Osteoarthritis and Cartilage (2009) **17,** 601–606

doi:10.1016/j.joca.2008.11.007

Osteoarthritis and Cartilage

International Cartilage Repair Society

OARSI OSTEOARTHRITIS RESEARCH SOCIETY INTERNATIONAL

A 5 year prospective study of patient-relevant outcomes after total knee replacement

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Summary

Objective: To prospectively describe self-reported outcomes up to 5 years after total knee replacement (TKR) in Osteoarthritis (OA) and to study which patient-relevant factors may predict outcomes for pain and physical function (PF).

Methods: 102 consecutive patients with knee OA, 63 women and 39 men, mean age 71 (51–86) assigned for TKR at the Department of Orthopaedics at Lund University Hospital were included in the study. The self-administered questionnaires Knee injury and Osteoarthritis Outcome Score (KOOS) and SF-36 were mailed preoperatively and 6 months, 12 months and at 5 years postoperatively.

Results: Response rate at 5 years was 86%. At 6 months significant improvement was seen in all KOOS and SF-36 scores ($P < 0.001$). The percentage of patients performing more demanding functions related to sports and recreation increased postoperatively. The best postoperative result was reported at the 1 year follow-up. Compared to the 1 year follow-up, a significant ($P \leq 0.01$) decline was seen at 5 years in the KOOS subscale activity of daily living (ADL) function (82–73) and the SF-36 subscale bodily pain (72–63), PF (61–51) and vitality (69–59). Patients who scored in the lowest quartile preoperatively in the KOOS subscales pain and ADL made the greatest improvements to 1 year (18–82, 22–80) but also declined the most from 12 months to 5 years (82–72, 80–66). Being 10 years older pre-operatively predicted 5–7 points worse scores in KOOS pain and KOOS symptoms at 1 and 5 years. When adjusted for age, sex and comorbid conditions, pre-operative SF-36 scores did not predict postoperative KOOS pain or PF scores.

Conclusion: Compared to preoperatively, a significant improvement was still seen 5 years postoperatively. However, the best result was reported at 1 year, indicating a decline from 1 to 5 years after TKR. To fully evaluate the results of TKR with regard to pain and PF, follow-ups longer than 2 years are needed, and items of more demanding PFs should be included. Older age to some extent predicted more postoperative pain and other symptoms, however, no predictors of postoperative PF were found, indicating the difficulty of determining preoperatively who will benefit more or less from the procedure.

Key words: TKR, OA, Outcome, Pain, Physical function.

Introduction

Knee osteoarthritis (OA) is a well known cause of pain and functional disability in the elderly. In patients suffering from severe OA total knee replacement (TKR) is the most effective treatment[1] and offers the patients pain relief and improved physical function (PF)[2,3]. Numerous follow-up studies after TKR have been performed during the last decade, most of which have a follow-up time of 1–2 years[3,4]. The knowledge about the longer term results from the patients' perspective is limited.

The optimal circumstances for performing total joint replacement is not known. It has been suggested that younger patients have a better outcome after total hip replacement[5] and that subjects with less preoperative pain and functional limitations have a better postoperative outcome after TKR[3]. On the other hand, younger patients with less severe symptoms may also benefit from non-surgical treatments which in turn are associated with less risk than surgical treatment. It is thus of interest to study if patient characteristics such as age, gender, comorbidities as well as preoperative pain and function may predict the postoperative outcome.

Considering the increasing demands on PF from the graying population[6], it is important to evaluate demanding physical activities for the population with severe OA who are assigned for TKR[7]. Commonly used instruments for predicting outcomes for OA and total joint arthroplasty, such as the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Oxford-12, evaluate PFs required for daily living only, while other methods, such as the Knee injury and Osteoarthritis Outcome Score (KOOS), also evaluate PFs required for sports and recreational activities. In this study KOOS pain and activity of daily living (ADL) are chosen as primary outcomes since pain is the primary indication for TKR and improving PF is the secondary objective of the procedure. As predictors of outcome we have chosen preoperative age, gender, Body mass index (BMI), comorbid conditions and the SF-36 subscales: PF, bodily pain (BP) and mental health (MH) since these predictors have been shown to influence the outcome after total hip replacement[5]as well as after TKR[3,8,9]. This study adds

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Received 26 July 2007; revision accepted 9 November 2008.

knowledge to whether the same predictors are relevant also at longer follow-ups.

