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KNEE ARTHROPLASTY

Appearance and evolution of radiolucent lines below the tibial implant in primary total knee arthroplasty

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Abstract

Background The aim of this study was to evaluate total knee arthroplasty (TKA) radiographically to detect the occurrence of radiolucent lines (RLL) under the tibial base plate and to determine what type of RLL may have a correlation with aseptic loosening (AL). The study had two hypotheses: (1) RLLs may have different radiological aspects and evolutions in time depending of different factors (2) Signs of micro- and/or macro-mobility of the implant are necessary before diagnosing aseptic loosening of the tibial component.

Methods Retrospective cohort study of 774 patients operated with a Vanguard TKA (Zimmer Biomet, Warsaw, IN, US) from 2007 to 2015. RLLs were recorded in a database and described according to their radiological aspect, localization, time of apparition, progression and eventual evolution to AL. Other collected parameters were pre- and post-operative HKA angles, amount of post-operative HKA correction, surgical, clinical and demographic data.

Results 178/774 TKAs (23%) showed RLLs under the tibial base plate including 9 (1.2%) tibial implants needing revision for AL. Three different types and two aspects of RLLs were observed. Important deformity corrections or undercorrected implants were recognized as a mechanical risk factor for loosening. Elderly women with osteoporosis and young men with important pre-operative deformities were identified as clinical risk factors for RLLs.

Conclusions RLLs are frequently present at the epiphyseal bone/implant interface after total knee arthroplasty, but do not mean the implant is loose. They can be considered a sign of reduced epiphyseal surface fixation due to micro mobility of the tibial implant. Aseptic loosening can be observed radiologically when signs of macro-mobility of the implant are present at the metaphyseal level.

Level of evidence III.

Keywords Radiolucent lines · Aseptic loosening · Total knee arthroplasty · Survivorship · Revision TKA

Introduction

Radiolucent lines (RLLs) in total knee arthroplasty (TKA) are radiologically defined as lucencies with either an osteolytic or osteosclerotic effect [1], between the cement/implant interface and the bone [2]. RLLs under the tibial base plate are the most frequent localization [3]. With the improvements in materials, other mechanisms than osteolysis [4] might be responsible for these peri-prosthetic radiolucencies.

The mechanical implications of RLLs are a reduction in the surface of fixation of the tibial implant and the potential development of micro- or macro-mobility. Aseptic loosening (AL) is the progressive disappearance or absence of stable fixation between the cement/implant-bone interface in the documented absence of infection. AL remains an important cause for revision [5–12].

Morgan Jones et al. have demonstrated in revision total knee arthroplasty that there are three zones of fixation [13]. The same principle can be applied to primary TKA, where these three zones are also anatomically present, but have not been modified by previous knee arthroplasty or a mode of failure. Especially, the epiphyseal and metaphyseal zone

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of fixation will be crucial in primary TKA. Three factors determine the potential of fixation in primary TKA: (1) TKA design factors, such as the coverage area of the epiphyseal tibial surface and the design of the tibial keel (shape, size and length) for metaphyseal fixation; (2) Patient factors, such as osteoporosis offering less construct support and sclerotic bone allowing less cement penetration and (3) Surgical technique factors, such as level of tibial resection, coronal alignment philosophy, amount of constraint and ligament balancing.

Depending on their time of apparition, RLLs can be related to surgical factors [14–20], post-operative alignment [21] or micro-motion of the implant [4, 22]. Because the literature is not clear about defining RLLs [23], in case of apparition on routine radiographs, it often remains a subjective decision to declare a component with RLLs loose. This perception-based decision can lead to higher revision rates in registries for the index surgeon or the individual implant [16, 24, 25], but also to disappointing results for the revised patient. Therefore, the value of the radiological observation of the apparition and progression of RLLs, a description of the type of RLLs that could behave badly in the future and the description of radiological signs of AL remains important.

The purpose of this scientific work was to study the morphology and time to apparition of RLLs, for one TKA design, according to patient's and surgical technique factors, while searching for a correlation between a specific type of RLL and AL.

The hypotheses for this retrospective study were that (1) RLLs may have different radiological aspects and evolutions in time depending on patients and surgical technique factors (2); Signs of micro- and/or macro-mobility of the implant are necessary before diagnosing aseptic loosening of the tibial component.

Methods

The authors present a single-center retrospective cohort study on 774 total knee arthroplasties (TKA), implanted between 2007 and 2015 for primary osteoarthritis by two surgeons using the same surgical technique and the same type of implant [Vanguard, Postero-Stabilized (PS) cemented device (Zimmer Biomet, Warsaw, Indiana, US)]. Surgical indication for TKA was pre-operative osteoarthritis of the knee with Kellgren–Lawrence grade 4 in more than two compartments, based on pre-operative radiographs (antero-posterior (AP), lateral, 30° axial patellar view) and a standing full leg alignment view. All components in this study were cemented and the patella was resurfaced when the surgeon considered it necessary. High viscosity cement was used in a one stage procedure for tibia and femur, with pulse lavage cleaning before cementing and drilling of the sclerotic surfaces allowing cement penetration when needed. Intra-medullary alignment was used on the femoral side and extra-medullary alignment on the tibial side. Sizing of the components was done intra-operatively according to the surgeons' experience and rotational alignment and gap balancing using a measured resection technique. The alignment target during this study period was adjusted mechanical alignment with 178° for the pre-operative varus patients and 182° for the pre-operative valgus patients [26–29]. All patients underwent routine post-operative clinical and radiological controls at 3, 6, 12, 24 weeks, as well as 1, 2 and 5 year(s) post-operative.

