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# Patient Reported Outcome Measures Review: Are current outcomes assessment tools sensitive enough to assess the reasons for patients' "unhappiness"?

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Abbreviations:
TKA Total knee arthroplasty
THA Total hip arthroplasty
PROMs Patient-reported outcome measures
HRQoL Health-related quality of life
SF-36 Short form survey – 36
QALYs Quality adjusted life years
PCS Physical component score
MCS Menta component score
AKS American Knee Society
WOMAC Western Ontario and McMaster Osteoarthritis Index
OKS Oxford knee score
OKS-APQ Oxford knee score – activity and participation questionnaire
KOOS Knee injury and osteoarthritis outcome score
HAAS High activity arthroplasty score
PREMs Patient-reported experience measures

Abstract

In an effort to improve patient quality of life after total knee arthroplasty, there is a growing focus on patient reported outcome measures (PROMs) to help clinicians gauge procedure success. Many existing PROMs are subject to the ceiling effect as the measures tested do not apply to younger patients and a more active older population with higher levels of function. Patient survey questions may lack the sensitivity and specificity to properly evaluate high performing total knee arthroplasty implants in high demand populations. Recently developed PROMs improve the ability to differentiate outcomes between patients with high levels of function but need to be tested on a wider scale. While objective measures and physician reports are still important, further work is needed to create PROMs that explain why certain patients are not satisfied with their total knee arthroplasty. The aim of this review is to evaluate the ability of current orthopaedic PROMs to detect patient "unhappiness".

1. Introduction

Total Knee Arthroplasty (TKA) is a financially and clinically effective treatment for the management of symptomatic end-stage knee arthritis. It relieves pain and  improves mobility and quality of life. TKA demand is expected to increase significantly over the coming years, with an estimated increase of up to 637% between 2005 to 2030 in the USA. This is due to a

combination of factors, including an ageing population, changing patient expectations and increasing population BMI.[1]

It is important to monitor outcomes of TKA in a quantitative, reproducible and clinically feasible manner. This is vital to assess quality of practice, for comparison of implants and the development of technologies and techniques. In excess of 100 outcome instruments exist in healthcare. Wilson and Cleary proposed a classification scheme of five levels of outcomes: biological and physiological variables (level one), symptom status (level two), functional status (level three), general health perceptions (level four), and overall quality of life (level five).[2] The concepts are in order of increasing complexity and difficulty to define and measure. From a patient perspective, quality of life is most crucial as this is what they aim to improve with any treatment or intervention.

Traditionally TKA success has been assessed using factors deemed important to orthopaedic surgeons such as implant survival, radiographical appearance and findings on objective clinical assessment. These assess outcomes in the first two or three Wilson and Cleary levels. There is now increasing emphasis on patient-centred care and satisfaction and therefore a need to assess the impact of TKA on the latter Wilson and Cleary levels.

Despite overall success of TKA, patient satisfaction is not unanimous and many report residual symptoms. A study of 10,000 patients included in the England and Wales National Joint Registry (NJR) found that a significant proportion had on-going issues: 57% had problems with kneeling, 20% had persistent pain and 17% had pain on walking.[3]  Less than 10% of patients reported no

knee problems following TKA. Physician-reported outcomes are susceptible to optimism bias, and surgeons are usually more satisfied with the results of arthroplasty surgery than patients.[4] In order to understand and assess reasons for apparent patient dissatisfaction, patient reported outcome measures (PROMs) have been developed. Terwee et al. propose that to do this well, PROMs should possess content validity, internal consistency, criterion validity, construct validity, reproducibility (agreement and reliability), responsiveness, floor and ceiling effects, and interpretability.[5] Their specific foci vary, but PROMs utilised in orthopaedics tend to assess symptom status, functional status, and general health perceptions.

PROMs are widely used in both clinical practice and in research. In this review the PROMs most commonly used in orthopaedics are discussed and evaluated for their ability to assess patient satisfaction and, where necessary, the reasons for patient "unhappiness".

2. Health-Related Quality of Life

The measurement of health-related quality of life (HRQoL) is necessary to compare quality of care provision and for resource allocation across medical specialties and institutions.

