Outcome Measurements Following Total Knee Arthroplasty

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Total knee arthroplasty (TKA) is a definite surgical treatment for late stage knee osteoarthritis. Currently, there are several outcome measurements following TKA which evaluate clinical signs and symptoms, functional activities, and postoperative radiographs. Patient-based evaluation with disease-specific assessment is simple while it provides good validity and reliability. Regarding patient-based evaluations with general health assessment, the short-form health survey (SF)-12 is less time consuming than the SF-36, while providing similar validity and reliability. Although the surgeon-based evaluation is still commonly used in outcome measurement following TKA, it has less responsiveness on the function subscale. Functional performance-based evaluation may not be a sufficient measurement at the immediate-term (< 3 months) follow up, as studies have shown poor improved function performance. However, to perform functional performance-based evaluation, the time-up-and-go test or 30-s chair stand test for performance functional-based evaluation are reliable and less time consuming assessments. On the other hand, the immediate post-surgery use of the 6-minute walk distance is somewhat questionable, as it takes a long evaluation time which may cause the patient to become exhausted.

Keywords: *Total knee arthroplasty, osteoarthritis, outcome measurements*

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Introduction

Total knee arthroplasty (TKA) is a definite surgical treatment for late stage knee osteoarthritis (OA). Although most patients are satisfied and have improved quality of life after TKA[(1)], the literatures demonstrated that 9-25% of them are not satisfied due to unfulfilled pre-operative expectations, including pain relief and experiences of being admitted to the hospital[(2-5)]. In the year of 2030, expected surgical treatment of knee OA in the United States will increase to 673%[(6)]. Therefore, suitable outcome measurements of surgical treatment for OA should be readdressed.

Outcome measurements following TKA

Currently, there are several outcome measurements following TKA which evaluate clinical signs and symptoms, functional activities, and postoperative radiographs. Based on evaluators, outcome measurements following TKA can be divided into 3 groups, including patient-based evaluation; where the patient answers a questionnaire according to his or her subjective perception to questions, surgeon-based evaluation; where the surgeon evaluates the patient according to the list of parameters and the patient's report on functions, and functional performance-based evaluation; where the performance on specific activities, such as stair climbing, getting up from a chair, and walking distance in a limited time are objectively evaluated by a clinical evaluator.

1. Patient-based evaluation

This evaluation is based on the patient's perception by responding to various forms of questionnaires or interviews, including clinical symptoms of pain and stiffness, satisfaction, expectation, and functional activities. Patient-based evaluation for outcome measurement following TKA is reported reliable and valid for the judgment of health status and treatment benefits[(7-8)]. Advantages of this group of evaluations include simple technique, a short time-required for the task[(9)],and high internal consistency[(10-12)]. On the other hand, disadvantages are a limitation to represent true functional activities[(13)], influenced by multiple factors, such as psychological status[(14)], and not covering all aspects to assess health outcomes[(15)]. Patient-based evaluation can be classified into 2 subgroups according to disease-specific or general health assessment. Combined use of disease specific and general health assessments is likely to cover more aspects of the outcome following TKA[(16)].

1.1. Disease- specific assessment

This assessment is rather specific to the health issues caused by the disease and more sensitive to the effects of a given condition on health.

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)[9]

The WOMAC, a disease-specific measurement of function, consists of 3 domains of questionnaire in a total of 24 items. It includes pain for 5 items, stiffness for 2 items, and physical function for 17 items. Each item is graded from 0 to 4 (0 = very well, 4 = very poor) with a maximum score of 96 points (the worst outcome) and a minimum score of 0 points (the best outcome). The WOMAC has been validated for telephone and computerized/electronic administration. Besides an English form, it is available in over 65 alternate language forms, such as Greece, Chinese, German, and Thai.

Several studiesreported that the WOMAC is suitable for evaluation in TKA patients[10-11]. According to the systematic review from 76 articles over 22 countries of Gandek et al.[10], the internal consistency reliability of WOMAC was consistently high (>0.90) for the function scale, and acceptable (>0.70) for the pain and stiffness scales. In addition, the test–retest reliability was acceptable. Similarly, the study of Papathanasiou et al.[11] found that repeat WOMAC score at an 8-day interval of patients with knee OA was good (0.804) to excellent (0.956) in internal consistency. Intra-class correlation coefficients (ICC) for test–retest reliability were excellent, ranging from 0.91 to 0.95. They concluded the WOMAC was a reliable and valid assessment tool for the evaluation of individuals with knee OA.

The Oxford Knee Score (OKS)[7]

The OKS has 12 items for evaluating patients' clinical symptoms and functional activities including 1) knee pain, 2) washing & drying, 3) getting in and out of a car, 4) walking time, 5) limping, 6) kneeling down and getting up, 7) standing from a chair, 8) night pain, 9) interfering with usual work, 10) giving way of the knee, 11) shopping, and 12) walking down one flight of stairs. Each of these 12 items is graded from 1 to 5 (1= best, 5 = worst, minimum = 12 points, and maximum = 60 points). Similar to the WOMAC, this measurement is available in several language forms.

