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ORIGINAL STUDY

Radiolucent lines around knee arthroplasty components : a narrative review

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Aseptic loosening of total knee arthroplasty (TKA) components is one of the frequent reasons for early revision together with infection and instability. Aseptic loosening is usually preceded by the observation of radiolucent lines (RLL) on radiographs. Radiolucent lines have conventionally been considered a sign of osteolysis due to particles disease of either polyethylene or cement wear. However, RLL can be observed quite early after TKA, way before wear and osteolysis can even occur. Immediate postoperative RLL are secondary to surgical technique with either inadequate cement penetration in sclerotic bone, insufficient preparation of the bone or malpositioning of the component relative to the bone cuts. This type of RLL can be observed radiologically but remains often without clinical symptoms. Early development of RLL, on an initially satisfying radiograph, is secondary to changes to the cement-bone interface. These are most often related to micromotion because of constraint, malalignment, remaining mechanical deformity, erroneous bone cuts or osteoporosis. This type of RLL are observed progressively on follow-up radiographs and can be accompanied by pain complaints despite of initial good outcome. Young age, male sex or osteoporotic bones often found in elderly females, are all risk factors.

A special form of aseptic loosening is tibial debonding that has been observed for different types of implants and different types of cement. It occurs at the cement-implant interface with cement remaining well attached to the trabecular bone. Probably it is a lack of cement adhesion between the high viscosity cement and the component. Revision is proposed upon diagnosis to avoid component's displacement with secondary destruction of the proximal tibial bone.

Finally, RLL can develop over time secondary to polyethylene wear. These lines appear because of osteolysis and bone loss and will lead at the end to aseptic loosening of the components. Symptoms are related to failure of the implant-bone construct.

Radiolucent lines without clinical symptoms should be analysed according to their potential reason of development and followed up closely with adequate radiological techniques. If symptoms develop or radiological imaging objectivizes failure and component mobility, revision knee arthroplasty might be necessary.

Keywords : aseptic loosening ; radiolucent lines ; knee arthroplasty ; cement, revision.

INTRODUCTION

Osteoarthritis (OA) of the knee is one of the future medical challenges for the next decades. An increase in total knee arthroplasty (TKA) demand

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of 673% is forecasted for 2030 with a cumulative rate of 306% increase between 2012 and 2030 for revision surgery *(47)*. Patients undergoing this type of surgery remain more active than ever before and have TKA performed much earlier in their lifetime than previous generations *(25,31,42,50,53,64,69)*. Knee OA is becoming more frequent because of an increase in body mass index (BMI) with a growing burden of obesity, due to the consequences of previous knee surgery (meniscectomy, anterior cruciate ligament (ACL) reconstruction) and because of lower limb malalignment. Bellemans *et al* have shown that especially athletes during their adolescence develop varus alignment, with potentially later in their lifetime the development of OA *(15)*.

Patients undergoing TKA expect longevity of the implant and wish to avoid revision of their arthroplasty. Failure in TKA can be either early or late. Instability, infection and aseptic loosening are the three most frequent causes of early revision *(30)*. Radiolucent lines (RLL) are often the reason to suspect aseptic loosening and to revise one or more components for loosening. Radiolucent lines come however in different shapes and forms. The radiolucency can be early or late onset. The most frequent causes for early RLL are bone osteolysis because of thermal necrosis during cementing, debonding at the cement-implant interface, mechanical bone resorption because of poor bone quality, micromotion of the implant at the cement-bone interface or cement allergy *(57,60,35,70)*.Sometimes it is a late stage development because of polyethylene wear and debris resorption.

Radiologic imaging can assess radiolucent lines if the imaging is performed according to standard guidelines and fluoroscopic positioning of the beam parallel to the components *(14)*. If the RLL are asymptomatic and stable over time, observation is sufficient. If however, the radiolucency is progressive and signs of component mobility are observed, surgery might be required. In those cases a diagnostic algorithm should help the surgeon identify and differentiate component loosening for aseptic or septic reasons.

This narrative review on radiolucent lines around knee arthroplasty components has the ambition to answer the following research questions. What does aseptic loosening of components exactly mean ? How should we define RLL according to literature ? How can we recognize and classify them ? How can we distinguish radiolucent lines from osteolysis ? Are all RLL identical ? Are all RLL diagnostic for loosening of the components ?

