Wylde, V., Penfold, C., Rose, A., & Blom, A. W. (2019). Variability in long-term pain and function trajectories after total knee replacement: a cohort study. *Orthopaedics and Traumatology: Surgery and Research*, *105*(7), 1345-1350. https://doi.org/10.1016/j.otsr.2019.08.014

**Original article**

# Variability in long-term pain and function trajectories after total knee replacement: a cohort study

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## ABSTRACT

### Introduction

Previous research suggests that patient-reported outcomes plateau by one year after total knee replacement (TKR). Analysis of trajectories to date has predominately been based on changes in median/mean scores over the first post-operative year, rather than variability in trajectory patterns over the longer-term. The aim was to evaluate variability in long-term pain and function trajectories after TKR.

### Hypothesis

There will be variability in long-term pain and function trajectories after TKR.

### Patients and Methods

266 patients undergoing a Triathlon® TKR because of osteoarthritis were recruited from one orthopaedic centre. Participants completed the WOMAC Pain and Function scales preoperatively and then at 3 months, 1 year, 2 years, 3 years, 5 years and 7 years post-operative. Longitudinal analyses evaluated patterns of clinically meaningful change.

### Results

Most patients had an improvement in pain and function during the first year post-operative; improvement was greatest in the first 3 months. By 1 year post-operative, 8% of patients had no change or a worsening of pain and 21% for function. Thereafter, approximately 15% of patients improved and 15% worsened between each assessment time. For those patients who had no change in symptoms from pre-operative to 1 year post-operative, one third had further improvement between one and 2 years post-operative.

### Discussion

This study identified clinically meaningful variability in long-term outcomes after TKR, which could be discussed with patients to ensure they have realistic expectations of their outcome. Further research is needed to evaluate determinants of this variability and whether patients who will do poorly can be identified early in their recovery pathway.

### Level of evidence

IV, prospective cohort study


**Keywords:** total knee replacement, pain, function, trajectories, PROMS

## INTRODUCTION

Total knee replacement (TKR) is a common elective operation, with more than 100,000 primary TKRs performed annually in the National Health Service [1, 2]. In the past, the length of time an implant remained in situ was the key indicator of a successful outcome, although it is now accepted that success should incorporate evaluation of patient-reported outcomes [3]. The most important expectations for patients electing to undergo TKR are improvements in pain and function [4] yet research has established that 10-34% of patients experience chronic pain, 20-30% patients have long-term functional limitations after TKR [5, 6]. Most patients are aware of their TKR as an artificial joint [7] and 30% are dissatisfied with their outcome after TKR [8]. Informing patients of this before surgery could help patients form realistic expectations of outcomes.

Previous research evaluating recovery trajectories after TKR has established that most improvement in pain and function occurs in the first 3 months post-operative, then further small improvement up to 1 year post-operative, after which outcomes plateau [9-18]. However, a limited number of studies have evaluated longer-term trajectories[19, 20], with most research evaluating patients up to 1 year post-operative. With limited research assessing patient-reported outcomes beyond 1 year after surgery, it is difficult to give patients a realistic expectation of long-term trajectories. Also, analysis of trajectories to date has predominately been based on median/mean scores over time, which provides limited information on variability in trajectory patterns over time. Using minimally clinically important differences (MCIDs) can provide further information on whether patients have a meaningful improvement or worsening in their symptoms over time [21]. Further information on likely individual patient recovery trajectories and variability in trajectory patterns would enable more detailed information to be provided to patients. The aim of this study was to evaluate the variability in long-term pain and functional outcome trajectories after primary TKR using MCIDs. The hypothesis was that there would be variability in long-term pain and function trajectories after TKR.

## PATIENTS AND METHODS

**Study design**

These analyses use data from an ongoing cohort study which is evaluating the long-term outcomes of the Triathlon ® (Stryker, Limerick, Ireland) TKR. Reporting of this cohort study follows guidance from the STROBE initiative and a checklist ( see electronic appendix 1).

