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A 9-Year Outcome Study Comparing Cancellous Titanium-Coated Cementless to Cemented Tibial Components of a Single Knee Arthroplasty Design

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ABSTRACT

Background: The cemented Advance Medial-Pivot total knee arthroplasty (TKA) was designed to reflect contemporary knee kinematics data and has shown satisfactory long-term outcomes.
Methods: We retrospectively evaluated prospectively collected data from 2 groups of patients. Group A consisted of 54 patients (54 TKAs), 18 men and 36 women, and mean age at surgery was 63.2 ± 5.2 years; group B consisted of 54 patients (54 TKAs), 17 men and 37 women, and mean age at surgery was 63.8 ± 5.1 years. Patients of both groups were matched for age, gender, side, body mass index, and length of follow-up. The cementless components of this design were implanted in group A and the cemented in group B. Implant failure, complication rates, clinical (both subjective and objective) and radiological outcomes were assessed in all patients of both groups.
Results: All patients of both groups were available for final follow-up evaluation at a mean of 8.6 ± 0.4 years. Survival analysis at 9 years showed a cumulative success rate of 100% in both groups with all end points. In neither group were implant-related, surgeon-related, or patient-related failures observed. When both groups were compared, in all time intervals, no differences were recorded on Knee Society system, Western Ontario and McMaster University Osteoarthritis Index, Short Form-12, and Oxford Knee Scores. On radiological examination, for both groups, all parameters evaluated were satisfactory.
Conclusion: This study presents satisfactory midterm clinical and radiological outcomes with the use of both versions of this design. Moreover, no implant-related failures were observed with the use of cancellous titanium-coated tibial implants.

Total knee arthroplasty (TKA) is one of the most successful operations performed for end stages of knee arthritis with 95 to 98 good to excellent results reported at 10- to 15-year follow-up [1]. When it comes to fixation, cemented, cementless, and hybrid (cementless femoral and cemented tibial components) components may be used [2,3]. Cemented fixation has resulted in satisfactory long-term outcome with low revision rates [2–5]. However, osteolysis often appears and the long-term durability of the interface is under question, especially in young patients [6,7].

Cementless fixation was developed in order to achieve a more physiological bond between implants and bone and in order to improve longevity of the interface especially in young patients. It has been available for more than 3 decades [3,8–12]. Due to the less than optimal outcomes of the old generation of prostheses, cementless fixation in TKA never gained popularity [3,11,12]. Osteolysis was still seen and radiostereographic analysis (RSA) studies have shown early migration of the tibial plate which is a long-term determinant of implant failure [13–15].

The indications for and numbers of TKA continue to increase [12], and younger and more active patients are undergoing the procedure. The proportion of patients younger than 65 years is increasing, and despite recent advances in operative technique, prosthetic design, and instrumentation, there is still concern that

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these implants will not last for the lifetime of many patients [16,17]. On the other hand, due to recent advances in metallurgy and basic sciences, new technologies for cementless fixation are available [11,17–19].

We report 8- to 9-year clinical and radiological outcomes of the cementless compared to the cemented components of the Advance Medial-Pivot (aMP) TKA system.

Patients and Methods

From January 2009 to February 2010, volunteer consecutive patients aged between 50 and 70 years who had osteoarthritis of the knee joint requiring TKA and who had been admitted to our Department under the care of one surgeon were considered eligible to participate in this prospective, nonrandomized study designed to evaluate the trabecular titanium cementless tibial tray technology newly available in Europe (group A) (Fig. 1). Written informed consent forms were obtained from all patients, and the study was approved by the National and Hospital Ethical Committees. Inclusion criteria were osteoarthritis of the knee joint, age between 50 and 70 years, good mental health, less than 20° varus or valgus deformity, fixed flexion deformity of less than 20°, flexion greater than 90°, and body mass index (BMI) less than 35. Exclusion criteria were rheumatoid arthritis, previous surgery on the same joint, and arthritis of the ipsilateral hip, contralateral hip, or knee joints. For reasons of comparison, an equivalent number of consecutive patients who had undergone cemented TKA from January 2008 to January 2009, fulfilling the same inclusion and exclusion criteria and matched for age, gender, side, and BMI, were also separated from our data bank and included in this study (group B). Patients of both groups were evaluated and compared at the same matching time intervals of follow-up evaluation.

