

# A FUNCTIONAL AND ROENTGENOGRAPHIC PRELIMINARY COMPARATIVE STUDY USING METAL-BACKED AND ALL-POLYETHYLENE TIBIAL COMPONENTS IN TOTAL KNEE ARTHROPLASTY

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## ABSTRACT

**Objective:** To describe and clinically and radiographically compare patients who underwent total knee arthroplasty (TKA) with all-polyethylene (ALP) and metal-backed (MTB) tibial implants. **Methods:** Patients who underwent TKA between January 1988 and December 2004 were grouped according to the type of implant received: all-polyethylene or metal-backed. Sixty patients came for evaluations, totaling 82 operated knees. Among these, 22 patients had undergone TKA only with ALP (12 unilateral and 10 bilateral cases), 33 patients only with MTB (26 unilateral and 7 bilateral cases) and five patients underwent TKA with ALP in one knee and MTB in the other. The knees were divided thus: group 1, 37 knees with ALP; and group 2, 45 knees with

MTB. **Results:** There were no differences in clinical or functional evaluations between the groups. The mean radiolucency in the femur was 0.838 mm for the patients in group 1 and 0.356 mm for the patients in group 2 ( $p = 0.049$ ). For the tibia, in the AP view, there was a mean value of 2.703 mm for group 1 and 0.733 mm for group 2 ( $p = 0.000$ ). In the lateral view, the mean values for osteolysis was 0.405 mm for group 1 and 0.200 mm for group 2 ( $p = 0.074$ ). **Conclusions:** There were no differences between the groups in the functional and clinical evaluations. However, greater radiolucency was observed in the arthroplasties with ALP, both in the femur in the lateral view and in the tibia in the AP view. Level of evidence IV – case series study.

**Keywords** – Knee; Arthroplasty; Radiography

## INTRODUCTION

Total knee arthroplasty promotes pain relief and improves the function of joints that have been seriously compromised by a variety of degenerative processes<sup>(1)</sup>. Some authors have documented its durability and the factors involved in clinical and radiographic failure of implants<sup>(2-4)</sup>. Among these, they have highlighted the adequacy of patient selection and implant choice and factors relating to the surgical technique, such as the alignment of the limb and the implants, the ligament balance and the quantity of bone resection<sup>(1)</sup>. The polyethylene debris has an influence on the success of knee arthroplasty<sup>(5,6)</sup>, given the complexity of the joint movement<sup>(7)</sup>, and its association with osteolysis has been well documented<sup>(8-10)</sup>.

All-polythene implants were widely used in the initial stages of knee arthroplasty, and these have shown

excellent clinical results in long-term studies. However, their use diminished considerably from the end of the 1980s onwards, in favor of metal-backed implants<sup>(11)</sup>, which were introduced into total knee arthroplasty with the aim of reducing the occurrences of aseptic loosening and improving the fixation and long-term functioning<sup>(12)</sup>, thereby diminishing the stress on the cement-bone interface and, through this, the occurrences of loosening of the tibial component. However, with metal-backed implants, a new interface was created, between the polyethylene and the metal base, which led to subsequent investigations on the quality of this new interface<sup>(13-16)</sup>. Despite the wide acceptance of metal-backed prostheses and the indication of all-polyethylene implants for patients in more elderly age groups with lower functional demands, a few studies have reconsidered the use of all-polyethylene implants

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with the aim of limiting the debris caused by the interface between the polyethylene and the metal base<sup>(17)</sup>.

The aim of the present study was to document and describe the short to medium-term results from patients who were under the supervision of a single surgeon, with attempts to analyze and compare radiographic, clinical and functional characteristics, in relation to two groups of tibial implants: metal-backed (MTB) and all-polyethylene (ALP).

## METHODS

Patients who underwent primary cemented total knee arthroplasty (TKA) at one public institution and two private hospital institutions in Belo Horizonte, MG, between January 1998 and December 2004, under the supervision of a single surgeon, were selected. Eighty patients were called in for a transverse clinical-radiological evaluation, of whom 60 attended, totaling 82 operated knees. Twenty-two patients had undergone TKA only with an ALP tibial component (12 unilateral and 10 bilateral cases), 33 patients had undergone TKA only with an MTB tibial component (26 unilateral and seven bilateral cases) and five patients had undergone TKA with both types of implant: ALP in one knee and MTB in the other. The type of implant at the time of the surgery was not randomized, but was chosen by the surgeon according to availability and personal choice. The same surgical technique was used, with placement of a patellar component and preservation of the posterior cruciate ligament in all cases. The cementation was performed in two stages, such that firstly the tibial component alone was cemented and subsequently the femoral and patellar components were cemented at the same time. Anterior subluxation of the tibia was performed in all cases, along with patella eversion and partial resection of Hoffa's fat.

