

Early aseptic loosening of a mobile-bearing total knee replacement

A case-control study with retrieval analyses

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Background and purpose — Registry-based studies have reported an increased risk of aseptic tibial loosening for the cemented Low Contact Stress (LCS) total knee replacement compared with other cemented designs; however, the reasons for this have not been established. We made a retrieval analysis with the aim of identifying the failure mechanism.

Patients and methods — We collected implants, cement, tissue, blood, and radiographs from 32 failed LCS Complete cases. Damage to the tibial baseplate and insert was assessed. Exposure to wear products was quantified in 11 cases through analysis of periprosthetic tissue and blood. Implant alignment and bone cement thickness was compared with a control group of 43 non-revised cases.

Results — Loosening of the tibial baseplate was the reason for revision in 25 retrievals, occurring at the implant–cement interface in 16 cases. Polishing was observed on the lower surface of the baseplate and correlated to the level of cobalt, chromium, and zirconium in the blood. No evidence of abnormally high polyethylene wear was present. For each 1 mm increase in cement thickness the odds of failure due to aseptic loosening decreased by 61%. Greater varus alignment was associated with a shorter time to failure. The roughness, Ra, of a new LCS baseplate's lower surface was 3.7 (SD 0.7) μm .

Interpretation — Debonding of the tibial component at the implant–cement interface was the predominant cause of tibial aseptic loosening. A thin cement layer may partly explain the poor performance. Furthermore, the comparatively low tibial surface roughness and the lack of a keeled stem may have played a role in the failures observed.

Aseptic loosening of the tibial component following total knee replacement (TKR) is the leading cause of revision (Gøthesen et al. 2013). Higher risk of revision for aseptic loosening has been reported for mobile-bearing TKRs than fixed bearing designs in recent registry-based studies (Graves et al. 2011, Namba et al. 2012, Gøthesen et al. 2013, Namba et al. 2014). In Norway, the cemented Low-Contact Stress (LCS) mobile-bearing implant (DePuy Synthes, Warsaw, IN, USA) has a 7-fold greater risk of aseptic loosening in primary arthroplasty compared with the best performing designs (Gøthesen et al. 2013). Higher aseptic loosening rates of the LCS were also shown in the US by independent register data (Paxton et al. 2011, Namba et al. 2012). Differences in undersurface texture, non-posterior-stabilized tibial inserts and flexion first gap-balancing technique have been put forward as potential explanations for the observed differences in outcome (Namba et al. 2012, Gøthesen et al. 2013, Namba et al. 2014).

We started a retrieval collection program with the aim to identify the mechanisms involved in early aseptic loosening of the cemented LCS. Retrieval cases were reviewed for evidence of failure mechanisms previously linked to aseptic loosening, including: wear particle exposure; implant alignment; cement mantle thickness; resurfacing the patella; and implant design.

Patients and methods

32 failed cemented LCS Complete implants were retrieved in 7 Norwegian hospitals from patients who underwent a TKR between 2004 and 2013. Cases with implant infection were

Table 1. Patient demographics

Factor	Retrieval group n = 32	Control group n = 43
Sex (female/male), n	20/12	27/16
Age (years) ^a	67 (40–80)	70 (47–81)
BMI ^a	28 (21–43)	29 (21–49)
Time to revision/follow-up period for control group (months) ^a	36 (8–97)	101 (66–118)
Available radiographs, n	29 ^b	43 ^c
Available periprosthetic blood and tissue samples, n	11	0
Available retrievals, n	32	0

^a median (range)
^b early postoperative and pre-revision; ^c early postoperative only

not included. Patients were linked with records from the Norwegian Arthroplasty Registry to check data quality and to access additional data (Ellison et al. 2012).

43 unrevised cemented LCS Complete cases were identified from a prior study (Lygre et al. 2010). Only cases without revision at 5 years and available radiographs were included. This cohort acted as a control group with which radiographic variables were compared. Retrieval and control groups were similar with regard to sex and BMI (Table 1).

