Knee Surg Sports Traumatol Arthrosc (2014) 22:1933–1939
DOI 10.1007/s00167-013-2776-5

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The minimal clinically important difference in the Oxford knee score and Short Form 12 score after total knee arthroplasty

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Received: 25 July 2013 / Accepted: 22 October 2013 / Published online: 20 November 2013

Abstract
Purpose The aim of this study was to identify the minimal clinically important difference (MCID) in the Oxford knee score (OKS) and Short Form (SF-) 12 score after total knee arthroplasty (TKA).
Methods Prospective pre-operative and 1 year post-operative OKS and SF-12 scores for 505 patients undergoing a primary TKA for osteoarthritis were collected during a one-year period. Patient satisfaction with their (1) patient relief and (2) functional outcome was used as the anchor questions. Their response to each question was recorded using a 5-point Likert scale: excellent, very well, well, fair, and poor. Simple linear regression was used to calculate the MCID for improvement in the OKS and physical component of the SF-12 score according to the level of patient satisfaction with their pain relief and function.
Results The OKS improved by 15.5 (95 % CI 14.7–16.4) points and the SF-12 physical component score improved by 10.1 (95 % CI 9.1–11.2) points for the study cohort. The level of patient satisfaction with their pain relief and function correlated with the improvement in the OKS ($r = 0.56$; $p < 0.001$, and $r = 0.56$; $p < 0.001$) and the physical component of the SF-12 score ($r = 0.51$; $p < 0.001$, and $r = 0.60$; $p < 0.001$), respectively. The MCID for the OKS was 5.0 (95 % CI 4.4–5.5) and 4.3 (95 % CI 3.8–4.8) points and for the physical component of the SF-12, it was 4.5 (95 % CI 3.9–5.2) and 4.8 (95 % CI 4.2–5.4) points for pain relief and function, respectively.
Conclusion The MCID identified for the OKS and SF-12 physical component score after TKA is the best available estimate and can be used to power studies and ensure that a statistical difference is also recognised by a patient.
Level of evidence Retrospective diagnostic study, Level III.

Keywords Minimal clinical important difference · Total knee arthroplasty · Outcome · Oxford knee score · Short Form 12

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Introduction

Total knee arthroplasty (TKA) is an effective procedure for the treatment of end-stage osteoarthritis, with pain relief and improved function [10]. There are numerous validated patient-reported outcome measures (PROMs) available to assess the outcome of TKA [12], of which the Knee Society Score [18], Western Ontario and McMaster Universities Osteoarthritis Index [4], Knee injury and Osteoarthritis Outcome Score [27], Short Form (SF-) 12 [33] and 36 [31] scores, and the Oxford knee score (OKS) [13] are commonly employed to assess the outcome of TKA. Some authors suggest that both joint-specific and generic health measures should be used to assess the outcome of TKA [5, 17], as they are thought to measure different but corresponding aspects of a patient's outcome. The joint-specific score is sensitive to improvement in knee symptoms,

whereas the generic measure assesses the general health of patient, which can influence the outcome of the joint-specific score [7]. The Oxford knee score (OKS) [13] is a joint-specific outcome measure and is the PROM of choice to evaluate TKA in England and Wales and has been approved for audit and performance assessment purposes [14]. The SF-12 score is a generic measure of a patient's general physical and mental well-being [33], which is based upon the SF-36 score [31]. Both the OKS and SF-12 score have been used extensively to measure the outcome of TKA [7, 8, 11, 29].

A greater improvement in the OKS and SF-12 score has been demonstrated to correlate with an increased rate of patient satisfaction with the outcome of their TKA [7, 10]. However, it remains unclear as to what change in these scores, be it statistically significant or not, results in a perceived clinical change from the patients' prospective. This has led some authors to define the minimal clinically important difference (MCID), being the minimal change in a scoring measure that is perceived by the patient to be beneficial or harmful [19, 21]. The MCID has been defined for the WOMAC score and the SF-36 after TKA [15, 20]. However, the MCID has not yet been defined for the OKS or SF-12 score, but some authors have previously used half the standard deviation to define the MCID after TKA [7, 9, 11]. This is, however, an estimate with some authors defining it as 5 points for the OKS [7, 9, 11], whereas others have suggested it may be as small as 2 points [22]. In addition, whether the MCID varies depending on the anchor question used has not been investigated to date, for example, whether this varies for pain relief and functional improvement.

