A flat all-polyethylene tibial component in medial unicompartmental knee arthroplasty: a long-term study

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1. Introduction

In the treatment of knee arthritis, unicompartmental knee arthroplasty (UKA) offers advantages in terms of tissue sparing with less bone resection and preservation of the cruciate ligaments [1,2]. Comparative studies between total knee arthroplasty (TKA) and UKA have shown superior patient satisfaction and joint kinematics for the latter [3]. Current unicompartmental implants using refined prosthetic designs, modern materials and correct treatment indications have resulted in survivorship rates greater than 90% at ten years and ranging from 70% to 92% into the second decade [4–6].

Several studies in the literature, including meta-analyses and randomized trials, have reported no differences between all-polyethylene and metal-backed tibial components in TKA in terms of revision rates, clinical scores and radiological parameters including radio-stereometric analysis (RSA) [7]. Fewer trials in the literature have presented the results of the performance and survivorship in UKA with an all-polyethylene tibial component. A recent radio-stereometry study by Ensini et al. [8] reported successful implant to bone fixation together with excellent clinical outcomes at a short follow-up using an all-polyethylene tibial implant. Bruni et al. [9] reported excellent results with no revision at 60 months follow-up with a similar all-polyethylene implant.

Fewer authors have assessed rates of survivorship and clinical performance of UKA using an all-polyethylene tibial component at a follow-up of at least 10 years. Heyse et al. [10] reported a survivorship of approximately 93% at 10.8 years follow-up in a non-homogeneous series of UKAs including medial and lateral components with both all-polyethylene and metal-backed tibial implants. At mean follow-up of ten years, Lustig et al. [11] reported a total survivorship of approximately 93% in all-polyethylene implants including medial and lateral components for patients with varying diagnoses. Studies have reported early failure in UKA

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using all-polyethylene implants. Aleto et al. [12] reported an early failure rate of approximately 87% in all-polyethylene implants associated with significant bony defects. Other authors reported similar early failure rates particularly in obese patients [13,14].

The aim of this study is to present the clinical and radiological results of a cemented UKA using a flat all-polyethylene tibial component at five, ten and 14.7 years follow up. The same implant was used in a homogeneous group of patients with medial femoro-tibial knee arthritis. The clinical outcomes were evaluated using the International Knee Society (IKS) and the functional score. A radiographic analysis measuring the alignment of the mechanical axis and implant loosening based on the method of the IKS was performed. The progression of arthritic changes in the non-resurfaced compartment was also assessed.

2. Materials and methods

Fifty-one patients (two cases bilateral), diagnosed with atraumatic unicompartmental arthritis, who underwent a medial UKA in our department between January 1998 and November 1999, were included in the study. Thirty-one of these patients were females and twenty were males. The mean age of the patients was 65.1 years (range: 57–73). All the patients gave informed consent and the study was approved by the ethics committee of the First Orthopedic Department, C.T.O. Hospital (Milano, Italy).

The same cemented implant (UC-Plus Solution, Smith and Nephew, Memphis, USA) with a flat all-polyethylene tibial component was implanted in all the knees. The inclusion criteria included a diagnosis of atraumatic arthritis, a pre-operative flexion greater than 100° with no flexion deformity, a varus deformity less than 10° and a BMI less than 35. Arthritic change was graded according to the Älback classification and did not exceed grade IV in the medial compartment and grade III in the patello-femoral compartment [15]. All patients had an asymptomatic patello-femoral joint and no clinical evidence of ACL laxity. The same surgical technique was used in all patients and all the operations were performed by or under the direct supervision of the most experienced surgeons in UKA surgery in our department (N.C., A.M.). Intra-operatively an anteromedial approach with arthrotomy was undertaken using a tourniquet. The patella was retracted laterally without dislocation. The bone cuts were performed with a "tibia first" technique using an extramedullary guide. The distal femoral cut was performed with the knee in full extension so as to achieve a parallelism with the tibial cut. All the implants were cemented using the same technique. The final surgical end-point was defined as correction of the varus deformity to achieve a mechanical axis of 180° according to this hypothesis: *"the thickness of the prosthesis should correct the joint deformity"*. For this purpose, preoperatively we templated all the radiographs to estimate the axial deviation angle in varus, and subtracted it from the minimum implant thickness of the prosthesis to determine how much bone needed to be resected from the tibia to achieve a limb alignment close to 180° (*rule of minimum bone cut:* the thickness of the prosthesis – axial deviation angle = tibial bone resection). The closed suction drain was removed at 48 hours after surgery. All the patients underwent a similar recovery protocol with full weight bearing allowed as soon as tolerated.

