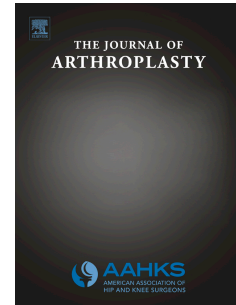


Accepted Manuscript

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PII: S0883-5403(18)30415-7

DOI: [10.1016/j.arth.2018.04.033](https://doi.org/10.1016/j.arth.2018.04.033)

Reference: YARTH 56597

To appear in: *The Journal of Arthroplasty*

Received Date: 2 March 2018

Revised Date: 17 April 2018

Accepted Date: 18 April 2018

Please cite this article as: Lizaur-Utrilla A, Serna-Berna R, Vizcaya-Moreno MF, Martinez-Mendez D, Marco-Gomez L, Lopez-Prats FA, Comparison of Functional Outcomes Between the First and Second Knee in Staged Bilateral Total Knee Arthroplasty with Diverse Intervals Between Stages, *The Journal of Arthroplasty* (2018), doi: 10.1016/j.arth.2018.04.033.

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COMPARISON OF FUNCTIONAL OUTCOMES BETWEEN THE FIRST AND SECOND KNEE IN STAGED BILATERAL TOTAL KNEE ARTHROPLASTY WITH DIVERSE INTERVALS BETWEEN STAGES

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1 **COMPARISON OF FUNCTIONAL OUTCOMES BETWEEN THE FIRST AND**
2 **SECOND KNEE IN STAGED BILATERAL TOTAL KNEE ARTHROPLASTY WITH**
3 **DIVERSE INTERVALS BETWEEN STAGES**

4

5 **ABSTRACT**

6 **Background:** To analyze if the length of interval time between stages influenced functional
7 and quality of life outcomes in patients with staged bilateral primary TKA.

8 **Methods:** Retrospective comparative study between 93 patients with an interval between
9 stages of 6-8 months (6-month group), 112 of 12-14 months (1-year group), and 108 of 24-26
10 months (2-year group). Outcome variables were Knee Society scores (KSS), Western Ontario
11 and McMaster Universities (WOMAC), Short-Form (SF12) and patient satisfaction.

12 **Results:** Overall, the mean follow-up for the first TKA was 8.2 (range, 7-10) years, and for
13 the second TKA 6.7 (range, 5-10) years. At last follow-up, functional and patient-related
14 outcomes were similar for both knees, regardless of the interval. However, mental score and
15 patient satisfaction were significantly better for the second than for the first TKA in the 2-year
16 group. Age did not correlate significantly with the functional scores but was significantly
17 correlated with the mental score.

18 **Conclusion:** The performing staged bilateral TKA with a wide interval between surgeries
19 provided equivalent functional outcomes and quality of life for both knees. Postoperative
20 outcomes were not affected by the length of the time interval between procedures or age. Our
21 results can help the surgeon to inform to the patients reliably about they can expect in the
22 delay of a second knee replaced. Thus patients could make an informed decision.

23 **Key words:** Total knee arthroplasty; Staged bilateral; Functional outcome; Quality of life;
24 Age

25

26 INTRODUCTION

27 Total knee arthroplasty (TKA) is an effective treatment to relieve pain and restore physical
28 functioning in patients with end-stage knee osteoarthritis [1]. Many patients with knee
29 osteoarthritis have bilateral symptoms [2], with a prevalence of severe bilateral involvement
30 as high as 19% [3]. In such patients, the surgeries can be performed either simultaneously or
31 in a staged operation with a variable length of time between each arthroplasty. However,
32 choosing between both bilateral procedures is controversial [4]. The decision to proceed with
33 bilateral surgery is made by the patient following discussion with the surgeon, on the basis of
34 the expectations, patient's physical condition and relative contraindications. Thus, many
35 elderly patients with bilateral osteoarthritis can decide to have TKA on the contralateral side
36 after the remission phase of the first stage [5]. Sesen et al [6] reported a refusal rate for the
37 second TKA of 37 %, and the patients older than 70 years had a higher refusal rate compared
38 to younger patients. On the other hand, many other patients present severe stage in one knee
39 but mild to moderate in the contralateral knee, which does not require surgery until after a
40 long time [7].