In patients of group A, the aMP system (MicroPort Orthopaedics Inc, Arlington, TN) cementless components (titanium porous bead–coated femoral component and cancellous titanium-coated, BIOFOAM tibial component) were implanted. In patients of group B, the aMP system cemented components were implanted (Fig. 2).

One surgeon performed all operations in a sterile orthopedic theater with a vertical laminar airflow system, using a mini midvastus surgical approach [20]. The patella was not replaced and instead patella aponeurosis (a 5 mm all around patella retinacular release with a cautery) removal of osteophytes and patellar reshaping was performed on all patients. Surgical computer-assisted systems were not used in this series. All patients had patient-controlled epidural anesthesia for 48 hours. Prophylactic antibiotics were used preoperatively and postoperatively for 2 days

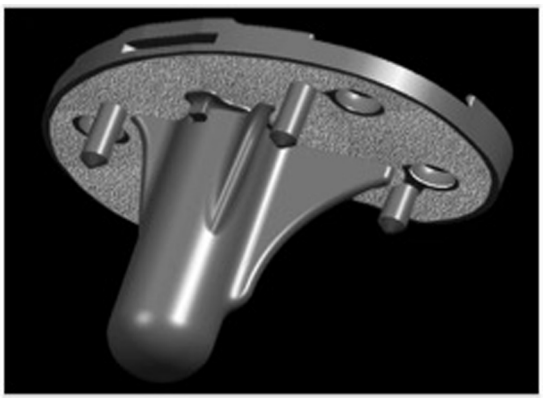

Fig. 1. The Advance Medial-Pivot cementless cancellous titanium-coated tibial component is shown.

Fig. 2. The Advance Medial-Pivot cemented tibial component is shown.

(until the removal of the drain) and anticoagulants (LMWH) for 30 days. Intensive physiotherapy was started from the first postoperative day.

Objective and subjective clinical and radiological data were prospectively collected preoperatively and at 3 and 6 weeks, 3 and 6 months, and at 1 year postoperatively, and yearly thereafter, and stored in the OrthoWave database (Aria Ltd, Lyon, France). The following validated scoring systems were used [21]: the Knee Society system (KSS, knee score and function score) [22], the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) questionnaire [23], the Short Form-12 (SF-12) questionnaire [24], and the original (60-12) Oxford Knee Score (OKS) [25]. The active range of movement, when sitting, was recorded using a goniometer. Standardized standing short anteroposterior and lateral radiographs were taken. The Knee Society system was used for radiological evaluation [26]. Changes in alignment and migration (α, β, γ, σ, and tibiofemoral angles) of the components were analyzed comparing the angles of the first and last available radiographs. All radiographs were examined for progressive radiolucent lines (RLLs) according to Ewald [26] by 3 surgeons and if all 3 found RLLs, this was defined as a consensus. The presence of RLLs measuring >2 mm, subsidence, or change in alignment of a component was considered to indicate loosening. The criteria for failure were the need for revision, either performed or planned, because of aseptic loosening, infection, patellar resurfacing, and dislocation or ligament instability.

Statistical Analysis

Data were analyzed for normal distribution using Kolmogorov-Smirnov analysis. Clinical scores (KSS, WOMAC, SF-12, and OKS) and α, β, γ, σ, and tibiofemoral angles were normally distributed. For statistical analysis, the *t*-test and the paired *t*-test were used in order to evaluate possible statistical differences of values within and between groups. The power for detecting the observed postoperative mean differences in knee score, function score, total score, SF-16, WOMAC, and OKS given that 54 patients were allocated to each group was 99% [27]. Kaplan-Meier analysis with calculation of 95% confidence intervals was performed to calculate survivorship [28,29]. All statistical analyses were performed using SPSS version 12.0 (SPSS, Chicago, IL) at the biostatistics department of our University. A P value of $\leq$.05 was considered significant.

Results

A total of 108 patients (54 in each group) were included in this study. There were 35 (33.7%) male and 69 (66.3%) female patients with 45 right and 59 left TKAs. Patients of both groups were

Table 1
Patient Demographics in Both Groups Are Shown.

