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Original research

A Short-Term Multicenter Analysis of Radiolucent Lines in a Single Uncemented Rotating Platform Implant for Total Knee Arthroplasty

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ABSTRACT

Background: Uncemented total knee arthroplasty is increasing as a potential solution for aseptic loosening via biologic fixation and to increase operative efficiency. However, postoperative radiolucent lines (RLLs) remain a concern for some clinicians. We report on a multicenter analysis of these RLLs over a 2-year period to identify their incidence, progression, and clinical significance.

Material and methods: Institutional review board approval was obtained for this retrospective, multicenter case series. A total of 312 patients treated with a single cruciate-retaining, fully porous coated femoral and tibial component design were included in the study. All patients were evaluated clinically and radiographically in the early postoperative period and at final follow-up (average 2.0 years). Average age of the study group was 58.2 years, and average body mass index was 30.7. Of the total, 66% were male, and 34% were female. Two independent surgeons evaluated the radiographs at the initial postoperative visit and at the most recent follow-up for RLLs. Knee Society Scores and range of motion (ROM) were collected at each visit.

Results: We identified RLLs in 25% of patients. All RLLs were less than 1 mm in size and located at the periphery of the tibial implant. None of the RLLs were progressive. At the final follow-up, compared with early postoperative imaging, no new RLLs were identified. Average ROM in flexion was 124 degrees, and the average Knee Society Scores at the most recent clinical follow-up was 96.

Conclusion: RLLs are commonly seen following cementless TKA, most commonly underneath the tibial tray. Based on this data set, there does not appear to be progression of these RLLs with time, and they do not appear to have an effect on ROM or clinical outcome at 2 years.

Introduction

Total knee arthroplasty (TKA) continues to be an excellent treatment option for severe arthritis of the knee, and the number of TKAs being performed in the United States is rising significantly. Despite acceptable survivorship and reasonable clinical outcomes, aseptic loosening is still considered the most common cause for aseptic revision in cemented TKA, especially in the younger patient population [1]. Additionally, the incidence of TKA is rapidly increasing in this younger, heavier, and more active patient group. These patients have a longer life expectancy, are more active, and place higher demands on their implants [2,3]. As a result, long-term fixation in this population of TKA patients remains a significant concern. Fixation in TKA is either cemented, cementless, or of a hybrid construct. Cemented fixation is widely reported to be the gold standard and supported by registry data. However, given the concern over aseptic loosening, there has been an increased

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interest in providing biologic fixation through cementless technology, similar to the success of cementless technology in total hip arthroplasty.

Prior cementless TKA studies raised concerns of early tibial failures and possibly poorer clinical outcomes [4]. Earlier cementless designs included inadequate tibial locking mechanisms, early generation polyethylene, and metal-backed patellae with high failure rates due to polyethylene wear [5]. Despite adequate biologic fixation, the outlined failure mechanisms have tainted some orthopedists' perception of cementless technology. Additionally, early studies on various uncemented tibial components showed a high incidence of radiolucent lines (RLL) of 13%-56.5% [6,7]. Although, the significance of the RLL was unknown, some speculated that RLLs might predispose the implants to early component loosening. Newer cementless knee implants potentially improve upon design flaws and have been developed with improved materials to enhance bone-implant fixation and improved instrumentation intended to achieve early ingrowth and long-term stability.

Currently, radiographic lucencies continue to be a concern, can be challenging for the surgeon to interpret, and can complicate how patient care is guided. While progressive TKA implant migration indicates loss of osteointegration and aseptic failure, the significance of RLLs in cementless implants and their natural history is unclear. There are few reports on the impact of RLLs on patient outcome [8]. The purpose of this manuscript is to identify the incidence and progression of RLLs in a multicenter study group and to determine their effect on knee functional outcome scores and survivorship at 2 years in patients treated with a single cruciate-retaining (CR), uncemented, TKA design.