The 36-item Short Form Survey (SF-36) was developed by RAND corporation as part of their Medical Outcomes study of patients in three US cities. The study aimed to investigate determinants of variations in patient healthcare outcomes. The survey contains eight scaled scores for dimensions affecting health-related quality of life to generate a single index measure of health. The SF-36 acts as a patient-reported survey of HRQoL which can be self-

administered.[6] This survey and its derivatives are often used in health economics in the

calculation of quality adjusted life years (QALYs). The SF-12 is a shorter form which has been

developed from this and allows accurate calculation of Physical and Mental Health Component

Scores (PCS and MCS), reducing time and resource commitments.[7] It has been shown to be as

accurate as the longer version (SF 36) although with reduction in number of parameters assessed,

the information available is limited and one may lose information on important aspects of patient

health.

Another widely used HRQoL measurement is the EQ-5D. It was first introduced as a postal

survey that evolved into a version with five descriptive questions was produced, covering five

dimensions of health state. This can also be combined with the EQ-VAS, which consists of a

visual analogue scale of self-perceived health state scored from 0-100. The EQ-5D and EQ-VAS

have been found to show significant agreement with the SF-36 and SF-12 surveys, but have been

shown to be less sensitive to differences in HRQoL associated with less severe morbidity.[8] This

is in part due to the ceiling effect seen with many of the PROMs.

PROMs which assess HRQoL allow a holistic assessment of patients. They can be used to

determine the global impact of TKA on patients as a whole. However, by their nature the

resultant PROMs score is very multifactorial. Factors independent of the TKA influence

outcomes, and these changes may indeed outweigh any caused directly by the procedure. Martin

et al. found that, compared with more specific PROMs scores, SF-36 was significantly less

responsive to interventions in patients with musculoskeletal disorders.[9] Further, McGuigan et al.

showed no significant change in patient health perception when measured using SF-36 following

TKA or THA despite positive outcomes, and an inability to predict post-operative improvement on an individual basis using SF-36 score.[10] This further confirms that existing PROMs and various outcome assessment tools may not be sensitive and specific enough to identify key improvements in quality of life form a patient's perspective.

3. Joint and disease-specific PROMs

PROMs which are joint or disease-specific are the most commonly used in orthopaedic research. Some earlier PROMs were initially developed as questionnaires to focus on symptoms and functional limitations expected as a direct result of joint dysfunction secondary to arthritis. Their use has subsequently been expanded for the comparison of arthroplasty patients pre- and post-operatively. Others were developed specifically for arthroplasty patients. The resultant score provides a measure of the effectiveness of the procedure in improving specific criteria. The PROMs use functional status and specific symptoms as a proxy for patient satisfaction following arthroplasty. Some scores combine patient's perception of outcomes, clinical function as well as surgeon / health care practitioners' assessments. One example of such a score is the American Knee Society (AKS) score, which includes an objective and a functional element to how it is scored. The objective score (maximum 100 points) assesses a patient's pain and adds information on range of movement, stability of the knee and limb alignment. It deducts points for flexion deformity, leg mal-alignment and extension lag. The functional element assesses patient's ability to walk, negotiate stairs and deducts points for use of a walking aid. Although overall useful, AKS can be difficult to interpret at times as pain is very subjective and the way questions are phrased, they can be interpreted in different ways by different patients.

The Western Ontario and McMaster Osteoarthritis Index (WOMAC) contains seven symptom questions (five for pain, two for stiffness) and 17 functional status questions. It was designed as a disease-specific set of questionnaires to evaluate patients with osteoarthritis. The potential of the WOMAC score to measure outcomes following interventions including TKA was recognised, and it has been extensively tested for validity, reliability, feasibility, and responsiveness in arthroplasty patients.[9]

The Oxford Knee Score (OKS) was first proposed in 1998 by Dawson et al. It contains 12 questions which combine symptoms and function, which are each scored out of five.[11] The OKS survey was designed specifically for the evaluation of TKA patients. It was proposed as a shorter and more specific alternative to the WOMAC score and showed good agreement with both SF-36 and the American Knee Society (AKS) score. The OKS was also found by Dawson et al. to have high internal consistency, reproducibility, satisfactory test-retest reliability, and to be more responsive to changes following TKA than the SF-36. The OKS has subsequently been found to be reliable, feasible with minimal imposed patient-burden, and at least as responsive as the WOMAC score.[12]

Both the WOMAC score and OKS are commonly used in both clinical practice and research to evaluate the outcome of TKA. However, the functional aspects of both surveys focus on activities of daily living, without assessment of impact on higher levels of function. Early knee prostheses were considered successful if they achieved pain relief and reasonable range of movement. With the improvements of outcomes following TKA, its indications have expanded

to include younger and more active patients with higher demands and all patients have increasing expectations of the result of their TKA. Previously patients were only offered a TKA when patient was more or less house bound and the arthritis was end-stage. With increasing evidence that TKA works well and with improved surgical techniques TKA is being increasingly offered to younger patients with less severe arthritis.

