

Knee arthroplasty system with medialized keel: Seven-year follow-up of a pioneer cohort

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Background: In this clinical investigation, a new design with a progressive increased keel medialization according to the size was implanted. The cohort of patients was followed up for seven years.

Methods: From May 2012 to November 2012, we implanted 70 total knee arthroplasties in 69 patients. The mean age of the patients was 76.2 years. We followed up 56 patients for seven years; we evaluated the patients at six and 60 months after surgery by Patient Reported Outcome Measures score. During the seven-year follow-up, all patients were clinically re-evaluated using the Knee Society Score and the Forgotten Joint Score. All patients underwent a preoperative and postoperative radiographic investigation. At the last follow-up the presence of any radiolucency lines was checked using the Knee Society Total Knee Arthroplasty Radiographic Evaluation and Scoring System.

Results: The patients defined the surgical results as excellent in 66% of the cases, very good in 23%, good in five percent. The analysis of the functional data at seven years, performed by administering the Forgotten Joint Score, showed average values of 70.4. The clinical analysis, performed through the Knee Society Score at the same follow-up, showed average values of 90.4. The seven-year radiological analysis revealed the presence of radiolucency lines in 20 implants. The sum of the line widths never exceeded the critical value of nine millimeters, always remaining below four millimeters. Only one patient was revised.

Conclusions: The results showed an excellent outcome of this design. The medialization of the tibial keel showed good bone fixation and component alignment at seven-year follow-up.

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1. Introduction

Total knee replacement is an effective surgical procedure for the treatment of pain and disability in patients with primary and secondary knee osteoarthritis with survival rates greater than 90% for 10- and 15-year implants [1].

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Patient satisfaction rate reported in the literature is between 75 and 89% [2,3]. The reason for failure to reach a greater percentage of satisfied patients is multifactorial and involves the surgeon's experience, the degree of preoperative osteoarthritis, the patient's expectations, and the achievement of adequate bone coverage and how long the fixed components lasted [4].

The development of new knee prosthetic models over the last decade has involved, in addition to the search for reproduction of the 'physiological' kinematics, a number of sizes and shapes sufficient and necessary to fit the prosthetic components to the morphological differences related to individual, gender and race variability.

The arrangement of the prosthetic models consists of designs that allow an optimization of the bone coverage without overhanging and underhanging and optimizing the bone coverage/rotation ratio on the tibia to facilitate correct rotational alignment.

Equal attention was paid to the design of the keel, to optimize the stability of the implant whether a full cemented technique was used or not.

The position of the keel, however, has been neglected, or at least less investigated; current literature is in fact poor on the subject regarding tibial keel position, considering that the central position under the tibial tray is necessary and sufficient to warrant stability, and not dependent on the prosthesis design.

In the specific implant of this investigation, the keel was purposely medialized with a progression of medialization proportional to the size. The progressive offset of the keel was conceived with the purpose of implanting the baseplate where the quality bone is more challenging due to the higher incidence of stress shielding [5]. However, the major advantage of the medialization of the keel is to provide a better alignment of the keel itself with the anatomical axis of the shaft.

The objective of this study was to evaluate the clinical and functional results after a seven-year follow-up of the first series of patients who underwent knee replacement using an anatomically designed tibial component implant with a proportional medialized tibial keel. At the last follow-up, a radiological analysis was also performed to investigate the real optimization of the tibial fixation, the behavior of the periprosthetic tibial metaphyseal bone as well as the correct alignment of the prosthetic components.

2. Patients and methods

This prospective study included a consecutive series of patients with primary knee osteoarthritis, who were candidates for total knee arthroplasty.

Inclusion criterion was primary end-stage osteoarthritis, while exclusion criteria were post-traumatic osteoarthritis, rheumatoid arthritis and haemophilic arthropathy. The study was approved by the Ethics Committee (no. 2015001968).