In accordance with the conventional radiological guidelines, the leg was positioned for the AP view with the patella facing towards the X-ray beam to be tangential to the tibial base plate and with controlled rotation of the leg. For the lateral view, the patient was lying on the operated knee, which was flexed at 30°. For the patella view, the beam was classically positioned at 30° from the floor with the knee flexed at 45°.

Demographic data (age at time of surgery, gender and BMI), clinical data about diseases at risk for poor bone quality (endocrinological or rheumatologic pathologies, renal disease, positive history of alcohol abuse or smoking and medication or treatments with a potential bone remodeling impact (steroids)), were recorded from the hospital medical data file system. The level of tibial resection, polyethylene thickness and tibial base plate size were also collected from the surgical procedure and included in the data base.

The authors studied the apparition of RLLs on the tibial implant because of the scarcity of RLLs observed around the femoral implant in this series, potentially because of superposition of the femoral component in the AP-plane.

All X-ray's were reviewed by one observer (DW) with a mean follow-up of 9 years (5–13 years). 178 TKAs presented tibial RLLs and were studied in more detail. The measurement system from PACs software (Carestream, Rochester, New York, USA) was utilized with an accuracy tolerance of 0.1 mm (mm) for RLLs size measurements and 0.1° for the HKA angle measurement. This author read the same radiographies more than five times at different time intervals. The Cohen's Kappa was almost perfect agreement with an intra-observer agreement score of 0.926 for the radiological RLLs screening.

Localization of RLLs under the tibial baseplate was classified in zones according to the Knee Society Scoring System [30, 31].

Radiolucent lines were classified as either being osteolytic and as an irregular and unclear (radiolucent) line between the implant/cement interface greater than 2 mm or as osteosclerotic when an osteodense area (white sclerotic line, thin layer of lamellar bone) was visible under the radiolucent area.

In this series, the time to apparition was defined by the authors as immediate when the RLLs appeared within 6 weeks post-operatively, early if the RLLs appeared within 3 months and late if the RLLs appeared at more than 3 months post-operatively. Their modification over time (still visible or disappearance) was noted as unchanged, progressive or resolved.

When a RLL was present in one compartment only (medial or lateral compartment of the tibial component) it was defined as an Isolated RLL. When it was bi-compartmental and the RLLs were present simultaneously in both compartments, it was called a Combined RLL. If the RLL was present in one compartment first, followed by the other compartment later in time sequentially, it was called a Sequential RLL. In case of sequential apparition of RLLs, the authors identified the time of apparition of the first RLL as Time 1. For the time of apparition of the second RLL, the authors used the term Time 2.

For all TKAs with RLLs (178/774), the following parameters were studied: mean load-bearing pre-operative and post-operative Hip–Knee–Ankle (HKA) angle (varus < 178° or valgus > 182°). The overall post-operative standing mechanical alignment was analyzed for its effective correction (under- or overcorrection, i.e. pre-operative valgus becoming post-operative varus or vice versa). The mean HKA correction realized was called "delta of correction" defined by the authors as a mathematical difference between the pre-operative and the post-operative HKA angle. For each TKA, the amount of correction in degrees was measured, but also whether a positive delta (positive difference = post-operative HKA angle < pre-operative HKA angle) or negative delta (negative difference = post-operative HKA angle > pre-operative HKA angle) of correction was present.

The percentage of patients with a post-operative HKA angle of more than 3°, outlier from the neutral mechanical axis of 180° was noted. For each type of RLL, the authors compared the demographics, clinical and radiological variables, to understand the differences between them.

To assess and describe the radiological signs of AL, the authors retrospectively reviewed the successive X-ray's and clinical symptoms of 9 TKAs needing revision of the implant for tibial AL. The authors have observed post-operative modifications around the tibial base plate that they qualify as signs of AL. The authors compared the group of patients with signs of AL and those without for demographics, clinical and surgical variables, to understand the differences between both groups.

All TKAs with RLLs were collected in a database, including their date of surgery, last consultation in our center and whether the TKA was revised or not (revision in- or out-house), the date (time from index surgery) and the reason for revision as noted in the National Joint Registry.

Descriptive statistics were used for demographics, clinical and surgical data and sample characteristics are presented as numbers, means and standard deviations; categorical variables are presented as percentages. For continuous variables, violations of the normality assumption were tested using the Shapiro–Wilk test. The Cohen's Kappa method was used to obtain the intra-observer reliability. Between-group differences were tested using unpaired *T* tests and chi-squared test was used for categorical variables. The authors used the Kaplan–Meier method to evaluate cumulative survivorship of the implant with the absence of revision as an end-point. A multiple logistic regression was used to observe a statistic link between variables observed and the apparition of signs of AL. GraphPad Prism software 8.0 (Graphpad, La Jolla, CA, US) was used for statistical analyses, and a p value < 0.05 was considered as statistically significant.