41 Many studies have been published on bilateral TKA, but most of them focused on
42 complications and socioeconomic implications of simultaneous versus staged TKA [8]. Some
43 others have compared overall functional outcomes between patient cohorts underwent these
44 bilateral procedures, although most of them involved relatively small cohorts of patients or
45 short follow-up [9,10]. However, studies comparing the functional outcomes of the first and
46 second knee in patients underwent staged bilateral procedures are few [9,11,12]. In addition,
47 the majority of patients included in those studies had an interval between stages less than 12
48 months, and follow-up was up to 1 year in all but one study [11]. Thus, although objective
49 outcomes for each knee may be reliable, quality of life outcomes for each knee may be
50 difficult to assess if the interval between surgeries was short. To our knowledge, no studies

51 had compared the functional and patient-reported outcomes between both knees in patients
52 underwent staged bilateral TKA with a relatively long time interval between stages and a
53 medium-term follow-up.

54 The aim of this study was to analyze if the length of interval time between stages influenced
55 functional and quality of life outcomes in patients with staged bilateral primary TKA.

56

57 **PATIENTS AND METHODS**

58 This was a retrospective cohort study of patients prospectively assessed. The study was
59 approved by our Institutional Review Board and informed consent was required for a new
60 evaluation. Patients who underwent bilateral TKA at our centre between 2006 and 2012 were
61 identified in our departmental arthroplasty database. This database prospectively collected
62 clinical and radiological data in a standardized manner with annual postoperative follow-up
63 for at least 5 years. TKA was recommended to patients who had radiologically Kellgren and
64 Lawrence grade III or IV knee osteoarthritis with related symptoms. In the case of bilateral
65 knee involvement, the first procedure was selected based on symptoms and patient preference,
66 and the time interval between stages was decided based on surgeon's recommendations and
67 patient preference. Simultaneous bilateral TKA was not performed at our centre.

68 Inclusion criteria were staged bilateral primary TKA, aged over 60 years, and minimum
69 postoperative follow-up of 5 years for each knee. Exclusion criteria were posttraumatic or
70 inflammatory arthritis, neurological disorder or need for constrained TKA in any knee. Like
71 other [12], because the objective was to compare functional and patient-related outcomes
72 between both knees, patients who had revision TKA were also excluded to limit outcome
73 bias.

74 There were 351 patients with staged bilateral TKA. Of these, 18 had surgical revision of one
75 knee and 20 other patients had one knee with follow-up less than 5 years. All these 38 patients

76 were excluded. The 313 remaining patients were classified into 3 groups according to the
77 interval time between stages. There were 93 patients with an interval between 6 and 8 months
78 (6-month group), 112 between 12 and 14 months (1-year group), and 108 between 24 and 26
79 months (2-year group). Baseline characteristics of each group are shown in Table 1.

80

81 **Surgical protocol**

82 Surgeries were performed by several consultant surgeons, although the same surgeon operated
83 both knees for the same patient. In addition, all procedures were standardized at our centre
84 and the same surgical techniques and postoperative protocols were used for both knees of all
85 patients. All surgeries were performed in operating room with laminar flow, under spinal
86 anaesthesia. A standard anterior midline skin incision and medial parapatellar arthrotomy
87 were used in all patients. Standard operative techniques with intramedullar alignments for
88 femur and tibia were used for all patients. The same modular TKA systems were used in all
89 patients (Trekking, Samo, Italy). Fixation was hybrid (cementless femur and cemented tibia).
90 Depending on the ligament balance at the time of surgery, a cruciate-retaining (CR) or
91 posterior-stabilized (PS) model was used. All patellae were routinely resurfaced with an all-
92 polyethylene cemented design.

93 According to the standard protocol, all patients received antibiotic prophylaxis with first
94 generation cephalosporin for 24 hours (started 1 hour prior to skin incision) and
95 thromboembolic prophylaxis with low-molecular-weight heparin for 30 days. Standardized at
96 our centre, continuous passive knee motion started on the first postoperative day and from the
97 third day active motion under the supervision of the therapist and full weight-bearing were
98 allowed.

