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ORIGINAL PAPER

Primary cementless total knee arthroplasty with or without stem extension: a matched comparative study of ninety eight standard stems versus ninety eight long stems after more than ten years of follow-up

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Abstract

Introduction Using a cementless fixation for total knee arthroplasty (TKA) is controversial. We hypothesized that cementless tibial base plate with a monoblock long stem (MLS) would provide secure tibial alignment and stable fixation when bone conditions were considered as poor for a cementless fixation. The purpose of this study was to compare the mean eight year survivorship of cementless standard keels (SK) vs cementless MLS.

Material methods We report a matched series of 98 cases of SK and 98 cases of MLS in patients with poor bone conditions. The two cohorts were statistically compared. Revision for tibial loosening was used as the endpoint in the survivorship analysis.

Results We recorded two cases of tibial loosening and three cases of bipolar loosening in the SK group (0% MLS vs 5% SK). No tibial loosening occurred in the MLS group (statistically significant). No tibial periprosthetic or intra-operative fractures occurred in either group. The survivorship at eight years of follow-up was 95.6% in the SS cohort vs 100% in the MLS cohort using revision for tibial loosening as the endpoint.

Discussion This study was not randomized. Its strength was that it took into account the comparative midterm outcomes of a matched cohort of patients implanted with two types of cementless components in the same bone conditions. We did not record any tibial loosening in the MLS group. Using long stems has been criticized but we did not observe any adverse reactions and no intra-operative tibial fracture occurred.

Conclusion MLS improves the alignment and fixation of cementless TKA. This is a safe solution when bone conditions are poor or modified by previous surgery.

Keywords Cementless total knee arthroplasty · Long stem · Standard keel · Survivorship at eight years · Poor bone conditions

Introduction

Primary total knee arthroplasty (TKA) long-term outcomes are usually good with a survivorship rate of at least 90% at ten years (1% of failure per year) [1, 2] whatever the fixation mode of the implant.

Cementing has been reported as the most common way to ensure short-, medium-, and long-term fixation in TKA [3, 4]. The first generation of cementless implants (PCA Howmedica™) was introduced by Krackow and Hungerford in 1980. The first clinical results [5–7] and midterm outcomes were similar to those of cemented implants. However, as for total hip arthroplasty (THA) fixation, we decided to routinely use cementless hydroxyapatite (HA)-coated TKA implants in 1996. Epinette [8] reported excellent results with this type of cementless biologic fixation after 11 years of follow-up.

Using a cementless fixation is more controversial in several critical and difficult conditions such as TKA after a previous surgery, high tibial osteotomy (HTO) [9–19], unicompartmental knee replacement (UKR) revision, anterior tibial tuberosity (ATT) transfer, and proximal tibia fracture (PTF) [20] as well as Ahlback's grade 4 or 5 osteoarthritis (OA), severe frontal deformity (HKA angle > 15° varus or valgus), and obese

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patients [21]. Therefore, it is necessary to secure alignment and immediate fixation for a long-term survivorship of the implant. There is currently no consensus on whether a higher rate of complications is observed in these poor bone conditions and which type of fixation should be recommended [9–20].

The cementless tibial base plate with a monoblock long stem (MLS) was introduced as a special component of the New Wave™ TKA system in 2004. We hypothesized that this modified implant would provide a secure tibial alignment and stable fixation when bone conditions were considered as poor or unfit for a cementless standard keel (SK) fixation.

The purpose of this study was to compare the midterm survivorship of cementless SK vs cementless MLS. We selected and matched (1:1) two cohorts of TKA cases among 635 cementless TKA cases performed between 2002 and 2014: 98 cementless SK and 98 cementless MLS.