The pre-operative data is reported in Table 1. The pre- and post-operative clinical scores were evaluated using both the IKS and the functional score [16]. The radiological assessments were made using the hip-knee-ankle (HKA) angle measured on a long leg standing anteroposterior (AP) radiograph using the same imaging protocol. Radiographs were repeated if any malrotation was detected. We painstakingly educated and communicated with our radiologists in order to obtain consistent films before embarking on this trial. Standing radiographs were obtained with the knee in maximum extension, the patella pointing forward and both hips and ankles visible on the film.

Table 1
The criteria used to assess arthritic progression in the knee.

	Radiological appearance
Grade I	Osteophytes without joint space narrowing
Grade II	Greater than 25% joint space narrowing
Grade III	Greater than 26% and less than 50% joint space narrowing
Grade IV	Greater than 50% joint space narrowing

The patients were assessed both clinically and radiographically at five, ten and 14.7 years (range 14.2–15.3) follow-up. A Kaplan-Meier survivorship analysis was performed with 95% confidence interval using revision knee surgery or loss to the follow-up as the end-point. Radiographic analysis of loosening was performed based on the IKS guidelines. The bone-cement interface and the prosthesis-cement interface were evaluated for radiolucency on the tibial side according to the modified knee arthroplasty roentgengraphic assessment (Fig. 1). Loosening was considered progressive if there was a development from one to an adjacent zone over time [17,18]. Arthritic progression of the non-resurfaced femoro-tibial compartment was evaluated at latest follow-up by comparing the most recent radiographs to the pre-operative radiographs (Table 1). Progression of arthritic change in the lateral femoro-tibial compartment was graded from I to IV based on the radiological appearance as detailed in Table 1 [18].

Statistical analysis of all the results using Statistica software (StatSoft Inc., Tulsa, USA), was performed with Wilcoxon non-parametric test. A proportional Chi-square test was used to determine whether both the differences in the number of implant radiolucent lines seen at five, ten and 14.7 years follow-up and radiolucencies incidence according to sex at the latest follow-up were statistically significant. We considered a difference significance threshold of $p \leq 0.05$.

3. Results

At the five year follow-up one patient had died and two implants had been revised to a primary TKA. In one patient a revision was performed because of a femoral component fracture and in another because of pain at the tibial compartment despite showing no major signs of loosening. As a result 50 knees (48 patients: 29 females and 19 males) were available for assessment at five year follow-up. At the ten year follow-up, 47 knees (45 patients: 28 females and 17 males) were available for assessment. Two patients failed to attend follow-up and one patient died during this period. Forty-one knees (40 patients: 26 females and 14 males) were available for assessment at latest follow-up. Two implants in the same patient had been revised to a TKA because of tibial component loosening. In this patient a primary TKA had been used on one side and a semiconstrained TKA on the other (fig 2). Three patients had died and one failed to attend follow-up at 14.7 years (Table 2). A further patient with evident tibial component loosening at latest follow-up refused revision surgery despite having a painful implant. All patients with loosening of the implant were female.