99

100 **Evaluations**

101 All patients had been prospectively assessed, clinical and radiologically, preoperatively and
102 postoperatively at each annual visit. Functional assessment was assessed by the Knee Society
103 scores (KSS) [13], and patient-reported outcomes with the Western Ontario and McMaster
104 Universities (WOMAC) [14] and Short-Form (SF12) [15] questionnaires validated for our
105 country. The WOMAC score was transformed to a 0-100 scale, so a higher value implies a
106 better outcome, and the result was shown overall for pain and function. Patient satisfaction for
107 each knee was measured at the time of the latest follow-up with a 0-10 visual analogue scale
108 (VAS). Comorbidity was assessed by the American Society of Anesthesiologists (ASA)
109 scores [16].

110 Radiological evaluation was performed using standing anteroposterior, lateral and standard
111 skyline views. The latest radiographs were assessed for presence and location of radiolucent
112 lines on the basis of Knee Society zones [17].

113

114 **Statistical analysis**

115 A posteriori analysis of statistical power was performed with a non-inferiority test.
116 Considering our sample size, a minimal clinically important difference [18] of 10 with
117 standard deviation of 10 for the physical component summary of SF12, and alpha
118 error of 0.05 %, the study had a power of 84%, which was considered appropriate.

119 Statistical analyses were performed with SPSS software v. 15.0 (SPSS Inc., Chicago, USA).
120 Normal distribution was determined by the Kolmogorov-Smirnov test. For paired comparison
121 between pre- and post-operative and between first and second knees data, the McNemar test
122 was used in categorical variables, and the paired t-test or non-parametric Wilcoxon signed-
123 rank test in continuous variables. Variance analysis (Anova) was use for comparison between
124 groups. Correlations were made by the Pearson coefficient test. Statistical significance was
125 considered for p values less than 0.05.

126

127 **RESULTS**

128 Overall, the mean follow-up for the first staged TKA was 8.2 (range, 7-10) years, and for the
129 second TKA 6.7 (range, 5-10) years. All the knees of each group improved significantly from
130 preoperative to the last follow-up.

131 In 6-month and 1-year groups (Table 2), there were no significant differences in objective or
132 patient-related scores between the first and second knee (all, $p < 0.05$). In 2-year group, there
133 were no significant differences in KSS scores, ROM, WOMAC or SF12-physical scores (all,
134 $p < 0.05$), but SF12-mental score was significantly higher in the second knee compared to the
135 first knee ($p = 0.041$).

136 Comparing the three groups (Table 2), there were no significant differences between the first
137 knees or the second knees in any score, except in patient satisfaction. Regarding patient
138 satisfaction at the last follow-up for each knee (Table 2), there was no significant difference
139 between the first and second knee in the 6-month group ($p = 0.411$) and 1-year group ($p =$
140 0.055). However, patient satisfaction was significantly higher in the second knee compared to
141 the first knee ($p = 0.012$). Comparing the three groups, there was no significant difference in
142 patient satisfaction for the first knee ($p = 0.454$). However, although for the second knee there
143 were no significant differences between 1-month and 1-year groups ($p = 0.181$) or between 1-
144 year and 2-year groups ($p = 0.140$), patient satisfaction was significantly higher for the second
145 knee in the 2-year group compared with the 6-month group ($p = 0.030$). Comparing TKA
146 types, CR or PS, there were no significant differences in satisfaction ($p = 0.732$).

147 Regarding the second staged TKA, the interval time between stages did not influence the
148 KSS-knee ($r = 0.4$, $p = 0.425$) or KSS-function ($r = 0.5$, $p = 0.237$) score at the last follow-up.

149 At the last follow-up, there were no significant differences between the TKA types (CR
150 versus PS) in KSS-knee ($p = 0.612$), KSS-function ($p = 0.497$), ROM ($p = 0.116$), WOMAC

151 (p= 0.197) or SF12 (p= 0.392). Likewise, the age at the time of the first TKA did not correlate
152 significantly with the KSS-function (r= 0.7, p= 0.317), WOMAC-function (r= -0.3, p= 0.637)
153 or SF12-physical (r= -0.4, p= 0.086) scores at the last follow-up in either the first or second
154 staged TKA. However, the age at the time of the second TKA was significantly correlated
155 with SF12-mental score at the last follow-up in the 2-year group (r= -0.6, p= 0.040).

156

157 **DISCUSSION**

158 The main finding of the present study was that functional and quality of life scores were not
159 significantly different between the first and second knee in any time interval. However,
160 mental score and patient satisfaction were significantly better for the second than for the first
161 TKA in the 2-year group but not in shorter intervals. Likewise, patient satisfaction for the
162 second knee was significantly higher in the 2-year group compared to 6-month group. Age at
163 the time of the first TKA did not correlate significantly with the functional scores for the
164 second knee, but was significantly correlated with the mental score.