Materials and methods

Implant characteristics

The New Wave™ TKA (groupe lepine, Genay, France) is a mobile-bearing, posteriorly-stabilized implant. The femoral condyle is symmetric, made of cobalt- chromium alloy; it is entirely coated with a bilayer of vacuum plasma-sprayed titanium (120 μm) and HA (80 μm) (Fig. 1). MLS were introduced in 2004 to solve complex cases in critical bone conditions as previously described, to improve alignment accuracy (90° in frontal and sagittal planes) and to increase the contact surface between the implant and host bone. The stem is perpendicular to the tibial plate (Fig. 1) and monoblock to avoid any risk of corrosion and breakage. The stem's location is chosen to avoid impingement with the posterior tibial cortex (PTC).

The monoblock SK used was 45 mm long in the whole series of tibial implants (size B to F). The MLS used was 100 mm long in size B and 120 mm long in size C to F. The stem is octagonal; its diameter (13 mm, 15 mm, and 17 mm) is not correlated to its size. It is fully coated. The increased fixation area between SK and MLS ranges from 30% (B size with 13-mm diameter MLS) to 40% (F size with 17-mm diameter MLS) (Fig. 2).

The mobile polyethylene (PE) insert is made of standard ultra-high molecular weight polyethylene (UHMWPE), sterilized by ethylene oxide. The patellar component is an 8-mm thick, full-PE, dome-shaped implant, cemented with two pegs.

Surgical technique

An anteromedial approach was used in patients with varus deformity and a Keblish anterolateral approach was used in patients with valgus deformity. ATT osteotomy was performed in patients with stiff knees and/or when patella infera had been detected pre-operatively based on Caton measurements [22, 23]. The instrumentation related to the intramedullary axis (tibia and femur). The tibial cut was made perpendicular to the diaphysis axis in the frontal and sagittal planes. The patellar implant was routinely replaced and cemented with standard viscosity, antibiotic-loaded bone cement. Full weight-bearing and early mobilization were recommended to patients immediately after surgery.

Morselized autologous bone grafts were used to fill bone defects, but no structural graft or metal augments were used in our series.

Statistical analysis

Qualitative variables were expressed as percentages and quantitative variables as mean and range values. Comparisons between cohorts were made using the chi-square or Fisher's exact test. Quantitative variables were compared between cohorts using the Mann-Whitney test. Survivorship probability was determined using the Kaplan-Meier method with 95% confidence intervals. Differences in survivorship probability were determined using the log-rank test. The statistical analysis was performed with Stata software. A result was considered statistically significant for $p < 0.05$.

Data collection

The data was prospectively collected in a computerized database (File maker Pro). The patients' characteristics such as age, aetiology, previous surgery, weight status (normal, overweight, obese, morbid obesity), surgical details, implant characteristics, and complications were recorded.

We identified 383 cemented and 635 cementless TKAs among the 1018 New Wave™ TKAs implanted between 2000 and 2015 by a single senior surgeon. Two hundred sixty-five of these 635 cementless TKA cases were SK and 370 were MLS (Fig. 3).

We closely matched TKA cases 1:1 to obtain a relevant comparison between SK and MLS, according to the following priority criteria as reported in Table 1.

1st—1 for 1 previous major surgery: UKR revision (six cases in each group), HTO-closed wedge (nine cases in group SK, eight cases in group MLS), distal patella realignment (four cases in each group), PTF (two cases in each group), and knee ligament reconstruction (five cases in each group)

2nd—1 for 1 major deformity: Ahlback grades 4 and 5 medial OA or lateral OA (13 cases in each group). In nine cases in each group, the HKA angle was < 166° (varus deformity) and in two cases, the HKA angle was > 196° (valgus deformity)