Demographics	Group A	Group B
Number of patients	54	54
Mean age at surgery in y (range)	63.2 (52-70)	63.8 (55-70)
Gender (female/male)	36/18	37/17
Left/right knee	30/24	29/25
Mean BMI value (range)	32 (26-35)	31.5 (25-35)
Diagnosis		
Osteoarthritis	46	44
Seronegative arthritis	6	9
Post-traumatic arthritis	2	1

BMI, body mass index.

matched for gender, age, operated side, BMI, and diagnosis (Table 1). The last patient was recruited in February 2010 and a final follow-up evaluation was performed in January 2018. At a mean final follow-up of 8.6 years (8-9), all patients were available for evaluation and there was 88% compliance in the time interval follow-up evaluations.

No implant-related, patient-related, or surgeon-related failures were recorded in either group and no revision surgery was performed on any patients in either group. Kaplan-Meier survivorship analysis showed a cumulative success rate of 100% (95% confidence interval, 100-100) at 9 years, in both groups with revision for any reason (including aseptic loosening, instability, infection, and dislocation), revision for aseptic loosening, and revision for all indications (including secondary patellar resurfacing) as the end points.

Preoperative and final follow-up evaluation values (mean value, range) and differences between and within groups of the objective knee score, function score, total score and the subjective SF-12, WOMAC, and OKS are shown in Table 2. In both groups, all patients showed a statistically significant improvement on the KSS (*t*-test, $P = .001$), WOMAC (*t*-test, $P = .001$), SF-12 (*t*-test, $P = .01$), and OKS (*t*-test, $P = .01$) scores (Table 2). No statistically significant differences (paired *t*-test) were observed when the knee score, function score, total score, SF-12, WOMAC, and OKS were compared between groups at different time intervals, and at final follow-up (Table 2). The parameter flexion of the knee score was raised from a preoperative mean of 101° (80°-120°) to a final postoperative mean of 116° (95°-135°) in patients of group A and from a preoperative mean of 108° (85°-125°) to a final postoperative mean of 118.5° (95°-130°) in patients of group B. At final follow-up, no statistically significant difference (*t*-test) was detected between groups. At final follow-up, fixed flexion deformity of up to 10° was found in 3 (5.6%) knees of group A and 4 (7.4%) knees of group B. In 1 knee in group A with a postoperative range of flexion of 0°-80° and in 1 patient in group B with a postoperative range of flexion of 0°-70°, manipulation under anesthesia was performed in order to improve postoperative flexion after the fourth postoperative week. These patients reached flexion of 95° and of 90°, respectively. Three (5.5%) patients in each group complained of anterior knee pain, while patella arthroplasty was not required by any patient.

Superficial wound healing problems were recorded in 2 (3.7%) knees of group A (marginal skin necrosis at the edges of the surgical wound) and in 2 (3.7%) knees of group B. No infection developed in any patient of this series. Deep vein thrombosis was detected, both clinically and with triplex ultrasound, in 1 (1.8%) knee of group A and in 2 (3.7%) knees of group B, while pulmonary embolism was not diagnosed in any patient in the series.

Radiological Evaluation

Postoperative and final follow-up mean values of implant alignment parameters of femoral valgus angle (α), tibial angle (β), femoral flexion (γ), tibial slope (σ), and knee alignment in both groups are shown in Table 3. No statistically significant changes developed when postoperative and final follow-up values were compared. In group A, RLLs were found in 7 (13%) knees in zones 1 and 2 on postoperative anteroposterior radiographs of the tibial component (Fig. 3). In the same group, RLLs were found in 3 (5.5%) knees in zones 1 and 2 on postoperative lateral radiographs of the tibial component. In group A, RLLs were found in 1 (1.8%) knee on the lateral radiographs of the femoral component. At final follow−up, no RLLs were recorded in either component of knees in group A (Fig. 4). In group B, nonprogressive RLLs were found in 4 (7.4%) knees in zones 1 and 2 on postoperative anteroposterior

Table 2
Preoperative and Postoperative Mean Values (Range) of Objective and Subjective Clinical Outcome Rating Scales, Used in the Study, Are Shown.

