that the differences in cement penetration could compromise long-term bone implant fixation and lead to higher failure rates with higher viscosity cements.

Several intrinsic and extrinsic cement factors affect the mechanical properties of PMMA bone cement including: cement mixing techniques, cement storage and mixing temperatures, ambient room and tissue temperature, cement molecular weights and cement sterilization methods [18,19]. Some sterilization techniques can lead to a reduction in molecular weight which decreases cement fracture toughness [20]. Higher viscosity cements have been associated with cement microfractures generating cement debris causing local bone osteolysis [21,22]. An inverse relationship between cement porosity and fracture toughness was demonstrated in one biomechanical study [23].

TKR implant aseptic loosening can be caused by imbalanced implant loading and liftoff during implant insertion and/or cement curing. Aseptic loosening of the tibial implant has also been seen with eccentric and increased implant loading from implant malalignment, most frequently varus tibial implant alignment [24]. The tibial implant is primarily subjected to compressive physiological loads, but shear and torsional forces are also present [25]. PMMA bone cement is quite strong in compression, but weaker when subjected to shear and tensile forces [26]. Tibial implant–cement surface geometry and textures vary significantly among different TKR systems and these differences may affect cement–implant interface construct strength. Even with appropriate axial alignment, failure at the cement–implant interface could occur with excessive shear and tensile forces in conditions weakening the cement–implant interface. Potentially, the greater propensity for higher-viscosity cement to develop microfractures could contribute to crack propagation and debonding at the cement–implant interface when subjected to shear and tensile forces.

There are several weakness of this early TKR failure case series report. This report is a retrospective review of symptomatic failed TKRs performed by several surgeons and surgical teams. Although the series is reported as a consecutive series, not all TKR patients during this time period were contacted. As a result, the actual number of failures due to aseptic loosening could be higher than reported in this series. No actual biomechanical testing of the retrieved implants or cement was performed to better understand the observed mechanism of failure. The unfavorable characteristics of HVC in this TKR case series have not been observed in registries or other larger clinical case series. The safety and efficacy of HVC prepared with vacuum mixing could better be studied through randomized prospective trial or laboratory studies assessing cement–implant strength in differing conditions and implant systems. The rotational alignment of the failed implants was not assessed other than rotational component alignment appearance at the time of revision surgery. Improper rotational malalignment could contribute to aseptic loosening secondary to increased resultant shear forces, however this has not been reported as associated with cement–implant failure in previous reports.

There are some strengths of this case series failure report. The failures were infrequent but occurred proportionally between several surgeons, surgical teams, TKR implant systems at one hospital using similar surgical techniques, OR conditions, nursing practices and OR/storage environments. This minimizes the potential impact of these variables and increases the significance of the identified common variable: use of HVC prepared with vacuum mixing.

5. Conclusion

This case series report describes an uncommon cause of TKR failure secondary to aseptic loosening due to cement–implant interface failure.
and de-bonding. The report is consistent with three previous reports of early TKR failure due to cement–implant fixation failure. The exact cause of failure described in this consecutive series as well as the previous failure reports remains unknown. Identified in this series of TKR cement–implant interface failures is a common variable; use of HVC prepared with vacuum mixing.

Conflict of interest

None of the authors received payments or services in support of this work. No author has any other relationships or other potential conflict of interest that has influenced what is written in this work.

Acknowledgements

The authors would like to thank Janet Beck for her assistance in the preparation of the IRB application.

References