All tibial baseplates were cemented and had a ribbed (non-keeled) stem (catalogue number: 1294-31-1x). All but 3 femoral components were cemented. All implants had a rotating platform with a non-posterior stabilized mobile bearing insert and the posterior cruciate ligament being sacrificed (catalogue number: 1294-05-x). Femoral and tibial baseplates were manufactured from a cobalt-chromium alloy. Tibial inserts were manufactured from GUR 1020 ultra-high molecular weight polyethylene (PE). In all cases Palacos bone cement, or its equivalent, was used (Hallan et al. 2012).

Radiographs

Implant alignment was assessed as recommended by the Knee Society (Ewald 1989) (Figure 1A). Radiographs were short-leg, taken postoperatively (median: 15 days (1 day–5 years)) in anteroposterior (AP) and lateral views. Tibial component alignment was considered to be neutral, varus, or valgus for β angles of 87–93°, < 87°, or > 93°, respectively. Tibiofemoral alignment ($\alpha+\beta$) was rated to be neutral, varus, or valgus for angles of 184–190°, < 184°, or > 190°, respectively. For all measurements, the mid-shaft of the bone was used to define the anatomical axis of femur or tibia.

Bone cement thickness under the tibial component was assessed on postoperative AP radiographs. Maximum thickness was measured in zones 1–4 (Figure 1B) and the average calculated. Cementing technique was recorded, being categorized as surface only or full cementation. Surface-only cementation was classified when cement was observed on the horizontal cut surface only, full cementation when cement was

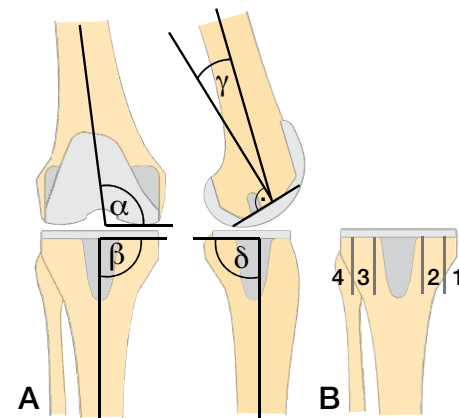


Figure 1. Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System. (A) Alignment angles of the tibial and femoral component in the frontal and sagittal plane. (B) Zones 1–4 under the tibial tray for assessment of cement thickness and radiolucent lines.

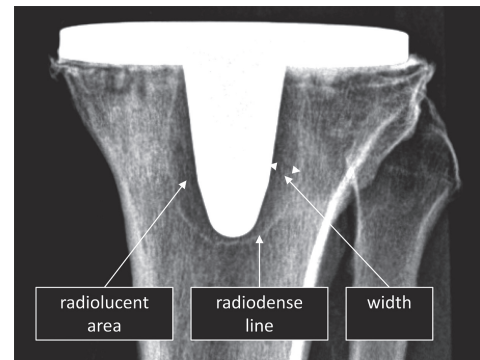


Figure 2. A 78-year-old male patient with a typical radiolucent area around the tibial stem 3 years postoperatively.

observed around the central peg additional to the horizontal cut surface.

Pre-revision (median: 3 (0–12) months) AP radiographs were inspected for radiolucent lines (RLL) beneath the plateau. Presence of RLL was recorded at the cement–bone and cement–implant interfaces. The maximum widths of RLL on the lateral and medial sides of the stem were measured perpendicular to the stem's surface and the average calculated (Figure 2).

Implant analysis

The upper and lower surfaces of the tibial baseplates were visually inspected for the presence of polishing and scratches. The upper and lower surfaces of the tibial inserts were inspected for burnishing, pitting, and scratching (Hood et al. 1983). In both cases a scale of 0 (none) to 3 (severe) was used to reflect the severity of each damage mode.

The roughness of the lower surface of an unused LCS Complete and Profix (Smith and Nephew, Memphis, TN, USA) tibial components were measured. The roughness parameters arithmetical average roughness (Ra) and root mean squared

(RMS) slope (Rdq) were calculated (van Tol et al. 2013). The Profix was chosen for comparison as it was the most frequently used design in Norway and the baseline for Cox regression analysis used by Gøthesen et al. (2013).

Tibia failure site

The site of implant loosening was categorized as implant–cement, cement–bone, or mixed. Implant–cement loosening was classified if the lower tibial surface was clearly polished, and an RLL between implant and cement was visible on the pre-revision radiographs. Cement–bone loosening was classified if the bone cement mantle was firmly attached to the retrieved implant, or RLL between cement mantle and bone were visible. A mixed failure was classified if both implant–cement and cement–bone loosening were present.

