



## Early aseptic loosening of the tibial component at the cement-implant interface in total knee arthroplasty: a narrative overview of potentially associated factors

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Total knee arthroplasty (TKA) is a highly effective surgical procedure, but in some patients TKAs fail early due to a variety of underlying factors. About 11% of revision TKAs within one year of primary TKA are the result of aseptic loosening of the tibial component at the cement-implant interface. Literature regarding the most important factors associated with this type of loosening is scarce.

The objective is to give an overview of the literature regarding factors associated with aseptic loosening of the tibia component at the cement-implant interface in total knee arthroplasty.

A narrative literature review based on publications identified through PubMed and CINAHL databases. Twelve studies were identified, which describe a total of 299 cases of early aseptic loosening of the tibia component at the cement-implant interface. The main associated factors reported were cementation factors. These factors included the use of high viscosity cement (HVC), cement application methods and cement thickness. Other main reported associated factor related to implant design factors, which included component shape and surface roughness. The least frequently reported associated factors related to the patient characteristics of body mass index (BMI).

Several factors associated with early aseptic loosening of the tibial component at the cement-implant interface in total knee arthroplasty were identified in this review. The most frequently reported associated factors related to cementation factors and implant

design factors. Because the literature in this area is scarce, further research is warranted in an effort to prevent early aseptic loosening in future TKAs.

**Keywords:** aseptic loosening; early debonding; cement-prosthesis failure; fixation strength; total knee replacement; total knee arthroplasty.

### INTRODUCTION

Osteoarthritis and rheumatoid arthritis are the most prevalent degenerative joint diseases among older people(1, 2). These degenerative conditions often involve the knee joint. One of the most effective treatment options for these degenerative joint diseases in restoring knee joint mobility and relieving pain is total knee arthroplasty (TKA) (3-6). The incidence of TKA is rising worldwide (2). For example, in The Netherlands the rates of TKA in people with osteoarthritis tripled between 1995 and 2005 (7). Currently, TKA is the most frequently performed surgical procedure, with

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29.221 primary TKA procedures performed in the Netherlands in 2017 (8). Due to an ageing population in The Netherlands the demand of primary total knee arthroplasties is expected to increase up to 57.893 in 2030 (7).

After primary TKA, about 90% of implants still function properly after 12 to 19 years (3-6).

In approximately 2-3% of patients total knee arthroplasties (TKAs) fail early, i.e. within 2 to 5 years of the index procedure (9, 10) due to a variety of underlying factors. These TKA failures require revision TKAs and the number of revision TKAs rise steadily (11, 12). In 2017 alone 3039 TKA revision procedures were necessary in the Netherlands (8). It is important to prevent revision TKA because the accompanying complications require more resources than primary TKA in terms of diagnostic procedures, implantation costs, lengths of hospital stay and postoperative care. As the burden of revision TKAs continues to increase it is crucial to understand the factors potentially associated with those failures.

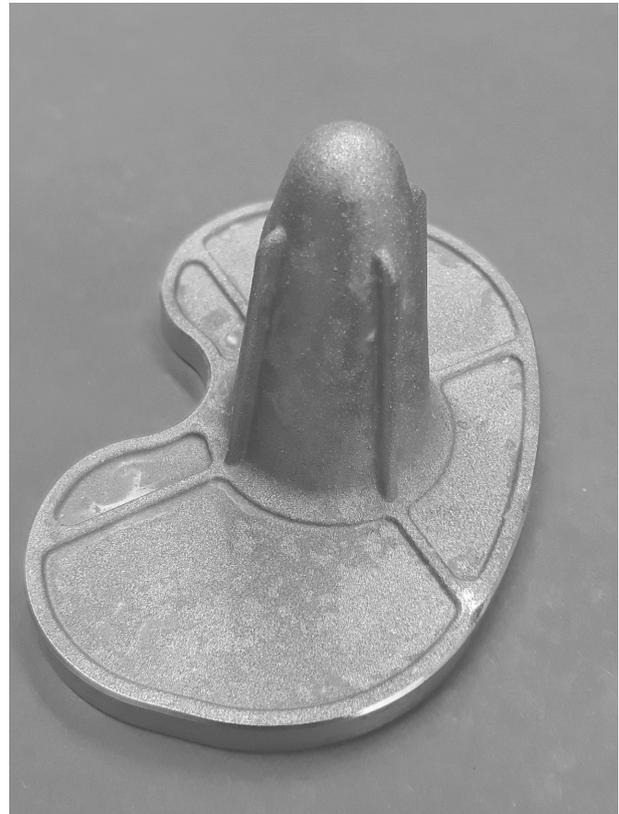
Failures of TKAs are frequently related to bacterial and inflammatory processes. Such septic processes lead to debonding or loosening failures due to aggregation of microorganisms at the implant surface (13). Aseptic loosening failures, i.e. those without the presence of an infection, account for between 15-31% of all revision surgeries (14-16). Early aseptic loosening can be the result of inadequate initial fixation, mechanical loss of fixation over time or biological loss of surrounding bone caused by particle-induced osteolysis (17).

