

# Total knee arthroplasty status and patient-reported, knee-related quality of life over a 4-year follow-up period: data from the osteoarthritis initiative

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**Purpose:** To examine the relationship between baseline total knee arthroplasty (TKA) status and patient-reported, knee-related quality of life (QoL) over a 4-year follow-up relative to no knee osteoarthritis (OA).

**Patients and methods:** Data from the Osteoarthritis Initiative were included, comprising 4,674 adults aged 45–79 years at baseline. Patients were categorized into four groups: no knee OA ( $n=3,711$ ), non-TKA ( $n=902$ ), pre-TKA ( $n=36$ ), and post-TKA ( $n=25$ ). QoL was measured using the Knee Injury Osteoarthritis Outcome Score-QoL subscale. General linear mixed models were used for the relationship between TKA and QoL.

**Results:** After adjusting for covariates, a reduced QoL was noted for patients in the non-TKA (mean [standard error],  $-13.97$  [0.73];  $P<0.0001$ ), pre-TKA ( $-21.34$  [3.57];  $P<0.0001$ ), and post-TKA ( $-9.68$  [3.94];  $P=0.0143$ ) groups compared with the no knee OA group. QoL in the non-TKA group also decreased over time ( $-0.16$  [0.07];  $P=0.226$ ).

**Conclusion:** Non-, pre-, and post-TKA status is associated with a lower QoL.

**Keywords:** arthroplasty, osteoarthritis, quality of life, knee

## Introduction

Total knee arthroplasty (TKA) is a surgical procedure, with excellent survival rates of 15–20 years routinely reported.<sup>1</sup> TKA has revolutionized the quality of life (QoL) of millions of patients and has proven to be a cost-effective and reliable treatment for knee osteoarthritis (OA).<sup>2,3</sup> Although most patients treated with TKA report decreased pain and improved function, nearly one in five patients report a reduced QoL,<sup>4,5</sup> the reasons for which are not well documented in the literature.<sup>5,6</sup>

Knee-related QoL after TKA is determined using patient-reported outcomes and clinician assessments.<sup>7,8</sup> Patient-reported outcomes are frequently used in clinical research<sup>9</sup> and routinely in health care<sup>10</sup> for evaluating QoL following TKA.<sup>11</sup> Among the few disease-specific, patient-reported outcome instruments, the Knee Injury and Osteoarthritis Outcome Score-QoL (KOOS-QoL) subscale measures QoL in patients with knee OA,<sup>12,13</sup> evaluating knee-specific mental and social aspects of knee symptoms that impact on patient QoL.<sup>14</sup> The KOOS-QoL subscale is regarded as the most reliable and valid patient-reported outcome instrument that considers QoL after TKA.<sup>14,15</sup> A recently published prospective cohort study evaluated the change in QoL after TKA according to patient-reported outcomes,<sup>8</sup> and found that patients generally reported improved QoL at 1 year after TKA.

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No previous studies have examined the patient-reported QoL over a 4-year follow-up in patients grouped according to their TKA and OA status. Therefore, the purpose of this study was to examine the relationship between baseline TKA status and patient-reported QoL over a 4-year follow-up period and to compare QoL with patients with no knee OA. It was hypothesized that treatment with TKA would reduce the patient-reported decline in QoL in patients with OA over a 4-year follow-up period.

## Patients and methods

In this 4-year longitudinal study, data were obtained from the Osteoarthritis Initiative (OAI). The specific datasets used correspond to version numbers: 0.2.2, 1.2.1, 3.2.1, 5.2.1, and 6.2.1. The OAI is a publicly and privately funded, multicenter, ongoing prospective cohort study. The OAI recruited and enrolled men and women (N=4,796) across four clinical centers (Baltimore, MA; Columbus, OH; Pittsburgh, PA; and Pawtucket, RI) in the United States from February 2004 to May 2006. A detailed description of the OAI objectives and protocol are available freely.<sup>26</sup> OAI recruited two primary subcohorts: 1) progression subcohort, consisting of 1,390 participants with symptomatic tibiofemoral knee OA in at least one primary knee at baseline; 2) incidence subcohort, consisting of 3,284 participants with an elevated risk of developing symptomatic knee OA during the study.