From May to November 2012, 70 knee prostheses with medialized tibial keel were implanted in our division by the same surgeon (70 implants in 69 patients). An anatomical tibial component prosthesis (Persona™) from a single manufacturer (Zimmer, Warsaw, IN, USA) was used. This tibial baseplate presented nine sizes for each side (18 total plates) with progressive increase of mediolateral (M-L) growth. The keel moves medially by 1 mm every two sizes. The features of this implant are summarized in Table 1.

We followed up on 56 patients for seven years (range: 79–85 months), giving a total of 57 prostheses (a bilateral case in the same session). Nine patients were unavailable for clinical and radiographic checkups because of their age and distance (dropouts), three died from causes unrelated to the knee prosthesis and one patient, who had undergone contralateral knee replacement, was excluded from the study because of a bilateral periprosthetic fracture following a car accident.

All patients received regular outpatient follow-ups at one month, three months, six months and then every year. To objectively evaluate patient satisfaction results, Patient Reported Outcome Measures score (PROMs) was administered in the preoperative period, and then at six months and at five years. From a recent 2017 review [6] only three patella tendon graft (PTG)-related PROMs have been shown to have positive evidence for evaluating results. Therefore, the questionnaire we used to evaluate functional outcomes in this study included three different scores (Oxford Knee Score (OKS), EQ-5D Index, EQ-VAS) to which we added additional questions in order to evaluate the results of the surgery, the change in symptoms compared with before the operation and the patients' subjective perception of disability.

All operations were performed by the same surgeon without a tourniquet, using a Mini-Trivector [7] approach and a measured-resection standard technique with anterior referencing for the femur.

The technique involved the distal femoral cut with intramedullary alignment, the proximal tibial cut that was always perpendicular to the mechanical axis of the tibia, the gap balancing with knee in extension and then the femoral chamfer cuts with an external rotation based on an anatomical axis such as the transepicondylar axis and the Whiteside lines. Cementation was always performed after pulse lavage but without inducing limb ischemia and with the cement placed both on the tibial bone (manually

Table 1
Features of the anatomical tibial component.

Size	A	B	C	D	E	F	G	H	J
Mediolateral growth, mm	58	61	64	67	71	75	79	83	88
Medialization, mm	1	1	2	2	3	3	4	4	5

