Relationship between cement penetration and incidence of a radiolucent line around the tibia 2 years after total knee arthroplasty: A retrospective study

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ABSTRACT

Objectives: Cement penetration (CP) plays a key role in implant stability for cemented total knee arthroplasty (TKA), and the radiolucent line (RLL) >2 mm is a preliminary sign for loosening of components. However, the direct relationship between CP and the frequency of RLL >2 mm is unclear, and the best cut-off value for CP to prevent RLL >2 mm also remains unclear. This study aimed to investigate this relationship between CP and RLL and to determine the clinical cut-off value for tibial CP in patients 2 years after TKA.

Methods: This retrospective study investigated 157 knees from 123 patients with osteoarthritis who underwent cemented TKA. The CP and RLL immediately after TKA and the RLL 2 years after TKA were measured for the medial, lateral, anterior, and posterior tibial baseplate zones. Receiver operating characteristic (ROC) curves were constructed to determine the best cut-off values for CP.

Results: RLL >2 mm was not observed just after TKA. An RLL >2 mm was observed in any tibial baseplate zone in 22 knees from 20 patients (RLL + group) and was not observed in the remaining (RLL − group) 2 years after TKA. The mean CP for all zones was significantly higher in the RLL − group (2.5 ± 1.1 mm) than in the RLL + group (1.7 ± 0.6 mm; P < 0.001). An RLL >2 mm was seen in 21 knees in the medial zone, 9 knees in the lateral zone, 8 knees in the anterior zone, and 3 knees in the posterior zone. CP values with RLL >2 mm were significantly lower than those without the RLL at the medial, anterior, and posterior tibial baseplate zones. The best cut-off values from the ROC curve of CP in each zone were between 1.1 mm and 2.1 mm.

Conclusions: The depth of the CP directly affects the incidence of an RLL >2 mm. The best cut-off value for tibial CP to prevent an RLL >2 mm is 2.1 mm.

What are the new findings?

- The depth of the cement penetration (CP) directly affects the incidence of tibial radiolucent line (RLL) >2 mm.
- CPs with an RLL >2 mm were significantly lower than those without the RLL at the medial, anterior, and posterior tibial baseplate zones.
- The best cut-off value for tibial CP to prevent RLL >2 mm is 2.1 mm.

Abbreviations: OA, osteoarthritis; TKA, total knee arthroplasty; RLL, radiolucent line; CP, cement penetration; CO2, carbon dioxide; ROM, range of motion; BMD, bone mineral density; BMI, body mass index; Hb, hemoglobin; KS, Knee Society; AP, anteroposterior; FTA, femorotibial angle; ROC, receiver operating characteristic; ICCs, intraclass correlation coefficients; THA, total hip arthroplasty.

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BACKGROUND

Total knee arthroplasty (TKA) is a very effective surgical option for advanced knee osteoarthritis (OA) [1], but problems with implant durability remain. The revision rate for TKA has been reported to be about 12% [2], with aseptic loosening identified as the most common cause of revision (21.8%) [3]. However, risk factors for aseptic loosening of TKA are not well known, with age, sex, osteoporosis, diabetes, and tibial extension stem use reported as influential factors [4–6].

A radiolucent line (RLL) >2 mm around implants has been reported as a valuable sign for a preliminary diagnosis of aseptic loosening [7]. In addition to reducing aseptic loosening, reducing the incidence of RLL is thus thought to be critical for successful clinical outcomes after TKA. One cause of aseptic loosening of a prosthesis in cemented TKA involves the interplay of debris at the bone–cement interface and low cement penetration (CP) [8]. Previous studies have reported that pressurized carbon dioxide (CO2) lavage could remove debris, improve CP, and reduce the incidence of RLL >2 mm at 2 years after TKA [9,10]. However, the association between CP and the frequency of RLL >2 mm in each zone around the tibial component remains unconfirmed. The best cut-off value for CP to prevent RLL >2 mm remains unclear.