Clinical Rating Systems	Group A	Group B	Difference
Objective knee score			
Preoperative	35.6 (16-67)	32.8 (14-70)	*t*-test, non-s.s.
Final follow-up	98.1 (94-100)	95.8 (85-100)	*t*-test, non-s.s.
Difference	Paired *t*-test, $P = .001$	Paired *t*-test, $P = .001$	
Objective function score			
Preoperative	46.4 (10-60)	46.5 (20-50)	*t*-test, non-s.s.
Final follow-up	97 (90-100)	95.1 (85-100)	*t*-test, *P*~.01
Difference	Paired *t*-test, $P = .01$	Paired *t*-test, $P = .01$	
Objective total score			
Preoperative	84.1 (45-115)	85.9 (57-110)	*t*-test, non-s.s.
Final follow-up	196.3 (180-200)	194.2 (115-200)	*t*-test, non-s.s.
Difference	Paired *t*-test, $P = .001$	Paired *t*-test, $P = .001$	
Subjective SF-12 physical component			
Preoperative	26.6 (20-40)	27.2 (20-40)	*t*-test, non-s.s.
Final follow-up	48.5 (34-56.2)	49.1 (30-56)	*t*-test, non-s.s.
Difference	Paired *t*-test, $P = .01$	Paired *t*-test, $P = .01$	
Subjective WOMAC			
Preoperative	31.8 (14-54)	32.4 (16-50)	*t*-test, non-s.s.
Final follow-up	69.2 (37-85)	70.1 (35-80)	*t*-test, non-s.s.
Difference	Paired *t*-test, $P = .001$	Paired *t*-test, $P = .001$	
Subjective Oxford knee score			
Preoperative	44.3 (38-50)	43.8 (39-51)	*t*-test, non-s.s.
Final follow-up	22 (14-28)	23.3 (20-32)	*t*-test, non-s.s.
Difference	Paired *t*-test, $P = .01$	Paired *t*-test, $P = .01$	

SF-12, Short Form-12; WOMAC, Western Ontario and McMaster University Osteoarthritis Index; s.s., statistically significant.

Table 3
Preoperative and Postoperative Mean Values (Range) of Alignment Parameters for Both Components Are Shown.

Radiological Evaluation	Group A		Group B	
	Preoperative	Postoperative	Preoperative	Postoperative
Mean femoral valgus angle (α)	96 (93-101)	97 (92-102)	96 (94-103)	97 (93-101)
Mean tibial angle (β)	89 (82-93)	88.5 (81-93)	89 (81-94)	89 (83-93)
Mean femoral flexion (γ)	1 (−3 to 4)	1 (−3 to 4)	1 (−3 to 4)	1 (−3 to 4)
Mean tibial slope (σ)	87 (82-91)	85 (83-92)	86 (83-91)	85 (81-92)
Mean knee alignment	5 valgus (8 valgus-4 varus)	4.7 valgus (7 valgus-4 varus)	5.2 valgus (8 valgus-5 varus)	4.8 valgus (7 valgus-3 varus)

radiographs of the tibial component only. There was no radiological evidence of osteolysis due to polyethylene wear debris in any knees in both groups.

Discussion

Despite satisfactory long-term cemented TKA clinical outcomes, aseptic loosening remains one of the most common indications for revision [30]. Several issues related to patient selection, surgical approach, abnormal artificial joint kinematics, optimum biomaterials, and ligament resection or preservation still remain controversial. The controversy related to TKA implant fixation has recently been revisited. A critical review of initial studies has shown that early cementless implants were used in young patients with higher demands and levels of activity. Aseptic loosening, more common in the young, varied between 5% and 30% at 5-year follow-up and was associated mainly with unacceptably high failure rates of the tibial components [31,32]. Moreover, it became apparent that inferior outcomes were related to poor osteoconductive surfaces, inadequate fixation mechanisms leading to micromotion, screw track osteolysis, poor-quality old polyethylenes, metal-backed patella component failures, and poor tibial tray designs implanted inappropriately in cancellous bone instead of on the cortical tibial rim [3,11,12,19]. It also became apparent that cementless fixation is more sensitive to component tibial tray malalignment due to abnormal concentration of loads [11,33,34].