Material and methods

Institutional review board approval was obtained for this retrospective, multicenter case series of 312 patients. All 312 patients were enrolled by 5 operating surgeons at 5 distinct study sites. All patients were treated with the identical CR, cementless porous coated femoral implant with pegs, a cementless tibial baseplate with 4 porous pegs and a central keel, and a cross-linked, rotating platform articular insert (Attune Total Knee; DePuy Synthes, Warsaw, IN). The porous coating consists of randomly arranged spherical beads that have demonstrated an excellent track record when applied to a prior cementless implant (DePuy LCS, DePuy Synthes, Warsaw, IN) [9]. The decision to use cementless implants in this study was based on patient age, preoperative radiographs, and intraoperative bone quality. The decision to use the cementless technology was left to the discretion of the surgeon, but there was no absolute cutoff for BMI, age, or deformity. However, the majority of patients were healthy with BMI below 35. No patients indicated by the surgeon preoperatively for cementless fixation were switched to a cemented design. Resurfacing of the patella was left up to the discretion of the surgeon. The study period began in December 2016 and included a minimum of 35 sequential cementless TKA procedures for each site, in an effort to limit the effect of any learning curve that might exist. To complete an enrollment target of 300 procedures, each of the 5 sites contributed patients for a minimum of 6 months. Demographic data such as age, gender, and BMI were collected. Men and women comprised 65% and 35% of the study group, respectively, with an average age of 58.2 years and an average BMI of 30.7 (Table 1). Follow-up analysis with radiographs, range-of-motion testing, and Knee Society Scores were recorded. Descriptive statistics were used to analyze the mean and ranges of different variables. The analysis was performed using Microsoft Excel (Excel version 2002, Microsoft Corp, Seattle, WA).

Table 1
Patient demographics.

Demographic	
Age (y) (range)	58 (35-74)
Gender	
Female	110 (35%)
Male	202 (65%)
Side	
Left	165 (53%)
Right	147 (47%)
Mean body mass index (kg/m^2)	31 (19-43)

All cementless TKAs in this study group were performed for the diagnosis of primary osteoarthritis. All were treated using a standard median parapatellar approach with similar anesthetic protocols (spinal or general). Tourniquet use or type of sawblade was not uniform among the study sites. The procedure was performed using standard manual TKA instrumentation, with particular attention to both extension and flexion space stability, using either a balanced or measured resection technique. All patients were allowed to bear full weight immediately postoperatively, and physical therapy was initiated on the day of surgery or on postoperative day 1. Postoperative pain management and deep vein thrombosis prophylaxis were initiated at the discretion of the surgeon and based on individual patient risk factors.

Clinical and radiographic evaluation was performed at the first follow-up visit, at approximately 1 year, 2 years, and the most recent follow-up. Radiographs included anteroposterior weight-bearing, lateral, and sunrise views. Attempts were carefully made at each site to perform tangential radiographs for each particular image that would best identify RLLs at the bone-implant interface. RLLs on each radiograph were measured using the standard Knee Society Scoring system and read by 2 separate fellowship-trained arthroplasty surgeons (Fig. 1). Any patient with RLLs identified on postoperative images were re-evaluated radiographically at a minimum of 2 years in follow-up. Follow up radiographic images were completed for 88% of the subjects in the study, with an average duration of follow up of 26.2 months (range 12-36). Knee society scores and range of motion were recorded at a minimum of 2 years for inclusion in the data set and for all radiographs that showed RLLs at 1-year follow-up.

Results

Of the 312 patients who met inclusion criteria, complete radiographic imaging of adequate quality to accurately identify RLLs was available for review in 277 subjects. We identified RLLs in 70 (25%) of the 277 patients in the study group. The RLLs were almost exclusively seen underneath the tibial tray (zones 8, 1, and 4) (Table 2). There were RLLs seen at the femoral component interface in 4 of the 277 patients (1%). All the tibial and femoral RLLs were identified in either the early postoperative period or by the 1-year follow-up visit. All RLLs were 1 mm or less in size, and none were progressive (Fig. 2). All patients with RLLs at 1 year were followed up for a minimum of 2 years with repeat radiographs. There were no new RLLs that emerged at the 2-year follow-up, and none were progressive. Femoral RLLs were rare and found in only 1.3% of patients. All femoral RLLs resolved at 2 years postoperatively. Although we identified RLLs in 25% of patients in the study group, clinical outcomes were excellent, with an average knee society score of 96 at the most recent follow-up. Knee range of motion averaged 124 (range 0-138) degrees at the most recent follow-up (Table 3).