Of the 4,796 participants, 4,674 participants were included aged between 45 and 79 years at baseline. Participants (n=122) who had no pain, aching, or stiffness; no radiographic findings of OA, and no eligibility risk factors in either knee in the past year were excluded from the analyses. All 4,674 participants at baseline were categorized into the following four groups, according to TKA or OA status, as confirmed by baseline X-ray: no knee OA (n=3,711), non-TKA (n=902), pre-TKA (n=36), and post-TKA (n=25). There were no drop-outs over the 4-year study period. Participants in the “no OA knee” group were those who, at baseline, had no symptomatic tibiofemoral knee OA in either knee. Participants in the non-TKA group were those who showed symptomatic tibiofemoral knee OA in either knee who were not considering (and did not receive) surgical intervention but were treated conservatively over the 4 years. Participants categorized as pre-TKA were those with OA in either knee considering TKA in the next 3 years, whereas those categorized as post-TKA were participants who had been treated with TKA in either knee.

The KOOS was developed to evaluate patients' opinions about their knees and associated problems,<sup>14</sup> and it comprises 42 items across 5 subscales: 1) pain, 2) other symptoms, 3) activities of daily living, 4) function in sport and recreation, and 5) knee-related QoL.<sup>16</sup> The KOOS-QoL subscale is used to assess patient-reported QoL<sup>17</sup> and comprises 4 items: 1) how often is the patient aware of their knee problem, 2) does the patient avoid potentially damaging activities, 3) how much is the patient troubled by the lack of confidence in their knee, and 4) how much difficulty does the patient have with their knee.<sup>14</sup> Scores are given for every item in the subscale using a Likert scale, ranging from 0 (no problem) to 4 (extreme problems). A QoL score is then calculated by summing the item scores and the data transformed to a 0–100 scale, with zero representing extreme knee problems (low QoL) and 100 representing no knee problem (high QoL).

## Statistical analysis

The descriptive statistics are summarized using the mean and standard deviation (SD) for continuous variables and count (percentage) for categorical variables. Pearson's  $\chi^2$ , analysis of variance, or post hoc Tukey tests were used to examine the distribution of covariates for participants by their TKA/OA status at baseline. General linear mixed models using the MIXED procedure were used to examine the patient-reported QoL (KOOS-QoL) over the 4-year period according to the participants TKA/OA status at baseline. We used autoregressive covariance matrices; this method uses all possible data for each subject and supports the use of realistic variance and correlation patterns.<sup>18</sup>

Two mixed models were constructed to examine the relationship between TKA/OA status and change in QoL over the 4-year period. Model 1 included group, time, age, sex, race, marital status, education, annual income, and health care coverage. Model 2 included all of the variables in Model 1 plus depressive symptoms, Physical Activity Scale for Elderly (PASE), body mass index (BMI), and comorbidities. Both models used an interaction term between non-, pre-, and post-TKA and time.

The two mixed models provided estimates of the least-squares means (standard error [SE]) at each time point (baseline, 1-, 2-, 3-, and 4-years). Model 1 included the interactions with time, age, sex, race, marital status, education, annual income, and health care coverage. Model 2 incorporated all of the variables in Model 1 plus interaction with time, depressive symptoms, PASE, BMI, and comorbidities. The primary purpose of including a covariate in the analysis was to ascertain a high or modest relationship between the covariate and the outcome

measure, as suggested in the literature.<sup>19</sup> All examinations were performed using the statistical analysis software (SAS)<sup>20</sup> for Windows, version 9.2 (SAS Institute, Inc., Cary, NC, USA).

## Results

Of the 4,796 participants at baseline, 4,674 participants were included in the current study. Among these 4,674 participants, 3,711 participants had no knee OA (79%), 902 had OA treated as non-TKA (19%), 36 were treated as pre-TKA (1.5%), and 25 had been treated with TKA and were treated as post-TKA (0.5%). The number of participants in each group was the same over the 4-year period (Figure 1).

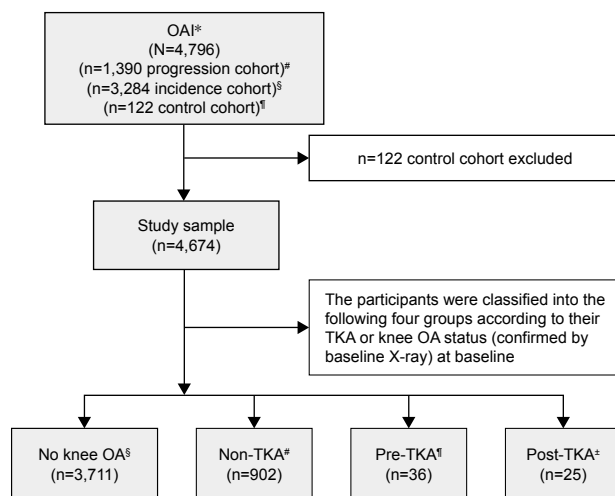
The mean age of the 4,676 participants was  $63.0 \pm 8.8$  years at baseline. Most were female (54%), white, or Caucasian (75%), had more than a high school-level education (79%), and had health care coverage (93%). The mean BMI score was  $30.0 \pm 5.0$ , the mean PASE score was  $144.0 \pm 81.4$ , and the mean KOOS-QoL score was  $57.0 \pm 24.3$ . Table 1 presents the baseline descriptive characteristics of the sample by TKA/OA status. The mean KOOS-QoL scores were  $69.7 \pm 28.3$  for participants in the no knee OA group,  $52.3 \pm 19.7$  for the non-TKA group,  $39.0 \pm 22.9$  for the pre-TKA group, and  $66.0 \pm 26.6$  for the post-TKA group. Participants in the post-TKA group were significantly older than the other 3 groups (by 9 years) and had a lower average PASE score ( $121.1 \pm 70.4$ ). Participants in the pre-TKA group were