All the pre- and post-operative clinical scores, including range of motion (ROM), were recorded in Table 2. The mean pre-operative ROM in terms of flexion was 115.9° (range 100–130°). The mean ROM in terms of flexion was 123.2° (range: 100–130°), 121.5° (range: 100–130°) and 120.6° (range: 100–130°) for five, ten and 14.7 year follow-up, respectively with a statistical significant ($p<0.006$) improvement at all post-operative follow-ups compared to the preoperative flexion. At five year follow-up, the mean IKS score was 81.3 (range: 90–73) and the mean functional score was 85.6 (range: 100–70). At ten year follow-up, the mean IKS score was 80.3 (range:

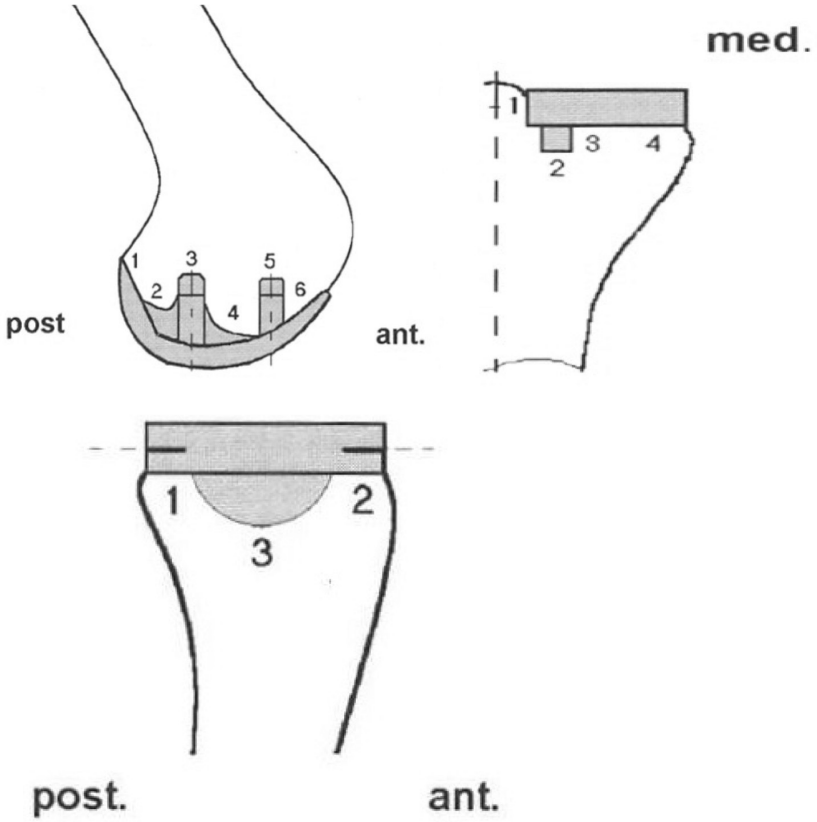

Fig. 1. Modified Knee Society knee arthroplasty radiographic scheme to assess radiolucency and its progression.

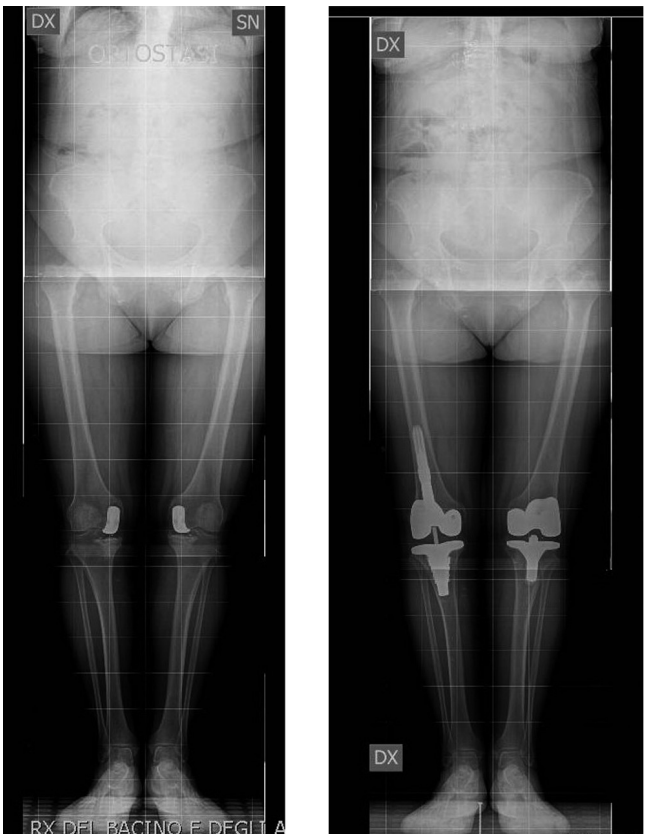

Fig. 2. Two implants in the same patient had been revised to a TKA because of tibial component loosening: a primary TKA had been used on one side and a semiconstrained TKA on the other.