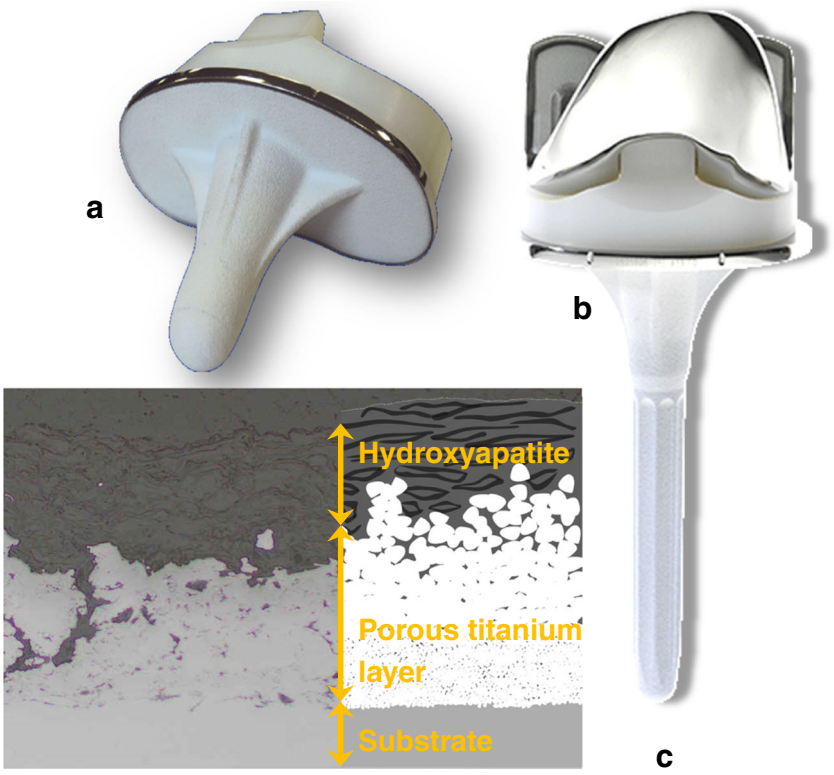

Fig. 1 New Wave™ implant design: HA coating on the tibial baseplate with a cementless standard keel (SK) (**a**) or with a monoblock long stem (MLS) (**b**). Bilayer coating of plasma-sprayed titanium + HA (**c**)

Standard Keel (SK)		
Size	Bone contact area (mm2)	
B	4,663	
C	4,909	
D	5,149	
E	5,353	
F	5,552	
Monoblock long stem (MLS)		
Size 13	Bone contact area (mm2)	Gain%
B	6,652	30
C	7,710	36
D	7,950	35
E	8,153	34
F	8,353	34
Size 15	Bone contact area (mm2)	Gain%
B	6,906	32
C	8,060	39
D	8,299	38
E	8,503	37
F	8,702	36
Size 17	Bone contact area (mm2)	Gain%
B	7,288	36
C	8,576	43
D	8,816	42
E	9,019	41
F	9,219	40

Fig. 2 Comparison of bone contact area in tibial baseplate with a standard keel and a monoblock long stem