The operated knees were divided into two groups according to the type of tibial implant: group 1, knees subjected to TKA with implantation of an all-polythene (ALP) component; and group 2, knees submitted to TKA with implantation of a metal-backed (MTB) component. Thus, group 1 was composed of 37 knees and group 2, 45 knees.

The prosthesis used in all the knees of group 1 was made by Zimmer (Zimmer Institute, Warsaw, IN, USA). In group 2, prostheses of three brands were used: Zimmer (Zimmer Institute, Warsaw, IN, USA); Johnson & Johnson (DePuy Orthopaedics, Inc. Warsaw, IN, USA); and

Aesculap (B. Braun Melsungen AG – Aesculap Inc.).

With regard to age, the mean was 72.2 years (ranging from 34 to 87 years), with equivalent distribution between the two groups. Females predominated in both groups, and there was no statistical difference regarding the side operated in each group, as shown in Table 1.

**Table 1** – Epidemiological analysis on the population

		Group 1	Group 2
		37	45
N Age	30-40	1	0
	40-50	2	1
	50-60	2	4
	60-70	9	7
	70-80	19	25
	80+	4	8
Sex	Female	30	39
	Male	7	6
Knee	Right	18	23
	Left	19	22

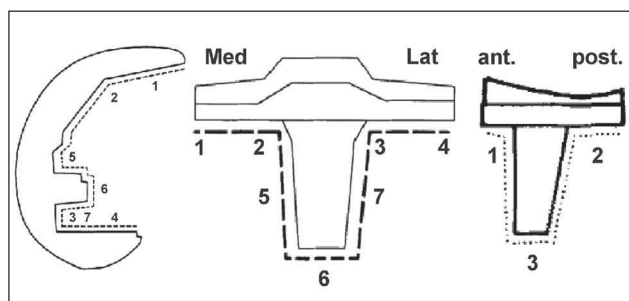
The minimum duration of postoperative follow-up was two years and the maximum was 9.7 years, with a mean of 5.2 years for the study population: 4.5 years for the ALP patients and 5.8 years for the MTB patients (Table 2).

The Hospital for Special Surgery Rating System<sup>(18)</sup> functional questionnaire and the Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System<sup>(19)</sup> radiographic protocol (both produced by the Knee Society) were applied.

The clinical and functional evaluation took into account the following variables: pain, range of motion, stability and functional ability to walk and go up and down stairs. This information was graded on a scale from 0 to 100 points, for the purposes of statistical comparisons<sup>(18)</sup>.

The evaluation on recently produced radiographs used two radiographic views: anteroposterior, standing on one foot (AP); and lateral, at 30 degrees of flexion (P). The measurements included the alignment of the knee and the femoral and tibial components in both radiographic views. Assessment of the radiolucency lines in the patellar component did not form an objective of this study<sup>(19)</sup>.

To assess the presence of osteolysis, a topographic classification was applied, dividing the femoral component in the lateral radiographic view into seven zones: zones 1 and 2, located on the anterior flange; zones 3 and 4, in the posterior area; and zones 5, 6 and 7, relating to the stem, or to the central portion when there was no stem. The tibial component was evaluated radiographically both in AP and in lateral view, and was divided into seven zones in the AP view (zones 1 and 2, located on the medial plateau; zones 3 and 4, located on the lateral plateau; and zones 5, 6 and 7, relating to the central stem) and into three zones in the lateral view (zone 1, anterior; zone 2, posterior; and zone 3, lower)<sup>(19)</sup> (Figure 1).