significantly younger, had less annual income (41%), high comorbidities, and high mean BMI ( $31.5 \pm 5.9$ ). Participants in the no knee OA group and non-TKA group had the same average age (61 years) and PASE score ( $161.0 \pm 83.3$ ).

Table 2 shows the general linear mixed models estimates for the KOOS-QoL subscale scores over the 4-year period by TKA/OA status at baseline. The adjusted rate of decline for the KOOS-QoL subscale score was 0.38 per year. After adjusting for age, sex, race, marital status, education, annual income, health care coverage, and time (Model 1), a significant decrease in the KOOS-QoL subscale scores for the non-TKA group (mean [SE],  $-14.28 [0.74]$ ;  $P < 0.0001$ ), the pre-TKA group ( $-21.50 [3.41]$ ;  $P < 0.0001$ ), and post-TKA group ( $-9.42 [3.91]$ ;  $P = 0.0161$ ) were found as compared with the no knee OA group. Considering the interaction term between non-, pre-, and post-TKA and time of follow-up (slope of KOOS-QoL subscale score over 4 years), a significant decline in the KOOS-QoL subscale scores for the non-TKA group ( $-0.15 [0.07]$ ;  $P = 0.0302$ ) was found.

In Model 2, after controlling for depressive symptoms, PASE, BMI, and comorbidities, together with the variables in Model 1, the non-TKA group ( $-13.97 [0.73]$ ;  $P < 0.0001$ ), pre-TKA group (Estimate =  $-21.34 [3.57]$ ;  $P < 0.0001$ ), and post-TKA group ( $-9.68 [3.94]$ ;  $P = 0.0143$ ) all remained significantly associated with a decreased KOOS-QoL subscale score. The interaction between the non-TKA group and time also remained significantly associated with a decreasing KOOS-QoL subscale score ( $-0.15 [0.07]$ ;  $P = 0.0226$ ) over the 4-year period.

Figure 2 shows the KOOS-QoL subscale mean scores over the 4-year period by TKA/OA status at baseline. Compared with the no knee OA group, the pre-TKA group had the worst QoL, followed by the non-TKA group and the post-TKA group. There was a significant interaction effect between time and QoL among the four groups (no knee OA, non-, pre-, and post-TKA), even after adjusting for the covariates ( $F = 45.5$ ,  $df = 19$ ,  $P < 0.0001$ ). Moreover, although the post-TKA group showed better QoL over the 4-year follow-up period, this group also showed a decline in QoL scores after 2-year follow-up.



**Figure 1** Flow of the study sample.

**Notes:** \*The Osteoarthritis Initiative Study has made large, heterogeneous datasets available for public use.<sup>26</sup> <sup>#</sup>Participants with symptomatic tibiofemoral knee OA at baseline. <sup>§</sup>Participants with no symptomatic tibiofemoral OA in either knee at baseline. <sup>¶</sup>Participants with no pain, aching, or stiffness in either knee in the past year; no radiographic findings of OA; and no eligibility risk factors. <sup>+</sup>Participants considering, for either knee, knee replacement surgery in the next 3 years. <sup>+</sup>Participants, for either knee, had undergone TKA at baseline, confirmed by baseline X-ray.