The use of OKS for knee OA patients who underwent TKA showed improvement of clinical outcome with satisfied internal consistency (preoperative and postoperative Cronbach alpha coefficients were 0.88 and 0.66, respectively)[12]. The Rasch-OKS was a modified 10-item OKS introduced by Ko et al.[17], which removed the items of limping and kneeling due to inadequate fit statistics. According to Ko et al.[18] study in 702 TKA patients, Raw-OKS and Rasch-OKS had comparable responsiveness.

The Knee Injury and Osteoarthritis Outcome Score (KOOS)[19]

The KOOS has 5 dimensions of scoring including 1) symptoms & stiffness for 7 items (Sy1-7), pain for 9 items (P1-9), function for daily living for 17 items (A1-17), function for sports and recreational activities for 5 items (Sp1-5), and quality of life for 4 items (Q1-4) with a total of 42 items. Each of 42 items is graded from 0 to 4 (0 = best, 4 = worst). Transformed scale of KOOS is shown below. The possible raw scores of Sy, P, A, Sp and Q are 28, 36, 68, 20, and 16, respectively.

Transformed scale of KOOS

$$= 100 - \frac{\text{Actual raw score x 100}}{\text{Possible raw score range}}$$

The KOOS was first presented by Roos et al.[19] in the study of patients undergoing anterior cruciate ligament (ACL) reconstruction. They found the ICC could all be regarded as high and were 0.85 for pain, 0.93 for symptoms, 0.75 for activities of daily living, 0.81 for sport and recreation function, and 0.86 for knee-related quality of life. They concluded that KOOS had sufficient reliability, validity, and responsiveness for surgery and physical therapy after ACL reconstruction. Regarding the use of KOOS in TKA patients, Roo et al.[20] reported that the ICC were over 0.75 for all subscales indicating sufficient test-retest reliability with the conclusion that the KOOS was valid, reliable, and a responsive outcome measurement in total joint replacement.

Lysholm Knee scale[21]

This measurement has 8 items for evaluation of patients' symptoms and function, including 1) limping (0-5 points), 2) using a cane or crutches (0-5 points), 3) locking sensation in the knee (0-15 points), 4) giving way sensation from the knee (0-25 points), 5) pain (0-25 points), 6) swelling (0-10 points), 7) climbing stairs (0-10 points), and 8) squatting (0-5 points). The maximum score is 100 points (best) and the minimum score is 0 points (worst).

The Lysholm knee scale is mostly used for measurements following the treatment of knee ligament injuries while it is not commonly used in TKA. Briggs et al.[22] reported the Lysholm knee scale has acceptable test-retest reliability (the ICC = 0.9) after anterior cruciate ligament treatment. Diduch et al.[23], studying 103 TKA patients for a mean 8-years follow up, found that the average activity score of the Lysholm knee scale improved from 1.3 points (range, 0 to 4 points) preoperatively to 3.5 points (range, 1 to 6 points) at the latest follow-up.

1.2. General health assessment

General health assessment represents the patient's overall health; however it does not refer to the disease or certain problems that may cause poor health.

The 36-item short-form health survey (SF-36)[24]

The SF-36 has 8 domains (36 items) of questionnaire with 2 components of summary scales; physical component summary (PCS) and mental component summary (MCS). The PCS is composed of 4 items, including 1) physical function (10 items, 10-30 points), 2) role limitations due to physical health (4 items, 4-8 points), 3) bodily pain (2 items, 2-11 points), and 4) general health perceptions (6 items, 6-30 points). The MCS is composed of 4 items, including 1) vitality (4 items, 4-24 points), 2) social function (2 items, 2-9 points), 3) role limitations due to emotional health (3 items, 3-6 points), and 4) general mental health (5 items, 5-30 points). Each of the 36 items is graded from 1 to 5 (1= best, 5 = worst, minimum score = 12 points, and maximum score = 60 points).

The Cronbach alpha coefficients of SF-36 was moderate to high (0.77-0.90) for domains' reliability, including 1) physical function (0.88), 2) role limitations due to physical health (0.90), 3) bodily pain (0.80), 4) general health perceptions (0.83), 5) vitality (0.88), 6) social function (0.77), 7) role limitations due to emotional health (0.80), and 8) general mental health (0.82)[16].

The 12-item short-form health survey (SF-12)[25]

The SF-12 is modified from the SF-36 by decreasing 36 items to only 12 items. Ware et al[25] showed that the SF-12 achieved a multiple coefficient of determination (r^2) of 0.911 and 0.918 in predictions of the SF-36 PCS and SF-36 MCS. Test-retest at 2-weeks reported the correlations of SF-12 PCS and SF-12 MCS were 0.89 and 0.76, respectively. The SF-36 obtained the better results; however, it was simpler and time-saving compared with the SF-36.