The original aspect of this study was to define the MCID for the OKS and SF-12 score after TKA, which would enable powering of future prospective studies, such as randomised controlled trials, and provide clinical significance to these commonly used outcome measures from a patient's prospective. The primary aim of this study was to identify MCID in the OKS and the SF-12 score according to patient satisfaction with pain and functional outcome. The secondary aim was to compare the satisfaction rate of pain with function, and the change in the OKS and SF-12 score for differing levels of patient satisfaction with their TKA 1 year following surgery.

Materials and methods

Patients for this study were identified retrospectively from a prospectively compiled arthroplasty database held at the study centre. During a 1 year period (January to December 2010), 578 patients undergoing primary TKA at the study centre were asked to complete a pre-operative patient questionnaire. Only patients with primary osteoarthritis were included. Patients who underwent simultaneous bilateral TKA during the study period were excluded, and for those patients who underwent a second TKA, after the index procedure, only the outcome of the first knee was used for analysis. Patients who did not complete the outcome assessments (OKS, SF-12, and level of satisfaction) at 1 year were also excluded from analysis.

Outcomes measured

The OKS [13] and SF-12 [33] were recorded pre-operatively and 1 year post-operatively. The OKS consists of twelve questions assessed on a Likert scale with values from 0 to 4; a summative score is then calculated where 48 is the best possible score (least symptomatic) and 0 is the worst possible score (most symptomatic). The SF-12 score has two components, the physical component summary (PCS) and the mental component summary (MCS) scores, which are both reported on a scale of 1–100 with a greater score representing a better health status [33]. This score of 1–100 is calculated independently for both the PCS and MCS according to the responses recorded on Likert scales to six questions (each), which are then converted into the validated score using a defined algorithm. It is recognised that the SF-12 MCS does not change significantly after TKA for a standard population [7] and for the purposes of this study, the MCID for the MCS was not calculated. The OKS and the SF-12 PCS score measure different aspects of the patient's functional ability and measure different aspects of their physical health. The OKS is a joint-specific score and measures symptoms directly related to the knee, whereas the SF-12 PCS score is a measure of the overall physical health of the patient. However, both of these scores correlate and improve significantly after TKA, but the magnitude of the improvement is different, with a mean improvement of 15 points in the OKS and 10 points in the SF-12 PCS [7], and hence, the MCID for these scores after TKA is different and should be assessed and used independently.

Defining the MCID

An anchor-based approach was used to establish the MCID [25]. Two anchor questions were used to assess patient satisfaction, being defined as the external indicator, and assigned to categorical groups according to their response. One question assessed patient satisfaction with their pain relief ("How well did the surgery relieve pain in your affected joint?"), and the other assessed their satisfaction with their functional outcome ("How well did the surgery increase your ability to perform regular activities?"). The response to each of these questions was recorded using a

5-point Likert scale: excellent, very well, well, fair, and poor.

The study centre and patient management

The study centre serves a population of approximately 780,000 people [16]. During the study period, the most commonly performed TKAs were the Kinemax (Stryker Howmedica Osteonics, Allendale, New Jersey), Triathlon (Stryker), and the PFC Sigma (DePuy, Johnson & Johnson Professional Inc., Raynham, Massachusetts). All patients were reviewed at a pre-assessment clinic. A standardised rehabilitation protocol was used for all patients, with active mobilisation on the first day post-operatively. Patients were then reviewed at 6 weeks, 6 months, and 12 months post-operatively.

Ethics

Ethical approval was obtained from the regional ethics committee (Research Ethics Committee, South East Scotland Research Ethics Service, Scotland [11/AL/0079]) for analysis and publication of the presented data.