Tissue and blood analysis

For 11/32 cases of the retrieval group, periprosthetic tissue and blood samples were obtained during revision surgery. The number of foreign-body giant cells present was counted using optical microscopy and graded as: 1+ (1 cell/image), 2+ (2–4 cells/image), 3+ (> 5 cells/image). The quantity of PE, metal, and bone cement particles present was categorized using a modified Mirra classification (Mirra et al. 1976, Doorn et al. 1996). Particle intensity was graded as: 1+ (1–10 particles/image), 2+ (10–100 particles/image) to 3+ (> 100 particles/image). Images were captured by ordinary light and polarization microscopy at 400× magnification. Additionally, the chemical composition of the metallic and ceramic particles in the tissue was determined with a field emission scanning electron microscope (FE-SEM) with an energy dispersive X-ray spectroscopy detector (EDXS).

The concentration of cobalt, chromium, and zirconium in the blood samples was determined by High-Resolution—Inductively Coupled Plasma—Mass Spectrometry (Element 2 Thermo Scientific, Germany). Information about additional hip or knee replacements that could contribute to metal wear was collected from the NAR (Furnes et al. 2002).

Statistics

A logistic regression analysis was performed to evaluate the influence of radiographic variables, BMI, age, and sex on the relative risk for implant loosening. Linear regression analysis was used to examine the effect of variables over time to failure within the retrieval group. Relationships between different parameters were analyzed using Pearson's correlation for continuous variables and Spearman's rank correlation coefficient for ordinal variables. The level for statistical significance was set at $p < 0.05$ for all tests.

Ethics, registration, funding, and potential conflicts of interest

The project protocol and biobank have been approved by the Regional Committee for Medical Research Ethics—Western

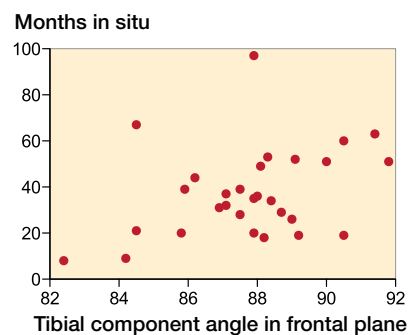


Figure 3. Dotplot showing the correlation between tibial component alignment in the frontal plane and time in situ of the failed LCS group ($r_{\text{Pearson}} = 0.38$, $p = 0.04$).

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Results

Registry data

Between 2004 and 2013, 404 cemented LCS Complete implants were revised in Norway. This was 4.4% of all those implanted nationally. Tibial component or femoral component loosening was the reason for revision in 184 and 52 cases, respectively. 103 cases were revised due to deep infection, 65 cases for other unspecified reasons.

The 32 retrieval cases analyzed in this study represent a subgroup of the 301 cases revised for reasons other than infection. The reason for revision indicated in the registry form was aseptic tibial loosening (25 cases), femoral loosening (6), instability (10), pain (7), malalignment (4), dislocation (2), or a combination of those reasons. In 27 cases the retrieved implants were primary replacements, in 4 cases secondary following a unicompartmental knee replacement, in 1 case secondary to a patellofemoral replacement.

Radiographs

In the frontal plane, a tendency towards varus alignment of the tibial baseplate was apparent both in the retrieval and the control groups (Table 2, see Supplementary data). No case of valgus alignment was observed. The femoral component angle in the failed group was 1.3° more varus aligned than the control group. For each 1° increase in femoral component alignment the estimated odds of loosening decreased by 19% in the isolated logistic regression model presented in Table 3 (see Supplementary data) ($p = 0.04$).

Within the retrieval group, time to failure was correlated with tibial component angle (valgus angle led to longer time to failure) in the frontal plane (Figure 3, Table 4, see Supplementary data).

