

Osteoarthritis and Cartilage



Comparative responsiveness of outcome measures for total knee arthroplasty



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SUMMARY

Objective: The aim of this study was to compare the responsiveness of various patient-reported outcome measures (PROMs) and clinician-reported outcomes following total knee arthroplasty (TKA) over a 2-year period.

Methods: Data were collected in a prospective cohort study of primary TKA. Patients who had completed Forgotten Joint Score-12 (FJS-12), Western Ontario and McMaster Universities (WOMAC) osteoarthritis (OA) index, EQ-5D, Knee Society Score and range of movement (ROM) assessment were included. Five time points were assessed: pre-operative, 2 months, 6 months, 1 year and 2 years post-operative.

Results: Data from 98 TKAs were available for analysis. Largest effect sizes (ES) for change from pre-operative to 2-month follow-up were observed for the Knee Society Score (KSS) Knee score (1.70) and WOMAC Total (–1.50). For the period from 6 months to 1 year the largest ES for change were shown by the FJS-12 (0.99) and the KSS Function Score (0.88). The EQ-5D showed the strongest ceiling effect at 1-year follow-up with 84.4% of patients scoring the maximum score. ES for the time from 1- to 2-year follow-up were largest for the FJS-12 (0.50). All other outcome measures showed ES equal or below 0.30.

Conclusion: Outcome measures differ considerably in responsiveness, especially beyond one year post-operatively. Joint-specific outcome measures are more responsive than clinician-reported or generic health outcome tools. The FJS-12 was the most responsive of the tools assessed; suggesting that joint awareness may be a more discerning measure of patient outcome than traditional PROMs.

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Introduction

The outcomes of total knee arthroplasty (TKA) can be assessed with various methods; implant survivorship, image-based assessment, clinical assessment and patient-reported outcome measures (PROMs). While the first three modalities are objective in nature, patient report can provide a subjective measure of the patients' perception of the success of an intervention.

The importance of including patients' views on treatment outcome in orthopaedics has been well established in recent years and a variety of patient-reported measures are available¹. Furthermore self-reported questionnaires are a potentially cost-effective

way of monitoring patient outcome in large volumes. PROMs can be broadly dichotomised into generic health status questionnaires such as the EQ-5D or SF-36 (that assess the individuals overall quality of life) and disease/joint-specific tools such as the Western Ontario and McMaster Universities (WOMAC) score which focus on specific constructs such as pain, stiffness and joint function in activities of daily living². These latter examples allow a more focused evaluation of an intervention such as TKA. The most common orthopaedic patient-reported outcome (PRO) tools have been extensively analysed regarding their validity and reproducibility^{3–5}. More recently researchers have turned to assess the responsiveness and floor/ceiling effects^{6,7}. Responsiveness to change is of particular importance in longitudinal studies where the scoring should reflect changes over time. If a questionnaire is not sufficiently responsive to the construct being assessed, it will not capture changes at follow-up, which is especially important in mid-to-long-term studies where changes in the patients' pain and function are typically not as pronounced as in the early post-operative phase. This is of direct relevance to measuring PRO following TKA where patient function

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changes markedly in the early post-operative phase but is followed by more subtle changes over time⁸.

Previous studies of instrument responsiveness however tended to focus on comparison of general health measures vs joint-specific measures^{6,9} or covered follow-up only up to 12 months^{10–13}. Comprehensive analyses of multiple outcome assessment tools at various time points over 2 years are lacking.

The aim of this study is to compare the responsiveness of various PROMs (FJS-12, WOMAC score, EQ-5D) and clinician-reported outcomes (Knee Society Score, range of motion) following TKA.

Patients and methods

Sample population

Data were collected in a prospective cohort study of primary TKA between 2007 and 2009 at Kantonsspital St. Gallen, Switzerland. This was a pragmatic study that reflected local surgical practice at the time using both, mobile and fixed bearing designs. Informed consent was obtained from the participants and ethical approval was granted by the local ethics committee. Patients who had completed FJS-12, WOMAC score, EQ-5D and Knee Society Score (KSS) were included. Participants were assessed at five different time points: pre-operatively, and at 2, 6, 12 and 24 months post-operatively. Socio-demographic and clinical data included gender, Body Mass Index (BMI), age at time of surgery and side of implant.