Aseptic loosening more frequently happens with the tibial component of the knee replacement rather than the femoral component (18). In the Netherlands, about 11% of revision TKAs within one year of primary TKA are the result of aseptic tibial loosening (8). In the past, tibial aseptic loosening frequently occurred due to debonding at the cement-bone interface. However, with the development of pulsed lavage techniques (19) and pressurization the cement penetration into the bone has significantly been improved. More recently, cases of tibial aseptic loosening at the implant-cement interface (22, 21) have come to light. In these cases the bone cement seemed to be non-adherent to the tibial tray at the time of revision surgery, resulting in the removal of

'clean trays' (Fig. 1). Patients experiencing this kind of aseptic loosening were initially asymptomatic, but subsequently developed increasing pain with weight bearing, small effusions and gradual loss of active range of motion (22, 23). To date it is unclear which factors are associated with this latter mode of early aseptic loosening. In order to prevent early aseptic loosening in future TKAs it is important to identify these factors. The objective of this paper is to summarize the literature regarding associated factors for aseptic loosening of the tibial component at the cement-implant interface of TKA.

## METHODS

The primary outcomes of interest for this narrative overview of the literature were studies describing factors associated with early aseptic loosening of the tibial component at the cement-implant interface in TKA (24).



**Figure 1.** — A clean tibial tray. Bone cement is non-adherent to the tibial component (LCS) at the time of revision TKA.

We included any publication that 1) described human subjects, made use of human material or were directly human oriented, 2) was reported in English, 3) was available full-text, 4) was published within the past 15 years and 5) specifically described the tibial component at the cement-implant interface. We excluded publications relating to uncemented TKAs, femoral aseptic loosening and papers not providing sufficiently detailed information about the patient characteristics or implant procedure.

The electronic databases PubMed and CINAHL were searched to identify publications published between 2004 and June 2019. The search strategy included both the MeSH terms ‘total knee arthroplasty’, ‘prosthesis failure’, and free text words ‘total knee arthroplasty’, ‘aseptic loose\*’, ‘tibia component’, ‘failure’, ‘fixation strength’, ‘cement-implant interface’, ‘roughness’, ‘cementation technique’, ‘debonding’, ‘\*interface’ and all synonyms, abbreviations and variation in spelling in these terms. Because orthopaedic implant companies regularly update and modify their implants and techniques (25) a search date timeframe of 15 years was used to ensure that the identified publications were relevant to current clinical practice. Reference lists of retrieved publications were hand searched for additional publications. Simplified versions of the database search strategies were applied in Google to find unpublished (grey) literature.

Titles and abstracts of retrieved articles were screened and duplicates were removed. Full text articles of selected titles were retrieved and assessed in accordance with the pre-specified inclusion and exclusion criteria.

## RESULTS

The search strategy used to identify publications are shown in Appendix 1. The database searches resulted in 133 references. Of these, 12 (9, 15, 20-22, 26-32) were deemed relevant to the topic and eligible for further assessment. In these publications a total of 29.867 primary TKAs were reported. Of all of the described patients, 299 experienced aseptic loosening of the tibia component at the cement-implant interface. Patient- and study characteristics

are presented in Table I. The most frequently reported associated factors to early aseptic loosening were cementation factors. These factors included the use of high viscosity cement (HVC), cement application method and cement thickness. Another main reported associated factor related to implant design factors, which included component shape and surface roughness. The least frequently reported associated factors related to the patient characteristics of BMI and age.

