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(Article begins on next page)

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TITLE

NexGen® LPS Mobile Bearing Total Knee Arthroplasty: five-to-ten year results.

Authors:

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ABSTRACT

Purpose Mobile bearing (MB) knee prostheses were designed to improve the performances of the total knee arthroplasties (TKA). The clinical superiority of MB prosthesis compared to its fixed bearing counterpart has remained elusive. This study prospectively evaluates the cumulative survivorship, clinical, radiographic results, and complications of a large series of MB TKAs in relation to patient age, sex, severity of arthritis, and patellar resurfacing.

Methods This study evaluates the 5- to 10-year cumulative survival rate of the NexGen_ LPS MB. Between 2000 and 2005, we performed a consecutive series of 332 MB, posterior-stabilized TKA in 249 patients (mean age 71.2 years, SD 6.9). The implants were clinically evaluated with the Hospital Special Surgery Knee Score (HSS-KS) and radiographically with the Knee Society Roentgenographic Evaluation System (KS-RES). The mean follow-up was 76.3 months (minimum 5 years).

Results The HSS-KS improved from 55 pre-operatively to 86 at the end of follow-up. According to the KS-RES, the implants were anatomically aligned and progressive radiolucent lines appeared in four knees (1.2 %). The patella was selectively resurfaced in 162 of 332 knees. Patients with the patella resurfaced had better clinical results compared to those not resurfaced, but there was no difference in terms of survival. The cumulative survival rate was 98.4 % at 10 years (Kaplan–Meier's analysis).

Conclusions This MB implant provided reliable and durable clinical results with a survivorship of over 98 % at 10 years, in unselected patients regardless of age, sex, severity of disease, and patellar treatment.

Level of evidence Therapeutic study, retrospective study (data collected prospectively), case series with no comparison group, Level IV.

INTRODUCTION

Total knee arthroplasty (TKA) has been shown to be effective, reliable [13, 22], and durable at relieving pain and improving function in patients with end-stage arthritis of the knee with survivorships ranging from 90 to 98 % at 10- to 15-year follow-up [5, 7–9, 15]. Mobile bearing (MB) knee prosthesis was designed and developed with the aim to provide a more physiological range of movement, to reduce the stress transfer at the bone–implant (cement) interface, and to reduce the stress on the tibial polyethylene insert, thus reducing wear [2, 28]. However, despite the theoretical advantages of a MB TKA, a significant difference in outcomes and longevity between fixed and MB knee prosthesis has not been reported [3, 12, 14, 17, 23].

Furthermore, there are few studies reporting long-term results and complications associated with the use of MB TKAs [27]. Finally, the question remains: Who is this technology best suited for? While the theoretical wear characteristics of MBs are appealing for use in the younger and more active population, concerns with bearing instability and other complications may require further definition of the ideal population best suited for this technology.

Therefore, the purpose of this study is to prospectively evaluate the cumulative survivorship, clinical, radiographic results, and complications of a large series of MB TKAs performed consecutively in non-selected patients using the Zimmer NexGen Legacy LPS mobile prosthesis (Zimmer, Warsaw IN). We compared these results in relation to patient age, sex, severity of arthritis, and patellar resurfacing.

We hypothesized that the NexGen Legacy LPS mobile TKA can achieve reliable and durable results in all patients regardless of age, sex, arthritis severity, and patellar resurfacing.

MATERIALS AND METHODS

Between 2000 and 2005, 332 NexGen Legacy LPS MB knees (Zimmer, Warsaw IN) were implanted in 249 consecutive, unselected patients at our institution. There were 197 women (79.1 %) and 52 men (20.9 %) with a mean age of 71.2 years (SD 6.9). The pre-operative diagnosis was osteoarthritis in 300 knees, rheumatoid arthritis in (n = 10), osteonecrosis of the medial femoral condyle (n = 18), and a failed unicompartmental knee arthroplasty (UKA) in four patients.

All knees were performed under tourniquet using a standard medial parapatellar approach. The osteophytes were removed, and the distal femoral resection was set at 5 degrees of valgus. The tibia was cut perpendicular to its axis, and ligament balancing was performed aimed to achieve a balanced flexion and extension gap and restoration of the anatomical axis of the limb. The patella was selectively resurfaced in 163 knees, while was not in 169 knees. The patella was resurfaced only in cases of severe articular cartilage degeneration, significant deformity, and maltracking. In all cases, the patella was treated with thermal denervation with electrocautery. Following trialing, all components were cemented into place. Following surgery, early patient mobilization was encouraged and received low molecular weight heparin (LMWH) for deep venous thrombosis prophylaxis.