The aims of this prospective study were(1) to describe the outcome (from the patient's perspective) up to 5 years after TKR in subjects with knee OA, (2) to evaluate the extent to which patients having TKR performed physical activities related to sports and recreation functions, (3)to identify preoperative characteristics predicting the postoperative outcome.

Methods

PATIENTS

125 consecutive patients who were on the waiting list for primary TKR at the Department of Orthopedics at Lund University Hospital, Sweden received questionnaires by mail. Patients were recruited from December 1999 to April 2001. Of these 125 patients, 23 were excluded, 13 underwent other operative procedures, eight were not operated on during the study period and two had rheumatoid arthritis. Thus preoperative data was available from 102 patients with knee OA, 63 women and 39 men. Mean age was 71 years (51−86).

QUESTIONNAIRES

All questionnaires were mailed to the patients and returned by mail in prepaid envelopes. In addition to the KOOS, patients were also sent the SF-36 and questions regarding background data. The patients received questionnaires on four occasions: preoperatively, and postoperatively after 6 months, 12 months and 5 years.

KOOS

The KOOS is an extension of the WOMAC[10]. KOOS was developed and is validated for several cohorts of younger and/or more active patients with knee injury and/or OA[11]. KOOS is a 42 item self-administered, self-explanatory questionnaire that covers five patient-relevant dimensions: pain, other disease specific symptoms, ADL function, sport and recreation function (Sport/Rec), and knee-related quality of life. The WOMAC pain questions are included in the subscale pain, the WOMAC stiffness questions are included in the subscale other disease specific symptoms and the WOMAC subscale function is equivalent to the KOOS subscale ADL. In comparison to WOMAC the KOOS is advantageous when assessing groups with high expectations of physical activity and when assessing long-term outcomes[12].

SF-36

The SF-36 is a widely used generic outcome measure[13] which consists of eight domains; PF, role-physical (RP), BP, general health (GH), vitality (VT), social functioning (SF), role-emotional (RE)and MH. The SF-36 is self-explanatory and takes about 10 min to complete. The SF-36 is scored from 0 to 100; 0 indicating extreme problems and 100 indicating no problems. The Acute Swedish version of the SF-36 was used[14].

COMORBIDITIES

Patients were asked to report comorbid conditions. They were asked if they were currently treated by a doctor, or had been treated during the last year, for any of the following 11 conditions: back problems, lung disease, high blood pressure, heart disease, impaired circulation in the lower extremity, neurological disease, diabetes, cancer, ulcer, kidney disease, impaired vision or eye disease.

STATISTICS

Statistical analysis was done using SPSS 15.0.

To describe the results, continuous outcomes are given as mean ± SD and range. The Wilcoxon signed-rank test was used for paired comparison. Ordinal data are given as percentages.

Age, gender, comorbid conditions, preoperative scores of SF-36 PF, BP and MH were entered as predictors in an analysis of covariance (ANCOVA) where the five different KOOS subscales were used as the dependent variable. BMI was assessed at the 5-year follow-up only and thus is not included in the predictive models. BMI at 5 years did not correlate with the dependent variables (KOOS subscales) at 5 years (ρ −0.16−−0.06, $P > 0.3$).

For correlations of the items of the Sport/Rec subscale of KOOS and continuous variables such as age and BMI, Spearman's rank correlation was used. The Chi-square test was used to test relationship to gender and for comparison of the proportions of patients performing items of the KOOS subscale Sport/Rec postoperatively and preoperatively.

Results

PATIENTS

At the 5-year follow-up, nine patients had died and responses were available for 80/93 (86%) patients, mean age 76 years (range 59−90), 47 women and 33 men, mean BMI 28 16−38. Preoperative patient characteristics are given in Table I.

KOOS

At the 6 months follow-up the patients had improved ($P = <0.001$) in all five subscales of the KOOS. At 12 months they had improved further in all subscales ($P = <0.001$) except Sport/Rec ($P = 0.75$). At the 5-year follow-up a deterioration was seen in the subscale ADL compared to the 12 months follow-up ($P = <0.001$), Fig. 1.

SF-36

At the 6 months follow-up the patients had improved in all SF-36 subscales ($P = <0.001$ for all subscales except GH, $P = 0.02$). At 12 months no further significant improvements were reported and at the 5-year follow-up deteriorations were seen in the subscales BP, PF and VT in relation to the 12 months follow-up ($P = <0.01$) Fig. 2.