MATERIALS AND METHODS

A systematic literature search was conducted by the authors (DW and SF). The senior author (ET) advised about inclusion of a paper in case of doubt between the other two authors. The electronic databases searched were: MEDLINE and Google Scholar. Search was based on “arthroplasty, replacement, knee”[MeSH Terms] OR (“arthroplasty”[All Fields] AND “replacement”[All Fields] AND “knee”[All Fields]) OR “knee replacement arthroplasty”[All Fields] OR (“total”[All Fields] AND “knee”[All Fields] AND “arthroplasty”[All Fields]) OR “total knee arthroplasty”[All Fields] AND ((radiolucent lines [Title/Abstract]) OR (radiolucency [Title/Abstract]) OR (osteolysis [Title/Abstract]) or (aseptic loosening [Title/Abstract])) Initially, 1121 articles were found. Based on the title and abstract read and after removal of duplicates, 286 articles remained. The full text of each of these articles was read and another 91 articles were considered non-relevant and removed from the database. The final number of articles included in this review was 71. Their data and content was used to define and answer the following questions covered in the discussion.

DISCUSSION

1) What does aseptic loosening of components exactly mean?

Aseptic loosening (AL) is a frequent mechanism of implant failure *(12)* because of the loss of fixation between the implant/cement and the bone because of inadequate initial fixation, mechanical loss of fixation over time or periprosthetic tissues remodeling associated or not with osteolysis due to an intra-articular inflammatory response.

Polyethylene (PE) wear, osteolysis and instability can all lead to AL *(48,53)*. The tibial component is the most common site of loosening in TKA *(13,22,68)*.

AL is the most common late mechanism of failure *(3,36,48,53,58,70)* over a period of 10 to 20 years *(2)* leading to progressive arising of pain, functional limitation, difficult weight-bearing and gait alterations, leading finally to component mobility, implant migration *(10,12)* and revision surgery *(19,28)*.

2) What is the frequency of AL according to both literature and registries?

A recent review *(30)* based on arthroplasty register data showed that the risk of revision after TKA in UK was <5%, 4% in Sweden, 5% in New Zeeland and 6.8% in Australia at ten years post operatively.

According to the registries, AL is still the main cause of revision with 29.8% *(27)* and this can reach up to 40% according to previous studies *(45)*, followed by 14.8 % for infection and 9.5% for pain. This finding is in contrast with retrospective studies based on US registries, which showed that infection was the first cause of revision followed by loosening, PE wear and instability *(5,35)*. In Asia *(32)* infection is still the most common cause of failure (38%) in the 5 first years followed by loosening 33%, wear 13% and instability 7%. But AL was the most common cause of failure after 2 years (*13,33,35,70)*, as shown in a recent multicentre study.

3) How can we define RLL according to the literature?

Radiolucent lines are defined as a radiolucent interval (measured in mm) between implant and cement or between cement and bone *(3,22,58)*. Radiolucent zones are quite often observed in the immediate post-operative phase *(3,22)*, and are frequently localized under the most medial or lateral zones of the tibial plateau (zone 1 and zone 4 according to Knee Society Roentgenographic Evaluation System) *(52,58)*. RLL may be attributed to poor cement penetration into cancellous bone or micromotion between the implant-cement or bone-cement interface, leading to bone resorption and cement loosening *(3,13,22)*.

Several studies have shown that the width and extent of RL zones of the tibia tend to progress from 3 months to 2 years post operatively *(3,13,22)* with a mean time to failure of progressive RLL within 3.7 years as observed by Berend *et al* *(11,55)*.

4) How can we recognize and classify RLL?

The Knee Society Roentgenographic Evaluation System of Ewald and the Modified Radiographic Evaluation System of Bach *et al* are the most reproducible and reliable protocols to study RLLs on radiography *(9,6)*. This method consists of adding in each of the specific component zones, the measured width of the RLLs present on the two radiographic views (frontal and lateral view) to classify it as narrow or wide. If the sum of the widths of the RLL is 4 mm or less, the category "narrow" is used, if the total is greater than 4 mm the category "wide" is used.

Widths numerical additional score of each zone for each component is calculated. For the tibial component a numerical score of 0-4 suggests a stable or non-progressive radiolucent line, followed by progressive RLLs (score 5-9) and finally failure implant status when the total score reaches 10 or more *(18)*.

A radio stereometric analysis (RSA) study by Ryd *et al*, showed that the tibial component is at higher risk for aseptic loosening than the femoral component *(68)*. Moreover, RSA permits to define and predict implant loosening, by observing early migration *(13,68)*. They define migration of more than 2 mm between 12-24 months to be considered as "continuous migration" with increased risk of AL *(68)*. A recent Cochrane review showed that cemented implants migrate less than uncemented components, but showed a higher risk for aseptic loosening due to a continuous migration pattern *(68)*.