Post-operatively, patients were evaluated at regularly scheduled intervals (3 weeks, 3, 6, 12 months, and annually thereafter). The patients who were unable to be evaluated in person were monitored using a validated telephone questionnaire [19]. The clinical outcome was evaluated using the Hospital for Special Surgery Knee Score (HSS-KS) [24]. The patellofemoral joint was evaluated for patellar mobility (absent, normal, hypermobile), anterior knee pain (absent, at rest, standing), and for the presence of patellofemoral crepitus (present or absent).

Radiographic outcome was evaluated using the Knee Society Roentgenographic Evaluation System (KS-RES) [10]. Serial radiographs were used to evaluate alignment, progressive radiolucent lines, osteolysis, and prosthesis loosening. Radiolucent lines were defined as progressive when greater than 2 mm and in cases if changes in at least two serial radiographs. Finally, each patient was asked

to report on the subjective outcome of the procedures by comparing their TKA to their pre-operative knee (1—no pain, 2—mild or moderate pain, 3—painful, and 4—as painful as prior to surgery) and to report their degree of satisfaction with the procedure (1—very satisfied, 2—satisfied, 3—not satisfied, and 4—very disappointed) [29].

All persons gave informed consent prior to their inclusion in the study, which has been performed in accordance with the ethical standards as certified by the protocol 0008016 from the Institution Citta` della Salute e della Scienza di Torino.

Statistical analysis.

The cumulative survivorship of the implant was determined using the Kaplan–Meier method. Failure was defined as revision of the implant for any reason. The clinical outcomes between patients who had a resurfaced patella compared to those who did not were compared using the Mann–Whitney test. A regression model was used to assess the relationship between pre-operative and post-operative knee scores. Because this analysis was performed at the ‘‘knee-level’’, the Huber–White estimator was used to adjust for correlation between observations contributed by the same patient. The nonlinear effects of covariates were modelled using a restrictive cubic-spline function, and their significance was assessed using the Chisquare test. The calculations were performed using R version 2.14 [25].

RESULTS

The average follow-up was 76.3 months (range 60–122 months). Eight patients died (8 knees), and twenty patients (27 knees) were lost to follow-up. Of the remaining 221 patients (305 knees) (92 %) included in the final analysis, 208 patients (284 knees) had complete records and were subjected to clinical and radiographic evaluation, while thirteen patients (13 knees) were evaluated by phone survey.Clinically, the total HSS-KS significantly improved after surgery (p\0.001) as well as all clinical parameters improved from the pre-operative evaluation to the final follow-up evaluation

(Table 1). There were no significant differences in the HSS-KS between men and women and among patients who were older than 68 years compared to those younger than 68 years of age at the time of surgery (Table 2). Patients presenting higher scores prior to surgery end up with higher scores after surgery. However, there was a significant difference in the improvement (delta) of HSS-KS between patients with HSS-KS less than 50 points prior to surgery (207 patients: mean pre-op HSS-KS 43.2 ± SD 5.6; mean post-op HSS-KS 79.6 ± SD 8.6) compared to those with scores greater than 50 points (125 patients: mean pre-op HSS-KS 57.2 ± SD 4.4; mean postop HSS-KS 87.8 ± SD 4.5) (p\0.01). Figure 1 reports the total knee score after arthroplasty as function of the preoperative score adjusted for age, sex, replaced patella, and pre-operative range of movement scores. Since this study reports on a single cohort of patients undergoing TKA, the clinical results throughout the entire study period are shown in Table 3.

There were no significant differences between patients undergoing patellar resurfacing and patients with unresurfaced patellae in terms of HSS-KS scores (Table 4). Also, the two groups showed no differences in terms of patellar mobility (p = ns). On the contrary, the unresurfaced group presented higher percentage of anterior knee pain (p = 0.013) and patellar crepitus (p\0.001) compared to the resurfaced group (Table 5).