## DISCUSSION

The aim of this narrative review was to summarize the literature regarding factors associated with aseptic loosening of the tibial component at the cement-implant interface of TKA. Although only 12 studies describing 299 cases (approximately 1% of a total of 29.867 primary TKAs) were identified, our findings can assist in identifying the most probable factors associated to this type of failure.

The most frequently reported associated factor was the cement type used during the TKAs. In the last decade HVC has seen a rise in use due to suspected advantages of shorter mixing and waiting phases with prolonged working and hardening phases compared to low viscosity cement (LVC) (33). However, despite the suspected advantages of HVC, early failures at the tibial cement – implant interface were reported in two case studies (9, 29). In these studies nearly complete absence of bone cement was observed on the tibial tray at the time of implant removal. In another study, patients who received either LVC or HVC were matched on demographics, surgeon characteristics and implant design. The results of this study showed that the probability of TKA revision was lower in patients receiving LVC (23). These findings have led several authors to hypothesize that the use of HVC is associated with early aseptic loosening (9, 29, 32). Because surgeon procedure variables and knee designs differed between these studies more research is needed to confirm this factor.

The cement application method is very important since bone cement is considered to be the weak mechanical link in TKA (34). Some authors have claimed that cementing the entire keel provides

Table I. — Characteristics of included studies relating to factors associated with aseptic loosening of the tibial component

Study	Number of TKA's per group and implant type	Age, years (range)	Gender (male/female)	BMI (kg/m <sup>2</sup> )	Implant type	Cement and application technique
Foran et al., 2011	Primary: 529 Revision: 8	? 61 (56-73)	? 3 / 5	? ?	NexGen	Palacos R+G; Vacuum mixed and fingerpacked application
Arsoy et al., 2012	Controls: 50 (out of 1337) Revision: 25	58 (42-78) 58 (42-77)	15 / 35 7 / 16*[18]	35.1 35.6 (24,5-45,9)	NexGen	Simplex LV, cement powder was warmed up before mixing
Ries et al., 2013	<u>Standard keel</u> Primary: 80 Revision: 0 <u>Short keel</u> Primary: 80 Revision: 5**	Primary: 65 (42-86) Revision: 63 (56 -74)	61 / 99 2 / 3	30 (20-53) 30 (26-33)	Genesis II <u>Standard</u> : Morse taper stem + two fins <u>Short-keel</u> : No morse taper + smaller fins	Refobacin
Gøthesen et al., 2013	Primary: 17772 Revision: 136	Primary: ACG (anatomic and universal); LCS(Classic and Complete); Duracon; NexGen; Profix 70 ± 9.1 ; 71 ± 9.2 ; 72 ± 9.0 ; 70 ± 9.6 ; 71 ± 9.3 ; 69 ± 10.5; 70 ± 10.0 resp.	Primary: 5612/12160	?	ACG (anatomic and universal); LCS(Classic and Complete); Duracon; NexGen; Profix	?
Lachiewicz et al., 2014	Revision***:58 Revision: 0	66.8 (47-85) -	26*[27] / 28*[31] -	33 (21.6-49.6) -	NexGen -	two packs of Simplex-P tobramycin cement, syringe delivery Placement of a 25-mm polyethylene cement restrictor, varus-valgus constrained
Hazelwood et al., 2015	Primary: 3048 Revision: 9	? 59 (50-75)	? 4* [5] / 4	? 34.3 (20.9-47.0)	PFC sigma and Genesis	Smartset HV and Palacos-R; Vacuum mixed, finger packed layered -application
Abdel et al., 2015	Primary: 5088 Revision: 52	69 (31-96) 61 ± 1.3	2037 / 3051 21 / 31	33(17-69) ?	PFC sigma, NexGen LPS, Stryker, Genesis II and Attune	?