Statistical analysis

Data analysis was performed using Statistical Package for Social Sciences version 17.0 (SPSS Inc., Chicago, IL, USA). Student's *t* test, paired and unpaired, and one-way analysis of variance (ANOVA), with Tukey's correction for multiple testing, were used to compare linear variables between groups. Dichotomous variables were assessed using a chi-square test. Simple linear regression analysis was used to identify the MCID, using the slope of the line for the change according to level of satisfaction, in the OKS and SF-12 PCS score for both pain and function. A p value of <0.05 was defined as significant.

Results

There were 505 TKAs performed during the study period with complete pre- and post-operative data that met the inclusion criteria. There were 210 male patients and 295 female patients, with a mean age of 70 years (SD 9.6, range 39–91). A significant improvement was observed in the OKS and SF-12 PCS at one year for the study cohort (Table 1).

Satisfaction with pain relief

The majority of patients declared their pain relief as excellent or very well (77 %), with 29 (5.7 %) patients stating their pain relief as poor (Table 2). There was a significant difference in the improvement in the OKS and SF-12 PCS according to level of satisfaction, with a greater level of improvement being observed for those patients with an increased level of satisfaction (Table 3). Increasing level of patient satisfaction with pain relief correlated with the improvement in the OKS ($r = 0.56$ $p < 0.001$ Spearman) and the SF-12 PCS score ($r = 0.51$ $p < 0.001$ Spearman) (Fig. 1). Simple linear regression identified the MCID for pain relief in the OKS to be 5.0 (95 % CI 4.4–5.5) and for the SF-12 PCS to be 4.5 (95 % CI 3.9–5.2).

Satisfaction with function

There were 293 (58 %) patients that rated their functional outcome as excellent or very well, but nearly one in ten patients declared their outcome as poor (Table 2). There was a significant difference in the improvement in the OKS and SF-12 PCS according to level of satisfaction, with a greater improvement being observed for those patients with an increased level of satisfaction (Table 3). Increasing level of patient satisfaction with function correlated with the improvement in the OKS ($r = 0.56$ $p < 0.001$ Spearman) and the SF-12 PCS score ($r = 0.60$ $p < 0.001$ Spearman) (Fig. 2). Simple linear regression identified the MCID for pain relief in the OKS to be 4.3 (95 % CI 3.8–4.8) and for the SF-12 PCS to be 4.8 (95 % CI 4.2–5.4).

Comparison of patient satisfaction with pain and functional outcome

Patients were significantly more likely to be more satisfied with their pain relief than with their functional outcome

Table 1 Pre-operative and post-operative (1 year) OKS and SF-12 PCS score for the study cohort ($n = 505$)

Outcome measure	Pre-operative		Post-operative		Difference	95 % CI		p value[a]
	Mean (range)	SD	Mean (range)	SD		Lower	Upper	
OKS	19.5 (4–44)	7.6	35.0 (7–48)	9.7	15.5	14.7	16.4	<0.001
SF-12 PCS	29.3 (14.3–55.5)	6.7	39.5 (14.9–61.2)	10.4	10.1	9.3	11.0	<0.001

[a] Paired *t* test

Table 2 Level of patient satisfaction with their TKA at 1 year according to pain and function

Score	Level of patient satisfaction					*p* value[a]
	Excellent	Very well	Well	Fair	Poor	
Pain (*n*, %)	207 (41.0)	182 (36.0)	52 (10.3)	35 (6.9)	29 (5.7)	<0.0001
Function (*n*, %)	111 (22.0)	182 (36.0)	89 (17.6)	75 (14.9)	48 (9.5)	

[a] Chi square

Table 3 The change in the OKS and SF-12 PCS for the cohort and for level of satisfaction with pain relief and functional outcome 1 year following TKA