90–73) and the mean functional score was 84.9 (range: 100–70). At latest follow-up, the mean IKS score was 80.1 (range: 90–50) while the mean functional score was 84.7 (range: 100–70). There were no statistically significant differences in the clinical scores at the five, ten and 14.7 years follow-up (Table 2). The mean HKA angle was 178.4° (range: 181–176°), 177.9° (range: 181–174°) and 177.1° (range: 182–171°) for five, ten and 14.7 year follow-up, respectively. The results showed a statistically significant worsening in the varus of the mechanical axis at 14.7 years compared respectively to the five year ($p<0.001$) and ten year ($p=0.01$) follow-up. There was no significant difference in the mechanical axis ($p=0.07$) between year five and ten (Table 2). At the latest follow-up, there were two patients with a mild overcorrection (181°) without apparent adverse influence on the survival rate as the corresponding implants were still functioning well.

An asymptomatic radiolucent line was present in eight patients at five year follow-up limited to the tibial component (involving zone 3,4 and zone 1,2 respectively in the AP and in the lateral radiographs). One of these patients missed the ten year follow-up. At ten year follow-up, 12 patients showed asymptomatic radiolucent lines around the tibial component (involving all the zones). Progression of the tibial radiolucent lines was present in all the six patients identified at the five year follow-up. At latest follow-up, two patients with clear signs of implant loosening and evident radiolucency around both the components had been revised, one patient had died, and another with evident symptomatic tibial loosening declined a revision procedure. Of the remaining patients, fourteen tibial implants, all in females patients, demonstrated radiolucency with a statistically significant higher incidence of tibial implants with radiolucencies compared to the opposite sex ($p<0.003$) (Table 2). There was no significant difference ($p>0.06$) in the development of radiolucent lines at five, ten and 14.7-year follow-up.

Table 2
Pre-operative and follow-up data including clinical scores, mechanical axes and radiolucency progression

	Pre-operative	5 year follow-up	10 year follow-up	14.7 year follow-up	p-value	
Number of cases	53 knees	50 knees	47 knees	41 knees		
ROM in flexion	115.8° (Range:100–130°) Std: 9.8	123.2° (Range:100–130°) Std: 7.8	121.5° (Range:100–130°) Std: 8.2	120.6° (Range:100–130°) Std: 8.07	ROM pre / ROM 5y ROM pre / ROM 10y ROM pre / ROM 14.7y Non significant differences in ROM post operatively	p=0.0001 p=0.0008 p=0.0053
International Knee Society score	45.5 (Range: 50–40) Std: 3.04	81.3 (Range: 90–73) Std: 4.9	80.3 (Range: 90–73) Std: 4.6	80.1 (Range: 90–50) Std: 6.06	IKS 5 / IKS 10 IKS 5 / IKS 15	p=0.12 p=0.12
Functional score	49.3 (Range: 56–44) Std: 3.5	85.6 (Range: 100–70) Std: 9.07	84.9 (Range: 100–70) Std: 9.1	84.7 (Range: 100–70) Std: 8.7	FUNCT 5 / FUNCT 10 FUNCT 5 / FUNCT 15 FUNCT 10 / FUNCT 15	p=0.5626 p=0.6492 p=0.8945
Hip-knee-ankle angle	173.9° (Range: 180°–170°) Std: 2.4	178.4° (Range: 181°–176°) Std: 1.3	177.9° (Range: 181°–174°) Std: 1.5	177.1° (Range: 182–171°) Std: 2.01	HKA 5 / HKA 10 HKA 5 / HKA 15 HKA 10 / HKA 15	p=0.07 p=0.0001 p=0.01
Percentage of patients with a radiolucency	Nil	18% 7 tibial components 1 femoral component	25% 11 tibial components 1 femoral component	34% 14 tibial components	R 5 / R 10 R 5 / R 15 R 10 / R 15	p=0.32 p=0.07 p=0.56

ROM range of motion, FUNCT Functional score, HKA Hip-knee-ankle angle, IKS International knee score, R percentage of patients with a radiolucency, Std Standard deviation.