More recently, a modern knee society radiographic evaluation system and methodology for TKA, has been developed, describing the general location/regions of RLL, and osteolytic lesions in primary and revision knee *(43)*. The lucent lines are graded as partial or complete and osteolytic regions should be documented in mm in the zone location *(43)*. This evaluation system is descriptive, not predictive or prognostic.

5) What is the difference between RLL and osteolysis? Which pathophysiological mechanisms and radiological observations can we make?

Constraint on the implant, leads to micro movement, bone or cement fracture and production of wear debris. These third bodies will create and maintain a biological inflammatory reaction, which leads to osteolytic lesions (osteolysis) and finally loosening of the implant *(21)*.

Osteolysis occurs as the result of a foreign body response to particulate wear debris from the prosthetic joint with a frequency between 0 and 16% for cemented TKA *(39)*. These particles of polyethylene (PE), polymethylmethacrylate (PMMA) cement or metal, will induce a distinct inflammatory response *(21,23,38)*. The macrophages and giant cells in the synovial and periprosthetic tissue will phagocyte these wear particles. These cells will induce osteolysis by direct bone resorption or indirectly by stimulating cellular inflammatory responses. The activated macrophage begins the production of cytokines, especially interleukin 1B, a pro inflammatory and pro osteoclastic cytokine. This IL-1B has also a minor effect on decreasing bone formation by its action on osteoblast activity *(38)*. Simultaneous, the inflammatory signal directs the growth of pseudo synovial granulomatous tissue and the secretion of joint fluid, all contributing to the expansion of osteolytic cavities around the TKA *(21)*. PE wear is a chemically inert material comparable to metal particles; in consequence macrophages are unable to degrade them once they have been phagocyted *(46)*. PE wear particles in joint arthroplasty may differ in type and size according to the wear mechanism. The generation of particles starts immediately after surgery, due to functional forces *(21)*, but the osteolytic potential of wear particles is dependent on particle size and volume *(46)*. PE wear in TKA occurs from a combination of rolling and sliding and rotational motion creating smaller bioactive particles. Other sources of wear such as third body wear, fatigue fracture or delamination of the PE surface or stress fracture of the post will create large flakes or pitting particles *(21,23,38)*. Osteolysis around the tibia tends to occur along the periphery of the component or along the access channels of the cancellous bone *(2,38)*.

6) What are the major causes of RLL? Why do they appear? What is their natural evolution?

Radiolucent lines, which often precede loosening, can be a direct witness of mechanical or biological processes firmly entangled that lead to weakening of the bone and loss of cohesion with the cement *(21)*. During the first year after TKA, the loss of bone density is almost 23% and generally normalizes in the majority of patients after 3 years *(21)*. However, mechanical factors such as daily life or physical activities in young patients, obesity, malalignment, are all influencing the bone cement interface *(21,23)*.

Loosening of an implant, in the early phase, may be due to a cementation complication such as thermal or chemical necrosis or a technical error. In younger and more active patients micromotion may induce loosening of the implant by loss of interlock between bone cement and trabecular bone *(40,41,68)*. Over time, loosening may occur due to an osteolysis phenomenon, by wear debris or loss of periprosthetic bone stock in older patients, influencing the longevity of the implant *(25,40,44,68)*.

It's important to distinguish failure due to mechanical, or cumulative stress on an initial well-fixed implant, and an early loosening due to technical error *(21)*.

In the past, many authors tried to explain the histology of RLL. Some theories proposed RLL as macrophage induced osteoclasis by Freeman in the 70s and 80s, another theory saw RLL as thermal necrosis and micromotion by Charnley in 1970 and a third potential explanation was seen in trabecular bone quality at the level of the bone cuts by O'Connor and Goodfellow in 1982 *(63)*. Since these times no new theories have been proposed.

The preparation of the tibial surface with cleaning and pulse lavage, the cementation technique and the technical side of the surgery are well known factors to have a significant effect on reducing the occurrence of RLL *(22,58)*. As well as imperfect cuts (stress shielding) and micromotion that both increase the risk of loosening *(58)*.