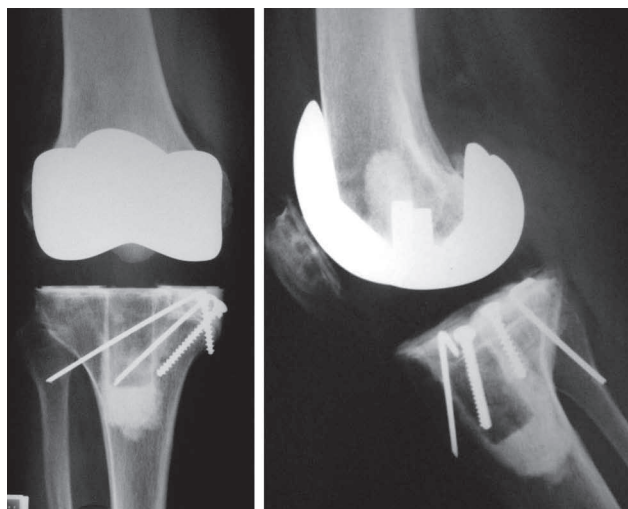


**Figure 1** – Femoral component in lateral view (left) and tibial component in anteroposterior view (center) and lateral view (right), divided into zones<sup>(19)</sup>

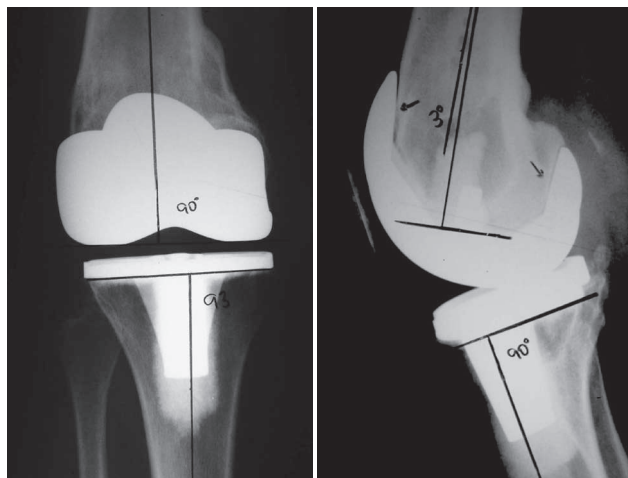
The evaluation on osteolysis consisted of observation, by the authors, of the presence of a radiolucency line in each of these zones at the prosthesis-cement or cement-bone interface, which was quantified in millimeters of thickness. All the zones in each view were then summed for the purposes of statistical comparison.

To compare the degree of osteolysis caused by the two types of implant, the Mann-Whitney U statistical test was used. This test is nonparametric, i.e. it does not require presuppositions regarding the underlying distribution of the data, and it tests whether two independent samples have been taken from populations with equal means. The data in this analysis was treated quantitatively, as data verification support. The statistical software used for treating the quantitative data was SPSS 15.0 for Windows (Statistical Package for the Social Sciences; SPSS Inc, Chicago, IL, USA). Continuous variables, including age, duration of postoperative follow-up, functional scores of the patient and knee, range of motion and radiographic alignment were compared. With the aim of investigating whether there was any significant

difference in the radiolucency lines between the two types of material (ALP and MTB), Mann-Whitney U hypotheses were tested using a minimum significance level of 5% (Figures 2 and 3).



**Figure 2** – Radiographic study on a knee belonging to group 1, in which no lines are observed in the AP and lateral views. In this case, an autologous bone graft was used because of medial loss



**Figure 3** – Radiographic study on a knee belonging to group 2, in which radiolucency is observed in zones 1 and 4, in lateral view

## RESULTS

After a mean of 5.2 years of postoperative follow-up (4.5 years for the ALP patients and 5.8 years for the MTB patients), there was no difference in the clinical and functional assessments between the study groups ( $p = 0.289$  for the mean pain,  $p = 0.068$  for the mean range of motion and  $p = 0.267$  for the functional means) (Table 2).

**Table 2** – Clinical and functional assessments in groups 1 and 2

	Group 1	Group 2	P-value
N	37	45	
Duration of assessment (months)*	54 ± 14 (24-92)	69 ± 26 (24-117)	
Pain*	40 ± 14 (10-50)	43 ± 13 (10-50)	0.289
Range of motion**	19 ± 4 (6-24)	21 ± (9-26)	0.068
Functional score*	63 ± 24 (15-100)	68 ± 22 (10-100)	0.267
Clinical score*	81 ± 14 (46-98)	84 ± 14 (48-100)	0.208

\*Mean ± SD; \*\*each point was taken to be five degrees of range of motion

The alignments of the femoral and tibial components in the AP and lateral views, and the total valgus angle of the knee in the AP view, were measured and compared between the two groups. For group 1, in the AP view, the valgus angle of the femoral component was  $92 \pm 4$  degrees, the mean tibial angle was  $89 \pm 3$  degrees and the total valgus angle of the knee was  $3 \pm 5$  degrees. In the lateral view, the mean femoral flexion angle was  $3 \pm 2$  degrees and the mean tibial angle was  $88 \pm 3$  degrees (Table 3).