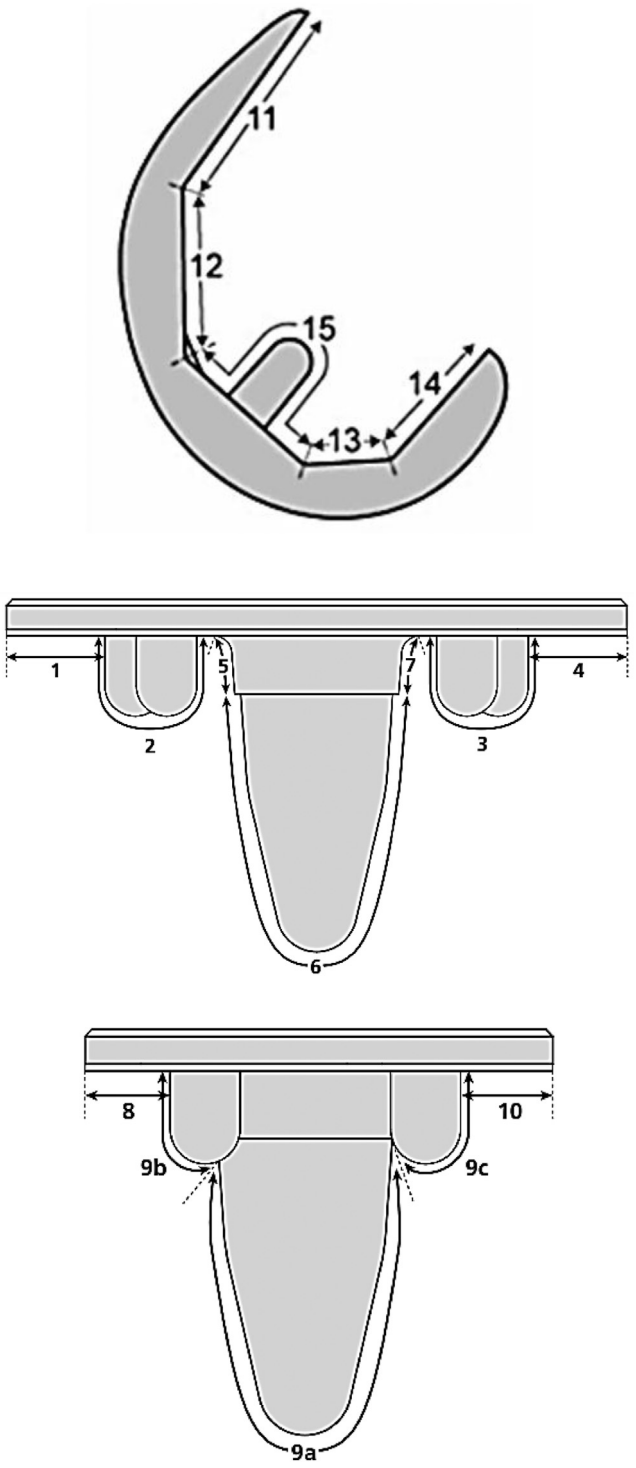

Figure 1. Scoring of radiolucent zones.

There were four revision surgeries during the study period. Two patients contracted periprosthetic joint infections and were successfully treated with a two-stage exchange. Another patient sustained a quadricep tendon rupture at 3 months after TKA. The tendon was repaired, and the patient sustained no further complications. The final adverse event requiring reoperation involved a 61-year-old female with a preoperative valgus deformity. The tibial implant subsided into varus early in the postoperative period. The obliquity of the implants did not allow for accurate evaluation of

Table 2
Radiographic evaluation of radiolucent lines.