Score	All patients	Level of patient satisfaction					*p* value[a]
		Excellent	Very well	Well	Fair	Poor	
Satisfaction with pain							
OKS	15.5	20.1	16.5	9.9	6.4	−0.5	<0.001
(mean, 95 % CI)	(14.7–16.4)	(19.0–21.1)	(15.4–17.6)	(8.0–11.8)	(4.7–8.1)	(−2.6 to 1.5)	
SF-12 PCS	10.3	14.9	9.6	5.0	2.3	0.9	<0.001
(mean, 95 % CI)	(9.4–11.2)	(13.5–16.2)	(8.2–11.1)	(2.8–7.3)	(0.2–4.5)	(−1.9 to 3.7)	
Satisfaction with function							
OKS	15.5	21.5	17.7	15.6	10.2	2.0	<0.001
(mean, 95 % CI)	(14.7–16.4)	(20.2–22.8)	(16.5–18.8)	(14.2–17.1)	(8.7–11.7)	(0.1 to 3.9)	
SF-12 PCS	10.3	17.6	12.0	8.1	4.2	0.7	<0.001
(mean, 95 % CI)	(9.4–11.2)	(15.6–19.5)	(10.8–13.2)	(6.0–10.2	(2.4–6.0)	(−1.2 to 2.5)	

[a] ANOVA

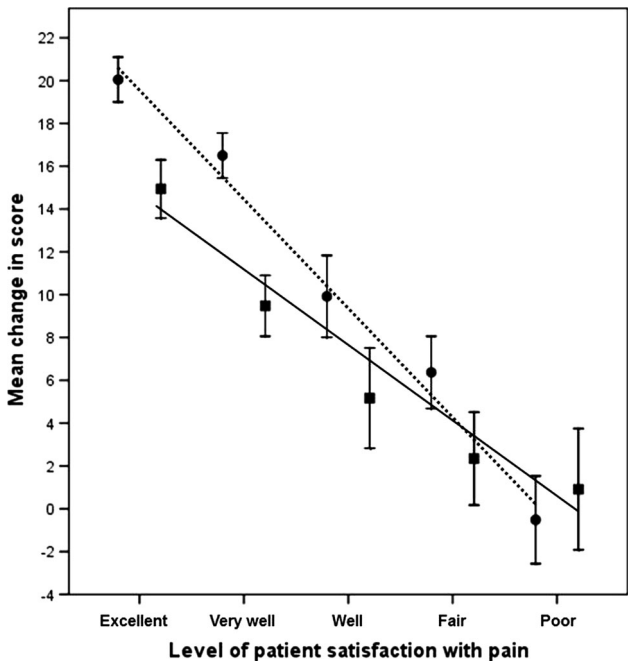

Fig. 1 Change in OKS (*circles*) and SF-12 PCS (*squares*) with 95 % CI at 1 year according to level of patient satisfaction with pain relief. The correlation between the change in OKS (*dashed line*) and SF-12 PCS (*solid line*) and level of satisfaction is illustrated

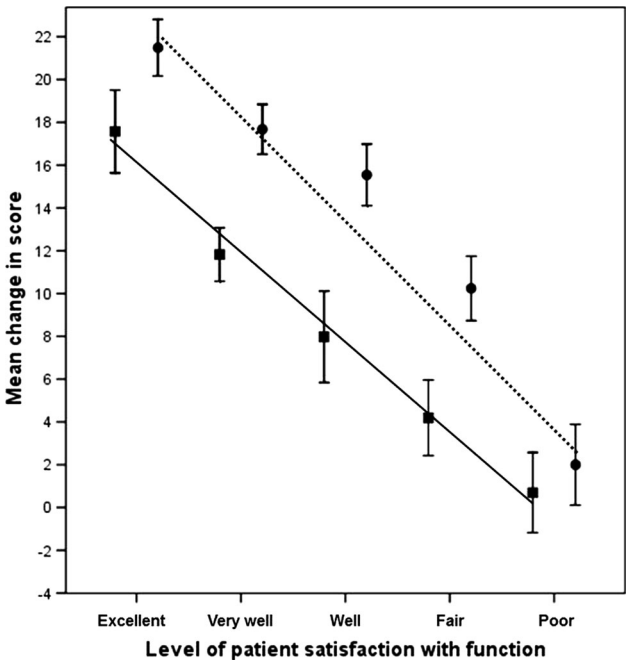

Fig. 2 Change in OKS (*circles*) and SF-12 PCS (*squares*) with 95 % CI at 1 year according to level of patient satisfaction with function. The correlation between the change in OKS (*dashed line*) and SF-12 PCS (*solid line*) and level of satisfaction is illustrated