Results

Isolated RLLs (Fig. 1a) are the most frequent RLLs in this series. They appear most frequently on the medial side of the tibial base plate (Table 1).

A statistically significant correlation ($p = 0.016$) was found between the pre-operative HKA-angle and the side of the Isolated RLL (Fig. 2a). A pre-operative varus knee, most often presents with a medial Isolated RLL.

If the pre-operative bone aspect is sclerotic on the concave side of the deformity, the aspect of the RLL post-operatively will also be osteosclerotic in a significant manner ($p = 0.008$) (Fig. 2b). Over time, 42% of isolated RLLs disappear at 2 years post-operatively, the other RLLs are often still visible, but without size modification (Table 1).

Combined RLLs (Fig. 1b) are the second most frequent RLLs in this series with a similar time of apparition as Isolated RLL and a majority of osteolytic lines (Table 1).

Sequential RLLs (Fig. 1c) represented 18% of RLLs in this series. The side on which appears the first RLLs in the equential group does not show a correlation with the pre-operative or post-operative HKA angle. The Sequential RLLs display a significantly earlier time of apparition of the first line ($p = 0.017$) and a delayed apparition of the second RLL (Table 1).

Isolated RLLs appear in patients with a moderate pre-operative HKA angle and good alignment correction. Combined RLLs are seen in patients with a high pre-operative HKA angle and a significantly higher ($p = 0.003$) positive delta of correction and with thicker polyethylene sizes ($p = 0.013$), than other types of RLLs (Table 2).

Sequential RLLs were typically present in younger patients ($p = 0.010$) and patients with more clinical risk

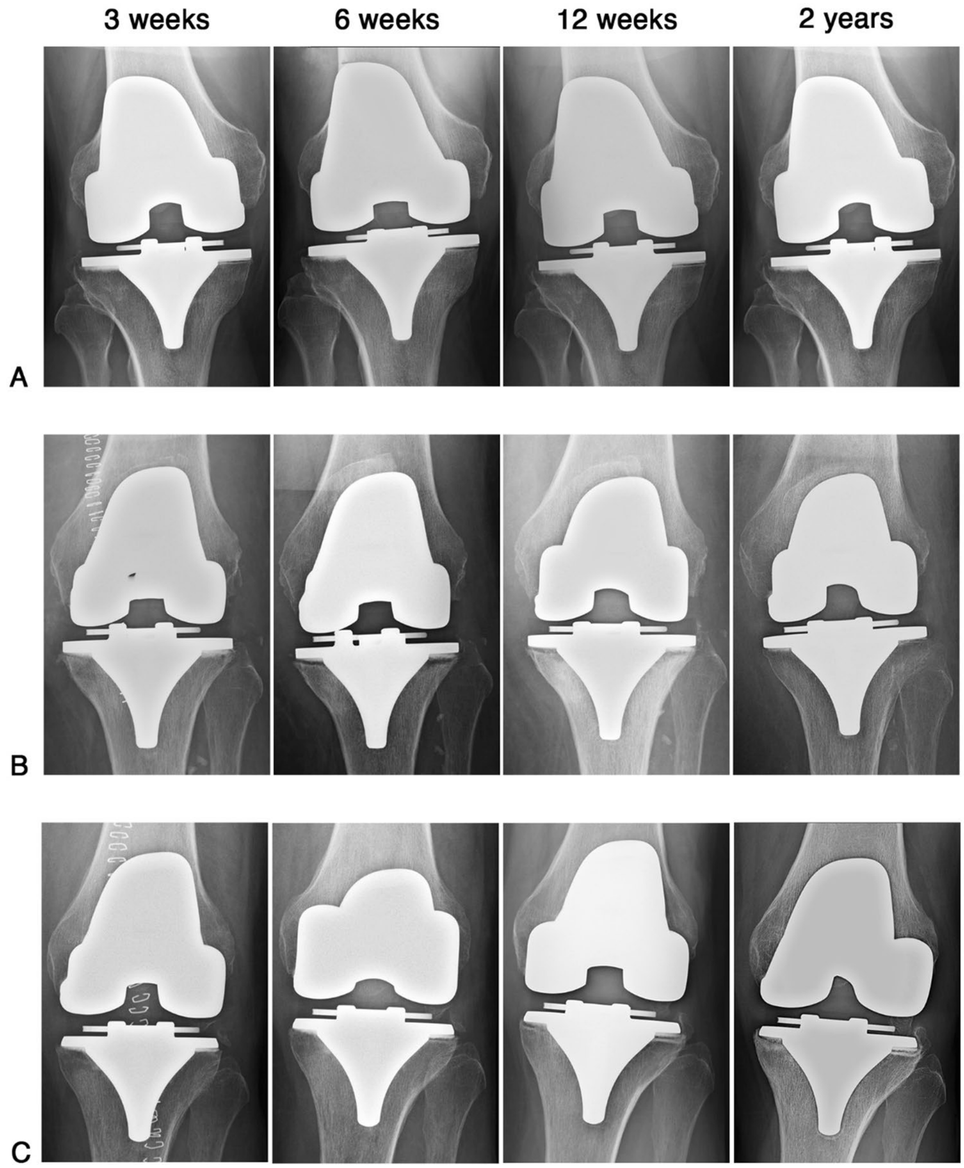

Fig. 1 Radiolucent lines aspect and characteristics on successive post-operative X-ray's at 3, 6, 12 weeks and 2 years, **a** *Isolated* RLL, sclerotic type, on the medial side visible at 6 weeks, **b** *Combined* RLL under the medial and lateral side simultaneously at 6 weeks, osteolytic aspect, **c** *Sequential* RLL with a first RLL on the lateral side at 6 weeks and the apparition of a second RLL on the medial side at 12 weeks