Fifty-eight patients (68 knees, 26.2 %) were very satisfied with surgery, 124 patients (182 knees, 56.1 %) were satisfied, twenty-six patients (34 knees, 11.8 %) were not satisfied, and thirteen patients (13 knees, 5.9 %) were very disappointed. When questioned about pain in their TKA compared to pre-operatively, 159 patients (219 knees, 71.9 %) were not painful and had no activity limitations, forty patients (53 knees, 18.1 %) reported mild pain, fifteen patients (17 knees, 6.8 %) had moderate pain restricting certain activities, and seven patients (8 knees, 3.2 %) reported increased pain compared to their pre-operative knees. Despite these results, 214 of 221 patients surveyed (97 %) said that they would undergo TKA for their knee arthritis.

The radiographic follow-up was 70 months (range 60–110). Serial radiographs from 284 knees (86 %) were available for final analysis. Table 6 reports the detailed results of radiological findings:

alignment and radiolucent lines. In this series, radiolucent lines were most commonly encountered in zone 6 on the tibial side on AP radiographs and zones 3 and 1 for the tibial and femoral components, respectively, on the lateral radiograph. There were no differences in HSS-KS, function, pain, stairs in patients with non-progressive radiolucent lines to patients without radiolucent lines (Table 7). Osteolysis without loosening was not observed.

There were no cases of bearing instability or dislocation. At final follow-up, five of 332 TKA (1.5 %) were revised. Three knees were revised for aseptic loosening and 2 knees failed secondary to infection. The Kaplan–Meier survivorship analysis using revision for any reason as an endpoint revealed a 98.4 % survivorship of this MB TKA design at 10 years. The 10-year cumulative survivorship rate for patient with resurfaced patellae compared to those with unresurfaced patellae was 99.3 and 97.5 %, respectively (n.s.).

Discussion

The most important finding was that this MB TKA design provided reliable pain relief and improved function in patients with end-stage arthritis of the knee regardless of age, sex, severity of arthritis, and patellar resurfacing. The cumulative survivorship of this particular implant with failure defined by revision surgery for any reason was more than 98 % at 10 years. There were no significant differences between male and female patients and between patients younger than age 68 compared to those older than 68 of age. These results are consistent with other published results on MB knees [16, 18]. Argenson et al. reported on a series of 116 consecutive rotating platform PS TKA using the same knee design. At 10 years, the authors reported a survivorship of 98.3 % and observed similar improvements in Knee Society scores and range of motion. There were also no differences in outcomes with regard to age or sex [1]. Meftah et al. also reported good midterm 10-year outcomes of MB PS knees using the Depuy LCS knee design (Depuy, Warsaw IN). In their series of 117 consecutive knees, 10-year survivorship due to mechanical failure was 100 and 97.7 % with revision at any end point [20]. Consequently, modern MB knee designs including the NexGen

LPS mobile TKA can provide reliable and durable clinical results with low failure rates at midterm follow-up.

In this study, there were no significant differences in HSS-KS, functional score, stair climbing, and range of motion between patients who underwent patellar resurfacing compared to those without patellar resurfacing. While there were no significant differences in patellar mobility between the 2 groups, a higher percentage of patients without patellar resurfacing reported residual anterior knee pain at rest and patellar crepitus. The aetiology of these findings is unclear, but others also had similar results comparing groups of patients undergoing patellar resurfacing in TKA. A recent meta-analysis showed no clinical differences between resurfaced and unresurfaced patellae,

but also indicated that patellar resurfacing reduced the risk of reoperation for persistent pain after TKA [11]. However, other studies have also shown significant association between knee flexion contracture and anterior knee pain in knees with patellar resurfacing [26], thus supporting the importance of both surgical technique and the design.

Nevertheless, the majority of the studies have demonstrated no clinical differences between resurfacing and nonresurfacing of the patella during TKA [4, 6]. In this series, the incidence of overall anterior knee pain was 4 % in the patellar resurfacing group compared to 12 % in nonresurfaced group. While one of the advantages of MB TKA is the ‘‘self-centering’’ motion leading to improved patellar tracking, our results showed that the use of MBs did not eliminate anterior knee pain or patellofemoral complaints (such as crepitus). These findings are consistent with other reports showing no significant benefit of a MB knee to the patella–femoral articulation [21].