Table I. — Characteristics of included studies relating to factors associated with aseptic loosening of the tibial component - *part 2*

Kopinski et al., 2016	Revision: 13	62 (49-84)	6 / 7	32.1 (20.9-47.0)	Vanguard	Cobalt HV
Crawford et al., 2017	Primary: 1851 Revision: 1	62 (28-89) 55	418 / 948 0 / 1	41.7 (35-76) 60.5	Vanguard	Cobalt HV and Palacos; Handmixed, finger packed layered application
Bonutti et al., 2017	Revision: 15	61 (47-84)	?	35 (21-54)	Attune Knee System	Ribbed stem (non-keeled)
Kutzner et al., 2018	Primary: 43 Revision: 32**	70 (47-81) 67 (40-80)	16 / 27 12 / 20	29 (21-49) 28 (21-43)	LCS Complete implants; Ribbed stem (non-keeled)	Palacos
Cerquiglini et al., 2019	Primary: 39 Revision: 3	? 59 (46-69)	? 2 / 1	? ?	PFC Sigma implants (titanium and cobalt-chromium), PFC sigma rotating platform implants (cobalt-chromium) and Attune implants	Palacos; Two sided cement application
<p>?, data not described; *, included patients with bilateral TKA; the absolute number of TKAs is presented within the brackets; **, although no distinction was made between cases with aseptic loosening at the cement-bone interface and those with loosening at the cement-implant interface, the majority of failures were due to the latter; ***, All subjects had experienced at least one TKA failure before participating in the current study. The initially condition could therefore not be labeled as 'Primary'. Neither can it be added to the total early aseptic loosening of the tibia component at the cement-implant interface cases.</p> <p>Note: Data is presented as mean (range) or as mean <math>\pm</math> standard deviation. Revision cases represent the patients with aseptic loosening of the tibial component at the cement-implant interface.</p>						

better fixation, makes the implant less vulnerable for micro movement and preserves long-term stability (35). Conversely, another study suggested that cementing the surface on the tibial plate provided sufficient stability (36). Although results from a sawbone study showed that full keel cementation techniques resulted in less initial micro-motion of the tibial baseplate, (37) no differences in mechanical strength were reported on the midterm between full keel and surface-cemented implants when cement layers were at least 3mm thick (38, 39). A recent study has also shown that the odds of failure due to aseptic loosening decreased by 61% for each 1mm increase in cement thickness (31). In addition, a more favorable strain pattern existed when the tray alone was cemented (40). This finding is in line with research suggesting that a thicker cement layer distributes stress more evenly and potentially allows for larger loads before failure occurs (31, 41, 42). These findings combined suggest that full-

cementation of the tibial baseplate has no true clinical value regarding mechanical strength when a sufficiently thick cement layer is being applied. Also, cementing the keel makes revision surgeries a more demanding task because the difficult task of removing all residual cement is of paramount importance to prevent secondary component loosening.

Some authors have suggested that the specifications of an implant design play a role in primary fixation of TKA (15, 21, 26, 27, 32). The prevalence of early implant failures might be associated with the stem design. High rates of early implant failures were found in short-keeled implants with small fins and no morse taper stem compared to standard trays (with fins and morse tapered stem) (26). No cases of aseptic loosening were found in cemented 30-mm tibial stem extensions (36) or in TKAs using pegged or stemmed tibial components (6). While LVC was used in the two latter studies it

is unclear whether this type of cement or the stem design were responsible for the positive results. Another component that could be attributable to the differences in revision risk are the cement pockets in the tibial tray. Proper cement pockets allow the creation of a thicker cement layer (15). For example, the standard Attune TKA design has more rounded edges and less insets for cement interdigitation relative to prior designs (22). This could provoke rotational instability and macro digitation and induce the risk of aseptic loosening (22). The Attune S plus design was developed with four additional cement pockets. The Press Fit Condylar (PFC) implant did rarely fail due the re-entrant profile of the cement pocket, providing an interlock with the cement (34).

Surface roughness of an implant component is proportional to an increase in both shear and bond strength (43). Implants treated with rough grit-blasted coating had an improved shear strength at the implant–cement interface (35). A rougher surface tends to have a stronger mechanical bond interlock between the metal and the cement (31, 44, 45). However, a recent retrieval study found no differences in cement adhesion properties between four tibial trays with varying backside roughnesses (15). Although the cement – implant interface is stronger with a rough surface, micromotion could accelerate its overall failure rate compared to a polished stem (46). Given these contradictory findings further research into implant surface roughness is needed.