The present study aimed to investigate the association between CP and the incidence of RLL >2 mm around the tibial baseplate and the clinical cut-off value for CP in patients 2 years after TKA. We hypothesized that there is a negative association between CP and the frequency of tibial RLL >2 mm and that there will be a statistically significant cut-off value for CP to prevent RLL >2 mm.

MATERIALS AND METHODS

Subjects

In this retrospective observational cohort study, the 273 knee joints in 212 consecutive patients (51 men, 161 women) with knee OA who underwent cemented TKA at our hospital between April 2015 and December 2020 were initially considered eligible for inclusion in the study. Exclusion criteria comprised use of implants other than Persona (Zimmer Biomet, Warsaw, IN, USA) (99 knees in 73 patients), femur fracture (1 femoral neck fracture, 2 femoral shaft fracture) during follow-up (3 knees in 3 patients), or follow-up of <2 years (14 knees in 13 patients). As a result, 157 knees from 123 patients were enrolled in this study. The study protocol was approved by our institutional review board (no. S-16-55).

Surgical procedures

All TKAs were performed under general anesthesia with tourniquet use, using a measured resection technique aiming at neutral alignment of the knee. The medial parapatellar approach was used. Distal femoral cutting was performed at a valgus angle of 6–7° using an intramedullary alignment guide. Rotation of the femoral component comprised 3–5° of external rotation from the posterior condylar axis, aiming at the surgical epicondylar axis. Proximal tibial cutting was performed with an extramedullary guide. Rotation of the tibial component was indexed to the Akagi line [11]. For patellar resurfacing, the thickness of bone resection was taken as the thickness of the patellar component to be placed. The patellar component was mediialized on the patellar resected surface, and the component with the largest diameter covering the whole medial aspect of the patella was selected. After placing the trial implant on the patella, lateral patellar facetectomy was performed using a bone saw for the lateral aspect of the patella, which was not covered by the implant [12]. All components were fixed with bone cement. Cementing was performed according to the previous report [8]. The pulsed lavage was applied to remove debris as far as possible before cementing the components [13]. Additionally, pressurized CO2 lavage (CarboJet, Kinamed, CA, USA) was used to remove debris for about 1 min just before cementing for the 138 TKAs after September 2016 [10]. Both the tibia and femur were cemented together without tibial drilling using 40 g of polymethylmethacrylate antibiotic-free cement. In tibia, full cementation both under the tibial baseplate and around the stem was conducted. The cementing time was about 5 min, and the cement-setting time was about 10 min. Although stemmed baseplates were typically used in this study, in the case of tibia extension stem use, 30-mm extension stemmed baseplates were used in 40 TKAs. A closed-suction drain was installed in the knee and retained for 24 hr in all cases. The operation was performed by 2 experienced surgeons.

Postoperative care

Full-weight-bearing walking and range-of-motion (ROM) exercises were started the day after surgery in accordance with pain tolerance. Postoperative osteoporosis treatment was conducted in 24 knees of 21 patients for 2 years (bisphosphonate 11 patients; alfalcacidol 8 patients; denosumab 1 patient; teriparatide 1 patient). Patients treated for osteoporosis included those who were originally undergoing treatment for osteoporosis and those who underwent osteoporosis screening during preoperative examinations, initiating treatment with the bone mineral density (BMD) <70% at the femoral neck or lumbar vertebrae.

Demographics and clinical evaluations

Preoperative medical records were reviewed to obtain information, including age, sex, body mass index (BMI), hemoglobin A1c, ROM of the affected knee, and Knee Society (KS) Knee Score and Function Score [14]. At 2 years after TKA, ROM of the knee and KS Knee Score and Function Score were examined. Postoperative complications that required additional surgery, such as infection, were also investigated.