**Patients**

Over a three year period from October 2006 to October 2009, consecutive patients were approached from pre-operative assessment clinics of 11 consultant orthopaedic surgeons at the Avon Orthopaedic Centre, Bristol; an elective orthopaedic centre in the UK. Inclusion criteria were patients listed for a primary Triathlon® TKR because of osteoarthritis. Exclusion criteria included revision TKR, inability to understand English and inability or unwillingness to consent to study participation. Of the 904 patients approached about the study, 266 patients (29%) were recruited into the cohort.

Ethical approval was obtained from the local Research Ethics Committee (Reference: 06/Q2002/80) and all patients provided informed, written consent.

**Surgery**

Prior to surgery, most patients had severe osteoarthritis, with 94% of participants having a Kellgren and Lawrence score of 3 or 4. In terms of surgical approach, 66% had a medial parapatellar approach, 33% had a medial subvastus and 1% a lateral parapatellar. Ninety two percent % of participants had a cruciate retaining prosthesis.

**Methods of assessment**

Outcome measures were collected preoperatively and then at the following post-operative time points: 3 months, 1 year, 2 years, 3 years, 5 years and 7 years. Ten year post-operative data collection is ongoing and was not included in these analyses. Assessment was by patient-reported outcome measures (PROMs), clinical assessment and medical records review to evaluate complications and survivorship. For these analyses, we used the Pain and Function scales of the Western Ontario McMaster University Osteoarthritis Index (WOMAC) [22]. The WOMAC was posted to participants for self-completion at home, and participants did not have access to previous questionnaire scores. The WOMAC Pain scale assesses the severity of knee pain when performing five daily activities and the WOMAC Function scale

assesses the extent of functional limitations during 17 daily activities. Total scores were calculated and transformed to range from 0-100 (worst to best). If only one response on the WOMAC Pain scale or ≤3 responses on the WOMAC Function scale were missing, then these were substituted with the average score from the other questions, and the total score was calculated [22].

Data on sociodemographics were collected in the pre-operative questionnaire, and co-morbidities were assessed using the Self-Administered Comorbidity Questionnaire [23]. Data on body mass index (BMI) were extracted from medical records

**Sample size**

This cohort study was designed to evaluate the long-term outcomes of the Triathlon ® TKR. Therefore, no formal sample size calculation was performed, and the sample size was pragmatically determined by the number of patients that consented to participate over a three year recruitment period.

**Statistical analysis**

The WOMAC Pain and Function scales were non-normally distributed and therefore median and inter-quartile ranges were used in the descriptive analyses. Change scores for each scale were derived from both the preoperative score and from the previous data collection timepoint (consecutive change scores). Consecutive change scores between one and seven years post-operatively, stratified by 1 year post-operative scores, were also derived.

The range for the MCID after TKR on the WOMAC Pain and Function scales has been found to be between 14 and 22 points [24]. This was calculated using an anchor-based method, using the mean change score for patients who defined themselves as “somewhat better” at 6 months post-operative [24]. We used the lower value (14 points) for our analysis to ensure we captured all variability in outcomes that was likely to be meaningful to patients. The MCIDs were used to categorise the change scores as follows:

1. ‘No change’ – change score within ±MCID
2. ‘Worse’ – change score < MCID
3. ‘Better’ – change score > MCID

Some participants did not complete every questionnaire and therefore predictive mean matching was used to impute plausible values for these missing data (25 imputed datasets).

All WOMAC scores were included in the multiple imputation models as well as additional variables which may have been useful for estimating missing values (age at the time of surgery, gender and marital status). Imputed data were used for our main analyses and these were repeated on the subsample of people who responded to every questionnaire using their unimputed data.

## RESULTS

### Participants' characteristics

Baseline characteristics of the 266 participants are provided in Table 1. Non-participants had a median age of 72 years (interquartile range 64–79) and 64% were female, which was similar to participant demographics. By 7 years post-operative, 9 patients had had their primary TKR revised, 14 had withdrawn from the study and 30 were deceased, and therefore 213 patients (80%) were eligible to be included in these analyses. A flow chart of study participation is provided in Figure 1.