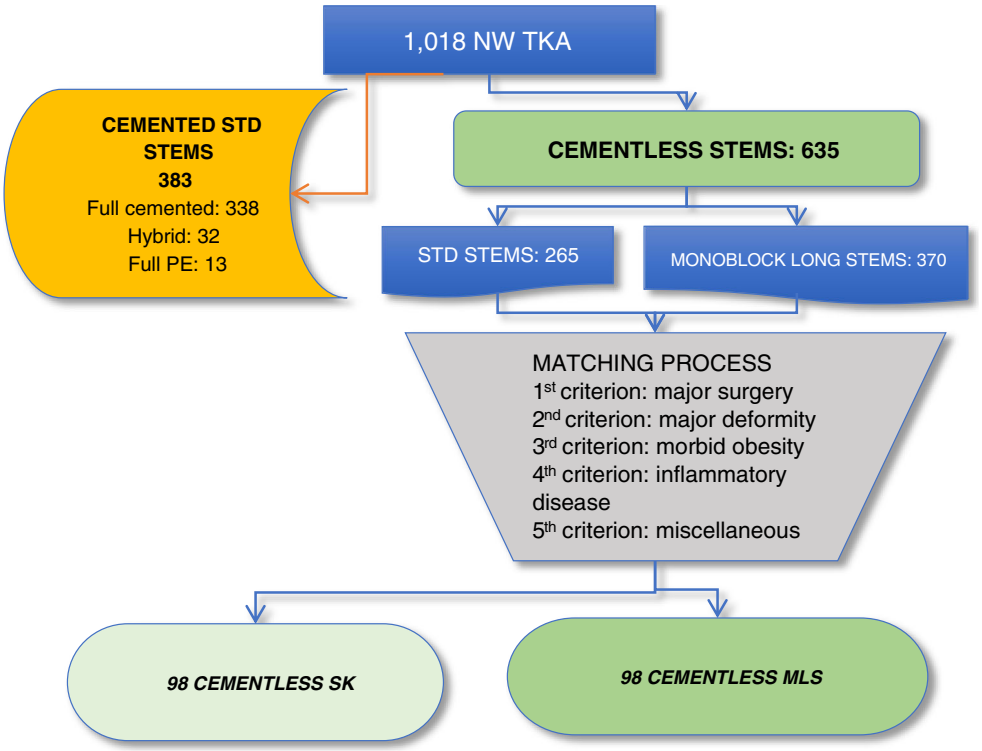

Fig. 3 A flow chart of cementless TKA cases selected for this study (SK, standard keel; MLS, monoblock long stem)

3rd—1 for 1 morbid obesity (BMI > 40) (nine cases in each group).
4th—1 for1 RA (three cases SK group, two cases in group MLS)

Fifty-one patients group SK and 49 group MLS were identified as the highest risk population. Forty-seven patients group SK and 49 patients group MLS were considered as with a lower risk and were matched 1/1 for the aetiology (Ahlback 2 and 3 OA, other aetiology, BMI, gender, and age at surgery (Table 1).

Both populations (SK and MLS) were strictly statistically comparable (Table 1).

The endpoint for the survivorship analysis was revision for tibial loosening (infection excluded).

The pre-op and post-op X-ray examination included standing X-ray in frontal and sagittal planes, and long standing X-ray (Fig. 4). The pre- and post-op angulations were measured as well as the implant subsidence, radiolucent lines, and bone reaction around the stem.

Results

Cementless SK

Ninety-eight cases were eligible after the matching process. The patient features are given in Table 1. There were 54 female patients. The mean age at index surgery was 72.9 (51–90) years. Three percent died of causes unrelated to the TKA. Fifteen percent were lost to follow-up (we considered as lost to follow-up patients who had not consulted for 2 years). Fifty-five percent of the remaining patients were reviewed during an outpatient visit with a clinical examination and X-rays, between 2013 and 2016. The remaining 27% of patients were contacted by phone or mail and X-rays were subsequently obtained.

One patient (1%) developed an infection six weeks after surgery. We performed open lavage with debridement, synovectomy, PE insert exchange, and prescribed an antibiotic treatment for three months. At the latest follow-up in 2015, there was no loosening of implants.

Three female patients (3%) presented with bipolar loosening: two at three years and one at eight years. They previously had undergone UKR revision (two cases) and Ahlback grade 4 medial OA (one case). Their BMI was respectively 22, 36, and 31. The three patients underwent bipolar revision with a cementless highly constrained implant.

Two female patients (2%) presented with a varus and anterior tibial subsidence and subsequent loosening within two years: Ahlback grade 4 medial OA in both cases. Their BMI was 36 and 24. They were treated by isolated tibial revision using a cementless tibial tray MLS, morselized bone grafts, without replacement of the femoral component. At the latest follow-up in 2015, both patients were doing well with a good functional result without loosening.