Smith *et al* *(3)* described on radiostereometric analysis (RSA), two types of RLLs. The first type is a non-progressive RLL that results from poor cement penetration into sclerotic bone. This occurs in about 15% of tibial implants on early-onset , they are non-progressive and typically in relation with pre-operative sclerosis, but no tibial osteolysis and no tibial component revision for AL are observed.

Non progressive RLL are <2mm thick, have shown no correlation with a poor clinical outcome and thus confirm other studies, which have suggested that tibial implants presenting these RLL were not automatically subject to revision *(13,63)*. Such RLL do not affect fixation, but they could facilitate the entry of debris into the interface, they can progress and become the second type, which is progressive, and can quickly expand to become obvious areas of osteolysis *(3,13,22)*.

Radiolucent lines can also be a sign of interface membrane growth with the mechanical and fluid pressures in association with the biological cascade of osteolysis and the AL process *(21)*. When a gap at the cement-bone interface occurs, it's always present immediately after TKA surgery *(21,51)*. This empty space at the bone-cement interface will be filled by fibrous tissues containing few cells and blood vessels. The mechanical stress and fluid movement induced by walking, leads to proliferation of fibroblast synthesizing extracellular matrix in order to adapt the stress and strain around the implant. The macrophages specially activated by PE wear and pressure increases their expression of cytokines *(21)*. In this environment, a combination of mechanical stress and hypoxic condition will lead to proliferation of fibrous tissues containing macrophages, fibroblast, and multinucleate giant cells *(21)*.

Aseptic loosening has a multifactorial etiology *(5,10,13,51)* with as main factors; the patient (age and BMI), the implant (type of polyethylene, type of constraint, design) and the interface (type of cement and cementation technique). Some surgical or technical errors such as inadequate fixation *(2)*, excessive tibial cut or varus alignment *(5,10,27)* but also bone quality, genetics, and endotoxin factors may be responsible *(2,13,27,49)*.

1. Patient Host Factors

A recent study on host factors affecting survival of the implant found a significant correlation between the age and sex of the patient, with especially young men at risk for aseptic loosening *(21,27,30,32)*. All studies agree that the revision rate increases with decreasing age *(27,30)*. According to the Swedish register, patients younger than 65 years have twice the risk of revision than those with an age of more than 75 years. In Australia, at 4 y follow-up, patients younger than 55 years have a more than 4.5 times increased risk for revision compared to those aged more than 75 years *(30)*. In Asia, a multicenter study *(33)* confirmed that loosening was the first cause of failure (33%) for people younger than 65 years. They also found that for each 10 years of increment of age, there is a decreasing risk of aseptic loosening of 70% *(33)*. Others found an increased risk of 5% per decreasing year of age *(51)*. Some report that men have a higher rate of revision than women, with a cumulative risk of revision (CRR) of 1.6.

In the English registries, the CRR for men aged more than 75 y is 2% at ten years and the CRR for men younger than 55 y is 12%. The main reason is that young people are more demanding and have higher expectations of their TKA combined with higher activity levels *(30,33,42)*. The consequence is that either PE wear or too much constraint on the bone-cement interface leads to loosening of the implant.

A recent study, based on the risk of AL in obese patients *(1,21)* found a significant correlation between a higher BMI of 35 kg/m², despite a well aligned TKA, and the risk of aseptic loosening. In their series, 1% of the TKA were revised for AL, closely matching the 1.3% rate previously cited by Breed *et al* with a mean time to revision of 5.6 +/- 0.4 years. They calculated a cumulative probability of revision of 0.8% and 2.7% at 5 years and 15 years respectively *(1)*.

They also found that obesity with a BMI > 35-40 kg/m² has a cumulative risk of revision for aseptic tibial loosening at 5 years and 15 years of 1.2% and 4.3% versus 0.5% and 2.2% respectively for normal weight, so 2 times more at 15 years.

Another potential factor adding to RLL, is excessive tibiofemoral varus alignment, varus tibial component positioning and excessive tibial resection *(21)*. Although studies have shown that residual varus alignment in patients with pre-operative varus leads to better clinical outcome *(31,33,64)*. Several biomechanical studies have demonstrated that postoperative tibial varus alignment of more than 3° increased medial tibial surface strain *(5,10,17,21,35,39,54,65,68)* with a load distribution over the medial plateau between 70 and 77% *(39)*. This overload on the medial side leads to asymmetrical PE wear but also medial cancellous bone strain and finally implant failure by medial collapse, especially in younger active patients *(39,65)*. Toksvig Larsen and Ryd *(52,58)*, reported that a gap of 1mm to 2mm between the lower and the uppermost point of the tibial plateau after cutting, will induce more tibial stress shielding. Berend *et al* showed that the cumulative risk of high BMI > 33.7kg/m² associated with varus tibial component alignment, increases the risk of failure by 168-fold *(1,10,17,55)*.