An increased body weight (and hence a higher BMI) is associated with the main cause for primary TKA, but the association between BMI and early loosening failures is still doubtful (20, 47). For example, research has shown that people with a BMI  $\geq 35$  kg/m<sup>2</sup> were almost twice more likely to experience aseptic tibial loosening regardless of age or coronal alignment (28). Similarly, the combination of BMI  $> 33.7$  kg/m<sup>2</sup> with a varus tibial component alignment was associated with a 168-fold increase in failure (5). Conversely, after a mean follow-up of 5.4 years only one case of aseptic tibial loosening was observed (30). Two case matched control cohorts revealed similar survival rates between obese and non-obese until the first

couple years (48, 49). Although a higher BMI may not be directly associated to early implant- cement loosening failures, it may well be a factor that plays a role in aseptic loosening of the tibia component in the longer term. More research is needed to elucidate these paradoxical findings. It may also be worthwhile to investigate the role of people's levels of physical activity because it is known that higher levels of physical activity can affect the implant longevity(50).

Although various authors (26, 51) have stated that early aseptic loosening of the tibia component was unrelated to patient factors such as gender or age, patients undergoing revision TKA due to aseptic loosening of the tibia component at the cement-implant interface were relatively young (around 62 years of age) (9, 15, 20, 29, 30, 48). Research with larger groups of patients is needed to show a possible association between age and the risk of loosening failures after TKA.

The findings of this narrative overview of the literature have some overlap with the results of a previous study that reviewed the mechanisms involved in early aseptic loosening of Low Contact Stress cemented total knee replacements (31). Main factors reported for loosening of the tibial baseplate at the implant–cement interface in that study were related to the thin cement layer, the tibial component's low surface roughness and the lack of a keeled stem. Cementation factors and implant design factors were also two of the main associated factors identified in this review. Especially the use of HVC seems to be associated with early aseptic loosening, but the lack of literature in this area limits generalizability of the results. Contradictory findings regarding possible associated factors such as cement application and thickness, the design of the implant design or BMI also make it difficult to draw firm conclusions. Since the good outcomes after use of the pulsed lavage technique and pressurization (19, 41, 51), the implant-cement interface seems to have become the 'weakest link' in the overall bone-cement-implant component. Improvements in strength of the implant-cement interface seems the next interface of focus. A recent review has already shown that the attendance of non-progressive radiolucent lines  $< 2$  mm should

not be considered as a sign for aseptic loosening of the tibial component (53). Patient factors such as BMI or age seem to be a limited factor, but more research in this area is warranted.

The increasing number of TKA revisions combined with the economic burden of the revision procedure necessitates improvements in primary TKA outcome. Knowledge about factors associated with loosening failures in general, and aseptic loosening of the tibial component in particular is scarce. This narrative review sheds some first light on factors associated with this type of aseptic loosening. This knowledge can assist orthopedic surgeons in taking steps to consistently collect data on factors that are potentially associated with this specific type of failure and assist the implant industry companies to optimize implant methods and designs. Several limitations of this review must also be acknowledged. Only two databases were searched in a non-systematic manner using a limited number of search terms. This may have introduced selection bias. Although two of the largest databases for biomedical literature were searched, a more extensive search could have identified more pertinent publications and hence more associated factors. Also, publications reported several factor contributing to aseptic loosening of the tibial component, and some factors might not be associated with the specific early aseptic failures occurring within the first two years. Data from worldwide registries such as the Dutch Arthroplasty Registry (LROI) could serve to assist in gaining more knowledge about the prevalence and other possible associated factors.

## CONCLUSION

The most frequently reported associated factors to early aseptic loosening of the tibial component at the cement-implant interface in TKA were cementation factors. These factors included the use of high viscosity cement (HVC), cement application method and cement thickness. Another main reported associated factor related to the implant design factors of component shape and surface roughness. The least frequently reported associated factors related to the patient characteristics of

BMI and age. Because the literature in this area is scarce, further research into these associated factors is warranted in an effort to prevent early aseptic loosening in future TKAs.

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