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## Unilateral versus bilateral total knee arthroplasty: A registry study on survival and risk factors

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1 **Original article**

2 **Unilateral versus Bilateral Total Knee Arthroplasty: A registry study on survival and**  
3 **risk factors**

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16

17

18 **Abstract**

19 *Background*

20 Bilateral cases, representing at least 25% of total knee arthroplasties (TKA), could convey a  
21 statistical bias linked to dependency. Registries allow exploring this issue, susceptible to  
22 question surgeon validated protocols. Do bilateral total knee arthroplasties behave differently  
23 than unilateral knees in terms of implant survival?

24 *Hypothesis*

25 Bilateral TKA have a better survival than unilateral TKA.

26 *Patients and Methods*

27 14652 bilateral and 27440 unilateral TKAs were compared. Influencing factors were tested  
28 with hazard ratios applied on bilateral knees.

29 *Results*

30 Bilateral knees had a better survival ( $p < 0.001$ ).

31 Delay between first and second side surgeries had an influence on survival of the first knee: if  
32 below a year, the first knee survival was superior to the second knee; more than three years  
33 between both arthroplasties significantly decreased the survival of the first implant. If the first  
34 knee was revised, the hazard ratio for revision of the second implant was 3.5.

35 *Discussion*

36 Series should include separate evaluations of bilateral cases, because they have a better  
37 survival than unilateral knees. A long delay between both knee replacements could impact  
38 both implant survivals.

39 *Level of Evidence:* III, Cohort Comparative Study

40 Keywords: total knee arthroplasty; bilateral ; registry; survival

41

42 **1. Introduction**

43  
44 Total Knee Arthroplasty (TKA) has been proven to be a safe and reliable surgical procedure,  
45 relying on extensive literature on approaches [1,2], surgical techniques [3,4],  
46 physiotherapy[5] and clinical follow-up[6]. The improvements made to optimize the knee  
47 procedure were obtained with the help of statistical evidence [7,8].  
48 Bilateral cases represent 15% of total hip arthroplasties [9] and 25% of total knee  
49 arthroplasties [10] in registries. From an orthodox statistical point of view, these cases  
50 represent a bias, as the samples are not all independent, as shown by Park *et al.* [11].  
51 Registries allow obtaining statistical knowledge of influencing factors on implant survival,  
52 information hard to extract from conventional studies, even randomized controlled trials. A  
53 few registry studies have tackled the issue of bilateral case dependency biases on risk factors,  
54 with the use of alternative Cox regression models such as shared gamma frailty models, after  
55 to deal with dependency issues, but with mixed results. In hips, Lie *et al.* [9] found an  
56 influence of bilaterality on the risk of revision for the remaining hip if the opposite hip had  
57 been revised. The influence of bilaterality was found negligible for standard risk factors, these  
58 results sharing the conclusions of Schwartz *et al.* [12]. Robertsson *et al.* [10] applied the  
59 shared gamma frailty regression model to knee arthroplasty and concluded of an absence of  
60 bias of ignored bilaterality. But their conclusions only could be applied on the factors they  
61 researched, *i.e.* the influence of unicompartmental arthroplasty on knee arthroplasty survival.  
62 No cohort study was only performed on bilateral total knees to look for differences on implant  
63 survival and risk factors. As bilateral cases in TKA represent a quarter of the knees, there  
64 remains an interest to focus on these knees to look for survival differences, in order to assist  
65 both patient and surgeon in choosing the implant characteristics and scheduling both  
66 surgeries. A registry was used to select only bilateral cases.  
67 Do bilateral total knee arthroplasties behave differently than unilateral knees in terms of

68 implant survival? What are the factors affecting survival of bilateral total knee arthroplasties?  
69 Our hypothesis was bilateral cases have a better survival than unilateral cases.