Table 1 Radiolucent lines: Proportion, time characteristics, aspect and evolution

Variables	Number of patients *N* (%)	Postoperative time of apparition of RLLs (in weeks)		Side of apparition	Radiological aspect	Radiological evolution at 5 years
		Time 1	Time 2			
TKAs without RLL	596/774 (77%)	–	–	–	–	–
TKAs with RLL	178/774 (23%)					
Isolated RLL	77/178 (43%) 77/774 (10%)	11 ± 14	-	70% medial 30% lateral	64% osteosclerotic 36% osteolytic	2% of RLLs disappear
Combined RLL	69/178 (39%) 69/774 (9%)	10 ± 9	–	Both sides	Osteopenic	52% disappear
Sequential RLL	32/178 (18%) 32/774 (4%)	6 ± 5 *	24 ± 19	Both sides	Both aspects	12% disappear

Values are expressed as Mean ± SD; Time is expressed in weeks by Mean ± SD. * Significant value

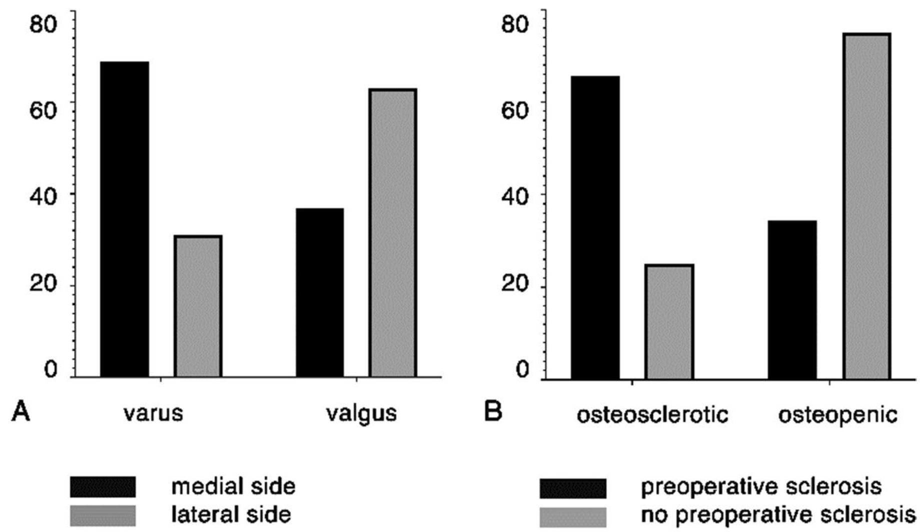

Fig.2 Isolated RLL characteristics with X-ray's representing radiolucent line with their location under tibial plate, **a** The graphs represent the proportion of RLLs on the medial and lateral side relative to their pre-operative HKA angle (varus/valgus), 63% of lateral RLL are relative to pre-operative varus and 69% of medial RLL are relative to pre-operative varus. **b** Proportion of pre-operative bone sclerosis or not in the osteosclerosis and osteolytic RLL, 66% of sclerotic RLL are relative to pre-operative bone sclerosis and 75% of osteolytic RLL are relative to non-sclerotic pre-operative bone

Table 2 Type of radiolucent lines: demographic data, surgical and mechanical values of the cohort of RLLs

Variables	Isolated $N=77$ (43%)	Combined $N=69$ (39%)	Sequential $N=32$ (18%)
Demographic data			
Age (years) ± SD	70 ± 10	68 ± 9	65 ± 10 *
Gender female/male	59/18 (3/1)	50/19 (3/1)	24/8 (3/1)
BMI (kg/m2)	30 ± 6	30 ± 5	29 ± 7
Patient with clinical risk factors for poor bone quality (%)	34/77 (44%)	40/69 (58%)	20/32 (63%) *
Implant size			
Tibial base plate (mm)	71 ± 4	71 ± 5	71 ± 4
Polyethylene (mm)	11 ± 2	12 ± 2 *	11 ± 2
Mechanical data (degrees)			
Pre-operative angle			
Varus	174 ± 4	171 ± 6 *	175 ± 5
Valgus	188 ± 4	188 ± 4	188 ± 6
Post-operative angle			
Varus	177 ± 2	176 ± 3	176 ± 3
Valgus	183 ± 2	183 ± 1	183 ± 3
Proportion of knees with positive delta of correction in the varus–varus group			
Proportion (%)	21/77 (27%)	21/69 (30%)	12/32 (38%)
Delta of correction (degrees)	3 ± 4	6 ± 6 *	1,5 ± 4
Proportion of knees with negative delta of correction in the varus–varus group			
Proportion (%)	7/77 (9%)	3/69 (4%)	8/32 (25%) *
Delta of correction (degrees)	2 ± 0	3 ± 0	2 ± 0
Proportion of knees with a post-operative HKA angle > 3 degrees of 180°			
Proportion (%)	(22/77) 28%	(16/69) 23%	(11/32) 34%
Post-operative angle (degrees)	175 ± 2	174 ± 3	174 ± 2