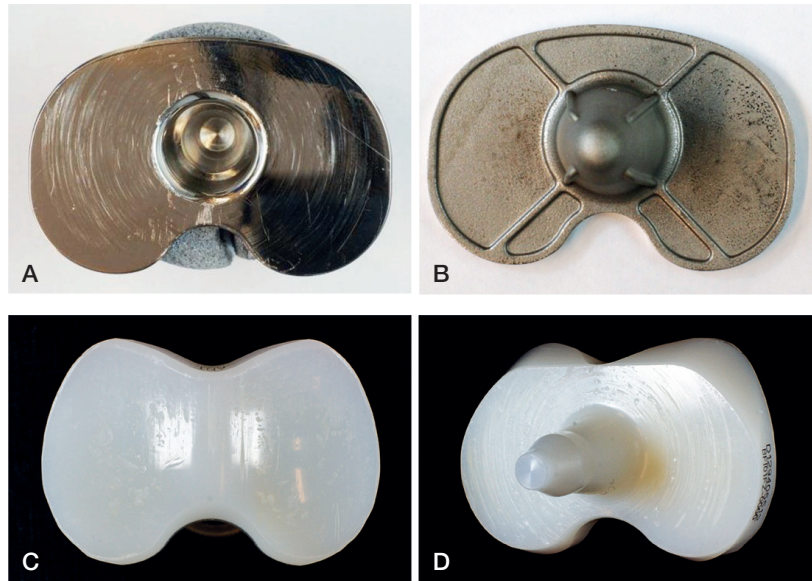


Figure 4. Typical damage pattern of the superior (A) and inferior (B) tibial component surfaces and superior (C) and inferior (D) polyethylene surface.

Full cementing (surface and stem) was observed in 3 and 4 cases from the retrieval and control groups, respectively. In all other cases the surface was cemented only. The thickness of the surface cement layer in the retrieval and control group was 2.8 versus 3.4 mm, respectively (Table 2). For each 1 mm increase in cement thickness the odds of failure due to aseptic loosening decreases by 61% ($p < 0.01$).

Radiolucent areas around the tibial stem with adjacent radiodense lines (Figure 2) were observed in 79% of the retrieval cases, with a mean width of 2.8 (0.6–7.0) mm. In 14 cases the width of the radiolucent area was greater than 2 mm.

Implant analysis

Retrieved tibial baseplates showed curvilinear scratches on the upper surface and polishing on the lower surface (Figure 4A, B). Polishing of the lower surface was found in 26 of 32 cases: 11 (grade 1); 6 (grade 2); and 9 (grade 3). No distinguishable signs of damage were observed in the remaining cases. On the upper surface, curvilinear scratches were apparent in 30 of the 32 cases: 13 (grade 1); 14 (grade 2); and 3 (grade 3).

Pitting and scratching was observed on the upper and lower surfaces of the tibial insert (Figure 4C, D). Curvilinear scratches were observed on the lower surface, linear scratches in AP direction on the upper surface. The average severity of scratching was graded as 1.7 (SD 0.7) and 1.6 (SD 0.7) for the upper and lower surfaces, respectively. Pitting was more prominent on the upper surface (average grade 1.6 (SD 0.9)) than on the lower surface (average grade 1.1 (SD 0.7)). Burinishing was noted only on the upper surface with an average grade of 2.0 (SD 0.6).

A statistically significant correlation ($R_{\text{Spearman}} = 0.82$, $p = 0.01$) was found between the width of radiolucent areas on the

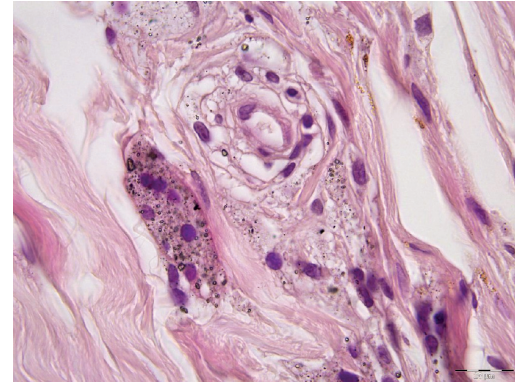


Figure 5. Example of a periprosthetic tissue sample showing multinucleated giant cells with ingested metal and bone cement debris particles

pre-revision radiographs and the polishing grade of the lower tibial surface. No statistically significant correlation between the damaging grades and time in situ or BMI was observed.