For group 2, in the AP view, the mean valgus angle was  $94 \pm 4$  degrees, the tibial angle was  $88 \pm 3$  degrees and the total valgus angle of the knee was  $4 \pm 4$  degrees. In the lateral view, the mean femoral flexion angle was  $3 \pm 4$  degrees and the tibial angle was  $88 \pm 3$  degrees (Table 3).

**Table 3** – Radiographic analysis on the positioning of the femoral and tibial components and alignment of the knee after the operation (mean ± SD)

	Group 1	Group 2	P-value
Femoral valgus angle in AP view	$92 \pm 4$ (82-100)	$94 \pm 4$ (80-100)	0.112
Tibial angle in AP view	$89 \pm 3$ (80-98)	$88 \pm 3$ (78-93)	0.109
Total valgus angle	$3 \pm 5$ (-8 -11)	$4 \pm 4$ (-8 -12)	0.708
Femoral flexion in lateral view	$3 \pm 2$ (0-12)	$3 \pm 4$ (0-20)	0.209
Tibial angle in lateral view	$88 \pm 3$ (80-94)	$88 \pm 3$ (75-94)	0.866

To evaluate the presence of radiolucency in the two groups, the mean radiolucency on radiographs of the femur in lateral view and on radiographs of the tibia in AP and lateral views were compared, as shown in Table 4. No signs of mechanical failure were detected in the study (such as luxation of the components or of the patella).

Comparison of the mean value for radiolucency of the femur between the two groups showed that it was 0.838 mm for group 1 and 0.356 mm for group 2 ( $p = 0.049$ ).

For the tibia, in the AP view, the mean value for radiolucency was 2.703 mm for group 1 and 0.733 mm for group 2 ( $p = 0.000$ ). In the lateral view, the mean was 0.405 mm for group 1 and 0.200 mm for group 2 ( $p = 0.074$ ). No extensive bone defects were observed.

**Table 4** – Analysis on radiolucency in each component

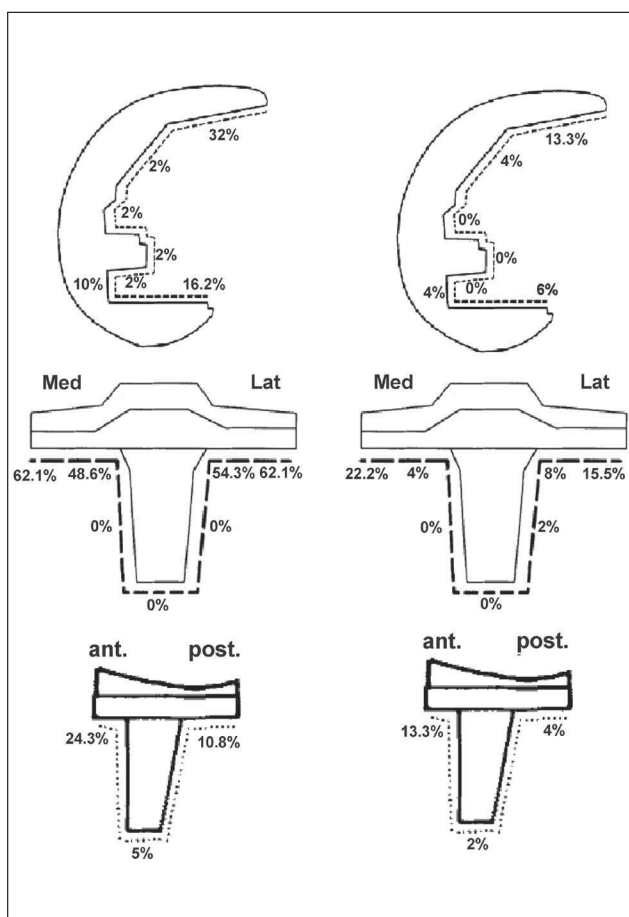
		Group 1	Group 2	P-value
N		37	45	
Radiolucency (mm)				
	Femur in lateral view*	$0.838 \pm 1.385$ (0-7)	$0.356 \pm 0.802$ (0-4)	0.049
	Tibia in AP view*	$2.703 \pm 2.146$ (0-8)	$0.733 \pm 1.405$ (0-7)	0.000
	Tibia in lateral view*	$0.405 \pm 0.686$ (0-2)	$0.200 \pm 0.588$ (0-3)	0.074