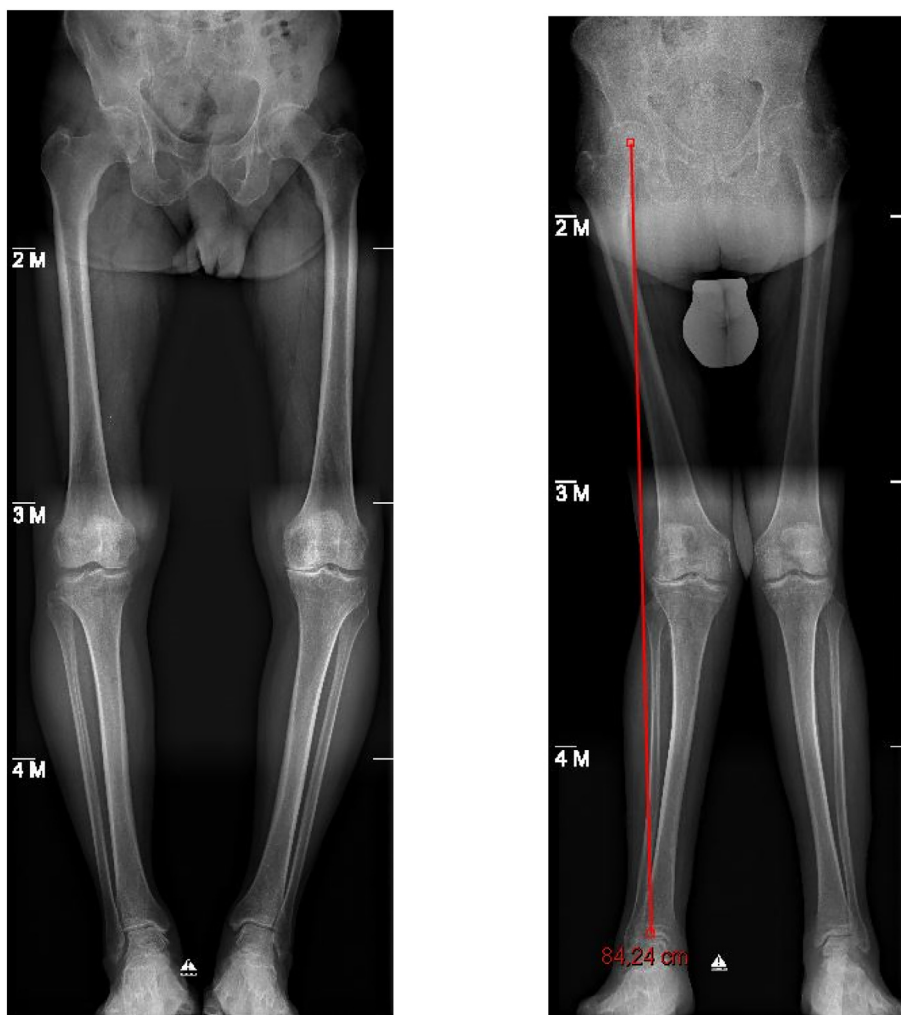


Figure 1. X-Ray images of lower limbs with load preoperatively.

pushed into trabeculae), and on the tibial plate including the keel. No drilling of sclerotic bone was performed. The curing of the low-viscosity cement was performed with a provisional liner two millimeters thicker than the final thickness and in extension.

During the seven-year follow-up, all patients were clinically re-evaluated using the Knee Society Score (KSS) [8] and the Forgotten Joint Score (FJS) [9].

All patients underwent a preoperative and postoperative radiographic investigation with weight-bearing full-length X-rays of the lower limbs (Figure 1) and X-rays of the operated knee in anter-posterior and lateral projections at six months and at one, two, five and seven years (Figure 2).

On preoperative X-rays, we calculated the hip–knee–ankle angle (HKA) to evaluate the axis of the lower limb (varus or valgus). At the last follow-up, a radiological analysis based on the study of the coronal alignment of the components and the behavior of the periprosthetic bone was performed by an independent radiologist. In particular, the mechanical axis was assessed on radiographs of the knee in anteroposterior projection by calculating the medial distal femoral angle (MDFA) and the medial proximal tibial angle (MPTA). To evaluate periprosthetic bone, conversely, the presence of any radiolucency lines was checked using the Knee Society Total Knee Arthroplasty Radiographic Evaluation and Scoring System [10]. In anteroposterior projection, the following areas were identified on the tibial component: 1–2 corresponding to the medial tibial plate, 3–4 to the lateral tibial plate and areas 5–6–7 corresponding to the fixation zones at the level of the contour of the keel. To quantify any osteolysis, the sum of the width (expressed in mm) of the radiolucency lines in each of the zones was calculated: this is considered not significant if <4 mm, requires regular follow-up if between five and nine millimeters, and is considered an important indicator of failure if >10 mm [10]. Data were statistically analyzed using IBM SPSS Statistics for Windows (Version 22.0; IBM, Armonk, NY, USA). A value of $P < .05$ was considered statistically significant.



Figure 2. X-Ray images postoperatively at six months and seven years of follow-up.

3. Results

The average age of the patients studied was 76.2 years (range: 60–93 years).

The operated knee was the right in 29 cases and the left in the remaining 28 cases. Preoperative varus was present in 42 cases (mean 7.5°; range: 3.8–10.2°), while valgus was present in 15 cases (mean HKA -7.2° ; range: four to 10.4°).

Seven patients had knee problems for less than a year, 27 patients for one to five years, 15 patients for six to 10 years, and seven patients for more than 10 years.

The postoperative follow-up period was between 79 months (the minimum) and 84 months (the maximum), with an average value of 82 months.