OUTCOME IN RELATION TO PREOPERATIVE PAIN AND FUNCTION

To demonstrate the possible influence of preoperative KOOS pain score on postoperative KOOS pain score at 6 months, 12 months and at the 5-year follow-up, the patients were analyzed according to preoperative KOOS pain score quartiles (≤28, 29−36, 37−50, ≥51). The mean KOOS pain score for each group at the different assessments are shown in Fig. 3. At the 6 months and 12 months follow-up the patients with a preoperative KOOS pain score in the lowest preoperative quartile (≤28) reached almost the same level as the patients in the upper preoperative quartiles, but at the 5-year follow-up the patients from the lowest quartile had declined the most, from 82 to a score of 72. Similarly, preoperative KOOS ADL score also correlated with the KOOS ADL score at the 5-year follow-up. The mean postoperative KOOS ADL score for the patients according to their preoperative KOOS pain score quartiles (≤32, 33−39, 40−49, ≥50) are shown in Fig. 4. The patients in the lowest quartile had the greatest improvements in mean score at the 5-year follow-up, and also comprised the group which declined the most between 12 months and 5 years 80−66.

Table I
Preoperative clinical characteristics

No. of comorbid conditions	1.26 ± 1.16
Percentage of patients with ≥2 comorbid conditions	36.5
No. of years the patient has considered TKR	2.43 ± 2.2
Expected time (months) for recovery	3.76 ± 2.22

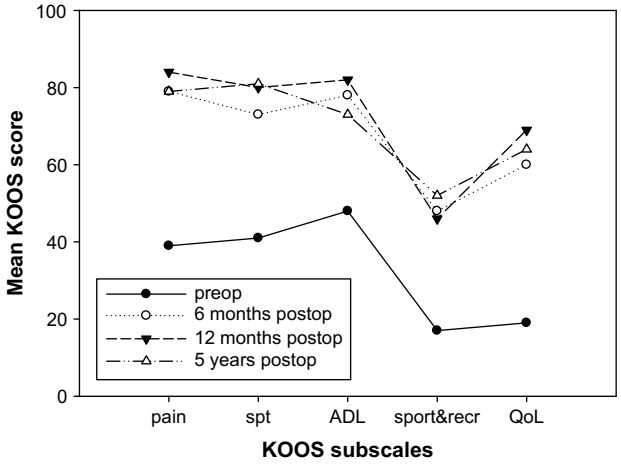

Fig. 1. KOOS profiles prior to and up to 5 years after TKR. Mean KOOS scores ($n = 80$) at the preoperative, 6 months, 12 months and 5 year assessments after TKR.

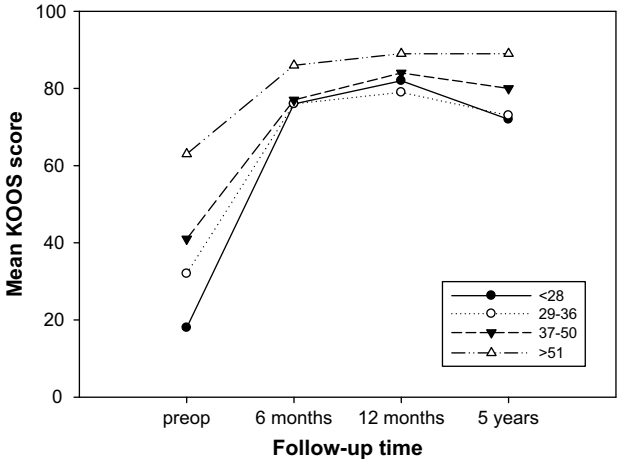

Fig. 3. KOOS pain scores before and after TKR. The mean KOOS pain scores at the preoperative, six months, 1 year and 5 years follow-up according to preoperative KOOS quartiles.

When analyzing the data on an individual level, patients improving 10 or less score units more often had a better than average preoperative score (Tables II and III). 88% of the patients improved more than 10 score units at the 5-year follow-up concerning pain and 81% concerning ADL.

SPORT AND RECREATION FUNCTION OF THE KOOS

To study the proportion of patients performing more demanding PFs, five individual items from the KOOS Sport/Rec subscale were analyzed pre- and postoperatively. At 6 months postoperatively, the proportions of patients performing more difficult PFs were increased. This was maintained at the 5-year follow-up; 30% were squatting preoperatively vs 41% at the 5-year follow-up ($P = 0.001$), running 17% vs 23% ($P = 0.001$), jumping 11% vs 20% ($P = 0.001$), twisting 43% vs 52% ($P > 0.6$). The proportion of patients kneeling decreased from 35% to 32% ($P = 0.002$). At the 5-year follow-up 31% of the patients performed at least three of the five items included in the subscale and a KOOS Sport/Rec subscale score could be calculated according to the scoring rules given in the KOOS Users Guide, www.koos.nu.