Incidence of Radiolucent llnes by zone and location	6 wk	1 y	Final
No radiolucency (% total)	268 (97)	216 (78)	256 (92)
Radiolucency < 1 mm (% total)			
Tibial	9 (3)	57 (21)	21 (8)
Zone 8	2	12	5
Zone 9	0	1	3
Zone 10	0	0	0
Zone 11	2	17	6
Zone 12	0	0	0
Zone 13	1	2	0
Zone 14	4	25	7
Zone 15	0	0	0
Zone 16	0	0	0
Zone 17	0	0	0
Femoral	0 (0)	4 (1)	0 (0)
Zone 1	0	3	0
Zone 2	0	0	0
Zone 3	0	0	0
Zone 4		0	1
Zone 5	0	0	0
Zone 6	0	0	0
Zone 7	0	0	0
Radiolucency > 1 mm (% total)			
Tibial	0 (0)	0 (0)	0 (0)
Femoral	0 (0)	0 (0)	0 (0)

RLLs, but migration and failure of fixation was obvious. Due to pain, radiographic abnormality, and symptomatic varus deformity, successful revision for aseptic loosening was performed 14 months after the index procedure using a tibial sleeve and stem with retention of the femoral component. No other implants were considered loose or at risk of loosening. Even though implant migration was rare, there was 1 other case of early subsidence of the tibial tray. A 63-year-old female patient, also with a preoperative valgus deformity and osteopenia, was noted to have subtle, early subsidence of the tibial implant (Fig. 3). Migration of the tibial implant into slight varus and extension was estimated to be less than 3 mm, occurred early in the recovery period, and was stable by 3 months. Radiographic images remain unchanged at 3 years of the follow-up, no RLLs have been identified, and the patient remains clinically asymptomatic and did not require further surgery.

Discussion

There is growing interest in cementless TKA, in part due to the increased demand for TKA in younger, more active individuals. The survivorship of cemented TKA in patients younger than 60 years was reported to be 82.6% at 15 years and 83.9% in patients younger than 50 years at 13 years [10,11]. In these studies, aseptic loosening was the primary mode of failure [10]. Cementless implants have multiple potential advantages, including long-lasting osseointegration, bone preservation, no cement debris, and shorter operative times [12]. Once osseointegration occurs with cementless implants, loosening is extremely rare in the absence of infection or osteolysis. Harwin et al. evaluated 31 cementless TKAs in patients younger than 50 years and reported 100% implant survivorship at a mean follow-up of 4 years [13]. Similarly, Tai and Cross prospectively studied 118 cementless TKAs in patients younger than 55 years, identifying only 2 revisions for aseptic loosening at 12 years, with an implant survival rate of 97.5% [14]. Given that younger and more active patients are now more commonly seeking TKA, cementless fixation may reduce the incidence of aseptic loosening that can occur with cemented designs in this patient population.

RLLs, most commonly under the tibial tray, are often identified when evaluating postoperative cementless fixation [9,12]. These