The surface roughness, R_a , of the new LCS tibial baseplate was 3.7 (SD 0.7) μm compared with 9.1 (SD 1.7) μm for the Profix implant. Similarly, R_{dq} was lower for the LCS (0.42 (SD 0.02)) when compared with the Profix (0.57 (SD 0.02)).

Failure site

From 22 cases of tibial loosening confirmed by retrieval analysis, 12 tibial baseplates loosened at the implant–cement interface and only 3 at the bone–cement interface. In 4 retrievals polishing of the lower baseplate surface was observed along with radiolucent zones at the cement–bone interface indicating a mixed failure mode. In 3 cases the failure site could not be determined due to insufficient information.

Tissue and blood analysis

Histological tissue examination revealed the presence of wear particles in all cases (Table 5, see Supplementary data).

Multinucleated giant cells with ingested foreign material (Figure 5) were observed in 10 cases and correlated with the grade of zirconium dioxide ($R_{\text{Spearman}} = 0.86$, $p = 0.001$), but not cobalt-chromium particles ($R_{\text{Spearman}} = 0.32$, $p = 0.3$) or PE particles ($R_{\text{Spearman}} = 0.35$, $p = 0.3$). Giant cells also correlated with damage grade of upper ($R_{\text{Spearman}} = 0.65$, $p = 0.04$) and lower ($R_{\text{Spearman}} = 0.77$, $p = 0.01$) baseplate surface. Zirconium dioxide was the predominant particle type, being grade 3 in 6 cases. A positive correlation between the zirconium dioxide and polishing grade of the tibial baseplate was observed ($R_{\text{Spearman}} = 0.69$, $p = 0.03$). No statistically sig-

nificant correlation was observed between the amount of wear particles found in the tissue and time in situ or BMI.

The mean concentration of cobalt, chromium, and zirconium in whole blood samples was 1.05 (0.05–4.4) $\mu\text{g/L}$, 1.48 (0.05–6.40) $\mu\text{g/L}$, and 0.68 (0.04–1.99) $\mu\text{g/L}$, respectively. The blood metal levels of cobalt and zirconium were correlated to the quantity of giant cells, $R_{\text{Spearman}} = 0.83$ ($p = 0.01$) and 0.78 ($p = 0.01$), respectively.

There was also a correlation between the damage grade of the lower baseplate surface and blood metal levels of cobalt ($R_{\text{Spearman}} = 0.77$, $p = 0.01$), chromium ($R_{\text{Spearman}} = 0.78$, $p = 0.01$) and zirconium ($R_{\text{Spearman}} = 0.60$, $p = 0.07$). None of the patients had a total hip replacement; 4 patients had a contralateral TKR.

Discussion

The LCS mobile-bearing implant has a 7-fold greater risk of aseptic loosening in primary arthroplasty in Norway compared with the best performing design (Gøthesen et al. 2013). Even though the relative risk was smaller, a higher risk for revision in mobile-bearing designs compared with other designs was also observed in 2 multi-registry studies (Graves et al. 2014) and the United States (Namba et al. 2012, 2013). Reasons for aseptic loosening in TKR include: wear particle exposure (Le et al. 2014, Lombardi Jr et al. 2014); implant alignment (Ritter et al. 2011, Kim et al. 2014); cement mantle thickness (Walker et al. 1984, Vanlommel et al. 2011); resurfacing the patella (Lygre et al. 2011); implant design (Gøthesen et al. 2013, Namba et al. 2013, Namba et al. 2014). In this study we reviewed 32 LCS retrievals for evidence of these factors with the aim of identifying the possible cause of failure. Aseptic loosening of the tibial component was the reason for revision in 25 of the LCS retrievals collected. Of these, loosening occurred most often at the implant–cement interface.

Wear particle exposure

All but 1 of the periprosthetic tissue samples contained foreign-body particles accompanied by macrophage infiltration and giant cell formation. The dominating particle type observed was zirconium dioxide, which is used as a radiopacifier in Palacos-type bone cements. We found a positive correlation between zirconium dioxide (particles in tissue and ions in blood) and polishing grade of the tibial baseplate, indicating abrasion between the tibial baseplate and cement. The presence of radiolucent areas around the tibial stem and the polished lower surface of the baseplate supports the hypothesis that particles are released by micromotion at the implant–cement interface, leading to third-body wear of PE and cobalt–chromium surfaces.