## 70 **2. Material and Methods**

### 71 2.1 Patients

72 This study was designed as a comparative study using a registry of orthopedic implants.

73 Patients were included from 01/07/2000 to 31/12/2015.

74 All analyses presented in this report are based on primary operations in patients resident in a  
75 specific region (Emilia-Romagna, Italy). The analysis was limited to this cohort of patients,  
76 with the exclusion of patients living outside the region, to avoid the bias of possible lost to  
77 follow up. The RIPO registry (Registro Implantologia Protesica Ortopedica, Bologna, Italy,  
78 <https://ripo.cineca.it>) covers the area of Emilia-Romagna region (4.5 million inhabitants) and  
79 has a capture rate of more than 95% on implants performed in all orthopedic departments of  
80 the region, both public and private (65 centers).

81 Each event (death, revision of any type) was strictly recorded and cross-checked with regional  
82 administrations; a period of time of one year after the last inclusion was included to allow  
83 collecting all data from the different centers and administrations. Loss of follow-up was  
84 evaluated to be below 2%.

85 The inclusion criterion was the recording of a primary total knee arthroplasty during the  
86 inclusion period. Was considered bilateral a primary TKA performed on each knee during the  
87 time of the study.

88 On the contrary, a knee arthroplasty was considered unilateral when only one side benefited  
89 from a knee implant during the time of the study. Only bi (without patellar resurfacing) or  
90 tricompartmental arthroplasties were included. The registry did not record arthroplasties  
91 before the inclusion period. Unicompartmental knees were excluded, due to survival

92 differences that could tamper with the results and provide an unwanted confusion bias. Pre-  
93 operative data was comparable in both groups.

94 14652 bilateral implants (7326 patients) and 27440 unilateral implants were performed in the  
95 period on 7326 patients and 27440 patients, respectively (Fig 1). 34.8% of the total knees  
96 arthroplasties were bilateral cases; 21% of total knee patients had bilateral total knees. Thirty  
97 knees (15 patients) benefited from a simultaneous bilateral knee arthroplasty.

98 Unilateral knees served as a reference group.

99

100 Bilateral TKAs had a mean follow-up of 5 years (0-14.7). Average time between the first and  
101 the second operation was 2.7 years (95% confidence interval 2.6-2.8), (min and max 0-14)..

102 Unilateral TKAs had a mean follow-up of 5.5 years (0-16),

103 Mean age was 72 years for females and 71 years for males. Primary etiology was

104 osteoarthritis (88%). Concerning the bilateral group, 64% of polyethylene inserts were fixed,

105 36% mobiles. 44% of implants were cruciate retaining, 56% were posterior-stabilized (Table

106 1). Concerning the unilateral group, 62% of polyethylene inserts were fixed, 38% were

107 mobiles. 44% of implants were cruciate retaining, 56% were posterior-stabilized.. Both

108 groups were comparable in terms of per operative characteristics.

109

## 110 2.2 Methods

111 Failures were recorded up to 31/12/2015. The recording of a revision and/or a complication is

112 mandatory for a hospital in the registry region; a period of time of a year was included in the

113 study to allow collecting all events (death, revision, complication). Revision for any cause

114 was set as the endpoint; revision was defined as the removal or change of any implant and

115 would impact the survival rate.

116

117 Bilateral and unilateral knees were compared with regard to survival rates.  
118 First and second knees of the bilaterals were also compared via the same methods.  
119 Three sub-groups were designed to look for survival differences with regard to the time  
120 between both surgeries: from 0 to 1 year, between 1 and 3 years, and over 3 years. The 3 sub-  
121 groups were set based on sub-group size comparability, as these thresholds allowed dividing  
122 the cohort into three groups of almost equal numbers. 1.6% of the first sub-group (30 cases)  
123 were simultaneous bilateral cases.  
124 All three sub-groups were found comparable with regards to all the influencing variables  
125 listed below, i.e. age, sex, Body Mass Index (BMI) and cause for revision. **Table 2** shows the  
126 population of the 3 sub-groups.  
127 To look for influencing variables on the outcome of the surgery, patient characteristics such  
128 as sex, weight and age at surgery, or implant characteristics such as the type of tibial insert  
129 (fixed or mobile) were extracted from the database when available.