165 Like us, Gabr et al [19] found similar KSS, WOMAC and SF12-physical scores between
166 knees at the last follow-up, and better SF12-mental score for the second knee compared to the
167 first. Other studies reported no significant differences between both knees at the last follow-
168 up [9,11]. Like us, Scott et al [20] found higher satisfaction for the second TKA.

169 Many patients have bilateral symptomatic knee osteoarthritis [21]. For these patients,
170 simultaneously or staged bilateral TKA has been proposed. However, the reported results
171 have been conflicting, such as similar [23,24], better [10], or worse [25] outcomes with
172 simultaneous TKA compared to staged bilateral TKA. Moreover, it has been reported that
173 patients undergoing bilateral simultaneous TKA tend to be younger and have better health
174 status [3,26]. The decision to proceed with simultaneous or staged bilateral surgery must be
175 done by the patient after receiving information from the surgeon, and it based on the physical

176 condition and expectations of the patient. Sesen et al [6] reported that 37% of patients refused
177 the second TKA, especially patients older than 70 years. On the other hand, many other
178 patients with unilateral TKA present only mild to moderate symptoms in the contralateral
179 knee that does not require surgery in that time [7]. Subsequent arthroplasty of the contralateral
180 knee following unilateral TKA has been reported in 36% of patients [27,28] with a wide
181 interval between surgeries [29]. Thiam et al [30] reported that not all patients with bilateral
182 knee osteoarthritis accepted bilateral TKA because unilateral TKA could restore quality of
183 life. These authors found also that 28% of patients with bilateral knee osteoarthritis did not
184 return for the second TKA within 2 years. Moreover, the patient's experience with the first
185 TKA has shown to have influence on the decision for contralateral surgery [5].

186 Some authors [5,19] have reported higher patient expectation for the second than for the first
187 TKA. Gabr et al [20] found improved function and psychological well-being after the second
188 surgery. Becker et al [31] reported that patient satisfaction was correlated with the functional
189 outcomes, and the indication for TKA should consider the general health and emotional role
190 in order to predict patient's outcome.

191 Time interval between surgeries did not influence the results in our study. A recent national
192 database study [26] reported a ratio of simultaneous to staged bilateral TKA of 1:4, and 94%
193 of staged bilateral TKA, and other recent study [32] found no significant differences in
194 functional outcomes or complication rate between surgery interval from 3 months to 1 year.
195 Moreover, many patients decide to have TKA on the contralateral side after the remission
196 phase of the first stage [5]. A study [33] of patients with unilateral TKA reported that the
197 nonoperated limb tended to weaken after 2 years of surgery, possibly representing changes
198 resulting from aging and progression of osteoarthrosis in some patients with unilateral TKA.
199 In the present study, age did not influence outcomes. Abram et al [9] also reported that age
200 did not affect the postoperative score in either the first or second staged TKA.

201 Strengths of the present study included the analysis of a single-centre with standardized
202 surgical and postoperative management. The size of our samples provided adequate statistical
203 power to detect significant differences. To our knowledge, this was the first study comparing
204 diverse intervals between TKA. In addition, this study had the longest follow-up published to
205 date comparing both knees. However, this study has also several limitations. Firstly, the study
206 was retrospective. Nevertheless, the data had been collected prospectively in a systematic and
207 standardized way, so the number of variables of interest was not limited. The cohort consisted
208 in selected patients due to the exclusion of those who need revision TKA. This was done in an
209 effort to minimize variables within the study population and thereby enhance the isolation of
210 knee outcome parameters. We believe that this fact enhanced the obtained comparative
211 results. In a study such as this, the patients compared themselves in the first and second knee.
212 Therefore, the patients could have difficulty discerning which of the two knees had a greater
213 or lesser effect on their quality of life.

214

215 **CONCLUSION**

216 This study suggested that performing staged bilateral TKA with a wide interval between
217 surgeries provided equivalent functional outcomes and quality of life for both knees.
218 Postoperative functional outcomes and quality of life were not affected by the length of the
219 time interval between procedures or age. Our results can help the surgeon to inform to the
220 patients reliably about they can expect in the delay of a second knee replaced. Thus patients
221 could make an informed decision.