Values are expressed as Mean ± SD; *Significant value

Table 3 Signs of aseptic loosening: proportion and time of apparition

Variables	Number of patients (%)	Time of apparition of signs of AL (months)
Radiolucent lines around the keel	31 (100%)	8 ± 5
Metaphyseal densification and epiphyseal bone apposition	15 (48%)	10 ± 6
Increase in HKA-angle	17 (54%)	18 ± 11

Values are expressed as Mean ± SD; *Significant value

factors for poor bone quality ($p = 0.004$). A higher proportion of negative deltas of correction was significantly correlated with this type of RLLs ($p = 0.012$), but this group remained overall undercorrected.

For all three types of RLLs, the percentage of TKAs with post-operative HKA angle outliers and the amount of deviation was not significant (Table 2).

The authors found 31 TKAs presenting with potential radiological signs of AL (Table 3) in patients with RLLs. The first sign was a RLL around the tibial keel, seen as a white sclerotic line around the keel (Fig. 3a).

Second, in 48% of patients with signs of AL, the authors observed the apparition of metaphyseal bone densification under the tibial base plate and epiphyseal bone apposition on the side of the deviation (Fig. 3b). Finally, 54% of patients with signs of AL, presented a progressive mean increase of their post-operative HKA angle of 4 ± 4 degrees (Fig. 3c), appearing within a mean of 18 ± 11 months post-operatively (Table 3).

The majority of RLLs represented in this group of patients with signs of AL were Combined RLL (Table 4). The Isolated RLLs were sufficiently followed-up, from 5 to 13 years, to be certain they were not Sequential RLLs. For Sequential RLLs, the first RLL was immediate with a mean general time of apparition significantly earlier in this group of patients (6 ± 4 weeks for Time 1 ($p = 0.028$) and 16 ± 14 weeks for Time 2 ($p = 0.078$)) (Table 4). In the group of patients with signs of AL, the authors did not observe any major increase in size of the RLLs under the tibial base plate.

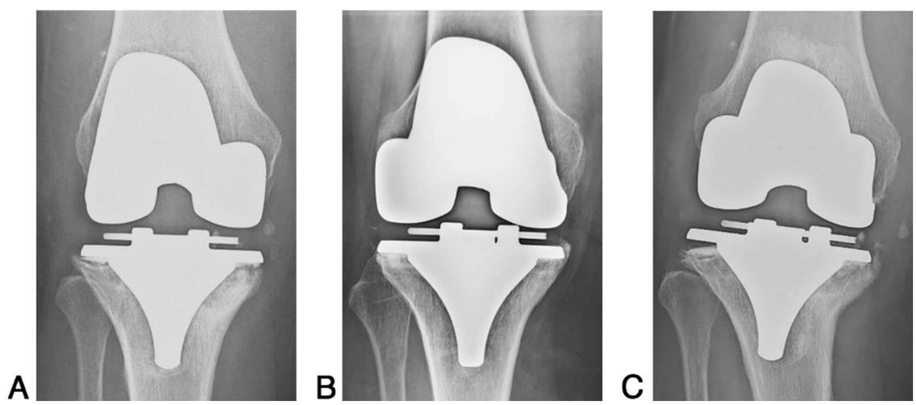

Fig.3 Signs of AL on post-operative X-ray's. **a** Radiolucent line around the tibial keel with bone densification and sclerosis at 1-year post-operative follow-up; **b** Metaphyseal densification and epiphyseal bone apposition on the medial side at 1.5 years; **c** Tilt of the implant with medial collapse at 3 years leading to revision

Table 4 Total knee arthroplasty with radiolucent lines without and with signs of aseptic loosening and revision cases: Time characteristics and time to revision

Variables	Number of patients (%)	Postoperative time of apparition of RLLs (weeks)		Postoperative time to revision of the implant (months)
		Time 1	Time 2	
TKA without signs of AL	147 (83%)	10 ± 12	28 ± 20	-
Isolated RLLs	74 (50%)	11 ± 14	-	
Combined RLLs	51 (35%)	11 ± 10	-	
Sequential RLLs	22 (15%)	7 ± 5	28 ± 20	
TKA with signs of AL	31(17%)	6 ± 4*	16 ± 14*	
Isolated RLLs	3 (10%)	3	–	
Combined RLLs	18 (58%)	7 ± 5	–	
Sequential RLLs	10 (32%)	4 ± 2	16 ± 14	
Revision cases	9 (5%)	4,7 ± 3	18 ± 19	55 ± 31