**Abbreviations:** TKA, total knee arthroplasty; OA, osteoarthritis; OAI, Osteoarthritis Initiative.

## Discussion

The relationship between TKA/OA status at baseline and QoL over a 4-year follow-up period and were examined and compared to participants with no knee OA. The rate of decline in the KOOS-QoL score was 0.38 points per year over the 4-year period, after controlling for all covariates. We found that participants in the non-, pre-, and post-TKA

**Table 1** Baseline descriptive characteristics of the sample, n=4,674

Variables	No knee OA N=3,711 (79%)	Non-TKA N=902 (19%)	Pre-TKA N=36 (1.5%)	Post-TKA N=25 (0.5%)	P-value
Age in years	61.2±9.1	61.4±9.2	60.0±9.7	69.8±7.1	<0.0001
Gender					0.0385
Male	1,505 (41)	411 (46)	17 (47)	12 (48)	
Female	2,206 (59)	491 (54)	19 (53)	13 (52)	
Race					<0.0001
White or Caucasians	2,959 (80)	676 (75)	18 (50)	24 (96)	
African American/Asian/non-whites	752 (20)	226 (25)	18 (50)	1 (4)	
Education					0.0303
High school or less	588 (16)	166 (18)	11 (31)	5 (20)	
More than high school	3,123 (84)	736 (82)	25 (69)	20 (80)	
Marital status					0.0115
Married	2,444 (66)	305 (34)	20 (56)	4 (16)	
Unmarried/divorced/widow	1,267 (34)	597 (66)	16 (44)	21 (84)	
Income per year in US dollars					<0.0001
<50,000	1,358 (37)	362 (40)	27 (75)	11 (44)	
>50,000	2,353 (63)	540 (60)	9 (25)	14 (56)	
Health care coverage					0.0189
Yes	3,553 (96)	852 (94)	31 (86)	24 (96)	
No	158 (4)	50 (6)	5 (14)	1 (4)	
Charlson comorbidity index					<0.0001
0	2,800 (84)	621 (79)	16 (59)	16 (84)	
>1	538 (16)	167 (21)	11 (41)	3 (16)	
Depressive symptoms					<0.0001
CESD <16	3,366 (91)	786 (87)	24 (67)	22 (88)	
CESD >16	345 (9)	116 (13)	12 (33)	3 (12)	
BMI, kg/m <sup>2</sup>	28.4±4.8	29.8±4.8	31.5±5.9	29.9±4.5	<0.0001
PASE	160.7±82.4	161.0±83.3	134.9±89.5	121.1±70.4	<0.0001
KOOS-QoL	69.7±28.3	52.3±19.7	39.0±22.9	66.0±26.6	<0.0001

**Note:** Values are presented as mean ± SD or n (%).

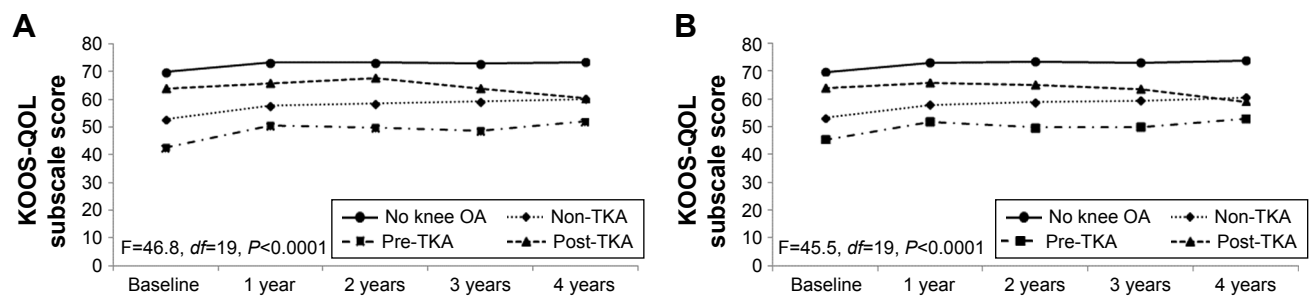
**Abbreviations:** BMI, body mass index; CESD, Center for Epidemiologic Studies Depression Scale; KOOS-QoL, Knee Injury and Osteoarthritis Outcome Score-Quality of Life subscale; OA, osteoarthritis; PASE, Physical Activity Scale for Elderly; SD, standard deviation; TKA, total knee arthroplasty.

**Table 2** General linear mixed model estimates for the KOOS-QoL subscale score over a 4-year period by TKA or knee OA status at baseline, n=4,674

Predictor variables	Model 1 estimate (SE)	P-value	Model 2 estimate (SE)	P-value
Intercept	51.22 (2.83)	<0.0001	61.74 (2.95)	<0.0001
Time	-0.38 (0.03)	<0.0001	-0.38 (0.03)	<0.0001
Main effect				
No knee OA	Reference		Reference	
Non-TKA	-14.28 (0.74)	<0.0001	-13.97 (0.73)	<0.0001
Pre-TKA	-21.50 (3.41)	<0.0001	-21.34 (3.57)	<0.0001
Post-TKA	-9.42 (3.91)	0.0161	-9.68 (3.94)	0.0143
Interaction with time				
No knee OA × Time	Reference		Reference	
Non-TKA × Time	-0.15 (0.07)	0.0302	-0.16 (0.07)	0.0226
Pre-TKA × Time	-0.50 (0.31)	0.1107	-0.25 (0.34)	0.4561
Post-TKA × Time	0.16 (0.36)	0.6626	0.15 (0.37)	0.6821