Radiological evaluations

For all patients, standardized anteroposterior (AP), lateral, Merchant, and standing whole-leg AP radiographs of the knee were taken before surgery, and the AP, lateral, and Merchant radiographs were retaken at 1, 3, 6, and 12 months postoperatively and then annually thereafter. Radiographs before surgery, just after surgery, and at 2 years after surgery were evaluated in this study. The femorotibial angle (FTA) was measured before surgery and 2 years after surgery. KS radiographic evaluations measured just after surgery included α, β, γ, and Φ [15]. The coronal alignment of the femoral component (α) was measured as the angle between the distal femoral component surface and the femoral shaft axis in the AP radiographs. Similarly, the coronal alignment of the tibial component (β) was measured as the angle between the baseplate and the tibial mechanical axis in the AP radiographs. The sagittal alignment of the femoral component (γ) was measured as the angle between the most distal femoral component surface and the femoral shaft axis in the lateral radiographs. Likewise, the sagittal alignment of the tibial component (Φ) was measured as the angle between the baseplate and the tibial mechanical axis in the lateral radiographs [15].

CP of the tibia was measured just after TKA and RLL of the tibia were measured just after and 2 years after TKA. The definition and the measurement method were the same as in previous reports [10,13,16]. The depth of the CP was defined in this study as the maximum depth of the CP for each of the medial, lateral, anterior, and posterior baseplate zones of the tibial component, as defined by the KS Radiographic Evaluation System [15]. Among them, the maximum values adopted as the CP of the case (Fig. 1). The RLL was also measured for each of the medial, lateral, anterior, and posterior tibial baseplate zones, with the maximum values adopted as the RLL of the case (Fig. 1). Measurements were collected on digital radiographs using a digital ruler calibrated to the thickness of each tibial baseplate (7 mm), which was identical for all sizes of this particular implant. These radiological measurements were conducted independently by two orthopaedic surgeons (RS and MN), with experience of 10.
and 23 years, respectively. The measuring results shown in this study were basically those of RS.

**Statistical analysis**

Patients were divided into two groups according to the presence (RLL+ group) or absence (RLL− group) of RLL >2 mm at 2 years after TKA. Descriptive analyses included reporting means and standard deviations for continuous variables and frequencies and percentages for discrete variables. First, categorical variables were compared between groups using the chi-squared test, whereas continuous variables were compared using independent samples t-tests or the Mann–Whitney U test as appropriate after confirming normality by the Shapiro–Wilk test. Second, mean CPs for all tibial baseplate zones were compared between groups. In each tibial baseplate zone, mean CP with and without RLL >2 mm were compared. Third, receiver operating characteristic (ROC) curves were constructed to determine the best cut-off values for CP at each tibial baseplate zone. The sensitivity and specificity of CP were calculated using the standard method of proportions. The reliabilities of CP and RLL measurements were assessed using intraclass correlation coefficients (ICCs). Two investigators (RS and MN) interpreted the same radiographs of 20 randomly selected patients twice at 2-month intervals. ICCs for inter-observer and intra-observer reliabilities were 0.89 and 0.87, respectively. Factors that achieved a value of P < 0.05 were considered statistically significant. A power analysis was performed to calculate the power for the study with a probability of 0.05. All analyses were performed using SPSS version 27.0 (IBM Corp., Armonk, NY, USA).

**RESULTS**

At just after TKA, there were no cases with RLL >2 mm. At 1 year after TKA, RLL >2 mm was observed in any tibial baseplate zone in 9 knees from 9 patients. At 2 years after TKA, RLL >2 mm was observed in any tibial baseplate zone in 22 knees from 20 patients (RLL+ group) and was not observed in the remaining 135 knees from 103 patients (RLL− group). Nine knees with RLL >2 mm at 1 year still exhibited RLL >2 mm at 2 years after TKA. The patient demographics of both groups are shown in Table 1. Preoperative clinical and radiological factors did not differ significantly between groups (Table 1). Tibial extension stem use did not differ significantly between RLL− group (44 knees; 32.6%) and RLL+ group (3 knees; 13.6%). Radiological evaluations just after TKA did not differ significantly between groups (Table 1).