At five year follow-up, two patients (4%) had worsening arthritic change in the opposite femoro-tibial compartment (in both cases from grade II to grade III) without further deterioration at subsequent follow-up. At the ten year follow-up, two more patients (4.3%) showed worsening of lateral component arthritis, from grade II to grade III. One of these two patients missed the latest follow-up while the other one remained stable. At 14.7-year follow-up none of the 41 patients, despite progression in the varus deformity, demonstrated any further deterioration in the lateral femoro-tibial compartment arthritic change. No implant was revised because of symptomatic arthritis progression in the opposite compartment during the study. A Kaplan-Meier survival rate of 96.1% was seen at both the five and ten year follow-up, however the survival rate had decreased to 91.6% at 14.7 years (Fig. 3).

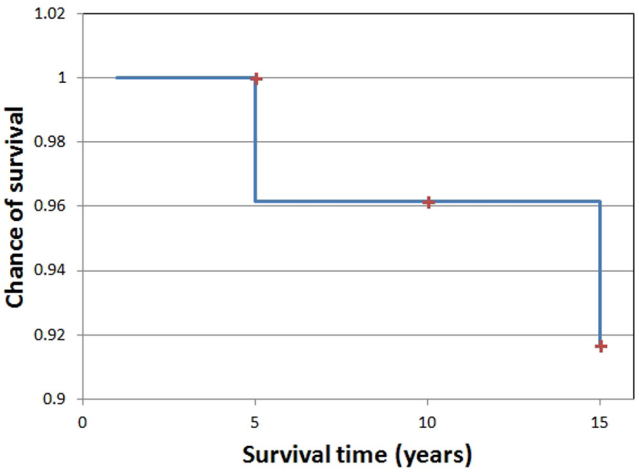

Fig. 3. Graph showing survivorship of the implants over time.

4. Discussion

Given the correct clinical indications UKA represents a valuable surgical option for the treatment of isolated femoro-tibial compartment arthritis with superior functional results compared to TKA [1,2,3]. Recently several authors have documented UKA survivorship similar to that reported for TKA. Polyethylene wear, often associated with malalignment, has been shown to be a potential cause of UKA failure [20,21,22,23]. Despite less than 1% of all primary TKA being performed with an all-polyethylene tibial component, clinical outcomes (in terms of revision rates and clinical scores) are similar to TKA with a metal-backed tibial implant [4,10].

According to the literature, the main benefit of a metal backed bearing in UKA can be hypothesised as an improvement in load transfer with a better cement fixation because of reduced compressive loads at the bone-implant interface despite an hypothetical higher bone sacrifice to permit the minimum 6mm recommended polyethylene inlay [24]. However, an all-polyethylene bearing permits less invasive bone resections with loads directly transferred through a single interface between bone and the polyethylene, finding its ideal indications in knees with poorer bone quality such as in patients with osteopenia or who are at risk to develop it [25].

Limitations of this study include the fact that is is a retrospective study and that there is no control group using a flat metal backed implant. In addition, the femoral implant design was modified after the first cases to reinforce the femoral fin and furthermore the surgeons were different. However to our knowledge, the present study of medial UKA with a flat all-polyethylene component performed for primary arthritis has the longest follow-up in the literature. The different surgeons belonged to the same surgical team and performed all the interventions with a standardized surgical technique aiming at achieving a neutral mechanical axis. The study showed excellent clinical outcomes (IKS and Functional scores) in the patient group at all three follow-up time periods without any statistically significant differences over time. The clinical results of this study were closer to those of several long-term studies of TKA than to the few reports for all-polyethylene UKA. At the latest follow-up, the IKS and Functional score were 80.1 and 84.7, respectively, compared to 94.3 and 94.8 in a similar study by Heyse et al. [10] at a 10.8-year follow-up. A possible explanation for this discrepancy may have been the marked difference in the mean age between the two studies. The mean age of patients in the current study was 65.1 years compared with 53.5 years in the study by Heyse et al. [10]. In addition, Argenson et al. [4] studied a series of cemented metal-backed UKA at 20 years follow-up and reported better clinical results than seen in the current study.