### Longitudinal analysis: Median scores

Median WOMAC Pain and Function scores at each assessment time are presented in electronic Appendix 2 The largest improvement in median scores occurred during the first 3 months post-operative. Further small improvements were observed between 3 months and 1 year, and then scores remained relatively stable between one and seven years post-operative.

### Longitudinal analysis: Minimal clinically important differences

#### *Pre-operative to post-operative changes*

The categorised change scores, based on the MCID, from pre-operative to each post-operative timepoint are presented in Table 2 and Figure 2. As with the median score analysis, the largest improvements were in the first 3 months after surgery, with 79% of patients having a clinically important improvement in their pain and 67% a clinically important improvement in their function. By 1 year, this had increased slightly but there was a subgroup of patients who had no improvement of their symptoms; 8% for pain and 21% for function. Between one and seven years, the proportion of people who had improved compared with their pre-operative scores remained relatively stable.

#### *Changes between consecutive post-operative assessments*

Consecutive categorised change scores between post-operative assessments are presented in Table 3 and Figure 3. Between 3 months and 1 year post-operative, 9% of patients had a worsening of their pain score and 10% a worsening of their function score, compared with 42% and 29% who had improvements in pain and function, respectively. Between 1 and 2 years, the proportions of patients with improvement and worsening of these symptoms were approximately equal (pain: 17% worse, 15% better; function: 12% worse, 14% better) and remained similar for the remainder of the follow-up period to 7 years post-operative.

***Stratified post-operative trajectories***

Table 4 provides a description of consecutive categorised change scores from one to seven years, stratified by whether patients had an improvement or no change in their pain and function between pre-operative and 1 year post-operative (people who had worse symptoms at 1 year comprised only ~1%). This revealed further variability in outcomes based on the amount of improvement achieved in the first year post-operative. Of those patients who had no change in their pain in the first year after surgery, 42% had an improvement in pain and 36% an improvement in function between 1 and 2 years post-operative.

***Sensitivity analysis: Comparison of imputed and unimputed results***

The results of the sensitivity analyses using unimputed data are in electronic Appendices 2-4. Although there were minor differences, the sensitivity analyses were generally in agreement with the main analyses. The median scores for the WOMAC Pain and Function scales were comparable with those using imputed data (electronic Appendix 2) but unimputed medians were slightly higher at later timepoints. Similarly, using unimputed data a slightly higher proportion of participants at later timepoints had a clinically meaningful improvement in their WOMAC Pain and Function scores (electronic Appendix 3) compared with results using imputed data (Table 3). Consecutive categorised change scores using unimputed data suggest that from one year onwards a slightly higher proportion of participants had no change in their symptoms (electronic Appendix 4) compared with results using imputed data (Table 4).

## DISCUSSION

Our longitudinal analysis of patient trajectories revealed novel complexities and variability in outcomes that are not apparent with the analysis of median/mean outcomes. We found that 42% of patients had a further clinically important improvement in pain and 29% in function

between 3 months and 1 year post-operative. After 1 year the amount of variability plateaus, but there is still variability in outcome, with approximately 15% of patients improving and 15% worsening between each assessment time. For those patients who had no clinically meaningful change in pain or function from pre-operative to 1 year post-operative, approximately one third of patients had clinically meaningful improvement between 1 and 2 years post-operative. This confirmed our hypothesis that there would be variability in long-term pain and function trajectories after TKR.

Previous research evaluating long-term outcome trajectories after TKR has found that after an initial improvement, pain and function decline with time. A large study of over 2,000 patients found that a small number of patients reported no improvement or a worsening on the Oxford Knee Score from pre-operative to 10 years after TKR [20]. Another study using the same PROM observed that the maximum average score was reported at two years post-operative, followed by a gradual decline up to 10 years [19]. Other studies have also found a decline in outcomes over time, although the starting point from this decline varies from between 3 and 5 years post-operative [25, 26]. Our key novel finding that adds to the literature is the quantification of longer-term variability in outcomes, highlighting the existence of small subgroups of patients that improve and worsen between assessment times.