Age was not related to performing these more demanding PFs, $r_S < 0.13$, $P > 0.9$, except for jumping $r_S = -0.62$, $P = 0.01$, where an experience of more difficulty with jumping was related to higher age. Men performed most of the functions more commonly than women; squatting (61% vs 28%, $P = 0.005$), running (33% vs 15%, $P = 0.051$), jumping (30% vs 13%, $P = 0.017$), twisting (58% vs 49%, $P = 0.004$), and kneeling (49% vs 21%, $P = 0.083$). BMI, only assessed at the 5-year follow-up, was not related to the ability to perform more difficult PFs at 5 years ($r_S < 0.2$).

PREDICTORS OF OUTCOME IN THE KOOS SUBSCALES AT THE 1 AND 5-YEAR FOLLOW-UP

Being 10 years older pre-operatively predicted a nine point worse KOOS QOL score at 1 year and five to seven points worse KOOS pain and symptom scores at 1 and 5 years. Greater age did not predict a worse score in KOOS

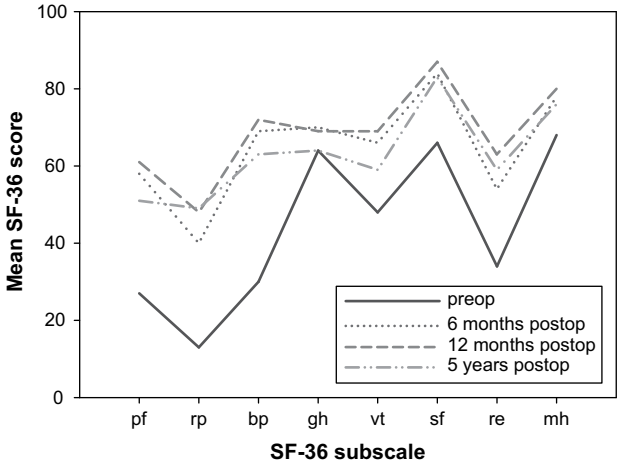

Fig. 2. SF-36 profiles prior to, and 5 years after, TKR. Pre- and postoperative mean values (n = 80) of SF-36.

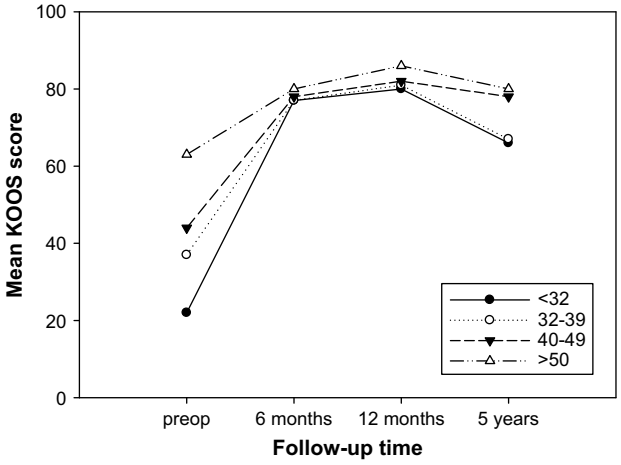

Fig. 4. KOOS ADL scores before and after TKR. The mean KOOS ADL scores at the preoperative, six months, 1 year and 5 years follow-up according to preoperative KOOS quartiles.

Table II
The number of patients in each preoperative KOOS pain quartile who improved 10 or less score units at the 12 months and 5-year follow-up

Quartile preop value	Preop-12 months postop $n = 86$	Preop-5 years postop $n = 80$
<28	0	1
29–36	0	1
37–50	1	3
>51	1	4
Total% >10 score unit change	84/86 = 98%	70/80 = 88%

Table III
The number of patients in each preoperative KOOS ADL quartile who improved 10 or less score units at the 12 months and 5-year follow-up

Quartile preop value	Preop-12 months postop $n = 86$	Preop-5 years postop $n = 80$
<32	1	2
33–39	0	4
40–49	2	3
>50	2	6
Total% >10 score unit change	81/86 = 94%	65/80 = 80%

ADL. Gender was not related to postoperative outcome. When adjusted for age, gender and comorbid conditions, pre-operative SF-36 scores did not predict the outcome with regard to any of the KOOS subscales (Table IV and V).