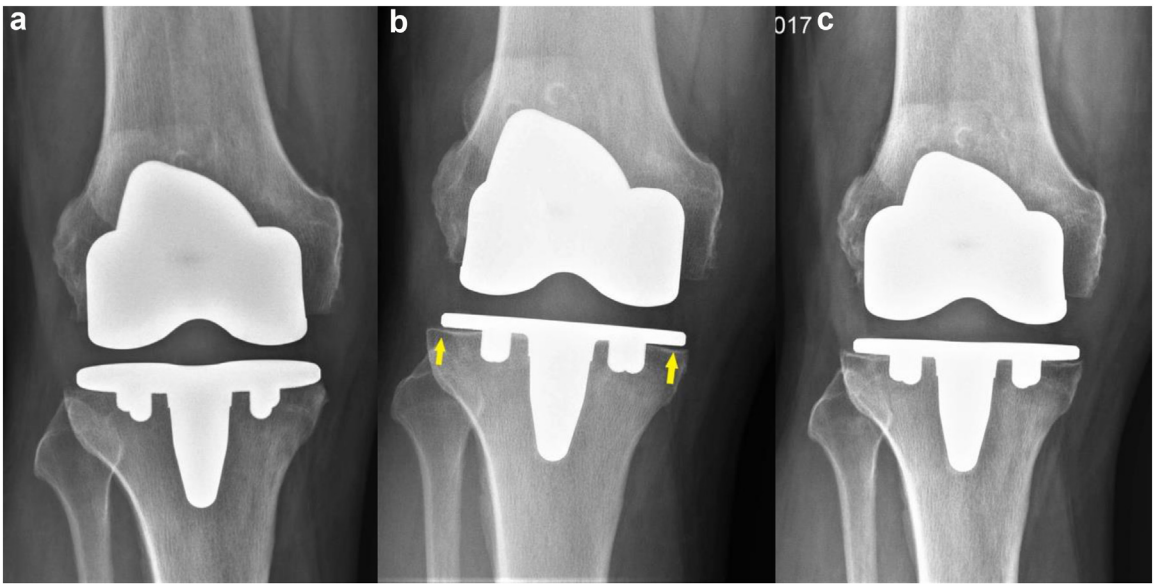

Figure 2. (a) Anteroposterior (A/P) radiograph of a 62-year-old patient, at 4 weeks after uncemented TKA. (b) A/P radiograph at 3 months after index procedure, identifying radiolucent lines (RLLs) in zones 11 and 14. (c) A/P radiograph at 2 years with significant resolution of RLLs.

RLLs can be misinterpreted as a source of pain leading to unnecessary TKA revision [9]. To our knowledge, the natural history and clinical significance of this radiographic finding has not been previously evaluated in a large, multicenter clinical study. Our multicenter study indicates that RLLs were common (25%), were rarely progressive, and did not alter clinical outcome or patient satisfaction. RLLs were uniformly small ($\leq$1 mm) and nonprogressive. Femoral RLLs were rare and found in only 1.3% of patients. All femoral RLLs resolved at 2 years postoperatively. Clinical outcomes in this study group identified an average KSS score of 96 and average ROM of 124 degrees at the final follow-up. The concern that RLLs are a sign of failed osteointegration and early clinical failure was not supported in our study.

In this study, asymptomatic clinical subsidence and symptomatic aseptic loosening were rare (0.6%). Tibial component varus subsidence occurred in 2 patients with preoperative valgus deformities and osteopenia. One of these patients required revision surgery. The varus subsidence was attributed to the weak medial tibial bone from stress-shielding secondary to valgus deformity (Fig. 2). This phenomenon was described in a case series by Thompson et al. [15], in which they observed cementless tibial tray subsidence in 7 patients, 5 of which had a preoperative valgus deformity. Therefore, tibial fixation in patients with preoperative valgus deformity, especially those with diminished bone quality, should be carefully selected to avoid tibial tray subsidence.

There are only a few other studies evaluating RLLs in TKA. Costales et al. [8] identified a relatively high early incidence of RLLs in a group of 21 patients, but with significant resolution over time and acceptable clinical outcomes at an average of 9 years in the follow-up. Other studies have compared aseptic loosening in cemented vs cementless fixation. A retrospective case control study by Miller et al. [16] evaluated 400 patients with the same implant design. Two hundred cementless TKA patients, with a mean age of 64 years and a mean BMI of 33, were matched to a control group of cemented implants. At a mean follow-up of 2.4 years, only 1 patient in the cementless group was revised for aseptic loosening compared with 5 patients in the cemented group (0.5 vs 2.5%). They concluded that cementless technology may lead to fewer revisions for aseptic loosening. Sinicrope et al. [17] evaluated cementless TKR in the morbidly obese. The retrospective study compared cementless patients with a mean BMI of 45.6 to cemented patients with a BMI of 45 to determine revisions for aseptic loosening. The cementless revision rate was a 0.9% compared with 18.8% in the cemented cohort. The study concluded that cementless TKA might provide improved fixation in the morbidly obese population compared with cemented technology. A similar study by Boyle et al. compared cemented vs cementless implants in patients with a BMI of over 30 [18]. They concluded that there was no difference in aseptic loosening between the 2 study groups [18]. These studies suggest that cementless implants perform as well, if not superior, to cemented implants in the obese patient population.