If our findings are confirmed in future studies, then they could be used to pre-operatively inform patients about different outcome trajectories, so that they have realistic expectations of their longer-term outcomes. Although our study did not explore why some patients had a worsening or improvement in symptoms over time, there is evidence that pre-operative status is a determinant of post-operative outcome [11, 16, 27]. Therefore, further research to evaluate pre-operative determinants of different outcome trajectories could inform pre-operative patient education and treatment planning. In addition, our finding that a third of patients who had no improvement in pain or function by 1 year post-operative are likely to have further clinically important improvements up to 2 years post-operative could provide reassurance to patients that further improvements do occur for some patients who do not improve in the first year after surgery.

A key strength of our study was the inclusion of regular long-term assessments to allow analysis of change between consecutive post-operative time points. However, our study does have some limitations. Patients were recruited from a single orthopaedic centre and therefore external validity is limited, although patient demographics were similar to those of the

broader UK population undergoing TKR [1]. Our recruitment rate was low at 29%, likely due to the high participant burden of extended follow-up. As with all longitudinal studies, there were missing data in the sample, however the impact of this was reduced by using data imputation. Another limitation is with the outcomes assessment; although the WOMAC is a validated joint-specific PROM, it has been found to be influenced by other factors, such as psychological status [31] and other painful joints [32], which may have affected our findings. Also inclusion of other PROMs, such as the Oxford Knee Score or Knee Osteoarthritis and Outcome Score, would have allowed us to compare findings using different tools. Our approach was to evaluate results from PROMs, although there are objective assessment tools that can be used to evaluate function, such as accelerometery and performance tests. However, there is a lack of correlation between PROMs and objective assessments of function [29] and our use of PROMs ensured that the patients' experiences were central to assessment and that assessment focussed on activities of relevance to patients. While our focus was on pain and function, future research could evaluate the variability in outcome trajectories for other important outcomes, such as social participation which has been shown to have a slower rate of improvement after TKR compared to physical impairment and activity limitations [10]. We used the MCID to define change, however, there is currently no consensus of the most robust methodology to apply when defining a successful outcome after TKR, and other methods include calculating the Patient Acceptable State, return to normal, and the OMERACT-OARSI responder criteria [30].

In conclusion, this study found long-term variability in pain and function outcome trajectories. Research studies should, where possible, incorporate long-term follow-up to capture variability in outcomes over time, using a robust methodology to identify clinically important change. Future research is needed to understand the causes of variation in outcomes over time and evaluate pre-operative determinants of different outcome trajectories .

## Conflicts of interest

VW and AWB are co-applicants on an institutional grant from Stryker which funded this study. CP and AR have no conflicts of interest to declare.

## Funding

This study was funded by Stryker UK. The funder had no involvement in the study design, data collection, data analysis, interpretation of data or writing of the manuscript.

This study was supported by the NIHR Biomedical Research Centre at University Hospitals Bristol NHS Foundation Trust and the University of Bristol. The views expressed in this publication are those of the authors and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health and Social Care.

## Acknowledgements

The authors would like to thank all the study participants and surgeons involved in the study.

## Author contributions

VW and AWB conceived the study, AR contributed to data collection, CP performed the statistical analysis, VW and CP drafted the manuscript and all authors critically revised it for important intellectual content.

**Table 1: Baseline participant characteristics**

| Characteristic | Median (IQR) or number (%) |
|---|---|
| Median age in years (IQR) | 70 (62-77) |
| N (%) female | 169 (64%) |
| Median BMI (IQR) | 30 (27-35) |
| Median number of co-morbidities | 2 (1-3) |
| N (%) married/cohabiting | 171 (66%) |
| N (%) white | 252 (98%) |
| N (%) retired | 180 (70%) |