130

### 131 2.3 Statistical analysis

132 The statistical analysis was performed using SPSS 14.0 for Windows, version 14.0.1 (SPSS  
133 Inc, Chicago, IL, USA) and JMP®, Version 12.0.1. (SAS Institute Inc., Cary, NC, 1989-  
134 2007). Kaplan Meier survival curves were used for survival analysis; log-rank tests looked for  
135 statistically significant differences between the survival curves. The significance threshold  
136 was set at  $p < 0.05$ . Hazard ratios were calculated via a Cox multivariate regression model.

137

## 138 3. Results

139

140 Survival analysis of unilateral knees was plotted against bilateral knees, without using  
141 statistical means to account for the dependency bias (**Figure 2**). Log-rank test was found

142 significantly different ( $p=0.0001$ ), in favor of bilateral cases. At 5 years, survival was 97.8%  
143 for bilateral TKAs [97.5-98] against 96.3 for unilateral TKAs [96.1-96.6]; at 10 years,  
144 survival was 96.0% for bilateral TKAs.

145 As the first side of the bilateral knees had functioned as a unilateral knee before the second  
146 surgery, we also tested unilateral knees against only the second knee of the bilateral knees.  
147 The results were even more in favor of the bilateral knees (Table 3,  $p=0.0001$ ).

148 Survival curves of both the first and the second knees of bilateral cases were plotted against,  
149 with a log rank test close to significance (Figure 3,  $p=0.0606$ ). Hazard ratio on the influence  
150 of implant order was also not significant. As the populations were comparable, the only  
151 difference between them being the bilaterality, we looked at differences within the bilateral  
152 group that could have ponderated the difference.

153 To search only for the influence of the time between both surgeries on implant survival,  
154 survival curves of the 3 sub-groups (shorter than a year, between one and three years, and  
155 over three years between both surgeries) were plotted against second side survival curve  
156 (Figure 4). All curves were found statistically different ( $p=0.0001$ ). Differences in favor of the  
157 first sub-group versus the second knee and in favor of the second knee versus the third sub-  
158 group, while no difference between the second sub-group and the second knee, were found  
159 when looking at hazard ratios.

160 Groups were also confronted pairwise using a Wilcoxon test and it could be concluded that all  
161 groups had significant differences, except when comparing second sub-group and second  
162 knee ( $p=0.753$ ). It is worth noting than the knees from first sub-group of under a year of  
163 duration between both knees were mostly staged bilateral knees,  
164

165 Hazard ratios were extracted from the Cox model to look for influencing factors on the  
166 survival of bilateral total knees (Table 4). Insert type had a strong influence on survival, with

167 a hazard ratio of 1.5 (95% confidence interval, IC95 1.24-1.885) unfavoring mobile liners  
168 versus fixed liners. Sex did not influence the results. A young age was also a revision factor,  
169 with a hazard ratio of 0.95 (IC95 0.936-0.961) for age at implantation. Weight did not  
170 influence survival, with a HR of 0.9 (IC95 0.718-1.11). The implant order played a significant  
171 role, as shown previously. Provided the first implant was revised, the influence of the first  
172 knee revision on the second knee survival was calculated. A hazard ratio of 3.4 on the second  
173 knee (IC95 2.07-5.468) could be extracted from these findings (p=0.001).

174

175

#### 176 **4. Discussion**

177

178

179 Bilateral knees had a better survival than unilateral knees, with a strong influence of the time  
180 between both surgeries on survival of the first knee. If the time between surgeries was below  
181 a year, first knee survival was superior to the survival of the second knee; a duration of more  
182 than three years between both arthroplasties significantly decreased survival of the first  
183 implant. If the first knee was revised, the hazard ratio for revision of the second implant was  
184 3.5. Mobile liners had a worst survival rate than fixed liners. Our hypothesis is confirmed.

185

186 This series demonstrated our hypothesis, with a difference in favor of bilateral vs unilateral  
187 knees with regard to total knee survival. These results follow the findings from the study of  
188 Namba *et al.*[13], who studied risk factors for total knee revisions and found bilaterality as  
189 being protective, and the study of Bohm *et al.*[14] which focused on revision rates (1.4% vs  
190 2.3% for the unilateral knees at 3 years). Our study allowed further explaining the reasons of  
191 this behavior. These conclusions were not present in hip arthroplasty for Lie *et al.* [9], who

192 found no incidence of bilaterality on survival. Robertsson *et al.* [10] or Hooper *et al.* [15] also  
193 found no differences in knees. But Robertsson's study focused on the effect of bilaterality in  
194 unicompartmental versus tricompartmental results, and Hooper's study only had a 5 year  
195 follow-up period which could have tampered with significance.