2. Bone quality

Successful TKA depends also on the quality and the mechanical properties of the periprosthetic bone *(55,65)*. This quality may be altered by preoperative conditions such as osteoporosis and osteoarthritis or because of the surgery leading to a higher risk of loosening and revision.

The measurement of bone mineral density (BMD), is based on the amount of mineral calcium of the bone by Dual-Energy X-ray Absorptiometry (DEXA), a validated and suitable method for monitoring bone remodeling close to the implant during the post-operative period *(21,65,68)*. However, measurements might be wrongly influenced by knee positions such as flexion or rotation *(65,68)*.

Studies based on this method have shown that BMD in a well aligned TKA decreases from baseline to the 12 month follow up but reaches baseline levels after 24 months suggesting that implant migration is related more to interface issues such as the general condition of trabecular bone than a change in BMD below the implant *(68)*.

Pre-operative osteoporosis seems to be a risk factor for TKA surgery, exposing patients to a higher risk of aseptic loosening and revision by a reduction of the bone mineral density (BMD) *(21,68)*. However, any significant correlation based on actual Dual-Energy X-ray Absorptiometry (DEXA) measurement and urinary DPD/creatinine ratio studies have been found *(25)*. Although, the use of bisphosphonates in post-menopausal women, has shown an increased BMD in spine and hip densitometry after 1 year of treatment *(37)*. Any significant results in terms of fracture prevention after TKA have been shown *(37)*.

The use of bisphosphonates 10 mg in association with calcium 500 mg per day during 6 months post operatively *(59)* prove to maintain bone microarchitecture and greater implant stability at 12-24 months postoperatively by a reduction of periprosthetic BMD loss reducing the rate of revision surgery *(25)*.

The tibial metaphyseal bone, can adapt to mechanical alterations such as malalignement caused by osteoarthritis *(21)*. For example, pre-operative varus knees have a higher BMD under the medial plateau due to mechanical stress caused by the mechanical deformity.

The change in BMD post TKA has been widely studied, from the early post-operative period to the long term, with a range of reducing BMD from 5.1 % up to 44% *(37,68)*. This change may be due to stress shielding or changes in load after correction of any preoperative malalignement *(26)*.

Patients with low post-operative BMD have demonstrated to be at higher risk of failure by prosthetic loosening and migration *(21,55)* but also those with a high BMD in the medial tibial region. This finding suggests that proper alignment might be important in maintaining optimal conditions for bone density *(36,55,68)*.

This change comes from the stress inducing strains on supporting bone, stimulating remodeling and resorption, leading to a postoperative decreasing bone density *(36)*.

In case of sclerotic medial bone, failure of implant may occur by poor penetration of cement into the trabecular bone. But when the BMD is lower, the process of failure comes from the possible fragility of the trabecular bone supporting the tibial component, leading to fracture or collapse under the tibial tray, suggesting that proper balancing of forces, to a more physiological status, and proper alignment, is more important to maintain good conditions for bone density *(55)*.

In 2014, Ritter proposed to use a routine x-ray protocol to predict failure on pre- and post-operative radiographs *(68)*. He observed in the general TKA population, a significant reduction of density in all regions over time, from 2 month to 10 years postoperatively, with a greatest decline in density in the medial regions, followed by the lateral and distal regions to the keel *(68)*.

In the progressive RLL and medial collapse knee group, he observed early on significantly higher medial bone densities beyond one year in all medial regions before failure *(55,68)*. He attributed this earlier (2 month) high medial density to an excess altered mechanical load (varus and BMI) increasing stress and bone remodeling leading to medial collapse or failure. This was confirmed by biomechanical studies showing a significant correlation between tibial strains and component malalignement *(68,55)*.

Another factor that may influence bone quality is bone resorption, induced by micro motion between cement and trabecular bone, leading to increased circulation of interstitial fluid, which causes fluid induced resorption of trabeculae. This strain shielding could also cause bone resorption *(64)* in younger and more active patients.

3. The Implant

The properties of the implant may lead to failure either by a mechanical or a biological loosening process. Due to excess wear, polyethylene particles produce a pro inflammatory state, which leads to increased osteoclast differentiation and macrophage production. This ultimately leads to local osteolysis and aseptic loosening around the prosthesis *(2,10,27,30)*.

