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NexGen® LPS mobile bearing total knee arthroplasty: 10-year results

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1 **TITLE**

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

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6

7 **ABSTRACT**

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

13 *Methods* This study evaluates the 5- to 10-year cumulative survival rate of the NexGen_ LPS MB.
14 Between 2000 and 2005, we performed a consecutive series of 332 MB, posterior-stabilized TKA in
15 249 patients (mean age 71.2 years, SD 6.9). The implants were clinically evaluated with the
16 Hospital Special Surgery Knee Score (HSS-KS) and radiographically with the Knee Society
17 Roentgenographic Evaluation System (KS-RES). The mean follow-up was 76.3 months (minimum
18 5 years).

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

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

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

30

31 **INTRODUCTION**

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

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

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

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

52

53

54 MATERIALS AND METHODS

55 Between 2000 and 2005, 332 NexGen Legacy LPS MB knees (Zimmer, Warsaw IN) were
56 implanted in 249 consecutive, unselected patients at our institution. There were 197 women (79.1
57 %) and 52 men (20.9 %) with a mean age of 71.2 years (SD 6.9). The pre-operative diagnosis
58 was osteoarthritis in 300 knees, rheumatoid arthritis in (n = 10), osteonecrosis of the medial femoral
59 condyle (n = 18), and a failed unicompartmental knee arthroplasty (UKA) in four patients.

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

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

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

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

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

87

88 **Statistical analysis.**

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

98

99 **RESULTS**

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

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

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

122 Fifty-eight patients (68 knees, 26.2 %) were very satisfied with surgery, 124 patients (182 knees,
123 56.1 %) were satisfied, twenty-six patients (34 knees, 11.8 %) were not satisfied, and thirteen
124 patients (13 knees, 5.9 %) were very disappointed. When questioned about pain in their TKA
125 compared to pre-operatively, 159 patients (219 knees, 71.9 %) were not painful and had no activity
126 limitations, forty patients (53 knees, 18.1 %) reported mild pain, fifteen patients (17 knees, 6.8 %)
127 had moderate pain restricting certain activities, and seven patients (8 knees, 3.2 %) reported
128 increased pain compared to their pre-operative knees. Despite these results, 214 of 221 patients
129 surveyed (97 %) said that they would undergo TKA for their knee arthritis.

130 The radiographic follow-up was 70 months (range 60–110). Serial radiographs from 284 knees (86
131 %) were available for final analysis. Table 6 reports the detailed results of radiological findings:

132 alignment and radiolucent lines. In this series, radiolucent lines were most commonly encountered
133 in zone 6 on the tibial side on AP radiographs and zones 3 and 1 for the tibial and femoral
134 components, respectively, on the lateral radiograph. There were no differences in HSS-KS,
135 function, pain, stairs in patients with non-progressive radiolucent lines to patients without
136 radiolucent lines (Table 7). Osteolysis without loosening was not observed.
137 There were no cases of bearing instability or dislocation. At final follow-up, five of 332 TKA (1.5
138 %) were revised. Three knees were revised for aseptic loosening and 2 knees failed secondary to
139 infection. The Kaplan–Meier survivorship analysis using revision for any reason as an endpoint
140 revealed a 98.4 % survivorship of this MB TKA design at 10 years. The 10-year cumulative
141 survivorship rate for patient with resurfaced patellae compared to those with unresurfaced patellae
142 was 99.3 and 97.5 %, respectively (n.s.).

143

144 **Discussion**

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

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

160 In this study, there were no significant differences in HSS-KS, functional score, stair climbing, and
161 range of motion between patients who underwent patellar resurfacing compared to those without
162 patellar resurfacing. While there were no significant differences in patellar mobility between the 2
163 groups, a higher percentage of patients without patellar resurfacing reported residual anterior knee
164 pain at rest and patellar crepitus. The aetiology of these findings is unclear, but others also had
165 similar results comparing groups of patients undergoing patellar resurfacing in TKA. A recent meta-
166 analysis showed no clinical differences between resurfaced and unresurfaced patellae,
167 but also indicated that patellar resurfacing reduced the risk of reoperation for persistent pain after
168 TKA [11]. However, other studies have also shown significant association between knee flexion
169 contracture and anterior knee pain in knees with patellar resurfacing [26], thus supporting the
170 importance of both surgical technique and the design.

171 Nevertheless, the majority of the studies have demonstrated no clinical differences between
172 resurfacing and nonresurfacing of the patella during TKA [4, 6]. In this series, the incidence of
173 overall anterior knee pain was 4 % in the patellar resurfacing group compared to 12 % in
174 nonresurfaced group. While one of the advantages of MB TKA is the “self-centering” motion
175 leading to improved patellar tracking, our results showed that the use of MBs did not eliminate
176 anterior knee pain or patellofemoral complaints (such as crepitus). These findings are consistent
177 with other reports showing no significant benefit of a MB knee to the patella–femoral articulation
178 [21].

179 Radiographic analysis of MB TKA in this series revealed the presence of radiolucent lines in 22.5
180 % of knees at a follow-up of more than 6 years, but only four knees had progressive radiolucencies.
181 Non-progressive radiolucent lines were more commonly present below the medial and lateral edges
182 of the tibial plateau in the AP view and behind the proximal flange of the femoral component in the
183 lateral projection. Osteolysis was not observed patients with non-progressive radiolucent lines.