($p < 0.0001$). Patients were more likely to rate their pain relief as excellent (odds ratio (OR) 2.46, 95 % CI 1.87–3.24, $p < 0.001$) compared to their functional outcome. In contrast, patients were more likely to perceive their functional outcome as "well" (OR 1.86; 95 % CI 1.29–2.69, $p = 0.007$), or "fair" (OR 2.34; 95 % CI 1.54–3.57, <0.001), or "poor" (OR 1.72; 95 % CI 1.07–2.78, $p = 0.03$) compared to their satisfaction with pain relief. Patients declaring their functional outcome as "well" ($p < 0.001$) or "poor" ($p = 0.004$) had a significantly greater improvement in their OKS than the comparative level of satisfaction with pain relief (Table 3). Comparing the MCID for satisfaction in pain relief and function, there were no statistically significant differences between the MCID identified for the OKS and the SF-12 PCS scores.

Discussion

The most important finding of the present study was the MCID identified for the OKS and SF-12 PCS scores, which confirmed and supported previously published estimates of the MCID. This study has demonstrated the MCID for the OKS and the SF-12 PCS score to be between 4 and 5 points for both pain relief and function. In addition, an interesting aspect of this study was the different level of satisfaction with pain relief compared to functional outcome, with 77 % of patients declaring their satisfaction with pain relief to be excellent or very well, which fell to 58 % for satisfaction with functional outcome. However, despite patients being more likely to be satisfied with their pain relief compared to the functional outcome, overall the MCID was not demonstrated to be different between these two anchor questions.

This study supports the previously proposed MCID for the OKS of 5 points, by authors using half the standard deviation for the population at risk [7, 9, 11], using the anchor method approach [25]. However, the standard deviation for the OKS, and hence the MCID, varies according to the time point measured as demonstrated in the cohort of this study, which is also different from that observed for the change in the score between the time points. The MCID in the OKS using the anchor method for pain was demonstrated to be 5.0 points and 4.3 points for functional outcome. The designers of the OKS acknowledge that there is no MCID, but suggest that it is likely to be between 3 and 5 points [22]. This was based upon halving the standard deviation of the OKS, which can range between 6 and 10 points. They also suggest that it may be as low as 2 points [22], as a prior study demonstrated a 2-point difference in the oxford hip score according to surgical approach [1]. This may, however, not be applicable to the OKS. Interestingly, there was a 0.7-point difference between the MCID for pain and function, although this was not statistically significant. Rounding these values to the nearest whole number would suggest that there is a difference in these two outcomes, where the MCID for pain is 5 points and the MCID for function is 4 points. However, this may be an inherent characteristic of the OKS, where six questions relate to pain and six to function, which may improve to differing degrees after TKA and hence the difference demonstrated in the MCID. It is interesting to note this difference, depending on the end point of the study when comparing cohorts or performing power calculations, in pain relief and functional outcome.

Keurentjes et al. [15] recently conducted a systematic review of the literature and reported the MCID for the SF-36 after primary TKA, which was, however, limited to a single cohort. They demonstrated the MCID to vary according to the dimension assessed, with wide 95 % confidence intervals. The developers of the SF-36 modified this eight-dimension (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotion, and mental health) score into two summary scores, which led to the development of the SF-12 score being reported as a PCS and MCS score [32, 33]. This was thought to help make trial and other longitudinal data easier to report and interpret. Hence, although the SF36 and SF-12 use the same questions, the reported scores are not comparable, being calculated and weighted differently, and the MCID identified by Keurentjes et al. [15] is not applicable to the SF-12 score. The original aspect of the reported study was to identify the MCID for the SF-12 PCS after TKA. Previous authors have, as for the OKS, used half the standard deviation to define the MCID for the SF-12 PCS, but this varies between 4 and 5 points [7, 9]. This study has affirmed these previous estimates, with 95 % CI between 4 and 5 points, but overall for both pain and function, the MCID was 5 points. Parker et al. recently demonstrated the MCID for the SF-12 PCS to be as small as 2.5 points [23] and as great as 8.1 points [24] for different spinal procedures. This suggests that the identified MCID illustrated for TKA may vary according to different knee procedures, and hence, it cannot be assumed that the values identified are universal to all orthopaedic interventions using the SF-12 PCS score.