Table 1 Characteristics of our series and details of the matching process: standard keels vs monoblock long stem

	Standard keel (SK)	Monoblock long stem (MLS)
Number of cases	98	98
Mean age at surgery (min–max)	72.9 (51–90)	73.1 (53–90)
Gender (females), *n*	54	54
Mean follow-up in years (min–max)	10.7 (1–14)	7.5 (1–11)
Group high risk	51	49
UKR revision	6	6
High tibial osteotomy	9	8
Patella (ATT transfer)	4	4
Articular fracture (proximal tibia fracture)	2	2
Ligament reconstruction	5	5
Ahlback grade 4–5 OA	13	13
Morbid obesity (BMI > 40)	9	9
Rheumatoid arthritis	3	2
Group lower risk	47	49
Ahlback grade 2–3 OA lateral	2	2
Ahlback grade 2–3 OA medial	37	35
others	8	12
Surgical approach, $n = 98$		
Anteromedial	90	89
Anterolateral	7	8
ATT osteotomy	1	1
Bone graft	8	9
Mean HKA angle pre-op	171	168
Mean HKA angle post-op	178	181
Patients died for unrelated causes	3	3
Lost to follow-up	15	10
Reviewed at outpatient visit	53	72
Patients contacted by phone or mail	27	13

ATT anterior tibial tubercle, *UKR* unicompartmental knee replacement, *OA* osteoarthritis, *HKA* hip knee ankle

The five previous patients were considered as presenting poor bone conditions and were included in the high-risk population.

Cementless MLS

Ninety-eight cases were eligible. The patient features are given in Table 2. There were 54 female patients and the mean age at index surgery was 73.1 (53–90) years. Three percent died of causes unrelated to the TKA. Ten percent of the patients were lost to follow-up. Seventy-four percent of the remaining cases were reviewed during an outpatient visit with a clinical examination and X-rays, between 2013 and 2016. The remaining 13% of patients were contacted by phone or mail and X-rays were subsequently obtained.

No tibial or bipolar loosening occurred. One patient (1%) developed femoral loosening five years after surgery (obese female patient with Ahlback grade 4 medial OA). She underwent bipolar revision with a cementless highly constrained implant.

Survivorship

The survivorship probabilities (with revision for tibial loosening as the endpoint) at an average eight years of follow-up were

100% for the MLS cohort (95% CI, 100%–100%)
95.6% for the SS cohort (95% CI, 88.6%–98.3%)
($p = 0.045$)

Discussion

The purpose of our study was to compare the survivorship of cementless SK vs cementless MLS. We did not observe

1. Any tibial loosening in the MLS group, which was statistically significant compared to SK group
2. Any bipolar loosening in the MLS group