196 No other series focused on the differences between the first and the second knee in bilaterals.  
197 Only in hip could we find the previously cited study from Lie *et al.* (9) with a difference  
198 found when time between surgeries reached two years. It is worth noting they also found a  
199 higher hazard ratio for second side revision when the first side was revised. When both sides  
200 were performed simultaneously, Seo *et al.*[16] showed similar revision rates of both sides.

201

202

203 One major revision risk factor found in our study was the time between surgeries. As it could  
204 be extracted from these findings that a threshold of a year should be set to avoid an incidence  
205 on revision, we couldn't go further into investigating the zero-to-one year period. The total  
206 amount of simultaneous bilateral knees was too small to compare them with staged bilateral  
207 knees. This issue of simultaneous versus staged is however still debated, with studies in favor  
208 of a staged procedure due to lower complication rates [17–21], in favor of the cost-  
209 effectiveness of simultaneous bilateral knees[20], or the absence of difference[15,21,22]. Ahn  
210 *et al.* showed a superiority for simultaneous knees [23]. Bohm *et al.*[14] in a significant-size  
211 registry study, showed that the populations involved in both groups were different. They  
212 found fewer infections in the simultaneous group but with more post-operative complications  
213 and no difference in revision rates.

214 We found an incidence of the type of insert in the survival of bilateral knees, in favor of fixed  
215 inserts. These results concurred with results from others like Gøthesen[24] or Namba *et*  
216 *al.*[25]. The multi-registry study from Namba *et al.* should allow modifying surgeon practice,

217 as the objective of the introduction of mobile inserts was to prevent wear and so increase  
218 survival rates.

219 A limitation of our study was the absence of clinical findings, a limitation specific to  
220 registries that only focus on revision as an endpoint. Patients unwilling to suffer a third knee  
221 surgery, or challenged due to health issues could not have been investigated. It seems  
222 nevertheless that these findings could only increase the differences shown in this study.

223 The most important limitation of not having clinical results could be the absence of  
224 satisfaction scores. There could be a selection bias, as patients recovering better from the first  
225 arthroplasty could be more eager to undergo another arthroplasty, thus resulting in shorter  
226 duration between surgeries, ultimately explaining the difference in survival of the sub-groups.

227 But as the three sub-groups shared the same characteristics (age, sex, weight, BMI, implants  
228 and, more importantly, complications and causes for revision) and so found comparable, the  
229 effect of patient satisfaction cannot account for the total of the difference found between sub-  
230 groups, as it would mean that patient satisfaction is not related to complications or survival.

231 Another limit was the absence of clinical value of the 2 thresholds (below a year and over 3  
232 years). These thresholds were data-driven, to separate the population into three comparable  
233 groups in terms of group size. While they allowed conducting an appropriate statistical  
234 analysis, they can't be considered as precise landmarks in the clinical follow-up. A last limit  
235 also has to be mentioned, as the registry does not include history of arthroplasties before the  
236 start of the inclusion period. There is no possibility to know how many "unilateral" knees  
237 were in fact bilateral knees, especially at the start of the inclusion period. This bias  
238 mechanically had lowered its effect the longer the registry lived on. With our study's results  
239 in mind, finding a better survival of bilaterals versus unilaterals, it would seem this bias did  
240 not affect the results from reaching a statistically significant difference but the difference  
241 might be higher than presented.

242

243 **5. Conclusion**

244

245 Bilateral total knee arthroplasties showed a better survival rate than unilateral total knees.

246 Total knee arthroplasty series should include a separate evaluation of bilateral cases to

247 prevent the dependency bias, as well as to measure its effect on the series results; or at least

248 use a statistical technique to account for bilaterality.