Values are express by Mean ± SD; * Significant value

In the group of AL, women were more represented ($p = 0.028$) (Table 5) with a higher risk of loosening associated with female gender (OR = 3.73, $p = 0.038$) (Table 6). Eighty percent of patients had clinical risk factors for poor bone quality ($p = 0.001$) (Table 5) with an OR = 4.21 ($p = 0.002$) (Table 6). The tibial base plate was smaller 69 mm ($p = 0.007$) (Table 5) and the multiple logistic regression showed that a bigger tibial implant size significantly positively influenced the absence or development of signs of AL (OR = 0.86, $p = 0.009$) (Table 6). The polyethylene size was significantly thicker ($p = 0.014$) (Table 5). Each increase of 2 mm of polyethylene thickness, increased the risk for signs of AL by a factor 1.3 (OR = 1.3, $p = 0.019$) (Table 6). The mean pre-operative HKA angle in the group of AL was significantly higher for both the varus ($p = 0.008$) and valgus ($p = 0.002$) group (Table 5). The majority of patients (29/31) with signs of AL had a post-operative varus angle, 11/31 were overcorrected from valgus to varus, and 18/31 were undercorrected varus. The post-operative HKA angle value was significantly ($p = 0.002$) higher in his group, and the analysis of the delta of correction showed that all patients with an increased post-operative HKA angle were in the post-operative varus group (Table 5). Forty-eight percent of patients in the AL group presented with a residual post-operative varus of the tibia of more than 3 degrees, compared to 22% for the group without signs of AL, and this difference was significant ($p < 0.001$) (Table 5). The multivariable logistic regression shows no significant increase of the risk for signs of AL according to age ($p = 0.2648$) or BMI of the patient ($p = 0.4294$). A post-operative HKA angle outlier > 3 degrees, significantly influenced (OR = 1.264, $p = 0.047$) the risk for signs of AL (Table 6).

Table 5 Signs of aseptic loosening: demographic data, surgical and mechanical alignment values

Variable	Radiolucent lines without signs of AL N = 147 (83%)	Radiolucent lines with signs of AL N = 31 (17%)
Demographic data		
Age (years)	69 ± 9	66 ± 9
Gender female/male	105/42 (3/1)	29/3 (9/1) *
BMI (kg/m2)	30 ± 6	29 ± 6
Clinical risk factor of Poor bone quality (%)	(67/147) 46%	(25/31) 81% *
Implant size		
Tibial base plate (mm)	72 ± 4	69 ± 3 *
Polyethylene (mm)	11 ± 1	12 ± 2 *
Mechanical data		
Pre-operative angle		
Varus	174 ± 5	170 ± 6*
Valgus	187 ± 4	181 ± 5*
Post-operative angle		
Varus	177 ± 2	175 ± 4 *
Valgus	183 ± 2	182 ± 0
Proportion of knees with a post-operative varus HKA angle > 3 degrees at 3 months		
Proportion (%)	39/177 (22%)	15/31 (48%)
Post-operative angle (degrees)	175 ± 2	172 ± 4 *
Proportion of knees with increased post-operative HKA angle at 4 years		
Proportion (%)	–	17/31 (54%)
From Valgus to Varus	–	7/17 (41%)
From Varus to Varus	–	10/17 (59%)
Delta of evolution (degrees)	–	4 ± 4

Values are expressed as Mean ± SD; * Significant value

Table 6 Multiple variable regression: clinical or surgical risk factors and signs of aseptic loosening

Variable	OR	IC	P value
Age	0,98	[0,94;1,02]	0,2648
Women	3,73	[1,24;16,19]	0,0378 *
BMI	0,97	[0,91;1,04]	0,4294
Clinical risk factor of poor bone quality	4,21	[1,79;11,13]	0,0018 *
Polyethylene size	1,3	[1,04;1,61]	0,0187 *
Tibial implant size	0,86	[0,76;0,96]	0,0089 *
Post-operative HKA angle > 3 degrees	1,264	[0,78;3,86]	0,047 *

*Significant value

Three TKAs (0.4%) were considered in need for revision because of loosening of the implant in our institution, because they combined clinical symptoms with radiological signs of AL (Table 4). Based on the National Joint Registry, six other TKAs with RLLs were revised for aseptic loosening in other centers. Three TKAs of that group only showed signs of RLLs and three others TKAs have indeed radiological signs of AL. This implies a survival rate of 98.4% for the entire cohort and 94. 9% in the series of 178 TKAs with RLLs under the tibial base plate (Fig. 4). It also implies that 33% of patients in this series were revised for RLLs and not for radiological signs of aseptic loosening.

Discussion

Fixation of all components, and more particular for this study, of the tibial component is a crucial factor to obtain pain relief and good functional outcome after TKA. Micromobility of the implant implicates the inability of the bone/implant interface to offer good early fixation. This can lead to macro-mobility of the implant when the bone is unable to compensate with remodeling and it will eventually lead

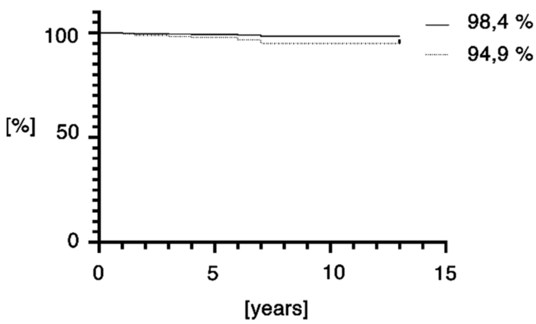

Fig. 4 Kaplan–Meier curve presenting survival of implant (absence of revision) as the endpoint in our series. The solid line: 98.4% of survival in the series of 774 TKAs; The dotted line: 94.9% of survival in the cohort of patients with RLLs

to tilt and aseptic loosening of the implant over time. In the recent literature there are, to the best of our knowledge, only rare descriptions and definitions of radiological lucent lines, their evolution and the difference with aseptic loosening at the tibial level component in TKA [3, 32].