We recorded a five-year increase in the OKS in 52 patients (92.8%) and a decrease in four patients (7.2%) compared with the preoperative period; at six months, we observed an increase in 30 patients (53.6%), a decrease in 17 patients (30.4%) and unchanged values in nine patients (16%) compared with their controls. The average value for the preoperative OKS was 21.6 (range eight to 39). At six months the average value increased to 39.5 (range: 11–47). The mean statistically significant improvement ($P < .05$) was 17.5 points (range was between -5 and 35). At five years, the average was 40.0 (range: nine to 48). The average improvement compared with the preoperative period at five years was 18.2 points (range was between -19 and 36 with $P < .05$), compared with the results at six months which was equal to 0.4 points (range between -26 and 13) although not statistically significant ($P = .87$), as shown in Figure 3(a).

The average value of the preoperative EQ-5D was 0.222 (range between -0.181 and 0.796). At six months, the average value increased to 0.838 (range: 0.274 to one). The average improvement was statistically significant with an increase of 0.644 points (range: 0–1.181; $P < .05$). At five years, the average was 0.715 (range: 0.016 to one). Therefore, at five years, the average improvement compared with the preoperative one was 0.497 points (range was between -0.434 and 1.181; $P < .05$). Compared with the results at six months, we observed a decrease of -0.122 points (range between -0.984 and 0.451; $P = .77$).

Lastly, the average value for the preoperative EQ-VAS was 39.0 (range: 0–70). At six months, the mean value increased to 75.6 (range: 20–100). The average improvement was 36.6 points (range between -30 and 95; $P < .05$). At five years, the average was 70.8 (range: 30–100), which was an improvement compared with the preoperative value of 31.6 points (range between -20 and 80; $P < .05$), while compared with the results at six months it was equal to -4.7 points (range between -50 and 50; $P = .21$). The values of the EQ-5D and EQ-VAS are summarized in Figure 3(b).

The results of the operation were confirmed at five years using a specific multiple-choice question about the operation results. Participants described the procedure as excellent in 37 cases (66%), very good in 13 cases (23%), good in three cases (five percent), moderate in one case (two percent) and poor in two cases (three percent).