249 Time between both surgeries could have an effect on implant survival in bilateral cases.

250 Surgeons could include this finding in their planning strategy and keep in mind that a period

251 of more than 3 years between both knees significantly decreased the survival of the first knee

252 arthroplasty.

253 **Conflicts of Interests:** Bertrand Boyer and Thomas Neri are consultants for SERF (Décines,

254 France). Aldo Toni receives royalties from Adler (Milan, Italy). The other authors have no

255 conflict of interest.

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258 (SOFCOT) for its grant, allowing this study to happen.

259 **Contributions**

260 Susanna Stea and Aldo Toni were responsible for data collect, loss of follow-up reduction

261 strategies and manuscript overseeing ; Barbara Bordini and Dalila Caputo were responsible

262 for the statistical analysis and survival modeling; Thomas Neri was responsible for

263 manuscript building and redaction, especially material and methods and results; Bertrand

264 Boyer organized the study, built the manuscript and was responsible for introduction and

265 discussion parts of the manuscript.

266

267

268

269 **7. References**

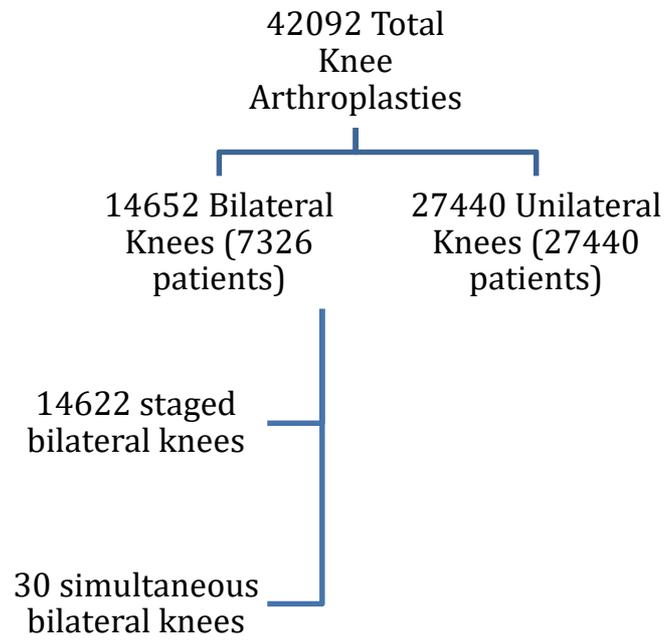
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- 341

342

343 **8. Legends**

344 fig 1. Flow-chart



345

346

347

348 Table 1. Repartition of implanted TKA (the two groups were found comparable with  
 349 regard to implants).

350

Bilateral knees	Type of insert	Implant name	Number (%)
	Fixed 9328 implants		Nexgen LPS (Zimmer)
		Nexgen CR (Zimmer)	421 (4.5%)
		Genesis II PS (Smith&Nephew)	721 (7.7%)
		Genesis II CR (Smith&Nephew)	332 (3.6%)
		Profix Conforming (Smith&Nephew)	748 (8%)
		Vanguard PS (Biomet)	764 (8.2%)
		Other	3944 (42.3%)
Mobile 5324 implants		TC-PLUS (EndoPlus)	719 (13.5%)
		PFC-RP-PS (DePuy)	616 (11.6%)
		Gemini MK-II (LINK)	610 (11.4%)
		LCS (Complete&Universal) RP (DePuy)	268 (5%)
		Genus (Adler)	326 (6.1%)
		Other	2785 (52.3%)

351

Unilateral knees	Type of insert	Implant name	Number (%)
	Fixed 17122 implants		Nexgen LPS (Zimmer)
		Nexgen CR (Zimmer)	846 (4.9%)
		Genesis II PS (Smith&Nephew)	1642 (9.6%)
		Genesis II CR (Smith&Nephew)	603 (3.5%)
		Profix Conforming (Smith&Nephew)	1117 (6.5%)
		Vanguard PS (Biomet)	1528 (8.9%)
		Other	7202 (42.1%)
Mobile 10313 implants		TC-PLUS (EndoPlus)	1146 (11.1%)
		PFC-RP-PS (DePuy)	1042 (10.1%)
		Gemini MK-II (LINK)	1310 (12.7%)
		LCS (Complete&Universal) RP (DePuy)	462 (4.5%)
		Genus (Adler)	566 (5.5%)
		Other	5787 (56.1%)

352

353

354 Table 2. Bilateral arthroplasties : Sub-groups of knees with regard to the duration between  
355 both arthroplasties.