The authors identified three types of RLLs, at the level of the tibial component, different by their radiological aspect (osteolytic or osteosclerotic), location, time of apparition and evolution. These observations at the epiphyseal bone/implant interface were, to the best of our knowledge, not described in literature before. Isolated RLLs were the most frequent type of RLL, followed by Combined RLLs and Sequential RLLs. Isolated RLLs appear early on the concave side of the corrected deformity, where the osteoarthritic wear was present. The medial side is, therefore, the most frequent location observed in this study, because of a higher proportion of pre-operative varus cases in this series [24, 27].

Combined RLLs appear early in both compartments under the tibial base plate at the same time and are observed in patients with bigger pre-operative deformities. They are probably explained by a simultaneous change of load on the epiphyseal bone on both sides under the tibial base plate. A higher amount of correction and the use of thicker polyethylene sizes in these cases, because of a lower tibial cut, can be the origin of this observation [33, 34].

Sequential RLLs appear on both sides under the implant, but sequentially in time. First, an early RLL is observed at the convex side of a residual post-operative deformity, corresponding with distraction forces. The second RLL is later observed at the concave side of the deformity with a compression of the tibial bone. These conditions were found more often in undercorrected patients, such as in constitutional varus or when the surgeon positioned the implants in varus on the tibia [19].

In Sequential RLLs, the observation of the apparition of the second line, some weeks after the first line, is important. Despite of the relative earlier apparition time of a lucent line in this type of RLLs, the apparition of a RLL in one compartment does not make it an Isolated RLL as it can always evolve to a Sequential RLL. Therefore, radiological follow-up remains important up to 1 year after surgery. In this study, the apparition of all types of RLLs, was within the first post-operative year, and more specifically within the first 3 months after surgery, in contrast to previous studies [7, 12, 16, 24, 35].

The authors observed two types of RLLs without any consequences on the survival of the implant. The most frequent radiological aspect was an osteosclerotic RLL, much more represented in Isolated RLLs, probably due to the absence of cement penetration at the side of pre-operative sclerotic bone in minimal tibial resections, as previously observed in the literature [2]. The other aspect is the osteolytic RLL, a radiolucency of 2 or 3 mm, associated with a metaphyseal densification under the RLL. The authors have observed a decrease in size and disappearance after 2 years by bone remodeling in a stable implant [4, 36]. Osteolytic RLLs are most often observed as either an Isolated or a Combined RLL. In the Combined RLLs, the osteolytic RLL does not disappear for 50% of patients, but remains stable if metaphyseal densification appears. The authors did not observe more cases of aseptic loosening in patients with osteolytic RLLs, so they do not consider this radiological aspect as a higher risk factor for loosening, in contrast to the past where osteolysis was a clear sign of polyethylene wear and secondary loosening [2, 30].

The authors demonstrated three progressive signs of AL appearing in a specific order and visible on successive post-operative X-ray's, with different rates of representation for each patient (1–3 signs), depending on the level of progress of AL in each case. These signs appear later, after first apparition of RLLs under the tibial implant, testifying of a progression of the micro-mobility to macro-mobility of the implant, at each apparition of a new sign. To the best of our knowledge, this sequence of apparition of signs of AL as the authors observed, has not previously been described in the literature. The authors only found one study, reporting patterns of migration without radiological description [42]. In this series, the first sign observed was a RLL around the keel, considered by the authors as the progression of the micro-mobility of the implant from the epiphyseal zone (RLL under the implant) to the metaphyseal zone (RLL around the keel). This aspect appears a few months after surgery due to an increase of the bone mineral density, inducing a mineralization of the mobility chamber, visible and stable for years as a white border around the keel [43–45]. The second sign observed, was an epiphyseal bone apposition on the load-bearing side of the post-operative HKA angle (medial for varus alignment). Easily explained by the modification of the cancellous bone elasticity (Wolff's Law) [38, 46], this reaction may be sufficient to compensate and "stabilize" the implant as observed in this and other studies [47, 48]. The third sign observed, was the increase of the post-operative HKA angle visible on successive standing full leg radiographs. The authors believe that this sign, visible from the second to the 4th year after surgery, is the most objective and pejorative sign of progression of the macro-mobility [49] and measurable by a medial shift of the load-bearing axis [50]. Ritter, described this mode of failure as the inability of the bone to compensate for the increased contact stress on the medial side, as observed in knees aligned in varus leading to failure by tibial collapse [48, 51].

The concept of potential AL observed by an increased size of RLL is a previous literature concept. Indeed, increases of RLLs is defined as a potential sign of AL, but in this study, the authors have found that only osteolytic RLLs showed small modifications in size: this can be both increase and decrease without necessarily an evolution to AL. The apparition of signs of macro-mobility as defined by the authors: RLL around the keel, periosteal epiphyseal apposition and increases in HKA angle, are objective radiological signs of AL.