Although PE particles were found in all tissue samples, no case was classified higher than grade 2+. Analysis of a cohort of rotating-platform PFC knees reported a similar aver-

age damage score for burnishing, pitting, and scratching at 2 (0.3–3.8) years' follow-up (Stoner et al. 2013). The absence of abnormally high PE wear in our cohort supports the general theory that PE wear in total joint replacement and subsequent osteolysis is not a main cause of early implant loosening but rather affects the long-term survivorship (Gallo et al. 2013, Chakravarty et al. 2015).

We observed elevated blood metal ion levels correlated to the damage grade of the baseplate's lower surface. Similar findings have been used as a surrogate for in vivo wear and have been associated with implant failure (Savarino et al. 2010, Matharu et al. 2015).

Implant alignment

Tibial components were in varus in both groups, which is reported to increase medial compartment loading in TKR (Halder et al. 2012) and the risk of failure (Kim et al. 2014) with an increased effect in the presence of valgus femoral alignment (Ritter et al. 2011). Within the retrieval group greater varus alignment was associated with a shorter time to failure. However, with the exception of femoral component alignment the groups were comparable. Because no full-leg radiographs were available and no standard protocol was applied, the precision of angular measurements is limited and the radiographic findings, especially regarding the overall tibiofemoral alignment, need to be interpreted with caution.

Cementing technique

9 cases had a 3–5 mm cement layer, which is within the recommended limits suggested by Vanlommel et al. (2011). The remaining 16 cases were between 2 and 3 mm which is within the range required to engage at least 1 level of transverse trabeculae and sufficient bends in the vertical channels to provide adequate fixation (Walker et al. 1984). Based on these criteria none would be considered at risk even though the average cement thickness was lower in the retrieval group. We observed failure at the bone–cement interface in 3 cases, which is the expected failure site for inadequate penetration of cement into the tibia. 12 cases had evidence of failure at the implant–cement interface. Our logistic regression model estimated an OR of 0.4 for cement thickness. This means that a reduction in cement thickness of 1 mm increases the odds of failure, due to aseptic loosening before 3 years, 3-fold relative to the control group. A thicker cement layer will distribute stress more evenly (Carter et al. 1982), thus potentially increasing the load required for failure at the implant–cement interface.

Our study is limited by the fact that only 2 aspects of the cementing technique were investigated. Further aspects like the use of a pulsed lavage, cement application, or 2 vs. 1 cement layer technique can be critical for implant fixation but could not be investigated in this study.

Implant-related factors

Implant design has been suggested as a key factor in aseptic

loosening of TKR (Gøthesen et al. 2013). The geometry of the tibial component, in terms of stem length, pegs, or keels, influences the stiffness of the tibial construct, forces at the interface, and implant micromotion (Scott and Biant 2012). In a different TKR design short-keeled cemented tibial components showed an increased risk for micromotion and aseptic loosening (Ries et al. 2013). Also the ribbed non-keeled stem of the LCS may provide less stability when compared with the keeled version (Bhimji and Meneghini 2014). Greater micromotion at the bone-implant interface has been reported for the uncemented non-keeled LCS Complete when compared with other tibial designs (Taylor et al. 2012). However, implant design cannot explain the difference in outcome we found as both groups were of the non-keeled design.

Roughness of the lower baseplate surface was lower for the LCS than the Profix. Roughness is proportional to an increase in both shear and bond strength (van Tol et al. 2013) and a decreased fixation strength of the LCS implant at the cement-implant interface has been demonstrated on post-mortem retrievals using a pull-out test (Gebert de Uhlenbrock et al. 2012).

In summary, debonding of the tibial baseplate at the implant-cement interface occurred in most cases of tibial aseptic loosening. Based on the collected evidence, loosening was more likely mechanical as opposed to polyethylene wear particle induced. A thin cement layer may partly explain failure. The low surface roughness and the non-keeled stem may make the LCS baseplate more susceptible to mechanical loosening, which could explain the recent reports of inferior survival in registry studies.

Supplementary data

Tables 2–5 are available as supplementary data in the online version of this article, <http://dx.doi.org/10.1080/17453674.2017.1398012>

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