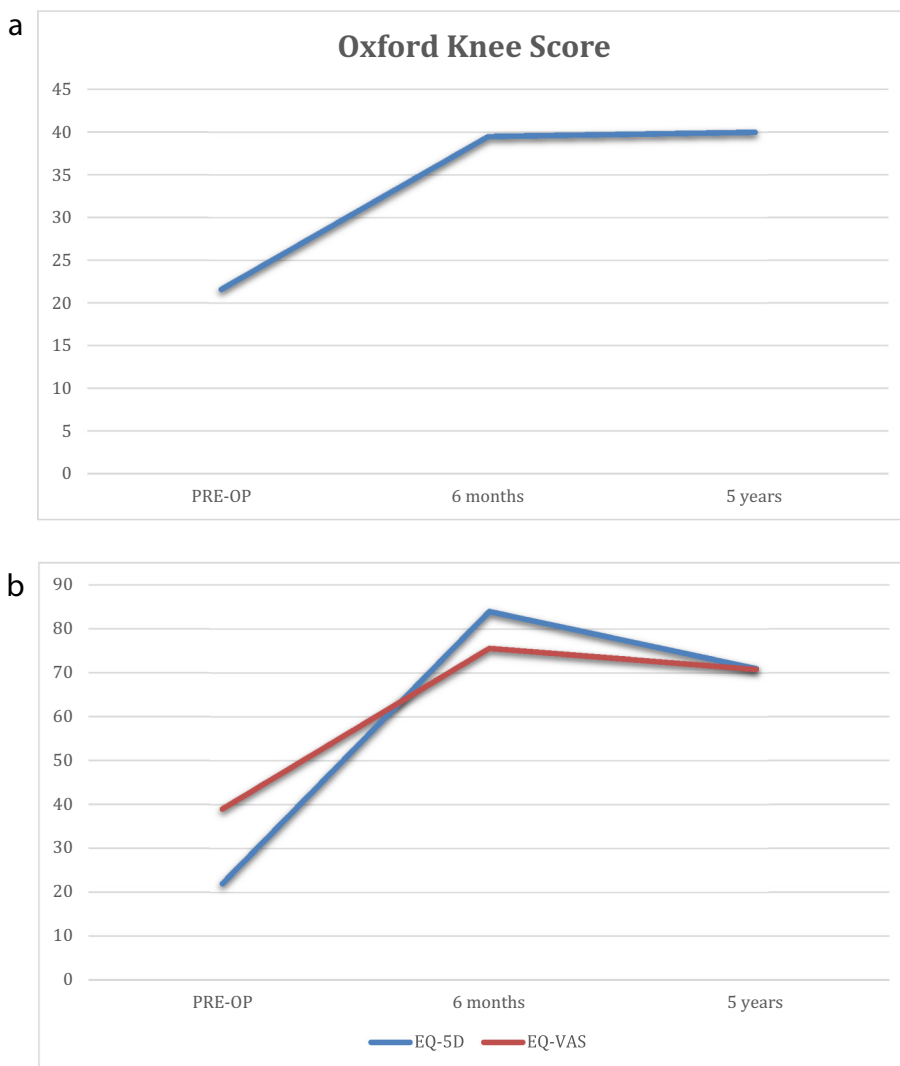


Figure 3. (a) Oxford Knee Score values preoperatively and at six months and five years postoperatively. (b) EQ-5D and EQ-VAS values preoperatively and at six months and five years postoperatively.

Knee-related symptoms improved significantly at six months in 40 patients (71%), somewhat improved in 12 patients (21%), were substantially unchanged in two patients (four percent), somewhat worse in two patients (four percent) and significantly worse in no patients. At five years, in the same reference group, results improved greatly in 46 patients (81%), slightly improved in six patients (10%), remained substantially unchanged in no patients (0%), slightly worsened in two patients (four percent) and greatly worsened in two patients (four percent).

Finally, at five years, disability was experienced by three patients (four percent), while the remaining 53 (94%) denied experiencing a disability, thus improving their preoperative data where 34 patients (60.4%) believed they had a disability.

The analysis of the functional data at seven years, performed by administering the FJS, showed average values of 70.4 in a range between 25 and 100.

The clinical analysis, performed through the KSS at the same follow-up, showed average values of 90.4 in a range between 25 and 100.

The seven-year radiological analysis revealed the presence of radiolucency lines in 20 implants; in 12 cases the radiolucency was concentrated in zone 1 only, four cases in zones 1–2 and four cases in zones 5–6 (Figure 4).

A study of the extension in width of the lines, which is useful for assessing the risk of implant failure, showed lines of an average width equal to 0.8 mm (range 0 to three millimeters) in area 1; in all of the evaluated implants, the sum of the line widths never exceeded the critical value of nine millimeters, always remaining below four millimeters.

The MDFA presented average values of 95.7° (range: 97–93°) and the MPTA 89.6° (range: 87–91°).

Only one patient was revised three years after the implant for aseptic mobilization, bringing the cumulative survival rate to 98% at five years.