Radiographic analysis of MB TKA in this series revealed the presence of radiolucent lines in 22.5 % of knees at a follow-up of more than 6 years, but only four knees had progressive radiolucencies. Non-progressive radiolucent lines were more commonly present below the medial and lateral edges of the tibial plateau in the AP view and behind the proximal flange of the femoral component in the lateral projection. Osteolysis was not observed patients with non-progressive radiolucent lines.

Similar radiographic results of no malalignment, no spinout, no osteolysis, and occasional presence of non-progressive radiolucent lines have also been reported in a similar series with a different implant [20]. The aetiology of radiolucent lines is unknown but may be multifactorial including surgical technique. Argenson et al. also reported nearly 14 % (15/116) non-progressive radiolucent lines in their series of MB knees of the same design without compromise of their durability [1]. Consequently, while a significant number of knees had radiolucent lines, the low rate of progressive radiolucent lines (3 %) and lack of osteolysis point to favourable wear characteristics of this MB knee design.

This study had several limitations. First, this is a retrospective review of our institutional experience using this MB knee implant. While the majority of these cases were performed by a single surgeon (MC), there were a few TKAs included for final analysis that was performed by others, potentially introducing surgical bias. However, this is a group of consecutive, unselected patients with prospectively collected data with high follow-up rate; thus minimizing the risk of recall bias. Second, there was a lack of a control or comparative group in this study. Therefore, this is simply a descriptive study, and no statements about superiority can be made with regard to this type of prosthesis over another. Third, the age of this cohort of patients in this study averaged more than 70 years (range 21–89), and therefore, this can affect the final results as demonstrated by the decreasing total HSS-KS throughout the study period. An advantage of MBs is a theoretical potential reduction in wear. However, if the prosthesis is used in older patients, it may lead to overstatement of longevity due to lower functional demands and understatement of potential complications. Nevertheless, younger patients in this series had equivalent clinical outcomes and prosthesis survivorship compared to older patients in this group. Consequently, MB TKAs can be used safely and reliably in patients of all ages and functional demands. Fourth, while the choice to resurface the patella during TKA was based on strict, criteria, the final decision can be modified by a surgeon’s preference and choice, thus introducing bias. This can potentially limit the comparisons

of patellar resurfacing and non-resurfacing in this series. However, because the groups of patellar treatment had similar characteristics, it allows for some conclusions about the patella in MB TKA. Finally, while this is a relatively large consecutive series of MB TKAs utilizing a single knee design, an average followup of 76.3 months is not long enough to derive significant conclusions with respect to longevity and durability.

However, this series represents a non-designing surgeon series with comparative outcomes and survivorships, thus validating the safety and effectiveness of this knee design with utility for surgeons' decisions in terms of implant selection.