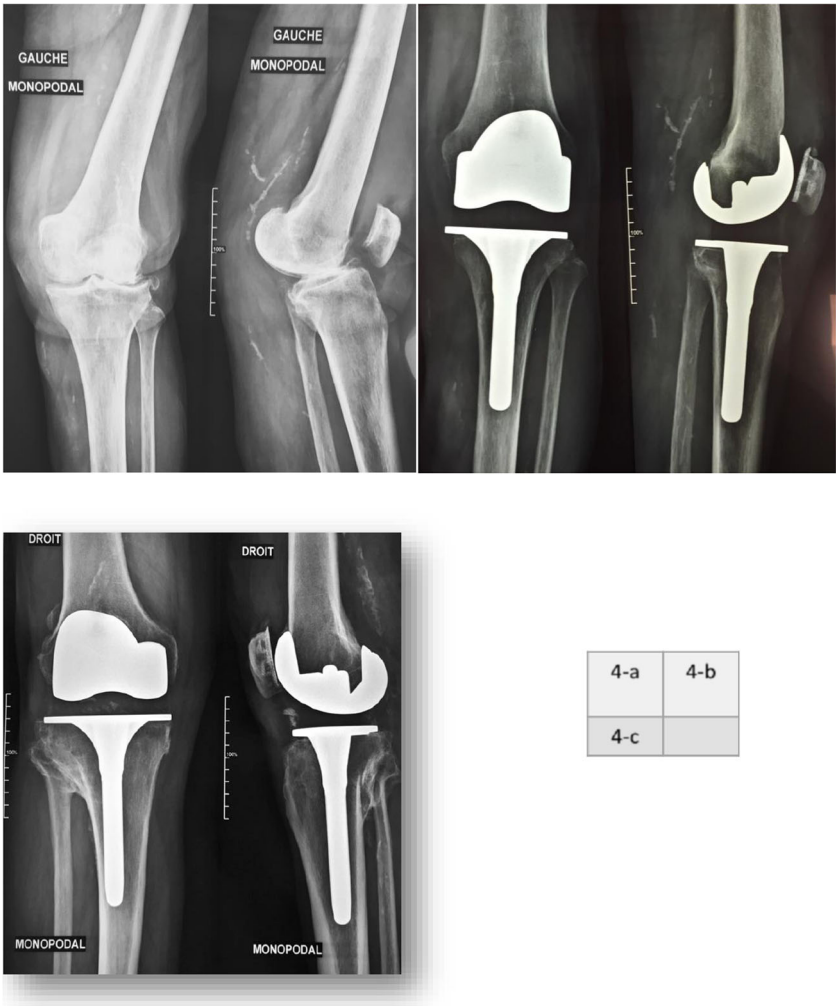

Fig. 4 (**a**, **b**) An 86-year-old female patient with rheumatoid arthritis and valgus deformity MLS at 2 years of follow-up. **c** At the 12-year follow-up of New Wave TKA cementless MLS after high tibial osteotomy

3. Any tibial periprosthetic or intra-operative fractures in either group

TKA components, in the 1970s, were fixed with cement as in total hip arthroplasty (THA) procedures [24]. Satisfying midterm results with cementless fixation in THA led to introducing this fixation mode for TKA in the early 1980s by Krackow, Hungerford, and Kenna [5–7]. Cementless fixation was obtained by a macroporous coating with a double layer of metallic beads. The authors also designed a specific ancillary device to achieve the closest possible contact between the implant and the host bone, so as to ensure immediate stability of the implant. The early results were excellent but some failures occurred, mainly due to the release and migration of metallic beads in the prosthetic joint. Miller and Galante (Zimmer™) addressed these metallic failures by using a titanium fiber-mesh coating [25]. Many surgeons shifted to cemented TKA, because of these cementless TKA failures, as reported in several national joint registries [26, 27]. Today, there is a renewed interest in cementless TKA due to the availability of improved biomaterials [8].

Table 2 Complications in the two series: standard keel vs monoblock long stem

Type of complication, *n*	Standard keel	Monoblock long stem
Infection	1	0
Bipolar loosening	3	0
Femoral loosening	0	1
Tibial loosening	2	0
Patellofemoral implant loosening	0	1
Type of treatment, *n*		
Global revision	3	1
Tibial revision	2	0

The theoretical benefits of cementless fixation are bone stock preservation, no cement-associated debris, and potential biologic fixation of the implant to the bone. Cementless fixation relies on a porous or roughened surface to facilitate bone formation. The initial stability present at the time of implantation influences the long-term fixation [28]. For this reason, it is important to prevent micromotion, as this would compromise

the chance of achieving osseointegration. The cementless New Wave™ implant is entirely coated with a bilayer of plasma-sprayed titanium and HA (Fig. 1). HA accelerates bone integration and thereby decreases the component's micromotion and increases its fixation [29]. Ferreira et al. reported excellent results with this bilayer coating. [30].

Cementless TKA survivorship can be evaluated in the short term, medium term, and long term.

Short term

Petersen et al. [31] analyzed the migration of the tibial component after uncemented TKA. Most of the migration, expressed as maximal total point motion (MTPM), occurred during the first year, with an average migration of approximately 1 mm. A regression analysis yielded a positive correlation between bone mineral density and MTPM. Nilsson et al. [32] compared 29 HA-coated Tricon II tibial trays to 28 cemented tibial components. After five years, no difference was detected between the two implants. Whiteside et al. [33] compared a group of 167 patients less than 55 years of age weighing more than 90 kg, with a gender-matched cohort of 167 patients more than 65 years of age weighing less than 80 kg. The mean Knee Society Score was similar between cohorts at five years of follow-up, and no loosening was observed in either cohort. We did not evaluate the bone mineral density in our series.