Some studies have pretended that the relative frequency at which RLLs appear on postoperative radiographs and their location depends on the design of the total knee arthroplasty *(22)*. Subsequent changes in design and surgical technique have decreased the risk of early aseptic failure of the tibial or femoral implant *(64)*. Historically, aseptic tibial implant loosening at the bone–cement interface was an observed cause of failure with semiconstrained TKA implant designs *(35)*. Cheng *et al* described early aseptic loosening of the tibial component after TKA with de-bonding between the tibial component and cement mantle and an intact cement–bone interface *(28,35)*.

It's well known that smaller tibial size and higher BMI have an increased cumulative risk of mechanical loosening and migration *(10)*. Kajetanek *et al* observed more aseptic loosening with smaller tibial keels in the same knee design *(29)*.

7) Cemented versus cementless implant, do new tech-nologies permit to forget the past?

New cementless implants have evolved considerably thanks to new surface coatings. Some are 3D printed and others are in trabecular metal, which allow better osteointegration with morphological and biomechanical properties approximating that of trabecular bone. This has potential benefits, but still these techniques remain more expensive *(8,7,16,45)*

Advantages of a cementless implantation are shorter surgical time, preservation of bone stock, revision without cement removal and elimination of complications associated with cemented fixation like third body wear and retained loose fragments *(20,45)*.

Compared to cemented implants which provide immediate stability, cementless implants have a higher risks of early post-operative loosening with nevertheless long-term results comparable to cemented implant *(8,45)*.

Previous studies reported that both clinical outcome and long term survival were inferior for cementless components, specifically on the tibial side *(20,8,4,45)*. This was observed for the first generation of cementless designs, metal backed patellae and the use of conventional polyethylene. With time, cemented implants became the gold standard but better surgical techniques and comprehension, improvement of biomaterials, and higher rates of osteolysis in the young patient lead surgeon to search for a new solution for fixation *(4,45)*. Specifically for patients younger than 65 years where the bone stock is good enough to allow osteointegration.

To ensure good primary stability of the implants bone resections must be performed accurately while avoiding gaps between the host bone and the components. In cemented TKAs, the cement mantle can easily fill small defects in resections without affecting the stability *(4)*. Rotating platform designs reduce the stresses at the tibial plateau interface and reduce shearing forces, often at the origin of early loosening *(4)*.

Literature reports similar long term results for modern hybrid fixation systems, combining a cemented tibial and patellar implant with a cementless femoral implant *(4)*.

8) Which indication is reserved for a cementless implant?

The number of patients younger than 65 years suffering from OA have considerably increased. These patients have high expectations and more demanding level of activities, despite the advances in surgical technique this remains a challenge. There is still concern that these implants will not last for the entire lifetime of many patients, with consequently a high revision rate due to more loosening phenomenons by greater stress on the implants *(4)*.

In THA, cementless implant have improved by decreasing the cause of failure, particular osteolysis around the implant and cementless TKAs in young patients (<65 years) with adequate bone stock is the concept that osteoconductive component surfaces, in the presence of a very active bone metabolism, show high biological properties *(4)*.

9) Which pattern of loosening can be observed with a cementless implant?

Fricka et al described that osteolysis patterns also differ depending on the mode of fixation. Among cemented components, loosening is characteristically preceded by the development of a linear radiolucency at the cement bone interface. In contrast, osteolysis associated with cementless implants typically demonstrates an expansive pattern in the metaphyseal bone that rarely interferes with component fixation *(20,4,45)*.

Radiostereometric analyses (RSA) allow to understand the different migration patterns shown by TKA components with the two different fixation methods. Cementless tibial baseplates may migrate early, i.e., in the first three months postoperatively, usually reaching stability after this interval; but cemented tibial components, on the other hand, do not migrate in the immediate postoperative period, while they may show micromotion over 60 months *(4)*. Cement is known to have poor resistance to shear and tensile forces, which can result in disruption of the bone cement or cement implant over time, creating third bodies leading to osteolysis and migration patterns *(45)*.

Recent RSA studies have shown better osteo-integration, mineral density and retention of bone stock and remodeling capacity, and so better long term survival *(8,4)*.

Cementless implants have shown in the morbidly obese better fixation and lower loosening rates, probably due to the osteoinduction properties and better peri-prosthetic BMD induced by stress loading *(7)*.

10) What is the role of cement and cementing technique in the development of RLL?