Conclusion

The studied MB knee prosthesis provided reliable and durable clinical results with a survivorship of over 98 % at 10 years, in unselected patients regardless of age, sex, severity of disease, and patellar treatment. Conflict of interest No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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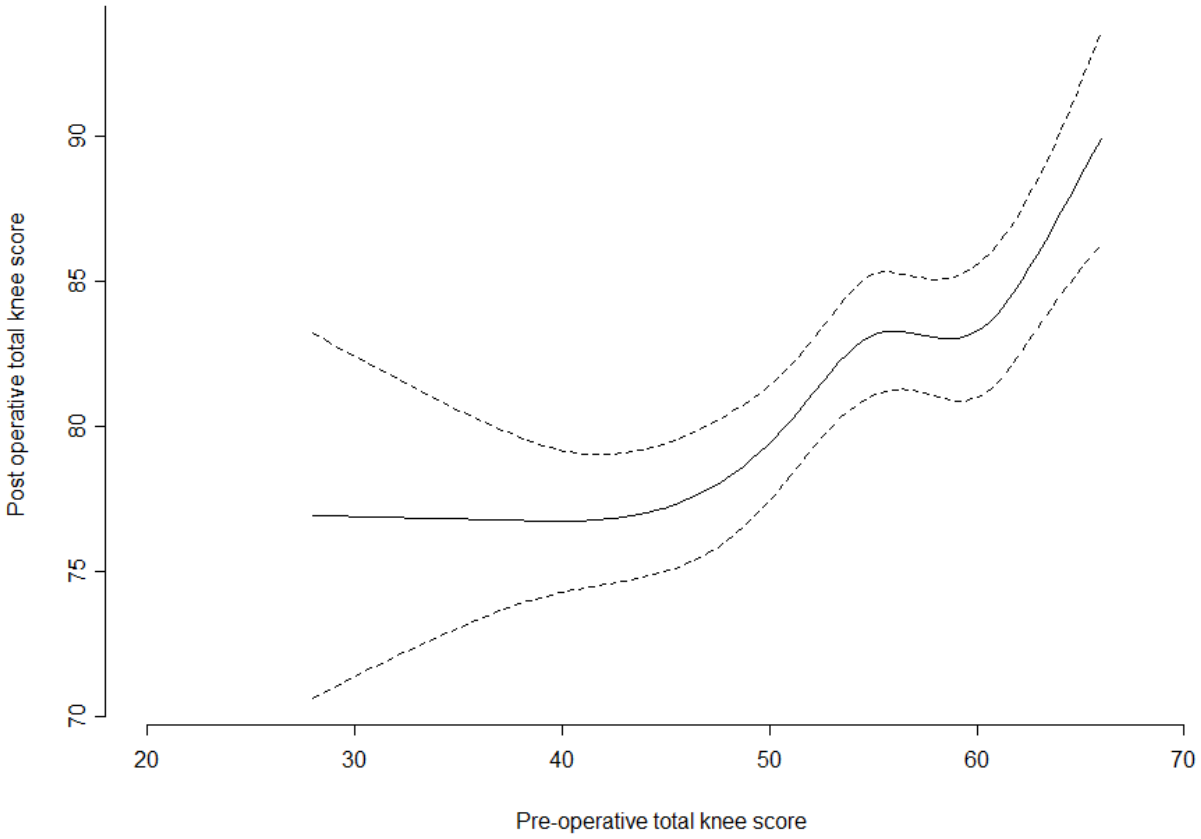

Figure 1. Total knee score after arthroplasty as function of the preoperative score adjusted for age, sex, replaced patella, and preoperative range of movement scores

Table 1. HSS-KS results for all patients. The numbers reported are mean(SD). N is the number of non missing value for each variable. The Wilcoxon test for paired data was used.

	N	Pre-operative	Post-operative	p-value
Total Knee Score	305	54.6 (7.2) Range (28-66)	86.3 (6.4) Range (43-98)	<0.001
Pain score	305	7.33(2.5)	13.74 (2.2)	<0.001
Functional score	304	6.41 (2.6)	10.9 (1.0)	<0.001
Range of movement (ROM)	304	67.16 (8.8)	114.3 (16.5)	<0.001
Pre-operative ROM classes				
(55;60]	95	-	124.9 (18.9)	
(60;65]	47	-	100.6 (8.9)	
(70;75]	109	-	107.3(8.0)	
(75;80]	53	-	121.7 (14.4)	
Stairs	304	2.2 (0.7)	4.4 (1.2)	<0.001

319 Table 2. Comparison of HSS-KS results by gender and age. The numbers reported are mean (SD).
320 The Mann-Whitney test was used at $p<0.05$.

	Females	Males	p-value	Age class: 55-68	Age >68	p-value
	(N=261)	(N=71)		(N=88)	(N=244)	
Total Knee Score	86.4 (6.4)	85.7(6.22)	ns	87.1 (5.8)	85.9 (6.5)	ns
Pain	12.3 (2.5)	12.1 (2.5)	ns	12.3 (2.5)	12.3 (2.5)	ns
Pain at test	13.8 (2.14)	13.5 (2.3)	ns	14.0 (2.0)	13.7 (2.2)	ns
Functional score	11.0 (1.0)	10.7 (1.0)	ns	10.9 (1.0)	10.8 (1.0)	ns
Range of movement	114.4 (16.5)	113.8 (16.6)	ns	113.3 (15.2)	114.6 (17.0)	ns
Stairs	4.4(1.2)	4.5(1.2)	ns	4.3(1.2)	4.4(1.1)	ns

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322

Table 3. Total HSS-KS, pain, functional score, range of motion, and stairs data of all time points