At 2 years after TKA, clinical and radiological evaluations did not differ significantly between groups. The mean knee extension angle in the RLL− group and RLL+ group were −0.6 ± 1.9° and −0.2 ± 1.1°, respectively, and mean knee flexion angles were 119.9 ± 6.1° and 119.8 ± 5.1°, respectively. The mean KS knee scores in the RLL− group and RLL+ group were 92.0 ± 2.0 and 90.7 ± 5.1, respectively, and mean KS

**Table 1**

<table>
<thead>
<tr>
<th>Variables</th>
<th>RLL− group (135 knees)</th>
<th>RLL+ group (22 knees)</th>
<th>P value</th>
<th>Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>73.7 ± 7.4</td>
<td>72.4 ± 8.0</td>
<td>0.48</td>
<td>0.11</td>
</tr>
<tr>
<td>Sex (female) (n)</td>
<td>103 (76.3%)</td>
<td>20 (90.9%)</td>
<td>0.12</td>
<td>0.26</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>25.7 ± 9.9</td>
<td>24.1 ± 4.5</td>
<td>0.08</td>
<td>0.33</td>
</tr>
<tr>
<td>FTA (°)</td>
<td>182.6 ± 9.5</td>
<td>184.0 ± 10.5</td>
<td>0.20</td>
<td>0.09</td>
</tr>
<tr>
<td>Extension (°)</td>
<td>−8.0 ± 6.1</td>
<td>−7.7 ± 9.2</td>
<td>0.18</td>
<td>0.05</td>
</tr>
<tr>
<td>Flexion (°)</td>
<td>119.9 ± 14.5</td>
<td>121.4 ± 13.8</td>
<td>0.95</td>
<td>0.07</td>
</tr>
<tr>
<td>KS knee score (points)</td>
<td>34.4 ± 17.5</td>
<td>30.7 ± 17.8</td>
<td>0.18</td>
<td>0.14</td>
</tr>
<tr>
<td>KS function score (points)</td>
<td>39.9 ± 9.5</td>
<td>42.6 ± 12.2</td>
<td>0.24</td>
<td>0.16</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>5.9 ± 0.5</td>
<td>5.9 ± 0.4</td>
<td>0.25</td>
<td>0.05</td>
</tr>
<tr>
<td>Osteoporosis treatment (n)</td>
<td>20 (14.8%)</td>
<td>4 (18.2%)</td>
<td>0.70</td>
<td>0.09</td>
</tr>
<tr>
<td>Implant alignment (°)</td>
<td>α 95.3 ± 2.0</td>
<td>95.8 ± 1.3</td>
<td>0.33</td>
<td>0.32</td>
</tr>
<tr>
<td>immediately after TKA</td>
<td>β 88.8 ± 1.2</td>
<td>88.3 ± 1.5</td>
<td>0.82</td>
<td>0.30</td>
</tr>
<tr>
<td></td>
<td>γ 2.2 ± 1.5</td>
<td>2.8 ± 1.7</td>
<td>0.31</td>
<td>0.32</td>
</tr>
<tr>
<td></td>
<td>δ 84.1 ± 2.0</td>
<td>83.1 ± 2.3</td>
<td>0.08</td>
<td>0.49</td>
</tr>
</tbody>
</table>

TKA = total knee arthroplasty; BMI = body mass index; FTA = femorotibial angle; KS = Knee Society; HbA1c = hemoglobin A1c.
The present results supported the hypothesis that there is a negative association between CP and the frequency of tibial RLL >2 mm. In each individual zone investigation, RLL >2 mm was most frequently observed in the medial zone, and CPs with the RLL were significantly lower than those without the RLL at the medial, anterior, and posterior tibial baseplate zones. The best cut-off values for CP to prevent RLL >2 mm in each tibial baseplate zone were from 1.1 mm to 2.1 mm.