In this series, some patients showed a slow increase of the HKA angle (< 3 degrees) and apparent progressive stabilization by epiphyseal and metaphyseal bone apposition on the side of the post-operative deformity. In the absence of pain and without a progression in their HKA-angle, they were not revised. Other patients, presenting with a sudden and important increase of the HKA angle without apparition of bone apposition, often being painful, were revised by the authors because of aseptic loosening. Full leg standing radiographs are not performed in all institutions, but this study emphasizes their importance as a load bearing analysis of the progression of deformity and the need for revision.

The signs of AL were observed in patients with early Sequential and Combined RLLs presenting clinical risk factors of osteoporosis and female gender, confirming previous studies [52]. AL might be explained as macro-mobility, after suboptimal epiphyseal fixation allowing micro-mobility of the implant, caused by more important constraints on poor bone quality, by the final alignment (varus) or by the more important lever arm on the implant induced by a lower cut and a thicker polyethylene, as previously observed [36, 47]. In these patients, the authors suggest to be attentive for the apparition of the first signs of macro-mobility, by following the post-operative HKA angle and the evolution of the mechanical pain. Therefore, clinical and radiological follow-up seems indicated.

In case of the presence of pre-operative risk factors for aseptic loosening, such as in women with clinical risk factor for osteoporosis and more important deformities, the authors suggest to adapt the surgery to the patient by choosing the best epiphyseal coverage possible and with more metaphyseal stability, as described for newer anatomic implants or by the use of short stem extensions [13, 36, 43].

This cohort study carries several limitations. First, it is a retrospective study, with all limitations of such a study design, because the study protocol had no impact on the quality control of specific incidences of the post-operative X-ray's. Fortunately, our radiology department has since many years been looking specifically for RLL on coronal X-ray's and knows the importance of rotation in the coronal plane. Furthermore, the exact timing of the radiological follow-up was less rigid than if this would have been a randomized controlled trial, but for 2 decades long all patients were seen at 3, 6, 12 and 54 weeks post-operatively, allowing some standardization. Some osteosclerotic RLLs may have disappeared, because of a wrong position of the beam more than a physiological evolution of the line, without CT or fluoroscopic evaluation impossible to say. Second, only two experienced knee surgeons were involved in the surgeries, what might have led to a reduction of alignment outliers despite of conventional instrumentation. Their alignment target was 178° HKA in the varus and 182° in the valgus knee [26] with one surgeon aiming for tibial neutral and femoral undercorrection and the other for tibial varus of 3°. This study overall alignment outlier cases included extra-articular deformities at the tibial or femoral level ranging from old fractures, bowing or constitutional varus of the tibia. Individual component positions were not measured as tibial or femoral coronal angles. Third, these findings potentially only apply to the Vanguard implant, which is known to have good survivorship [38]. The keel design, with a cruciate finned tray, is intended to be press-fit and used without cement application, but does not allow for a stem extension to the primary components. Fourth, although our series contains 774 patients, the authors found only a small amount of RLLs (4%) with predictive signs of aseptic loosening and only 9 cases needing revision (1.2%). Fifth, in this study, the absence of clinical data collection and individual component positioning for patients without RLL, did not allow the authors to use that group as a control for statistical comparison. Another limitation would be that the authors have observed RLLs only on an AP and not on lateral views because of the ease of observation, the presence of a validated Knee Society Classification System for the coronal plane and sometimes the absence of true lateral views. A combination of a RLL in two planes might have another impact than only in the coronal plane, but the end-result of an aseptic loosening should than be observed anyway. A final limitation is that the description of RLLs of the femoral component was not performed in this study, because the authors rarely observed RLLs around the femoral implant in this series.

Conclusion

RLLs about the tibial implant are frequent (23%) and do not necessarily mean that the component is loose and should be revised. These radiological lines are indicative of bone remodeling around the implant, induced by the surgery. Combined and sequential RLLs could be behaving badly and should be closely followed at least for 1 year after surgery with radiographs. Isolated RLLs can be considered stable, if no change appears after 3 months. Radiological signs of AL, as described in the current study, in the presence of pain should be considered an indication for revision. For the same implant, surgical and patient risk factors for loosening are lower levels of tibial resection, undercorrected varus deformities in the young and active person and overcorrected valgus deformities in the osteoporotic elderly female patient.

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Data availability Data may be available on request.

Declarations

Conflict of interest DW declares no conflict of interest in regard to this work. ET reports personal fees from Conformis (Billerica, MA, US) in the amount of USD 10,000–USD 100,000, Lima (Udine, Italy) in the amount of USD 10,000–USD 100,000; Zimmer Biomet (Warsaw, IN, US) in the amount of USD 10,000–USD 100,000. ET has received royalties for a patent from Conformis (Billerica, MA, US), Lima (Udine, Italy) and Zimmer Biomet (Warsaw, IN, US). ET) has received institutional research support from Zimmer Biomet (Warsaw, IN, US) for an amount of USD 10,000–100,000.

Ethics approval All investigations are conformed to the Declaration of Helsinki and are approved by the ethical committee of Comité Ethique Hospitalo-Facultaire Saint-Luc-UCL: 2017/10MAI/262.

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