	N. primary implants	Mean Follow-up (min-max) in y	N. of revision at 31/12/2015
First implants – <1 year	1917	6.5 (0-15.3)	35 (1.8%)
First implants – 1-3 years	3037	7.1 (0-15.5)	83 (2.7%)
First implants - >3 years	2372	9.2 (0-15.4)	138 (5.8%)
Second implants	7326	5.0 (0-14.7)	142 (1.9%)

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359

360 Table 3. Comparison of the number of revisions of bilateral second knee versus unilateral

361 knees. Results are significantly different (p=0.0001, Log-Rank test)

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	N. primary implants	Mean Follow-up (min-max) in years	N. of revision at 31/12/2015	% survival (Confidence interval 95%)
Bilateral –second side only	7326	5.0 (0-14.7)	142 (1.9%)	96.7 (96.0-97.3)
Unilateral	27440	5.5 (0-16)	955 (3.5%)	94.8 (94.4-95.2)

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367 Table 4. Hazard ratios extracted from the Cox model to look for influencing factors on the survival of

368 bilateral total knees. NS= non-significant. HR= hazard ratio. 95%LB & UB=95% confidence interval.

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	HR	95% LB	95% UB	p
Insert type (reference: fixed)	1.529	1.240	1.885	0.001
Age (years)	0.948	0.936	0.961	0.001
Time between first and second side (reference: second implant)				
< 1 year	0.644	0.432	0.961	0.031
Between 1 and 3 years	0.899	0.670	1.206	NS
> 3years	1.518	1.175	1.960	0.001
Weight (reference: >80 kg)	0.893	0.718	1.11	NS
Revision risk of the second side if the first side is revised	3.364	2.070	5.468	0.001

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Figure 2. Kaplan-Meier survival of the first TKA according to the duration between both arthroplasties was compared with the survival of the second TKA.