Time	N	Total knee score	Pain	Functional Score	Range of montion (ROM)	Stairs
Pre-op	332	54.6(7.2)	7.3(2.5)	6.4(2.6)	67.2(8.8)	2.2(0.7)
3 months	332	80.6(5.4)	12.8(2)	8.8(1.1)	108.5(18.5)	3.5(1.6)
6 months	332	81.5(5.9)	13(1.9)	9.8(1)	111.9(17)	3.8(1)
1 year	332	85.1(6.9)	13.4(1.5)	10(1.4)	112.8(17)	3.9(1.2)
2 years	332	85.4(3.8)	13.5(1.8)	10.8(1.2)	112.9(16.5)	4(1.2)
3 years	331	87.2(6.8)	13.9(1.3)	11.5(0.8)	113.8(16)	4.1(1.2)
4 years	331	90.1(6.6)	14.3(1.9)	11.6(10)	114(16.5)	4(1.3)
5 years	331	89.5(5.9)	14.3(1.6)	11.5(1)	115.8(16.6)	4.6(1)
6 years	325	88.9(6.7)	14.1(2.9)	11.5(1)	117.4(16.8)	4.6(1.1)
7 years	317	88.5(6.4)	14(3)	11.5(0.9)	116.5(16)	5.6(1)
8 years	268	88.2(6.9)	14(2.4)	11.5(0.9)	116(15.9)	4.8(1.3)
9 years	169	86.5(7.2)	14.2(3.1)	11.3(0.9)	115.8(15.4)	4.9(1.2)
10 years	103	85.2(8.1)	13.6(2.9)	11(0.9)	116(15.6)	4.9(1.1)

Table 4. HSS-KS results by patellar resurfacing The numbers reported are mean (SD). The Mann-Whitney test was used.

	Pre-operative			Post-operative		
	Resurfaced (N=163)	Not resurfaced (N=169)	p-value	Resurfaced (N=46)	Not resurfaced (N=151)	p-value
Total Knee Score	54.8 (6.7)	54.4 (7.6)	0.91	87.2 (5.8)	85.4 (6.8)	0.03
Pain	7.4 (2.5)	7.2 (2.5)	0.25	14.0 (2.0)	13.5 (2.3)	0.07
Functional score	6.5(2.6)	6.4 (2.7)	0.88	10.9 (1.0)	10.9 (1.0)	0.95
Range of movement	67.2 (8.7)	67.0 (9.0)	0.82	115.2(16.0)	113.4 (17.1)	0.17
Pain at test	6.3(3.0)	6.2(3.3)	0.74	12.3(2.5)	12.3 (2.5)	0.99
Stairs	2.2(0.8)	2.2(0.7)	0.86	4.4(1.2)	4.4 (1.2)	0.85

Table 5. HSS-KS results regarding the clinical evaluation of the patella. Numbers reported are percentage and absolute frequency. Test used: chi square.

	pre-operative			post-operative		
	Replaced (N=163)	Not replaced (N=169)	p-value	Replaced (N=146)	Not replaced (N=159)	p-value
Motility			ns			ns
Absent	72% (110)	60% (99)		7%(11)	9%(15)	
Normal	26% (40)	40% (66)		93% (141)	91% (150)	
Hyper-motility	1% (2)	0% (0)		0%(0)	0%(0)	
Pain			<0.001			ns
Absent	18% (27)	37% (61)		96%(146)	88%(146)	
At rest	12% (18)	13% (21)		4% (6)	12% (19)	
Standing	70% (107)	50% (83)				
Crepitus			ns			<0.001
Absent	12% (19)	25% (42)		98%(149)	72% (119)	
Present	88% (133)	75% (123)		2% (3)	28% (46)	

Table 6. Results of the radiographic evaluation in terms of component alignment, according to the Knee Society Roentgenographic Evaluation System (KS-RES) and incidence and location of the radiolucent lines.

Parameter	N	Final follow-up
Femoral components position, degrees		
Antero-posterior view		96.56 (1.77)
Sagittal view		3.57 (2.61)
Tibial components position, degrees		
Antero-posterior view		88.18 (2.82)
Sagittal view		88.37 (2.53)
Total radiolucent lines	157	157 lines in 65 knees
Progressive		3% (4)
Non Progressive		98% (153)
Radiolucent lines divides for zones		
Tibial antero-posterior	157	31% (49)
Principal zone: **6**	49	27% (13)
Tibial lateral	157	32% (50)
Principal zone: **3**	50	50% (25)
Femoral	157	37% (58)
Principal zone: **1**	58	45% (26)