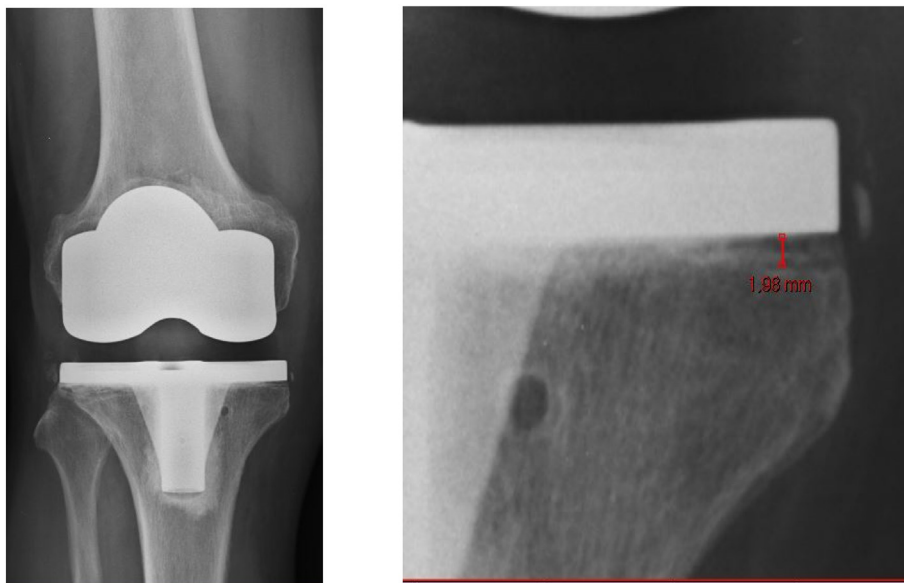


Figure 4. X-Ray images at seven years of follow-up: the radiolucency area can be observed localized in zone 1 on the medial tibial plate. Once measured, it still appears as being <2 mm.

4. Discussion

This medium- to long-term follow-up study (seven years) is interesting because it focused on a uniform group of patients, who were operated upon consecutively over a short period of time using the same technique. The patients received a newly designed prosthesis, with an anatomical tibial plate design (to eliminate the usual compromise between bone coverage and component rotation) and were provided with a medialized keel proportional to its size. It is, therefore, appropriate to start the discussion with the particular design of this tibial plate.

The keel medialization was adopted in order to allow for better alignment between the tibial component and tibial shaft.

At the last follow-up, we performed a radiological analysis to study how the implantation of the medialized keel prosthesis affects the behavior of the periprosthetic bone; our results showed that the keel with progressive medial off-set proved to be right for correct alignment and positioning in all cases except one, where impingement with the cortex occurred medial to the plate, but in relation to the dysmorphism of the tibial metaphyseal zone (see Figure 5). However, this event was not relevant to both the clinical and radiographic results, as shown by the radiographic follow-up performed seven years after surgery (Figure 6). Stability of the implant did not change during the seven-year radiographic check-ups and only in one case was a revision for aseptic mobilization necessary. In a recent work by Li et al. [11] it was shown that the greatest bone density was concentrated in the anteromedial portion of the proximal tibial epiphysis. The same authors reported that the tibial component was less stable when bone sclerosis was not present at the level of the medial tibial epiphysis in the most common morphotype (varus); this data is also confirmed by other recent papers [12,13]. Furthermore, as described by Jaroma et al. [14], both in the varus and valgus morphotype, the greatest reduction in bone mineral density seven years after a knee replacement operation occurs at the proximal and medial metaphyseal level of the tibia. In our series the calculated radiolucency lines were less than four millimeters in all cases and never greater than nine millimeters in any case, which is the value proposed as an indicator of implant failure [10]. For these reasons, in our experience, we can assume that the tibial keel with medial offset could be, therefore, intended to give greater support in this critical region.

Bone resorption can be influenced by other factors, such as underhanging the tibial component itself [16]; this problem is overcome with the anatomical design of this implant, with a lower incidence of downsizing (three percent compared with 39–60%) demonstrated by Dai et al. in 2014 [17]. Finally, the study conducted by Smith et al. [15], based on the study of radiolucency in 207 cemented knee prostheses in a 10-year follow-up, confirms the good choice of cemented fixation of the tibial component, with radiolucent lines present in 15% of cases and less than four millimeters.

As far as clinical data are concerned, all the scores have proved positive, proving that the surgical technique adopted by the surgeon (which is no longer considered ‘up-to-date’ in the era of kinematic alignment and robotics) yielded valuable clinical results.

The outcome in terms of subjective well-being assessed with the PROMs at five years was very satisfactory; in fact, while at six months from the operation only 71% of the patients had declared themselves as being very satisfied, at five years 81% had achieved the same feelings. This figure is in line with the slight improvement in the OKS score, demonstrating that on the one hand the perceived overall health level had slightly decreased because of the increase in the average age of the patients, while



Figure 5. Postoperative checkup: slight tibial keel conflict at the level of the medial metaphyseal cortex.

on the other hand the level of ‘joint well-being’ had continued to increase. There was a marked improvement in all scores over the postoperative period; in particular, the OKS maintained a slightly positive trend during the five-year follow-up. The EQ-5D and EQ-VAS instead showed a slightly negative trend at five years compared with the preoperative period, probably because these scales are influenced by the general health condition of the patient, which modifies the reported value, along with the significant increase in the average age, which probably had a negative effect, as confirmed by other studies [18].