\*Mean ± SD

The evaluation on radiolucency in relation to the topographic classification, in the femoral component of group 1, presented incidences of 32% in zone 1, 2% in zone 2, 10% in zone 3, 16.2% in zone 4 and 2% in zones 5, 6 and 7. In the femoral component of group 2, there was 13.3% in zone 1, 4% in zones 2 and 3, 6% in zone 4 and 0% in zones 5, 6 and 7.

In the tibial component of group 1, in the AP view, there was a radiolucency rate of 62.1% in zone 1, 48.6% in zone 2, 54% in zone 3, 62.1% in zone 4 and 0% in zones 5, 6 and 7. In the tibial component of group 2, in the AP view, the radiolucency was found to be 22.2% in zone 1, 4% in zone 2, 8% in zone 3, 15.5% in zone 4, 0% in zones 5 and 6 and 2% in





**Figure 4** – Frequency and distribution of the radiolucency lines in the femoral and tibial components. Group 1 on the left and group 2 on the right. Abbreviations – Med: medial; Lat: lateral; Ant: anterior; Post: posterior(19)

zone 7. In the lateral view, the radiolucency observed in group 1 was 24.3% in zone 1, 10.8% in zone 2 and 5% in zone 3. In the lateral view, in group 2, the presence of osteolysis was 13.3% in zone 1, 4% in zone 2 and 2% in zone 3 (Figure 4).

## DISCUSSION

Osteolysis is one of the main causes of later revision of TKA due to aseptic loosening<sup>(19)</sup>. Imaging methods for measuring osteolysis in TKA have recently been developed and require refinement and validation. Radiographs in two views (AP and lateral) continue to be the technique most used for identifying osteolysis (radiolucency lines with a sclerotic border). Theoretically, radiolucency lines greater than 2 mm showing a progressive pattern are considered to indicate osteolysis and are associated with loosening of the components.

The present study used radiographs in the AP and lateral views. The difficulty in determining the extent of these radiolucency lines, through two-dimensional projection of complex three-dimensional geometry is a limiting factor in this study. Engh *et al*<sup>(20)</sup> recommended that investigators should use a single reviewer of radiographs and should report the intra-observer concordance before concluding the measurement. Temporal evaluation of the operated knees also helps to identify cysts and disuse osteopenia, which are factors confounded with osteolysis<sup>(20)</sup>. Some studies have suggested that computed tomography and magnetic resonance should be used in order to map the osteolysis in three dimensions. However, these authors did not suggest that these techniques should be used routinely, but that they should be indicated only when considering revision of arthroplasty for patients with discordant clinical and radiographic findings, or when determining the real extent of large areas of radiolucency, in order to make plans regarding the most appropriate bone grafts and implants<sup>(21)</sup>.

The aim in introducing MTB and modular systems of tibial components for TKA, in 1978, was to increase the load transmission from the implant to the tibial plateau, increase the longevity of the implant and facilitate its implantation and possible revision. However, formation of polyethylene debris between the polyethylene and metal surfaces, due to loss of stability between the two modules, has been recognized to be a negative factor that can cause periprosthetic bone reabsorption and loosening of the components in TKA<sup>(15,21,22)</sup>.

The approximately 30 to 50% greater cost of MTB components, in relation to ALP, ought to correspond to proportional increases in both the functional results and the durability of these implants. Comparison between two similar populations of patients who underwent TKA using two different implants would help in answering this point<sup>(23)</sup>.