Although RLL at the bone–implant interface of 1 mm on radiographs usually develops in the first year after surgery and does not progress over the longer term [13], an RLL >2 mm has been reported as a valuable sign for preliminary diagnosis of implant loosening [7,16]. It was reported that there was a positive correlation between the presence of RLL >2 mm and the risk of revision TKA [16]. In addition, it was reported that increasing percent involvement of RLL was associated with failure of TKA on multivariable analysis [17].

Several factors for aseptic loosening after TKA have been reported, including young age, male sex, obesity, diabetes, no tibial extension stem use, and osteoporosis [4,6,18]. A large cohort study reported that the risk of revision TKA and total hip arthroplasty (THA) at >70 years age was about 5% and did not differ between males and females, but for patients undergoing surgery at <70 years age, the risk of revision was higher for younger patients and for male patients [19]. Obesity (BMI >30 kg/m²) was indicated to cause aseptic loosening in THA [18], but few papers...
have identified obesity as a risk factor for aseptic loosening in TKA. A systematic review of 21 studies also found that obesity was not a risk factor for aseptic loosening in TKA [20]. A retrospective study of TKA and THA reported that diabetes was not associated with increased risk of aseptic loosening, whereas perioperative hyperglycemia was one [5]. The type of tibial baseplate was also an influential factor in aseptic loosening, and Robertsson et al. reported that a four-pegged tibial baseplate increased the risk of loosening more than a stemmed baseplate [6]. In the present study, although four-pegged tibial baseplates were not used, stemmed and extension stemmed tibial baseplates were used. While tibial extension stem use was reported as an influential factor for aseptic loosening [21], no significant relationships between stem types and development of RLL >2 mm were identified in this study.

Previous studies have highlighted that CP plays a key role in implant stability after TKA [22,23]. An in vitro study compared TKAs between 3-mm and 1-mm CP groups and observed implant instability in the 1-mm CP group but not in the 3-mm CP group [24]. Walker et al. evaluated a correlation between RLL and initial CP by follow-up radiographs of 44 TKAs and performed laboratory studies, suggesting that the ideal depth of CP was 3–4 mm. However, few reports have evaluated the relationship between CP and RLL incidence for each tibial baseplate zone and analyzed the ideal depth of CP for each tibial baseplate zone based on clinical analysis. The present findings suggest that the ideal depth of CP was >2.1 mm for preventing RLL >2 mm, and we should strive to increase CP, particularly in the medial zone, with frequent medial osteosclerosis in varus knee OA.

To increase CP, pulsed lavage, pressurized CO2 lavage, tourniquet use, and the modern cement technique are reportedly effective [8–10]. The depth of CP directly affects the incidence of RLL >2 mm. The best cut-off values for CP to prevent RLL >2 mm in each tibial baseplate zone appear to be between 1.1 mm and 2.1 mm. It is recommended to achieve tibial CP of >2.1 mm in cemented TKA.

CONCLUSIONS

The depth of CP directly affects the incidence of RLL >2 mm. The best cut-off values for CP to prevent RLL >2 mm in each tibial baseplate zone appear to be between 1.1 mm and 2.1 mm. It is recommended to achieve tibial CP of >2.1 mm in cemented TKA.

Ethics approval and consent to participate

Approval for conduct and publication of this study, including all accompanying images, was obtained from the institutional review board of International University of Health and Welfare (approval no. 5-16-55). Informed consent was waived by the ethics committee of International University of Health and Welfare.

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Authors’ contributions

RS and MN conceived and designed the study. RS, MN, KT, and KT wrote the paper. RS and MN performed the surgery. All authors edited and approved the manuscript prior to submission.

Consent for publication

Not Applicable.

Availability of data and material

The datasets for the present study are available from the corresponding author upon reasonable request.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.
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Not applicable.

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