To be useful in clinical and research contexts for the assessment of patient satisfaction, PROMs must differentiate across the full range of patients. When observed in the context of PROMs, the "ceiling effect" is a measurement limitation which occurs when a considerable proportion of subjects score the best or maximum score. This is primarily due to the way the questions are framed and interpreted by a patient. For example, Oxford Knee Score has 12 questions primarily assessing patient's pain and function. Both are assessed through a 5 point question (5 for pain and 7 for function) and the questions can easily be answered with a maximum score, especially in the younger patients as they can easily indulge in the activities that are asked in the questionnaire (such as ability to get in and out of a car, getting up from a sitting position, go down one level of stairs etc.). Elderly patients may not be able to do these activities and at times their inability may not be primarily due to the problems in the knee itself.

In orthopaedics it is generally considered to be acceptable if less than 15% of patients achieve the maximum score.[5] When this threshold is exceeded it becomes more difficult to differentiate between patients with good outcomes and those with excellent outcomes. The WOMAC score has been shown to demonstrate a ceiling effect in patients evaluated following both TKA and

THA,[13] and several studies have also reported a ceiling effect in the OKS for patients following TKA.[14]

The Lysholm Score and Tegner activity scale have been validated for use in TKA and demonstrate little or no ceiling effect. This is likely because they were originally designed for use in an active and more demanding population. However, they have questionable construct validity as the items used are surgeon-derived and may not reflect important outcomes for patients.[15] In TKA patients they also showed only moderate correlation with SF-12 scores, and the Lysholm score had low reliability for some criteria.

4. Higher functional status PROMs

New PROMs have been developed in response to the increasing patient demands and expectations following TKA and are designed to discriminate better between patients with a higher level of function.

The Oxford group which developed the original OKS published a supplementary PROM for the measurement of activity and participation (OKS-APQ), designed to be used in addition to the standard OKS.[16] The authors recognised the increasing numbers of younger patients undergoing TKA and their increased functional expectations. They showed this PROM to have good correlation with AKSS, OKS and SF-36. It was found to be both reliable and valid. The OKS-APQ was developed in 99 younger patients (mean age 61.5 years), but the authors recommended its use in the assessment of all patients. Although developed recently, this questionnaire may

become a default PROM for assessment of outcomes post-TKA if it is used in a variety of settings.

Roos et al. developed the self-administered Knee Injury and Osteoarthritis Outcome Score (KOOS) for the assessment of patients with meniscal and ligamentous knee injuries. All questions from the original WOMAC survey were included. The authors also added further questions about knee symptoms, and two further subsections of questions regarding sport and recreation function and knee-related quality of life. KOOS was specifically developed for younger patients with knee injury or osteoarthritis and higher levels of function. The same group validated KOOS in total knee replacement in 2003, and found it to be at least as responsive as WOMAC, in addition to have improve validity and greater sensitivity.[17,18]

The High-Activity Arthroplasty score (HAAS) was developed and reported by Talbot et al. in 2010 and takes a purely functional approach to assessment of PROM.[19] It consists of four questions which assess patient ability to walk, run and climb stairs, and also queries their general activity level. The authors found that HAAS produced a wider range of scores in patients following TKA and THA as compared with WOMAC, Knee society and Oxford score, suggesting an increased ability to differentiate. In their study of 100 patients operated for TKA, Jenny et al. found no ceiling effect as compared with AKSS (53%) and OKS (33%) despite a smaller number of questions.[14]  A low level of correlation of HAAS with these reference scores was found. The authors suggest this is because HAAS captures a different component of the functional result of TKA and suggest its routine use in all TKA patients as a complementary outcome measure.

The Forgotten Joint Score was validated in TKA and THA patients by Behrend et al. in their 2012 paper, where they proposed "a new aspect of patient-reported outcome: the patient's ability to forget the artificial joint in everyday life".[20] The resultant 12 item survey (FJS-12) showed high internal consistency and correlated well with WOMAC. It also had a much lower ceiling effect compared with WOMAC subscales and was able to differentiate between scores even in healthy controls. Subsequent studies provided more evidence for the superiority of FJS-12 compared with WOMAC. They additionally demonstrated excellent test-retest reliability and strong correlation with OKS and KOOS, whilst also demonstrating a much lesser ceiling effect.[13]