The aMP TKA was first introduced in 1998 by Wright Medical Technology incorporating contemporary knee kinematic principles, and the cemented version has shown satisfactory long-term outcomes [35–37]. Later on, a cementless version with a titanium porous bead–coated femoral and a cancellous titanium-coated tibial component became available. Cancellous titanium is a porous reticulated titanium material developed for load-bearing orthopedic implants with a compressive modulus similar to bone. It also shows improved material properties with increased porosity and friction coefficient which enhances early stability and osseointegration [38]. Cancellous titanium cementless tibial components were launched in the United States and Canada in 2007 and the first implantation was performed in May 2007. The first implantation in Europe was performed in January 2009 in our department as a part of planned prospective clinical trials following our extensive clinical experience with the use of the aMP TKA system [35,36]. These studies were discontinued in February 2010 due to the premium cost of the implant in the middle of an economical crisis. There is only 1 clinical report showing satisfactory short-term clinical and radiological outcomes of these implants [39].

In this study, satisfactory clinical outcomes scores were recorded in both groups using both objective and subjective rating scales at 8- to 9-year follow-up. No differences were found when the cementless implants were compared to cemented ones which have

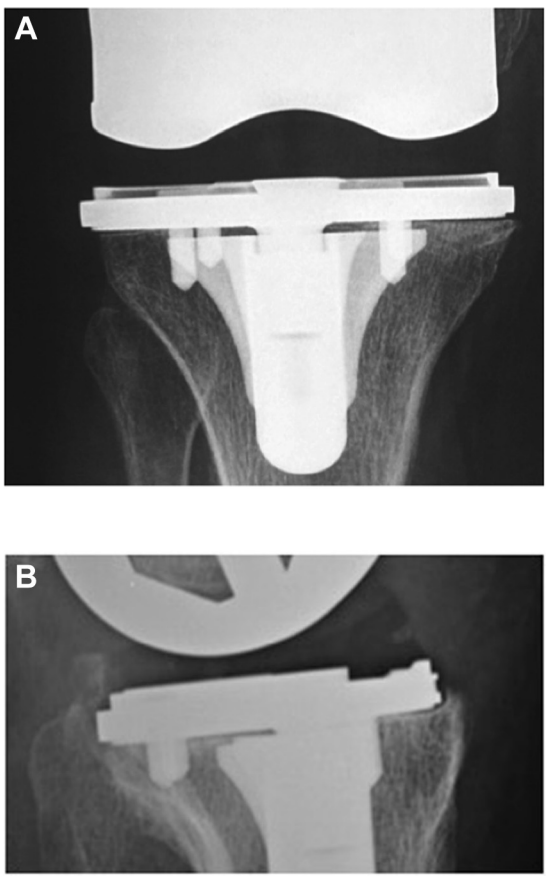

Fig. 3. Postoperative radiographs of cementless tibial components: a radiolucent line in zone 2 on an anteroposterior view (A) and a radiolucent line in zone 1 on a lateral view are shown (B).

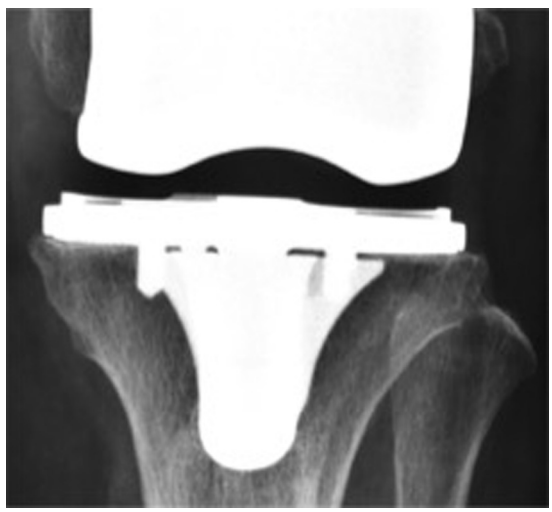

Fig. 4. Anteroposterior radiograph of a cementless tibial component at 9-year follow-up. Sound healing of the interface is shown.

shown satisfactory long-term outcomes [35–37]. It is important to stress that in the cementless group, no implant-related failures were found. The radiological appearance of the cementless interface was also satisfactory. Despite the fact that RLLs were evident in the postoperative radiographs of the cementless implants, none of them were progressive and, at 9-year follow-up, all of them had healed. No implant change in alignment and migration was recorded in both groups. No other adverse radiological signs were observed. Due to the possibility of late appearance of complications and adverse reactions, long-term, second-decade, clinical outcome studies are required in order to confirm outcomes achieved with these implants.