Medium term

Kim et al. [34] compared cementless and cemented TKA in patients with OA less than 55 years of age. The results were encouraging; however, they found no evidence to prove the superiority of cementless over cemented TKAs. The authors of a randomized controlled trial (RCT) of outcomes at five years compared HA-coated tibial implants with cemented tibial fixation in primary TKA [35]. There was no difference between cementless fixation with HA and cemented fixation at five years post-operatively. The authors of a study of 1000 patients with HA-coated TKA reported that, at nine years of follow-up, the revision rate for aseptic loosening was 0.5% [36]. In another study of 146 primary HA-coated TKA cases, the survivorship was 98.14% at a mean follow-up of 11.2 years (endpoint, mechanical failure) [8]. Voigt and Mosier, in a meta-analysis of 926 TKA cases [37], concluded that HA-coated implants could provide better durability than other modes of fixation including cemented TKA.

Long term

The best TKA fixation mode is still the subject of debate in terms of clinical and radiological outcomes. Baker et al. [38] performed a RCT of cemented vs cementless condylar TKA. The 15-year survivorship rate was 80.7% (95% CI, 71.5 to 87.4) for cemented TKA and 75.3% (95% CI, 63.5 to 84.3) for cementless TKA. There was no significant difference between the two groups. However, there was a significant gender difference, with male patients having a higher failure rate with cemented fixation (HR 2.48, $p = 0.004$). Ritter et al. [39] reported on a series of 73 cementless TKAs. The survivorship for the cementless tibial component without screws was 96.8% at 20 years.

MLS were first used in 2004 for TKA and indicated in patients with critical bone conditions. They were designed to

- Achieve better alignment in the frontal and sagittal planes
- Achieve better fixation in the proximal tibia
- Achieve better bone contact, biological bone ingrowth, and long-term fixation
- Increase contact surface (30 to 40%) with the host bone
- Avoid impingement with the tibial cortex

Monoblock manufacturing was preferred to a modular configuration to prevent implant corrosion and breakage. Primary fixation is insured by press fit and no additional screws are required.

We found only few publications with the following keywords: *primary TKA*, *stem extension*, *long stem*, and *additional keel*. Cameron [40] compared the clinical outcomes and radiolucent lines between three groups of cementless tibial trays (Tricon II). He concluded that the addition of a diaphyseal stem extension reduced the amount of radiolucent lines in the tibial component in non-cemented TKA. Barlow et al. [41], in a registry review (HSS) of 13,507 TKAs, reported a 2.3% incidence of stemmed TKA use. They concluded that use of long stems could provide an improved survivorship in complex primary TKA cases on the short term and found no adverse effect on patient outcome or satisfaction. Mittal et al. [42] reported on a large an original series of stress fracture in arthritic knees treated by cementless long-stem tibial implant, bridging the fracture without any fixation failure.

Old age and obesity [43] are also risk factors for tibial loosening as well as severe deformities or post-operative malalignment [21]. We did not observe any tibial loosening in the MLS group with critical bone conditions, in our series. There were two cases of tibial loosening and three cases of bipolar loosening in the SK group (0% MLS vs 5% SS). The use of long stems has been criticized because of the possibility of stress shielding or pain due to contact between the stem and the cortical bone. We did not find any of these adverse events at the longest follow-up (14 years) and no intra-operative tibial fractures occurred.

Even though our study was not an RCT, the sample size was limited, the series was continue, monocentric, retrospective, and mono observer. Its strength is that it reports comparative midterm outcomes (8-year average follow-up) of a matched cohort of patients implanted with two types of cementless tibial components in the same bone conditions.

Conclusion

Our study clearly demonstrates that

1. Cementless fixation is a reliable option in TKA even though cemented fixation is largely predominant worldwide.
2. Cementless MLS appears to be a safe surgical option when bone conditions are poor or modified by previous surgery. Survivorship is improved with this implant; no significant adverse effects and no radiological modifications have been identified over time. Long stem secures positioning of the tibial component and ensures immediate and midterm fixation. This type of implant is recommended for poor bone conditions when knee replacement is indicated.

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