Only one patient was revised three years after the implant for aseptic mobilization, probably due to a possible insufficient cementation of the tibial component, which led to an osteolysis, located mainly at the level of zones 1–2 of the tibial component, which made the revision necessary. Therefore, the survival rate at five years was 98.2%, while the failure rate was 1.8%, values comparable to those found in literature, where the Australian Registry reports a five-year revision rate of 2.9%, while the National Joint Registry of England and Wales report 1.65% [19].

The average value of the OKS at five years was 40.0, highlighting an average improvement of 18.2 points compared with preoperative results and 0.4 points compared with the six-month values. This indicates a positive trend that we do not find in the



Figure 6. Follow-up at seven years: the impingement has not influenced implant stability.

literature where, instead, a decline in values is reported after the first two years post-surgery [20]. At five years the OKS showed values lower than the preoperative ones in only three cases (6.2%), one of which was due to stiffness in a patient who had not undergone physiotherapy because of the onset of deep vein thrombosis immediately after surgery.

Williams et al. [20] examined the OKS trend in a series of 1547 PTGs with an average preoperative OKS of 19.5. He reports an average increase in the OKS of 14.8 points (34.3) in the first year, and a subsequent decline of one point from one to five years.

Scott et al. [19] in a 2015 study on a series of 462 PTG Triathlon TKR (Stryker Orthopedics, Mahwah, NJ, USA) with an average preoperative OKS of 18.7 points, observed an average increase of 17.4 points (36.1) at one-year follow-up and maintenance of the same values at five years with the percentage of satisfied patients at 88%.

Hakki et al. [21] in 2013 studied a series of 79 patients who underwent a Columbus Navigated Aesculap AG (Tuttlingen, Germany) prostheses implant and found a change in the OKS from 18.9 average points preoperatively to 38 points during a six-month follow-up. These values were maintained for five years.

Asif et al. [22] in 2005 studied 44 patients who underwent PTG surgery with PFC Sigma system (DePuy, Warsaw, IN, USA) and documented an average five-year OKS value of 38 points.

In our series, therefore, patients showed a better improvement in knee-related outcomes, in terms of OKS, compared with the literature. Moreover, unlike most of the series in the literature, patients in our study showed an improvement in the same values at six months and five years of follow-up (even though this was not statistically significant).

Furthermore, at the last seven-year follow-up, considering the maintenance of good results obtained in the PROMs at the five-year follow-up, we decided to implement only clinical data using KSS and self-assessed functional data using FJS. Analyzing the

data that emerged from the FJS at the final follow-up shows that our results are better than those that emerged in a recent review by Carlson [23], where out of a total of 566 patients undergoing PTG, a maximum value of 76.4 was recorded at two years with a subsequent slow decrease up to 64.4 in five years. This trend is also confirmed in other works in the literature [24,25].

One major limitation of our investigation is the small population number, due to patients lost during follow-up. In fact, of 13 patients lost at seven years of follow-up, nine were unavailable for the last clinical and radiological checkups because of the age and distance (dropouts). For this reason, we had the opportunity to perform only a telephone interview, in which they confirmed that no disability or complication appeared. This was, however, counteracted by the mid- to long-term follow-up period, to show the stability of the implant. Also, the specific type of tibial tray used in this study was unavailable at the end of 2012 and before the official launch of the system (2013) due to the hypothetical and theoretical risk of cortical impingement and cortical violation on the medial side of the tibia, particularly in case of metaphyseal dysmorphism, as in the presented case (Figure 5).

However, despite the above-listed limitation, this study involving a medium- to long-term follow-up has shown the validity of the concept, with a durable fixation leading to excellent clinical results overall; for these reasons this solution could be adopted in other possible future designs.

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