The strengths of this minimum 2-year follow-up study are the large sample size from multiple centers with detailed evaluation of RLLs using a single CR cementless TKA design. This short-term follow-up of an implant-bone fixation interface (POROCOAT, DePuy Synthes, Warsaw, IN) compares favorably to the proven track record of predicate designs. This technology, first used in the 1970s [9], has provided satisfactory outcomes in the cementless low-contact-stress implant (DePuy, LCS). McMahon et al. [9] reviewed the long-term outcomes of this implant, identifying a 20-year survivorship of 97.4% for all-cause revision, with only 4 of 141 failures for aseptic loosening or tibial tray subsidence. The Attune cementless tibial component, rotating platform design, has similar design features to the LCS implant, as mentioned above, in addition to 4 enhanced porous fixation pegs to help with initial implant stability and potential bone ingrowth. Furthermore, the most recent cemented version of the total knee implant in this study has been shown in video fluoroscopy to perform well kinematically [19,20].

Table 3
Mean preoperative and postoperative assessments.

Parameter	Median preoperative value (range)	Median postoperative value at the last follow-up (range)
Knee Society Score	49 (3 to 94)	97 (61 to 100)
Alignment	4 (20 varus to 18 valgus)	5 (5 varus to 3 valgus)
Extension	3.6 (0 to 17)	0.4 (0 to 5)
Flexion	118 (45 to 140)	126 (110 to 140)