The wide 95 % confidence intervals demonstrated by Keurentjes et al. [20] in the MCID for each of the eight dimensions within the SF-36 after primary TKA led them to conclude that a single value may not be reliable. In contrast, the 95 % confidence intervals for the MCID presented in the current study are relatively narrow and do not range outside of 4 or 5 points for the OKS or the SF-12 PCS for either pain relief or function. In addition,

Keurentjes et al. [20] also stated that a 'one-size-fits-all' MCID may not be justified as patients suffering from osteoarthritis of differing joints may have different MCIDs despite being regarded as similar disease entities. To expand upon this point further, the MCID may also vary according to the differing case-mix variables of the cohort examined. Patient factors such as age [8], socio-economic status [9], mental health [11], and general physical health [7] influence the OKS and SF-12 score after TKA. The reported population is, however, typical of that undergoing TKA, with a mean age of 70 years, a female predominance, and pre-operative PROMs that are similar to National Joint Registry data [3], and hence, MCID presented in this study represents the best available estimate for a standard population.

The use of triangulation, using multiple anchor questions, is thought to be a more reliable method of identifying the true MCID [25]. The recent systematic review by Keurentjes et al. [20] was not able to identify any study that used an additional secondary anchor question for the validation of the MCID. They raise this point in their discussion and expand upon it further commenting on the small group sizes reported in the literature, which may limit the precision of the MCID estimate without the application of additional validation [30]. Hence, the reported study seems to be original using two questions, assessing patient satisfaction with pain and their functional outcome, to validate the MCID values obtained for the OKS and SF-12 score. The MCID for both of these questions was not statistically different, with overlap of the 95 % CI and range between 4 and 5 points. Further external validation to establish the MCID for the various outcome tools that are employed in orthopaedics is required, which would enable powering of trials and demonstrate whether a statistical difference equates to a clinical difference from a patient's prospective. Until further studies validate the MCID identified by this study, the authors suggest that a 4-point MCID be used to power trials, as to avoid under-powering and a type II error, and a 5-point MCID for cohort studies to avoid a type I error, as both of these values are within the 95 % CI identified for the OKS and SF-12 score.

A limitation of this study was the relatively early assessment of patient satisfaction, with their TKA, at 1 year following surgery. Potentially, some patients' perception of pain and function may continue to improve after this time point, and hence, their level of satisfaction may change [6]. However, a study of over 27,000 TKAs performed in Sweden demonstrated the level of patient satisfaction to be "remarkably constant" 1 year after surgery for unrevised cases, with no significant change with time [26]. Furthermore, this study did not analyse the effect of factors that have previously been shown to influence patient satisfaction, such as gender, diagnosis, comorbidity, and mental health [2, 28], upon the identified MCID values for pain and function. Inclusion of these variables in the analysis may have identified differing MCID according to case-mix variables, but this would have resulted in multiple MCID, which may be beyond clinical use. Future studies should aim to confirm and validate the reported values and assess other aspects of a patient's subjective outcome, such as their expectations, as these may have differing MCIDs as well as the potential effect of case-mix variables upon these values.

Conclusion

The MCID identified for the OKS and SF-12 PCS after TKA is the best available estimate and can be used to power studies, such as randomised controlled trials, and ensures that a statistical difference also equates to a clinical difference for a patient. The MCID facilitates interpretation of what an improvement of X point's means to a patient from a clinical prospective, and factors that influence the clinical outcome of TKA can be identified and communicated to the patient or modified if possible to obtain the best possible outcome.

Conflict of interest The authors declare no conflict of interest with the content of this study.

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