The limitations of this study are the small sample of relatively young and healthy patients which may underestimate possible future complications and failures and the performance of all operations by 1 dedicated orthopedic surgeon in a specialized center. The matching process also of the 2 groups does not allow further analysis and comparisons between groups related to the variables age, sex, side, and BMI. On the other hand, the strengths of the study are the lack of dropouts and deaths and the midterm to long-term follow-up. To the best of our knowledge, this is the study with the longest ever, globally, reported follow-up of this modern cementless tibial implant technology.

A meta-analysis, by Gandhi et al [40], evaluated the survivorship of cemented and cementless TKA in 11 studies (5 randomized, controlled trials and 10 observational). It was found that the odds ratio for failure of the implant due to aseptic loosening and the cumulative success rates were in favor of cemented fixation. However, when the 5 randomized studies were isolated and evaluated, no differences in survivorship were detected between cemented and cementless implants. The authors concluded that the higher failure rate of cementless implants in observational studies was due to the younger age and increased activity levels of the patient populations of these studies. In a more recent systematic review and meta-analysis, by Mont et al [19], 37 studies were evaluated comparing cemented to cementless TKA. It was found that cementless implants had comparable survivorship to that of cemented. The mean survival rate was 95.6% and 95.3% for cementless and cemented TKA, respectively, at 10 years. At 20-year follow-up, survival rates for cementless and cemented TKA were decreased to 71% and 76%, respectively. In more recent publications with newer designs, satisfactory outcomes have been reported in the midterm and long term for cementless implants [41]. Due to the fact that in old and new observational studies nearly all failures for aseptic loosening were related to the tibial tray component, several surgeons have suggested the use of hybrid fixation in TKA because of the satisfactory midterm and long-term results [42]. In a Cochrane database report, evaluating cemented, cementless, or hybrid fixation options in TKA for osteoarthritis and other non-traumatic diseases, there was a smaller migration (assessed by RSA) of tibial components with cemented fixation in relation to cementless fixation, in studies with osteoarthritis and rheumatoid arthritis patients who underwent primary TKA, with a follow-up of 2 years; however, the cemented fixation presented a greater risk of future aseptic loosening than cementless fixation [43]. In a systematic review study by Voigt and Mosier [44], early implant stability was evaluated by RSA in 3 groups of patients (hydroxyapatite [HA] coated, porous coated, and cemented). It was found that the HA-coated implants without screw fixation were less likely to be unstable at 2 years compared to porous-coated and cemented implants. In a prospective, randomized trial, at 5-year follow-up, there was no difference between cementless tibial fixation with HA and cemented tibial fixation in terms of self-reported pain, function, health-related quality of life, postoperative complications, or radiographic scores [45].

Recently, the cementless TKA has made a comeback with newer designs, and improved materials and manufacturing techniques. It has been understood that the longevity of fixation depends on joint alignment (surgical technique and instrumentation), bone quality, patient factors (age, level of activity, weight), implant features (stems, pegs), and implant surface characteristics (coating, material). Additionally, factors affecting bone ingrowth or ongrowth for implant coatings are related to the structure of the material, porosity of the structure, and type and size of the porous material. A series of new structures have been developed, tested in animals, and applied to humans, for example, tantalum trabecular metal technology, Tritanium dimensionised matrix, regenerex, and titanium foam. Trabecular metal technology tibial tray implants were the first to be used in humans. Satisfactory clinical and radiological results have been reported from different centers with a follow-up ranging from 5 to 10 years [46,47]. Fernandez-Fairen et al [48], in a prospective randomized trial, found at 5-year follow up comparable outcomes of tantalum cementless and cemented tibial implants. These new structures for cementless tibial tray fixation present different material and manufacturing features, and clinical outcomes should be evaluated separately. Outcomes achieved in our study are material and implant specific and generalization should be avoided.

Conclusion

Old cementless TKA designs produced unsatisfactory midterm and long-term outcomes for various reasons. Clinical outcomes of newer designs are comparable to those of cemented designs. The application in TKA designs of new materials and technologies shows promising midterm to long-term results [49]. The issue of the cost-effectiveness of such technologies, either in young or in all patients generally, remains unclear because cementless TKAs cost 3 times more than cemented TKAs in most countries [45].

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