Discussion

This prospective study of 102 patients who have received a TKR for OA adds to previous knowledge because of its long follow-up time and extensive evaluation of PF. It shows that the patient-relevant outcome concerning pain and PF is the very best after 12 months. At the 5-year follow-up there is an increase in pain and decrease in PF not explained by age and gender or comorbid conditions.

5-YEAR FOLLOW-UP TIME

Long-term follow-ups of patients with TKRs are available, most however are based on retrospective as well as prospective data from registries focusing on ''hard'' outcomes such as failure of the prosthesis (knee.nko.se), and thus not useful for longitudinal evaluation of patient-relevant outcomes such as pain and function. In previous studies of patient-relevant aspects of TKR, patients have been followed for 1 or 2 years, time points in many countries coinciding with the final clinical assessment. The patient-relevant outcomes after TKR at this time point are generally good[3,4]. The advantage of our study is that we have assessed patient-relevant outcome after a relatively long-term follow-up.

The current trend is to operate on a broader spectrum of patients, not only older patients with more comorbidities but also younger patients with less severe disease. These latter patients will live longer with their prosthesis and have higher demands on physical activity. Thus it is increasingly important to follow TKR patients for an extended time, and to evaluate outcomes relevant for younger and physically more active people. By doing so, we found that difficulty with knee-specific ADL function increased from 1 to 5 years, together with increase in generic pain, and decrease in general PF and VT. There is certainly an advantage in combining a disease specific and a generic outcome measurement since there is the opportunity to catch different outcome aspects.

We studied the change over time according to preoperative quartiles of KOOS pain and ADL to further elucidate these changes and found that the patients who were worst off improved most up to 1 year, though they did not reach the highest absolute score; these patients then deteriorated the most to the 5-year point. This is in accordance to Lingard's study where the patients were followed for 2 years[3]. This information raises the question of how to interpret this type of ordinal data[16]. Is a greater improvement a better result than a high absolute score? Or is the fact that patients with a poor preoperative score have more scope for improvement?[17] Patients in the highest quartile also declined concerning PF at the 5-year follow-up but they still had a high absolute score which is an indication for not operating too late in the course of disease.

The smallest detectable clinical improvement in KOOS pain and ADL is suggested to be 10 score units[15]. When analyzing the data on an individual level, we found that patients improving 10 or less score units more often had a better than average preoperative score (Tables II and III). However, it is important to realize that 88% of the patients improved more than 10 score units at the 5-year follow-up concerning pain and 81% concerning ADL. Thus most patients had a clinically significant improvement from surgery.

Possible explanations for the deterioration in PF may include musculoskeletal comorbidities where irreversible effects of disease (OA) and factors predisposing some individuals to joint degeneration probably are important[7]. The postoperative report of comorbidities such as low back pain and aching joints were however, not more frequent in the patients of the lower KOOS pain and ADL quartiles (data not shown).

Table IV
Predictors of change at 1 year after TKR. All predictors are adjusted for each other. Coefficient of determination (R^2) is given for models including all six predictors

	Female gender	Older age (10 yrs)	Comorbid conditions ≥2	SF-36 PF	SF-36 BP	SF-36 MH	R^2
	Regression coefficient (95%CI)						%
KOOS ($n = 78$):							
Pain	0 (−8, 7)	5 (1, 10)	−3(−13, 7)	0 (0, 0)	0 (0, 0)	0 (0, 0)	9
Symptoms	2 (−5, 10)	6 (1, 10)	−1 (−12, 10)	0 (0, 0)	0 (0, 0)	0 (0, 0)	10
ADL	0 (−7, 7)	2 (−2, 7)	−3 (−13, 8)	0 (0, 6)	0 (0, 2)	0 (0, 0)	5
Sport/Rec	12 (−13, 37)	15 (−2, 31)	12 (−23, 46)	1 (−1, 2)	0 (−1, 1)	0 (0, 1)	22
QOL	3 (−8, 13)	9 (3, 16)	−1 (−15, 14)	0 (0, 1)	0 (−1, 0)	0 (0, 0)	14

Table V
Predictors of change at 5 year after TKR. All predictors are adjusted for each other. Coefficient of determination (R^2) is given for models including all six predictors