5. Current Limitations and Development

OKS and WOMAC remain the most commonly used specific PROMs used both clinically and in research.[21] For assessment of global HRQoL, these may be used in conjunction with SF-36 or a derivative of this survey. At an individual level, patients are clinically and radiologically assessed by operating surgeons. The study of these outcomes at the lower levels of the Wilson and Cleary model[2] is of course necessary to continued high quality outcomes. However, it is no longer sufficient. As outcomes and implant quality improve, justified confidence in TKA has permitted expansion of indications, and it is now routinely offered for much younger and more active patients. Additionally, older patients are becoming more active with greater longevity, and so also expect to return to increasingly demanding lifestyles. Earlier PROMs were designed to assess symptoms and basic activities of daily living.[19] The presence of pain, stiffness and a low level of functionality are used as proxies for patient satisfaction. As a result of improving

outcomes, significant ceiling effects are now present in these outcome measures. These prevent detection of patient unhappiness, and why this occurs. Rastogi et al. investigated common patient concerns in the early post-operative period and found that many of these were not accounted for in traditional scoring systems. These included the ability to drive, quality of sleep, being dependent on others, and returning to sports and hobbies.[22] Although important to the patient, it is difficult if not impossible to understand whether the ability or inability to perform these activities is solely due to the knee. Other issues important to patients include awareness of increased weight of TKA and increased awareness at extremes of temperature. These aspects are not assessed by any of the existing assessment tools and specific questionnaire(s) will need to be developed to gain a better understanding. Generic HRQoL measures also often lack the necessary specificity and responsiveness to adequately assess the impact of TKA on patient quality of life.[9,10]

The development of more recent PROMs has focused on measures which allow improved discrimination between patients with higher levels of function, and PROMs such as KOOS, HAAS and FJS-12 demonstrate little if any ceiling effect,[13,14,17,18] despite assessing patients with a greater range of much better outcomes. The welcome inclusion of quality of life elements within some more recent PROMs allows the assessment of the wider impact of TKA on quality of life in general, whilst also allowing specificity to eliminate confounding factors.[17]

Other factors independent of technical, symptomatic and functional success also affect patient satisfaction with TKA. Patients may report good levels of satisfaction despite poor clinical outcome, and vice versa.[3] Patient experience of receiving care is one of the factors involved.

Measurement of this has required the introduction of patient-reported experience measures (PREMs). The concept of the "Net Promoter Score" was introduced to the business world by Reichheld in 2003,[23] and has since been adapted by the UK government to be used as the "friends and family test" PREM in the National Health Service. It assesses whether patients would recommend a service or intervention to a loved one. The results of this simple PREM was studied in lower limb arthroplasty patients, and found that the factors most predictive of satisfaction were achievement of pain relief, the meeting of pre-operative expectations, and the general hospital experience.[24]

6. Conclusion

The assessment of patient-reported outcomes allows impartial measures of the success of TKA and orthopaedic procedures in general. The information from these PROMs is combined with objective measures of technical success and clinician assessment and are vital for the further development of TKA systems. To be successful, PROMs should be developed with patient involvement to ensure content validity; in addition to impartiality, surveys must contain questions about outcomes most important to patients. These must be up to date and relevant to prevent the development of ceiling effects with time. Despite widely reported success of TKA in the treatment of end stage arthritis,[25] less than 10% of patients report no problems with their TKA.[3] This is quite different to patients who have undergone a THA. A vast majority of patients with THA report no problems with their THA. Although exact reasons are not known for this discrepancy it is likely to be multi-factorial and include biomechanics, demands placed on the knee by the patient and ability of the spine to compensate for hip pathology.

PROMs continue to improve and better fulfil the goals laid out by Terwee et al,[5] but their constant revalidation and regular incorporation of better PROMs into routine practice and research is key to a better understanding of reasons for patient "unhappiness". A holistic approach to patient services must also be employed, and the use of PREMs allows further elucidation of healthcare factors outside the realm of PROMs which influence patient satisfaction.

One may decide to ask patients more open-ended questions rather than closed questions to get a better understanding of their dissatisfaction or concerns. However, this is not without its own issues. Open ended questions can lead to replies which are difficult to interpret and are more time consuming. They provide useful information but are more of a research tool rather than for routine clinical use.

In conclusion, existing PROMs and PREMs are an important and useful tool to impartially assess outcome of a TKA. However, they are far from perfect and further work is needed to develop questionnaires which will help clinicians understand why certain patients are not satisfied with their TKA whilst others are although there is no difference in any of the objective measures that are assessed.

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