The occurrence of implant loosening has decreased following improved cementation techniques. Fehring *et al*, observed a decreasing rate from 40% to 25% of revisions in case of well-balanced cemented TKA *(36)*. Initial fixation of cement by adequate preparation of the bone surface is paramount for avoiding long-term failure of the tibial component *(22,61)*.

The intrinsic and extrinsic properties of bone cement such as preparation and application techniques are among many factors that affect the strength and stability of the bone–cement–implant interface *(35)*.

1. Cement properties

Polymerization of bone cement occurs by mixing 2 co-polymers, polymethylmetacrylate powder and the methylmetacrylate monomer, forming the crystal PMMA during an exothermic reaction. This polymerization progresses through four phases: a mixing phase, a waiting phase, a working phase and a hardening phase. This late phase can continue four weeks after implantation *(59)*.

These 4 phases can be modified by properties of the cement, such as the porosity *(61)*. High viscosity cement (HVC) has relatively shorter mixing and waiting phases due to a fast polymerization process. The amount of temperature created by an exothermic reaction is correlated with a faster polymerization process and a shorter setting time *(59)*. HVC has a longer working and hardening phase in comparison to lower viscosity cements, diminishing the depth of bone penetration to almost the double *(13,28,35,59)* as shown by Rey et al *(28)*.

Secondly, these properties will also affect the strength of cement, stronger with compressive forces than compared to shear and tensile forces *(45)*. These properties can lead to the development of micro fractures, which could contribute to crack propagation and de-bonding at the cement–implant interface *(35,59)*.

Thirdly, thermal bone necrosis is temperature and time exposition dependent *(9,52,38)*. Below 47°C, literature reports no osseous injuries, but when the bone is exposed at temperatures between 47-50°C for 1 minute or more, bone absorption, fat cell degeneration and vascular necrosis injuries occur *(13,59,70)*. Furthermore, higher saw blade temperatures on sclerotic bone may induce necrosis *(70)*.

Animal models show that thermal necrosis occurs after an exposition of > 1 minute above temperature of 53° leading to bone remodeling 3-5 weeks after thermal event.

The exothermic reaction of the polymerization of 100 G of methyl methacrylate monomer used for cemented implants produces 13Kcal of heat, equivalent to in vivo bone temperatures of greater than 100°C.

Modern techniques of cementation, such as cooling the cement permits to obtain better penetration of cement, with narrow thermal safety margins (36.81 +/-4.71) as shown on cadaveric models suggesting that increased cement penetration did not augment mantle temperatures and bone necrosis *(70)*.

2. Cement penetration

Cement penetration into the microstructure of cancellous bone leads to implant fixation *(22)*. Component stability is obtained by achieving micro lock with trabecular bone *(70)*. In case of poor cement penetration, an early non-progressive radiolucent line under the tibial component following cemented TKA can occur *(68)*. The development of third generation cementation techniques has shown to improve cement penetration in the cancellous bone and decrease the rate of implant loosening *(22,68)*.

Ritter *et al* demonstrated that the proper preparation of the cancellous bone and pressurization of the cement reduces the initial occurrence of RLLs *(68)*.

Multiple studies, have shown that an adequate technique of cementation depends on the cement and its application, but also on the bone quality and its preparation *(13,59,61,68)*.

Bone quality depends on the pre-operative bone status but also on the tibial cut. A lower tibial cut leads to a smaller surface and another type of cancellous bone less compatible with cement penetration *(13,68)*.

In case of medial sclerotic bone, studies have shown that drilling the sclerotic bone *(13,59)* with a 4.5 mm drill bit, allows better cement penetration and enhances tibial fixation with an occurrence rate of RLLs of 5.5% at 24 months postoperative compared to 20% with a 2.0 drill bit *(69)*. The RLLs vary in size and location according to the technique of pressurization, with progressive radiolucent lines commonly associated with early failure *(22,52, 68)*.

The degree of penetration depends on the quality and porosity of the cancellous bone. In osteoporotic bone, Van Lommel *et al* observed an insufficient penetration with isolated application of cement on to the tibial component and excessive penetration when using a cement gun, and confirmed the adequate cement penetration by spatula or finger packing *(13,61)*.

Krause and Walker demonstrated in the past, that timing of application of cement after mixing is inversely proportional to the depth of penetration *(13)* and that the better technique involved mixing for

4 minutes and fenestration of the tibial cancellous bone.