	Female gender	Older age (10 yrs)	Comorbid conditions ≥2	SF-36 PF	SF-36 BP	SF-36 MH	R^2
	Regression coefficient (95%CI)						%
KOOS ($n=71$):							
Pain	−2 (−12, 8)	7 (1, 13)	0 (−14, 14)	0 (0,1)	0 (0, 0)	0 (0, 0)	11
Symptoms	−3 (−11, 5)	7 (2, 12)	0 (−12, 12)	0 (0, 0)	0 (0, 0)	0 (0, 0)	14
ADL	−4 (−13, 5)	4 (−2, 9)	6 (−7, 20)	0 (0, 1)	0 (0, 0)	0 (0, 0)	18
Sport/Rec	3 (−33, 38)	10 (−1, 28)	−6 (−66, 55)	0 (−1, 2)	0 (−1, 1)	0 (0, 1)	16
QOL	−4 (−17, 8)	4 (−3, 12)	13 (−5, 30)	0 (0, 1)	0 (0, 1)	0 (0, 0)	14

KOOS VS WOMAC PF

The outcome measures in rheumatology clinical traits (OMERACT) guidelines for evaluation of OA include pain and PF[18]. PF is however, evaluated as related to daily living. A number of studies have pointed out increasing demands on PF by OA patients[6] suggesting it is appropriate to evaluate more demanding PFs. Weiss and co-workers showed in their study that as many as 10% of the patients performed highly demanding physical activities after TKR. In our evaluation of more demanding physical activities in our study we found that TKR improved the ability to perform PFs such as running, jumping, squatting and twisting, especially so in men. This information would not have been obtained by evaluation of ADL functions only, and indicates good face validity of the Sport/Rec subscale of the KOOS in physically more active TKR patients. The circumstance that as many as one third of the patients in this study performed functions related to sports and recreation at the 5-year follow-up supports the assumption that a substantial proportion of older people with knee OA are physically active and have great demands.

It is known that TKR does not restore normal knee function independent of the effects of age and gender. When comparing age matched healthy controls and patients who had undergone TKR 1 year earlier, there was a clear difference concerning demanding activities[7]. In our study, there was no correlation found between patients who were able to perform difficult PFs and age.

PREDICTORS OF OUTCOME

Previous studies have shown that preoperative pain and PF are the strongest predictors for postoperative outcome pain and PF; but the follow-up period has been limited to 1 or 2 years [3,4,19]. However, when adjusting for the patient characteristics age, gender and comorbid conditions, preoperative pain and function measured by the SF-36 did not predict the outcome in KOOS pain or ADL function after 5 years. Patient characteristics, including preoperative pain and function, explained only 5−18% of the variation in the postoperative pain and ADL function, indicating the difficulty to preoperatively foresee the postoperative outcome.

STRENGTHS AND LIMITATIONS

Strengths of the study are the prospective design, the long follow-up time and the high follow-up rate of 86%. A limitation of the study includes the fact that since BMI was not assessed preoperatively it could not be tested as a predictor or outcome. Another limitation of the study is that we did not specifically assess the number of joints affected by OA. A preoperative Charnley classification would have added to the information from the predictor analysis.

Since no data was collected between the 1 and 5-year follow-ups, it is not possible to know when, within this time interval, declines occurred; this also could be regarded as a limitation of the study. Inclusion of a group of matched controls would have helped us sort out if the decline in KOOS ADL at 5 years was OA specific or age related.

We are aware of the problem of generalizing data from one population to another. As an example, patients in Europe are older at time for TKR and have a lower BMI compared to patients from the United States[3]. Thus, it is important to present data originating from different countries to broaden the knowledge of outcome after joint replacements.

The aim of this study was to evaluate the long-term patient-relevant outcomes following TKR, thus no objective data such as alignment, range of motion or radiographs were obtained. Including such data would have given a fuller perspective of the outcome following TKR.

Conclusion

Compared to preoperatively, a significant improvement was still evident 5 years postoperatively. However, the best results were reported at 1 year, thus there was a decline from 1 to 5 years after TKR. To fully evaluate the results of TKR with regard to pain and PF, follow-ups longer than 2 years are needed, and items of more demanding PFs should be included. Older age to some extent predicted more pain and other postoperative symptoms, however, no predictors of postoperative PF were found, indicating the difficulty of determining preoperatively who will benefit more or less from the procedure (Table V).

Conflict of interest

No interests are declared.

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