No differences in clinical and functional performance between the groups evaluated were observed. In an attempt to standardize the clinical and functional assessments on the groups, two scoring methods that are well-established in the literature were chosen. However, these methods did not include the variables of diagnosis, weight, height, body mass index or comorbidities, and this limited the evaluation. Furthermore, because this was a cross-sectional study, the

lack of preoperative clinical and functional investigations made it impossible to make other comparisons, or to correlate radiolucency lines with loosening of components or other events of clinical relevance. Udomkiat *et al*<sup>(24)</sup> made paired selections of 96 patients who had received two models (ALP and MTB) of Apollo implants (Suzer Medical Orthopedic), and observed over a mean follow-up of two years that the two groups were clinically and functionally similar. Najibi *et al*<sup>(11)</sup> evaluated 98 knees that underwent arthroplasty with posterior stabilization (half ALP and half MTB) and did not find any functional differences between the groups over mean follow-up periods of 6.02 and 5.35 years, respectively. However, there were a greater number of individuals with lower functional demands in the group with ALP implants, which was not found in the present study. Apel *et al*<sup>(25)</sup> and Rand<sup>(26)</sup> also observed similar functional scores in the two groups studied, over follow-up periods of eight and ten years.

If the surgical technique is adequate, the process of degradation of the polyethylene and subsequent osteolysis is minimized. Incorrect positioning of the femoral and tibial implants in the coronal, sagittal and axial planes may make it difficult to restore the mechanical axis of the operated knee, thus causing early degradation of the polyethylene. In the present study, there was no difference in the positioning of the components and the restored mechanical axis between groups 1 and 2 (Table 3), which underwent operations using the same technique. Udomkiat *et al*<sup>(24)</sup> obtained similar mechanical axes in the ALP and MTB groups ( $p = 0.19$ ), as measured using simple radiography during the final evaluation of the study, with a mean axis of  $6.4 \pm 2.6$  degrees of valgus in the ALP group and  $5.6 \pm 2.7$  degrees of valgus in the MTB group. These values were close to those found in the present study.

The wear on the polyethylene and the consequent osteolysis of the implants are dependent on several factors, independent of the specific type of tibial component (ALP or MTB). It is known that polyethylene can wear out in different ways: wear due to abrasion and adhesion, fatigue of the material and delamination of the material<sup>(27,28)</sup>. Other variables, such as the use or nonuse of cement for fixation of the components, type and molecular weight of the polyethylene, type of sterilization (ethylene oxide or gamma irradiation),

surgical technique used and type of metal used in the femoral component (chromium-cobalt versus zirconium), among others, are factors that significantly interfere with the final result and that sometimes are poorly controlled for in the studies analyzed. Fhering *et al*<sup>(11)</sup> and McGovern *et al*<sup>(29)</sup> found correlations in their respective studies, between the length of storage (shelf life) and early wear on the polyethylene, particularly when this period was greater than four years. Because of the cross-sectional nature of the present study, these variables could not be evaluated.

In this study, higher incidence of radiolucency was found in the ALP components. According to Ecker<sup>(30)</sup>, the different radiolucency lines in the components do not have any clinical significance and are not signs of imminent failure. Their finding was confirmed by the present study. The short duration of the follow-up (mean of 5.2 years) limited the correlation between possible development of osteolysis and consequent loosening of the components in groups ALP and MTB. Identification of significant radiolucency (osteolysis) requires a longer follow-up period and for this reason, the two groups will continue to be assessed. Taking the revision as the final point, Rand and Ilstrup<sup>(31)</sup> found that the survival rate was 98% for the MTB group, versus 94% for the ALP group. On the other hand, in independent studies, O'Rourke *et al*<sup>(9)</sup>, Rodriguez *et al*<sup>(32)</sup> and Ranawat *et al*<sup>(33)</sup> demonstrated survival rates of between 95% and 98% in the ALP group, versus 90% to 94% in the MTB group, over follow-up periods ranging from eight to twenty years. As a preliminary assessment, the present study demonstrated greater radiolucency in the operated knees with the ALP tibial component. Longer follow-up is expected to confirm this trend.

The methodology used in this study (cross-sectional study) made it impossible to infer any causal relationship between the radiolucency lines and the diagnosis of aseptic loosening, and this will stimulate further follow-up of the study groups in the future.

## CONCLUSION

This study, with a mean follow-up of 5.2 years, found that there was higher incidence of radiolucency in the femoral and tibial components of the knees operated with the all-polyethylene implant, without any clinical or functional correlation.

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