Bone preparation consists of cleaning all debris and blood with a pulsed lavage because it is a more effective debridement than manual flushing *(13,53,61)* and drying with sponges and suction *(13,22,59,68)* because the presence of blood reduces shear strength of cement up to 50% *(13)*.

Previous studies have shown that hand mixing tends to be inferior to vacuum mixing in terms of increasing porosity and decreasing tensile forces, but it is superior in antibiotic elution *(59).*

Based on radiographs and biomechanical experiences, Walker *et al* , suggests a mantle of 3-4 mm as the optimum depth for the penetration of cement *(53,56,70)* into the bone as the limit, with the risk of having collagen destruction if more penetration than 5mm occurs and substantial bone loss at time of revision *(3,13,52,53,61)*.

Currently, there is some debate about the best application of cement and its technique *(61)*. There are many possibilities to prepare and apply cement, hand mixing and application or with a cement gun vacuum-packed. Based on a recent study about cementing techniques *(13)*, it's recommended to use a low or medium viscosity PMMA, hand packing, with a time to application of 3-4 minutes, and low storage temperature *(35,61)*.

Guha demonstrated in his study *(22)* that a single-stage cementing technique may be superior to the two-stage technique in avoiding RLLs in the immediate postoperative TKRs by observing on cemented TKA 52% RLLs, with more significant RLLs in the two stage (68 %) than one stage (36%) with a prevalence of wide category RLLs in zone 1 and 4 *(22,68)* This observation was attributed to the pressurization technique of the cemented implant, being more effective when the leg is placed in full extension for final pressurization as in the one stage technique *(22).*

The application of cement, only to the tibial base plate or full cementation of the tibial keel still remains controversial *(35)*. Previous studies claimed that full cementing provides better fixation, less potential for micro movement and higher long-term stability *(13,61)*. However, Cawley *et al* demonstrated in their experimental studies, that fully cemented implants had greater proximal tibial bone resorption by the induction of stress shielding in the proximal tibia and potential bone loss, which could lead to early loosening in the long term *(13,61,62)*. More recent studies, showed no difference regarding implant survival between a fully cemented group and an interface cementation group, with a mean follow-up of 8 years and 9 years respectively *(62)*. This issue is however more complex than a choice between two cementing techniques since the main point will be the need for fixation and that a malaligned TKA in an osteoporotic patient might need two zones of fixation instead of only one.

A recent study by Hazelwood *et al* observed debonding between implant and cement, with a mean time to revision of 17 months, using Palacos R+G (HVC) cement, 50% of the tibia implant surface was devoid of adherent cement. The authors speculated that factors inherent to Palacos cement might have contributed to the loosening (*35*).

11) Motion of components

According to the Knee Society, the definition of implant loosening is identified radiographically as a change in implant position or as the development of a progressive RLL at the bone-cement or bone-implant interface *(24)*.

Tibial debonding is a specific type of gross loosening of the tibial component with most of the cement mantle still attached to the bone *(11,34)*. Previous studies have shown that patients are little symptomatic, and that debonding can be observed early on radiographs. No correlation was found with overall alignment, component positioning or BMI. This particular mode of failure can be explained by some mechanical theories such as impingement of the post against the box, increasing stress to the modular interfaces of the tibia and could be a cause of failure *(5)*. Cheng *et al* described early aseptic loosening of the tibial component after TKA with debonding between the tibial component and cement mantle and an intact cement–bone interface *(28,35)*. They also observed more mechanical debonding with titanium implants than with chrome cobalt *(2,50)*. Once debonding is observed, most authors recommend revision of the implant, in an effort to minimize damage to the proximal tibial bone stock *(5)*.

CONCLUSION

In modern knee arthroplasty, aseptic loosening is one of the rare reasons of early failure among infection and instability. Radiolucent lines are one of the indicators of potential aseptic loosening of a component. However not every radiolucency is pathognomic for loosening and should lead to revision.

This narrative review showed that several factors determine the appearance of radiolucent lines like there are osteoporosis, alignment, type of cement used, level of the tibial cut and the implant utilized. Radiolucent lines that are < 2mm and non-progressive without signs of instability of the implant should not be considered as a sign of aseptic loosening. If the RLL are progressive, increasing in size and accompanied by signs of mobility of the implant revision can be considered in the presence of symptoms of pain and swelling for the patient.

Radiolucent lines secondary to osteolysis appear later during the follow-up of the implant and are related to bone resorption as a reaction to particles wear. These are a sign of wear of the implant and revision surgery is indicated in those cases.

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