222

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311

312

313 **Table 1.** Preoperative data at the time of each surgery

	6-month group n= 93	1-year group n= 112	2-year group n= 108	p-value
Gender, F/M	69/24	79/33	77/31	0.833
ASA, I-II/III-IV	71/22	81/31	74/34	0.467
BMI, kg/m ²				
1 st knee	31.2 (5.9)	30.9 (6.3)	30.6 (6.7)	0.798
2 nd knee	30.4 (6.1)	31.4 (6.4)	31.7 (5.8)	0.296
p-value	0.364	0.556	0.197	
ROM, degrees				
1 st knee	88.4 (11.3)	89.2 (10.8)	89.8 (10.6)	0.661
2 nd knee	89.9 (12.1)	90.4 (12.6)	91.2 (11.3)	0.739
p-value	0.383	0.445	0.348	
KSS-knee score				
1 st knee	39.4 (13.7)	40.4 (13.3)	41.8 (14.4)	0.463
2 nd knee	41.2 (14.3)	42.3 (15.1)	44.3 (13.8)	0.299
p-value	0.379	0.318	0.194	
KSS-function score				
1 st knee	40.8 (12.7)	41.7 (12.8)	42.9 (13.8)	0.522
2 nd knee	43.5 (13.2)	42.8 (13.6)	45.5 (12.7)	0.294
p-value	0.156	0.533	0.151	
WOMAC				
1 st knee	40.3 (10.1)	41.2 (9.9)	41.7 (9.6)	0.599
2 nd knee	42.4 (11.2)	42.9 (11.7)	43.8 (12.4)	0.692
p-value	0.181	0.241	0.165	
SF12-physical				
1 st knee	29.7 (8.3)	31.1 (8.4)	30.4 (7.8)	0.473
2 nd knee	31.3 (10.1)	33.3 (10.3)	34.6 (9.4)	0.064
p-value	0.239	0.081	0.001	
SF12-mental				
1 st knee	36.4 (12.6)	36.9 (10.7)	38.4 (9.4)	0.390
2 nd knee	38.7 (10.3)	39.3 (10.1)	41.3 (9.6)	0.148
p-value	0.174	0.085	0.025	

314 Continuous data as mean (SD).

315

316

317

318

319 **Table 2.** Outcomes for both TKA

320

	6-month group	1-year group	2-year group	p-value
KSS-knee				
1 st knee	86.1 (7.1)	87.0 (7.9)	85.9 (7.1)	0.504
2 nd knee	86.7 (8.2)	85.9 (9.1)	86.2 (6.4)	0.773
p-value	0.594	0.335	0.744	
KSS-function				
1 st knee	86.3 (8.2)	86.9 (8.4)	85.6 (9.7)	0.773
2 nd knee	87.0 (9.1)	88.1 (9.8)	87.3 (7.9)	0.656
p-value	0.582	0.326	0.159	
ROM				
1 st knee	102.6 (9.8)	104.7 (11.1)	101.8 (10.6)	0.112
2 nd knee	105.5 (10.3)	102.9 (10.0)	104.1 (11.7)	0.224
p-value	0.051	0.203	0.131	
WOMAC				
1 st knee	82.5 (11.2)	86.2 (12.4)	83.4 (13.5)	0.081
2 nd knee	84.3 (12.3)	87.1 (10.9)	85.1 (12.9)	0.123
p-value	0.298	0.564	0.345	
SF12-physical				
1 st knee	43.9 (9.4)	44.2 (9.1)	43.8 (8.7)	0.943
2 nd knee	44.6 (8.8)	45.7 (9.4)	44.3 (8.6)	0.477
p-value	0.601	0.226	0.671	
SF12-mental				
1 st knee	44.3 (10.2)	44.8 (10.3)	45.1 (9.5)	0.850
2 nd knee	45.6 (10.6)	46.4 (9.8)	47.6 (8.4)	0.329
p-value	0.395	0.234	0.041	
Satisfaction				
1 st knee	7.3 (1.5)	7.0 (1.7)	7.1 (1.9)	0.454
2 nd knee	7.1 (1.8)	7.4 (1.4)	7.7 (1.6)	0.030
p-value	0.411	0.055	0.012	

321 Data as mean (SD)

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