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

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

209 of patellar resurfacing and non-resurfacing in this series. However, because the groups of patellar
210 treatment had similar characteristics, it allows for some conclusions about the patella in MB TKA.
211 Finally, while this is a relatively large consecutive series of MB TKAs utilizing a single knee
212 design, an average followup of 76.3 months is not long enough to derive significant conclusions
213 with respect to longevity and durability.
214 However, this series represents a non-designing surgeon series with comparative outcomes and
215 survivorships, thus validating the safety and effectiveness of this knee design with utility for
216 surgeons' decisions in terms of implant selection.

217

218 **Conclusion**

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

223

224 **Conflict of interest**

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226 directly or indirectly to the subject of this article.

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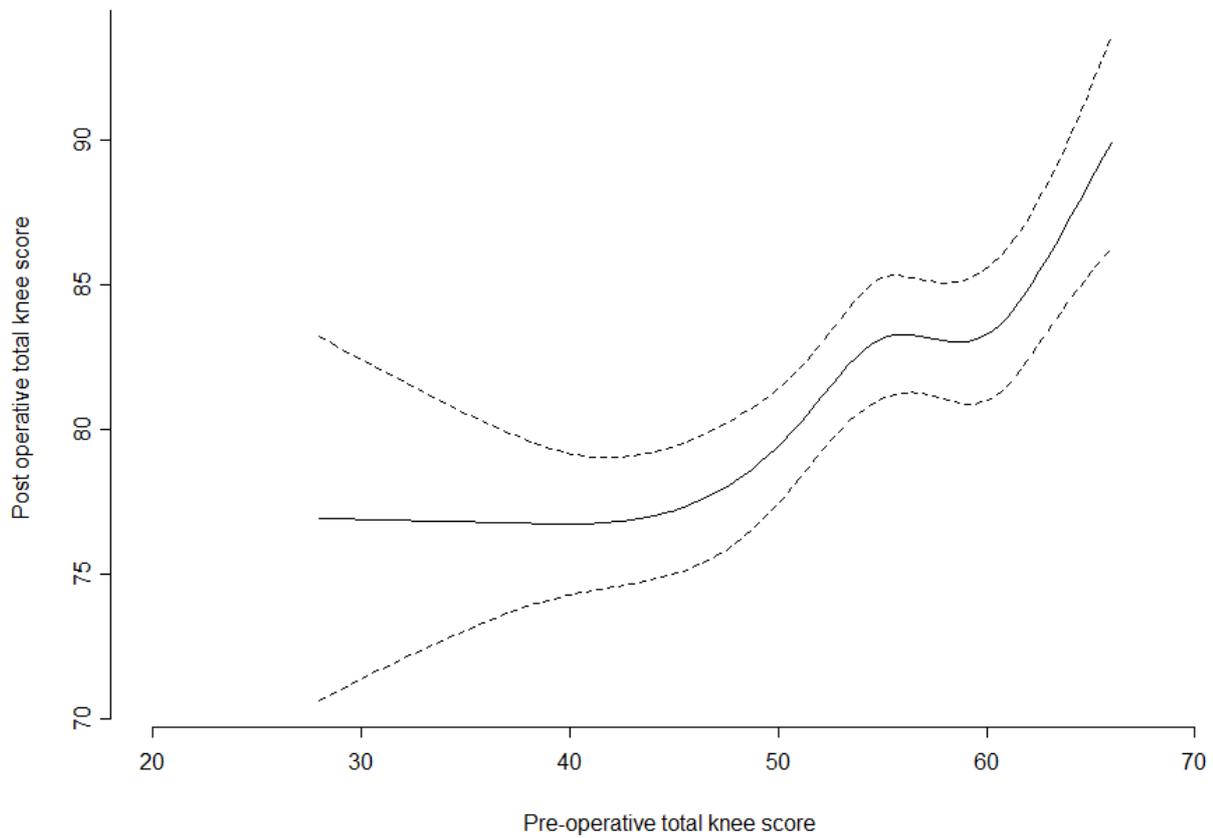
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306 Figure 1. Total knee score after arthroplasty as function of the preoperative score adjusted for age,
307 sex, replaced patella, and preoperative range of movement scores

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311 Table 1. HSS-KS results for all patients. The numbers reported are mean(SD). N is the number of
 312 non missing value for each variable. The Wilcoxon test for paired data was used.
 313

	N	Pre-operative	Post-operative	p-value
Total Knee Score	305	54.6 (7.2)	86.3 (6.4)	<0.001
		Range (28-66)	Range (43-98)	
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

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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 (N=261)	Males (N=71)	p- value	Age class: 55-68 (N=88)	Age >68 (N=244)	p- value
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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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 motion (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(1.0)	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)

325

326 Table 4. HSS-KS results by patellar resurfacing The numbers reported are mean (SD). The Mann-
 327 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

328

329

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

	pre-operative		p-value	post-operative		p-value
	Replaced (N=163)	Not replaced (N=169)		Replaced (N=146)	Not replaced (N=159)	
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)	

332

333

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

Parameter	N	Final follow-up	337
Femoral components position, degrees			
Antero-posterior view		96.56 (1.77)	338
Sagittal view		3.57 (2.61)	339
Tibial components position, degrees			
Antero-posterior view		88.18 (2.82)	340
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			
<i>Tibial antero-posterior</i>	157	31% (49)	
Principal zone: 6	49	27% (13)	
<i>Tibial lateral</i>	157	32% (50)	
Principal zone: 3	50	50% (25)	
<i>Femoral</i>	157	37% (58)	
Principal zone: 1	58	45% (26)	