**Notes:** Model 1: Adjusted for time, age, sex, race, marital status, education, annual income, and health care coverage. Model 2: Adjusted for depressive symptoms, PASE, BMI, comorbidities along with variables in Model 1.

**Abbreviations:** BMI, body mass index; KOOS-QoL, Knee Injury and Osteoarthritis Outcome Score-Quality of Life subscale; OA, osteoarthritis; PASE, Physical Activity Scale for Elderly; SE, standard error; TKA, total knee arthroplasty.



**Figure 2** Means for the KOOS-QoL subscale score over a 4-year period, by TKA or knee OA status at baseline,  $n=4,674$ .

**Notes:** (A) Adjusted for sociodemographic variables. (B) Adjusted for sociodemographic and health variables.

**Abbreviations:** CG, ; KOOS-QoL, Knee Injury and Osteoarthritis Outcome Score-Quality of Life subscale; OA, osteoarthritis; TKA, total knee arthroplasty.

groups at baseline were associated with decreased QoL as compared with the no knee OA group, even after controlling for all covariates. The association was robust for the non- and pre-TKA groups. We also found an association between the non-TKA group and time, even after controlling for all covariates.

We found that the non- and pre-TKA groups were associated with greater decreases in the KOOS-QoL subscale scores. Interestingly, the KOOS-QoL subscale score in the non-TKA group significantly declined over the 4-year follow-up period. Comparatively, after adjusting for socio-demographic and health covariates, the post-TKA group had a lower decrease in the KOOS-QoL subscale score than the non- and pre-TKA groups. This confirmed the hypothesis that TKA would minimize the decline in patient-reported QoL over the 4-year follow-up period.

Participants in the post-TKA group were, on average, 9 years older than participants in the other groups, and had lower levels of physical activity. Intriguingly, these participants also showed a decline in the mean KOOS-QoL subscale scores after the 2-year follow-up period. The reasons for this decline in QoL after the 2-year mark are not well understood. Two recent papers found no association among age, physical activity, and KOOS-QoL scores.<sup>21,22</sup>

The current results are in line with other previously published studies.<sup>8,17,23,24</sup> For example, KOOS was used a primary outcome measure in a single-center, randomized, double-blind study of 129 knees in 115 patients, where functional outcomes pre- and post-TKA (1- and 3-year follow-up) were measured. In that study, the average patient age was 70 years, and 67 (58.3%) participants were female. The authors found a statistically significant association between the mean subscores (pain, symptoms, sport/recreation, and QoL) for the KOOS and TKA.

## Strengths and limitations

The present study has several strengths. First, data from a multicenter, ongoing, prospective cohort study were

used. Second, patient-reported QoL was examined using the KOOS-QoL subscale, which is a more contemporary outcome measure developed for more active patients.<sup>14</sup> Third, patient-reported QoL over the 4-year follow-up period was examined in a well-defined community sample, who were grouped according to their TKA/OA status. Fourth, there were no dropouts, and data from the no knee OA group were used as a comparison. Finally, time-dependent effects were determined using a mixed models analysis.

However, the study has some limitations. First, the measure of QoL was self-reported, and QoL may have different meanings for different participants. Second, there was a lack of information regarding biomarkers, knee muscle strength, or knee flexion ranges of the participants, and no data pertaining to surgical procedure or techniques used to manage the condition during the study period.<sup>25</sup> Third, most of the participants were Caucasian; thus, it may not be relevant to extrapolate the results of this study to describe other races. Finally, because the number of participants in TKA groups falls below the number of participants in the other groups, limited statistical power due to small sample size should be considered when interpreting the findings.

## Conclusion

The present study is the first aimed at examining the relationship between TKA/OA status at baseline and QoL over a 4-year follow-up period, with the data compared to participants with no knee OA. The results of this study indicate that participants with a non-, pre-, or post-TKA status were all associated with a lower QoL. However, this association changed longitudinally in the non-TKA group. The slopes related to the data changed in all groups over the 4-year follow-up. Future studies are needed to understand the factors that influence QoL over time, particularly after TKA.

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## Disclosure

The author reports no conflicts of interest in this work.

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