Outcome measures

A single experienced study performed the clinical examinations and handed over the questionnaires to the patients who completed them independently.

WOMAC

WOMAC osteoarthritis (OA) index is a widely used self-report outcome measure in patients with lower limb OA that was introduced by Bellamy and Buchanan¹⁴. The original score with 5-point Likert response categories consists of 24 questions covering three dimensions: pain (five questions), stiffness (two questions), and function (17 questions). The WOMAC has been extensively tested for validity, reliability, feasibility, and responsiveness for measuring changes after different OA interventions^{14–17} and has also been evaluated in an electronic form¹⁸. WOMAC scores were linearly transformed to a 0–100 scale with higher scores indicating more severe impairment.

Forgotten Joint Score (FJS-12)

The FJS-12 is a recently published PRO scale to assess joint awareness in hips and knees during various activities of daily living^{19,20}. It uses a 5-point Likert response format, consisting of 12 equally weighted questions with the raw score transformed to range from 0 to 100 points. High scores indicate good outcome, i.e., a high degree of being able to forget about the affected joint in daily life. In its validation study¹⁹ it showed a low ceiling effect and high internal consistency (Cronbach's Alpha 0.95) and discriminated well between patient groups known to show different outcome.

EQ-5D

The EQ-5D is a standardised generic quality of life assessment instrument with five items for use as a measure of self-reported general health²¹. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status. It is one of the internationally most frequently used measures to gain quality of life scores for analysis in

health economics as utility weights (ranging from 0 to 1) for calculating quality of life adjusted life years (QALYs) can be obtained²².

KSS

The KSS²³ is a widely used clinician-reported outcome score with good published validity data²⁴. The clinical part (Knee Score) of the KSS covers pain, range of movement (ROM), alignment and stability. The functional part (Function Score) of the KSS covers the patient's mobility (walking distance and stairs) and potential walking aids. Score range of the KSS is from 0 to 100 points for each part with higher scores indicating less severe impairment.

ROM

Active measures of flexion and extension were determined using universal goniometry. A high level of accuracy has been previously demonstrated assessing knee range of motion with this instrument in the clinical setting²⁵ and specifically in this patient group²⁶. All measurements were made by the study nurse.

Statistical analysis

Sample characteristics are given as means, standard deviations (SDs), ranges, and frequencies. As measures of responsiveness we provide effect sizes (ES, mean difference divided by SD at earlier assessment), standardised response means (SRMs, mean change divided by the standard deviation of the change score) and relative validity (RV). RV was obtained from the ratio of the F-statistics from an analysis of variance for repeated measures, comparing two time points. As a reference measure (the denominator) we used the WOMAC total scale for all time points. In addition, we provide percentages of patients obtaining the highest or the lowest possible score on a measure (i.e., floor and ceiling effects). Statistical analyses were performed with SPSS 20.0.

Results

Patient characteristics

During the study period 537 patients underwent TKA at our institution. Our part-time study nurse recruited 98 of these for the study. Mean age at baseline was 68.1 years (SD 8.6), 49% were female (Table I). The number of subjects for whom data was available varied according to the different time points as shown in Table II. All available data points were included in the analyses.

Responsiveness over time

To highlight how the different measures perform over different time-intervals following surgery we analysed data by investigating responsiveness compared to baseline and also to the previous follow-up assessment. Presenting responsiveness indices this way allows to demonstrate more clearly at which time point after surgery the various measures are able to capture change. Baseline comparisons are also detailed in the Tables III and IV.

Table I
Patient characteristics at baseline (pre-operatively, $n = 98$)

		Mean (SD)	
		Range	
Age		68.1 (8.6)	
		49–80	
Sex	Men	51.0%	$N = 50$
	Women	49.0%	$N = 48$
Side	Left	49.0%	$N = 48$
	Right	51.0%	$N = 50$
BMI	Mean (SD)	28.8 (4.5)	
	Range	19–41	

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