In the literature, arthritis progression to other compartments has been described as a potential cause of implant failure ranging in incidence from 3.4% to 25% [11,22,23]. Arthritis progression in the opposite compartment was quite uncommon in this study and did not cause any episodes of implant failure. The main reason for this, we believe, is that, despite the aim to correct the limb alignment to neutral in all the UKA performed, the resultant alignment achieved mild varus on average in all the three follow-ups thus avoiding excessive load on the opposite compartment despite two cases of slight asymptomatic overcorrection.

Lustig et al. [11] reported a 26.5% incidence of radiolucent lines all in the first years post-operatively without further progression. These radiolucent lines were more commonly seen in the medial compartment [11]. In their study Steele et al. [5] reported tibial loosening as the main cause of revision at greater than ten year follow-up. The authors noted that this was despite the fact that as the patient aged they placed less demand on their implants [5]. Radiolucent lines were seen in the current study, mainly limited to the tibial components and were present at all three follow-up periods. Only at the latest follow-up two patients requiring revision because of aseptic loosening showed clear radiolucencies at the femoral side questioning if the progressive tibial loosening had influenced the femoral component stability. In addition, a progressive deterioration over time ending in component loosening was seen in three patients. In the present study the mechanical axis showed a statistically significant progressive worsening into varus at 14.7 years compared to the first two follow-up periods. As a result, increased weight bearing on the medial compartment may have contributed to the long term tibial component loosening and increased radiolucency.

The main cause of revision in this study was aseptic tibial loosening of two implants in the same patient revised to TKA. A third patient declined any further surgery despite evidence of tibial loosening at the latest follow-up. At five year follow-up, two cases were revised, one because of femoral component breakage and the other because of an unexplained painful tibial component, which was not improved, even after revision. Implant breakage in the early case was thought to have occurred as a result of using the original UKA design without the reinforced femoral fin [26,27]. Despite all the tibial failures seen at a long-term follow-up being in female patients there were no statistically significant gender-based differences in terms of failure. Likewise at the latest follow-up tibial implants with radiolucency were statistically more frequent in female patients raising the question as to whether this implant may be contra-indicated in women at least at long follow-up despite what is suggested in literature [25]. Although the use of flat all-polyethylene tibial components is not uncommon in UKA only two long-term studies dealing with this type of implant were found in the literature [4,10]. Both these studies reported a survivorship of 93.5% at ten year follow-up implanting medial and lateral components for varying diagnosis [4,10]. In a study by Steele et al. [5] using a conforming all-polyethylene tibial implant, a survival rate of 85.9% was reported at 20-year follow-up. In the current study, implant survival was constant for the first ten years and decreased to 91.7% at the final follow-up. The survivorship would have been worse at 14.7 years if the patient with a loose implant had not declined a revision procedure.

5. Conclusions

In conclusion, our long-term follow-up study using an all-polyethylene flat tibial component demonstrated good reliability of this implant in the treatment of unicompartmental knee arthritis with consistent clinical results over time. We showed both a progressive deterioration of the mechanical axis into varus and progressive radiolucent lines around the implant overtime. Increased numbers of revision operations were seen in female patients due to aseptic loosening of the tibial component at latest follow-up without statistically significant difference with male patients. However a further analysis of the results at the latest follow-up identified a statistically significant higher tibial radiolucencies incidence in female patients questioning at least a potential higher rate of loosening at longer follow-up.

6. Conflict of interest

N. Confalonieri declares: Consultant: Medacta, Depuy, B Braun. The other authors have no conflict of interest to report.

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