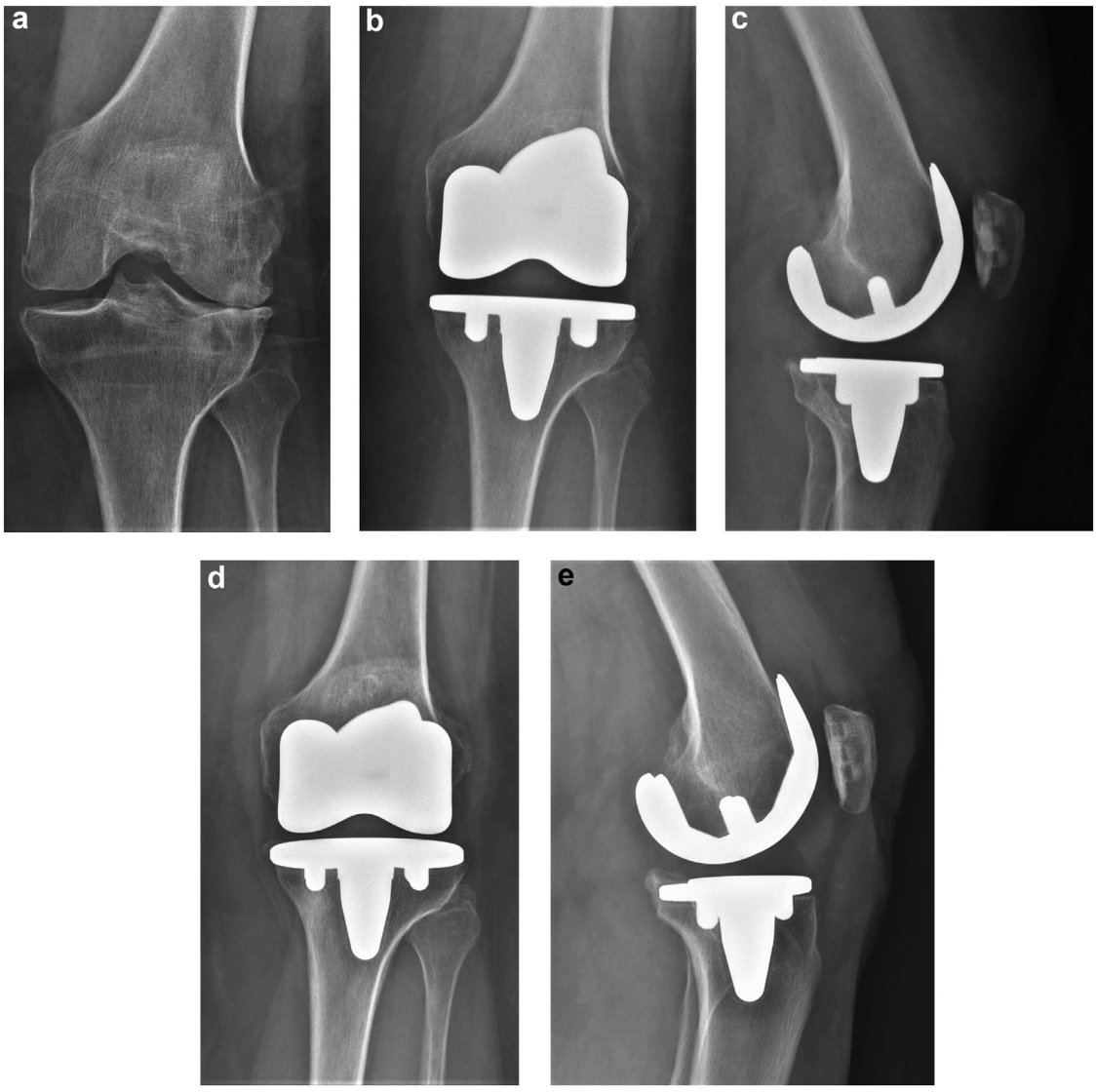

Figure 3. (a) A/P preoperative radiograph of a 62-year-old female patient with valgus osteoarthritis and moderate osteopenia. (b) A/P and (c) lateral radiographs at 4 weeks after uncemented TKA with slight subsidence into varus and flexion. (d) A/P and (e) lateral radiographs at 2.5 years showing stable fixation, without further subsidence, in an asymptomatic patient.

Limitations of this study include the inherent biases that occur with retrospective reviews and the possibility of selection bias that would optimize the success of cementless implants. There was no specific selection bias in favor of males in this study although 65% of all patients represented the male sex and only 35% represented female. This could relate to the fact that, across all sites, bone quality was assessed using preoperative imaging and intraoperative observation. The decision to use a cementless vs cemented component was left up to the surgeon at each site, and thus, inclusion may have been biased toward cementless fixation in males and those in a younger age group and biased against cementless fixation in postmenopausal females. Second, the short-term nature of the study could imply that it was not powered enough to capture episodes of aseptic loosening. Additionally, tangential images are important to carefully identify RLLs, thus malposition of the patient during imaging might not allow for accurate review to detect all RLLs. Finally, there were 35 patients (11%) lost to follow-up. The patients lost to follow-up included those whose clinical or radiographic data were not recoverable due to a change in health plan coverage or those who were not reachable via telemedicine or for a clinic visit. It is remotely possible that these patients could have migrated to other providers or health systems with loosening or failure, potentially contributing to a higher failure rate than currently reported. However, the sites included in this study are major referral centers in their respective region, and it is unlikely that the patients sought care elsewhere without the primary surgeon being notified.

Conclusions

This multicentered study of a large subset of patients reveals that RLLs are common in cementless TKA but that the great majority are nonprogressive and have no impact on implant survivorship or clinical function in this group of subjects. Although the data presented in this manuscript are encouraging, follow-up studies should be considered on this young and active patient population to confirm long-term survivorship.

Conflicts of interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing

interests: D. Dalury receives royalties from, is a paid consultant for, and receives reseach support as a principal investigator from DePuy Syhthes and has stock or stock options in Foundry Therapeutics. T. L. Bernasek receives royalties for intellectual property transfer from DePuy Syhthes; gave paid lectures for DePuy Syhthes; is a paid consultant for and receives reseach support as a principal investigator from DePuy Syhthes; receives fellowship meeting support from Stryker and DePuy Synthes; and is a trustee in Florids Orthopaedic Society and Hillsborough County Medical Association. R. M. Nunley receives royalties from Microport and DePuy Synthes; is a paid consultant for DePuy Synthes, Ethicon, Medtronic, Mirus, Rom Tech, Smith & Nephew, and Surgical Care Affiliates; has stock or stock options in Hyalex and Rom Tech; receives reseach support as a principal investigator from Biomet, DePuy Synthes, Smith & Nephew, and Stryker; and is a treasurer in AAHKS and past president of SOA. R. S. Gorab receives royalties from, is a paid consultant for, and receives reseach support as a principal investigator from DePuy Syhthes. D. A. Fisher receives royalties from and is in the speakers' bureau of DePuy Synthes.

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