**Table 2: Categorised change from preoperative measurements of WOMAC Pain and Function between 3 months and 7 years postoperatively, N=213 (imputed dataset)**

| | MCID* | Preop to 3 months | Preop to 1 year | Preop to 2 years | Preop to 3 years | Preop to 5 years | Preop to 7 years |
|---|---|---|---|---|---|---|---|
| WOMAC - Pain | Worse | 2.3% | 1.0% | 2.0% | 2.3% | 1.8% | 2.8% |
| | No change | 18.9% | 8.0% | 10.2% | 7.7% | 11.6% | 12.1% |
| | Improved | 78.8% | 91.0% | 87.7% | 90.0% | 86.6% | 85.1% |
| WOMAC - Function | Worse | 1.8% | 0.8% | 1.4% | 1.1% | 1.6% | 3.7% |
| | No change | 30.8% | 20.8% | 18.5% | 21.6% | 22.0% | 24.8% |
| | Improved | 67.4% | 78.3% | 80.1% | 77.3% | 76.4% | 71.5% |

* Change in WOMAC Pain and Function were categorised as follows: 'Worse' (change= < -MCID), 'No change' (change= -MCID to +MCID), 'Improved' (change= > MCID)

**Table 3: Categorised change between consecutive measurements of WOMAC Pain and Function, N=213 (imputed dataset)**

| | MCID* | Preop to 3 months | 3 months to 1 year | 1 to 2 years | 2 to 3 years | 3 to 5 years | 5 to 7 years |
|---|---|---|---|---|---|---|---|
| WOMAC - Pain | Worse | 2.3% | 9.3% | 16.8% | 15.2% | 16.4% | 19.2% |
| | No change | 18.9% | 49.2% | 68.4% | 71.3% | 67.6% | 63.0% |
| | Improved | 78.8% | 41.5% | 14.8% | 13.6% | 16.0% | 17.8% |
| WOMAC - Function | Worse | 1.8% | 9.7% | 12.1% | 14.2% | 14.0% | 18.6% |
| | No change | 30.8% | 61.7% | 73.9% | 76.3% | 70.5% | 71.5% |
| | Improved | 67.4% | 28.6% | 13.9% | 9.4% | 15.5% | 9.9% |

* Change in WOMAC Pain and Function were categorised as follows: 'Worse' (change= < -MCID), 'No change' (change= -MCID to +MCID), 'Improved' (change= > MCID)

**Table 4: Categorised change between consecutive measurements of categorised WOMAC Pain and Function between 2 and 7 years postoperatively, stratified by change in pain and function between pre- and 1 year postoperatively, N=213 (imputed dataset)**

| | Change from preop to 1-year | MCID* | 1 to 2 years | 2 to 3 years | 3 to 5 years | 5 to 7 years |
|---|---|---|---|---|---|---|
| WOMAC – Pain | No change | Worse | 7.0% | 22.9% | 17.1% | 18.8% |
| | | No change | 51.3% | 65.7% | 58.0% | 50.0% |
| | | Improved | 41.7% | 11.3% | 25.0% | 31.3% |
| | Improved | Worse | 17.8% | 13.8% | 16.5% | 18.2% |
| | | No change | 70.3% | 72.5% | 69.3% | 64.9% |
| | | Improved | 11.9% | 13.7% | 14.2% | 16.9% |
| WOMAC – Function | No change | Worse | 3.4% | 15.2% | 13.5% | 21.9% |
| | | No change | 60.9% | 73.0% | 69.6% | 66.7% |
| | | Better | 35.7% | 11.8% | 16.9% | 11.5% |
| | Improved | Worse | 14.1% | 14.1% | 14.0% | 17.1% |
| | | No change | 77.6% | 77.4% | 71.0% | 73.3% |
| | | Improved | 8.3% | 8.5% | 15.0% | 9.6% |

* Change in WOMAC Pain and Function were categorised as follows: 'Worse' (change= < -MCID), 'No change' (change= -MCID to +MCID), 'Improved' (change= > MCID)

Figure 1: Flow chart of study participation

Figure 2: Post-operative change in WOMAC Pain and Function scores from pre-operative scores, categorised into worse (change= < -MCID), no change (change= -MCID to +MCID), or improved (change= > MCID)

Figure 3: Post-operative change in WOMAC Pain and Function scores from previous timepoint, categorised into worse (change= < -MCID), no change (change= -MCID to +MCID), or improved (change= > MCID)

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