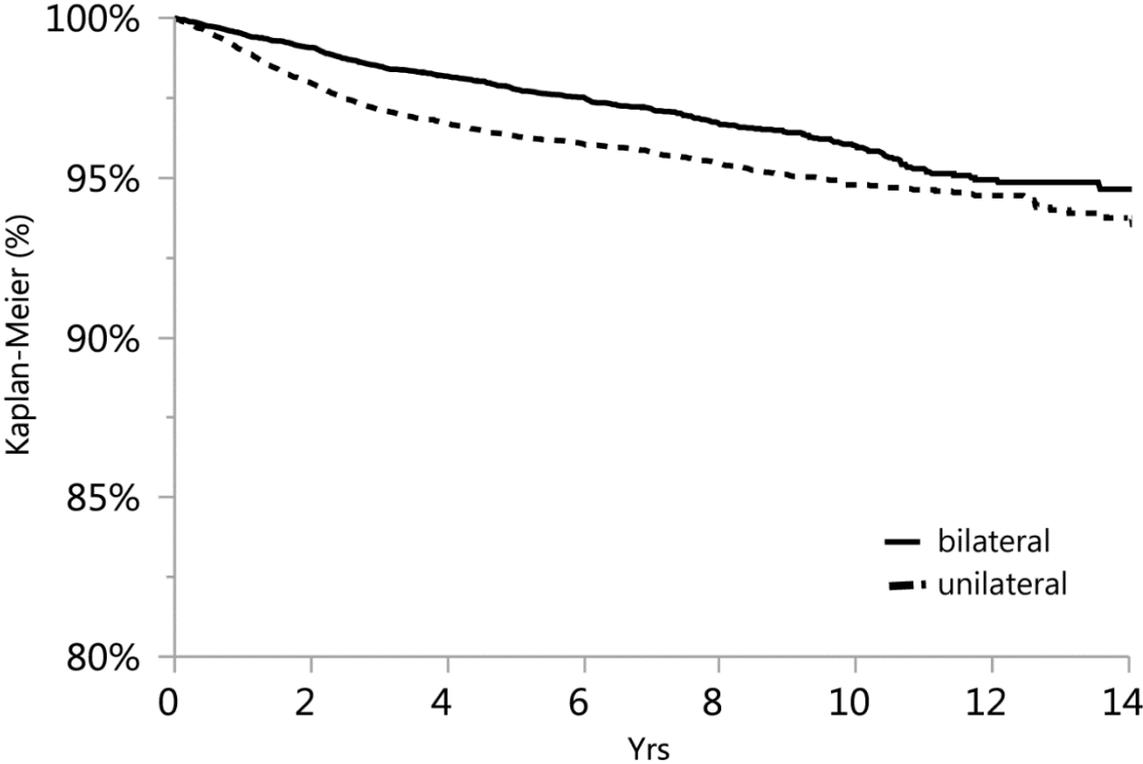


Figure 3. Kaplan Meier survival analyses of first and second knees of bilateral total knee arthroplasties were compared via a log rank test.

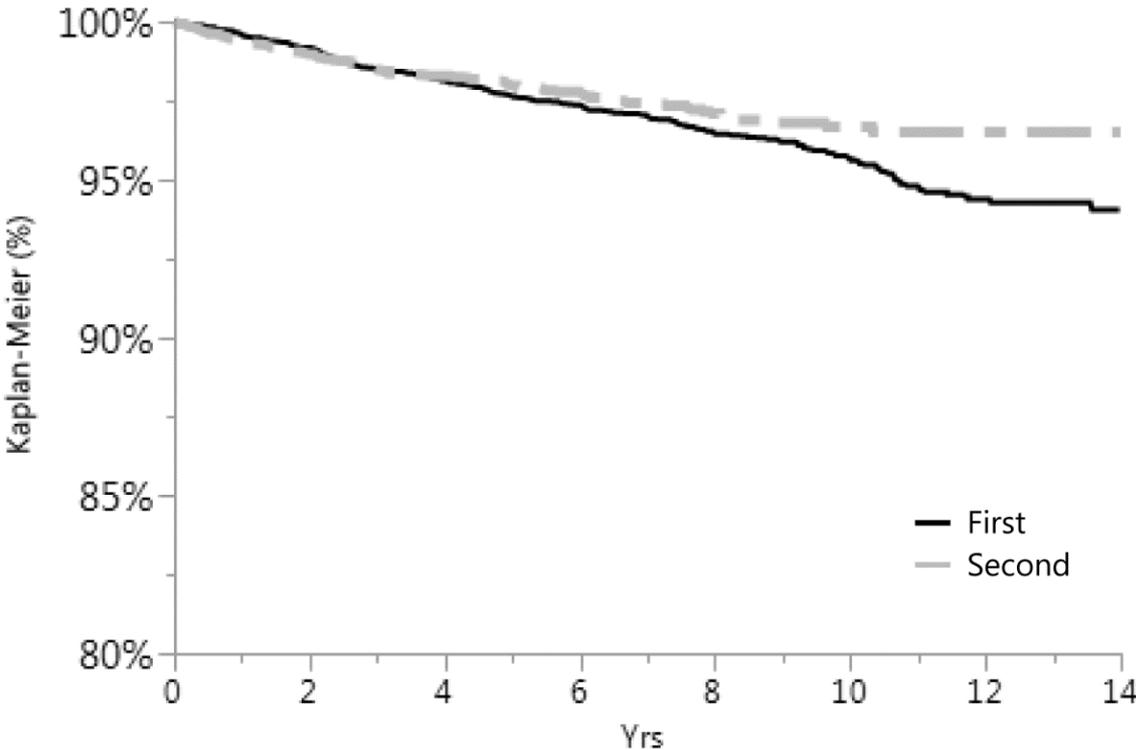


Figure 4. Kaplan-Meier survival of the first TKA, according to the duration between both arthroplasties, was compared with survival of the second TKA via a log-rank test.