The EuroQol (EQ-5D)[26]

The EQ-5D was initiated in 1987 by the EuroQol group. This measurement is a nondisease-specific instrument for describing and valuing health-related quality of life. The EQ-5D is divided into 2 parts; 1) EQ-5D self-classifier which has 5 dimensions, including 1) mobility, 2) self-care, 3) usual activity, 4) pain/ discomfort, and 5) anxiety/depression, and 2) EQ VAS which is self-evaluation of the patient's health, ranging from 0 to 100 points (0= worst, 100= best) or 20 cm vertical visual analogue scale (vas), ranging from 0 (worst imaginable health state) to 100 (best imaginable health state). The EQ-5D is easy to use, capable of self completion, taking only a few minutes, relevant to all respondents, and good cost effectiveness[26]. Fransen and Edmonds[27] tested the validity of the EQ-5D in 82 patients with knee OA and found that the EQ-5D had good reliability with the ICC of 0.70 and the ICC for EQ-VAS was 0.73. The EQ-5D has good validity and reliability when compared to WOMAC and SF-36.

The UCLA Activity Score[28]

The UCLA is a 10-point scale measurement which evaluates patients' daily activity levels. The 10-point scale is leveled from 1 to 10 (1= worst, 10 = best). The level 1 is wholly inactive and dependent on others, while the level 6 is unlimited housework and shopping and the level 10 is regular participation in impact sports, such as jogging or tennis.

According to the study of Amstutz et al.[28] in 285 patients with primary hip OA who underwent total joint and surface replacement, and the study of Zahiri et al.[29] in 100 total joint replacements, the UCLA activity was valid for routine activity assessment in a clinical setting of total joint and surface replacements. The limitation of the UCLA activity score was that the categorical nature of the descriptions for the 10 activity levels, making the UCLA activity rating scale insensitive to the frequency and intensity of an activity.

2. Surgeon-based evaluation

This evaluation is based on the surgeon's interpretation on the history taken, physical examination, and radiographic evaluation. However, some parameters in the evaluation consist of the patient's subjective report, including pain, satisfaction, expectation, and activity level. Surgeon-based assessments include American Knee Society Score (AKS)[30], and New Knee Society Score (New KSS)[31]. The advantages are that it is simple and more objective, however, it requires surgeons' time to evaluate.

The American Knee Society Score (AKS), The Knee Society Clinical Rating System[30]

This measurement is composed of 2 parts; 1) knee score and 2) functional score. The knee score is calculated from the subtotal score minus the deduction score (probable score is 0 (include zero and minus point) to 100 points). Subtotal score includes 1.1) pain (KS-P) (0-50 points), 1.2) range of motion (ROM) (5-25 points), and 1.3) stability (anterior/posterior 0-10 points, and medial/lateral 0-15 points). One study combined ROM and stability and known as clinical judgment (KS-C)[18]. The maximum subtotal score is 100 points. The deduction score includes flexion contracture (0-15 points), extension lag (0-15 points), and malalignment (0-20 points). The maximum deduction score is 50 points. Similarly, the functional score is calculated from the subtotal score minus the deduction score (probable score is 0 (include zero and minus points) to 100 points). The subtotal score includes 1) walking (0-50 points), and 2) stair climbing (0-50 points). The

maximum subtotal score is 100 points and the maximum deduction score is 20 points.

The New Knee Society Score (New KSS) [31]

In 2011, Scuderi et al.[31] modified the AKS in order to increase radiographic assessment in the objective score and to add patients' expectations, demands, and functional requirements into the report. The measurement is divided into 3 parts, including 1) initial assessment of demographic details, 2) the objective knee score evaluated by a surgeon in 3 domains; 2.1) alignment (-10 to 25 points), 2.2) instability (medial/lateral 0-15 points and anterior/posterior 0-10 points), and 2.3 joint motion (ROM 1 point for each 5 degrees with deduction by flexion contracture (2-15 points), and extensor lag (5-15 points), 3) the patient's subjective evaluation in 4 aspects; 3.1) symptoms (0-25 points), 3.2) patient satisfaction (0-40 points), 3.3) patient expectations (3-15 points), and 3.4) functional activities which is divided into 4 levels; 3.4.1) walking and standing (-10 to 30 points); 3.4.2) standard activities (0.-30 points); 3.4.3) advanced activities (0-25 points), and 3.4.4) discretionary knee activities (0-15 points).

Noble et al.[32] demonstrated Cronbach's alpha values for the individual subscales of the functional activities ranged from 0.68 to 0.95, which suggested an acceptable level of internal consistency and concluded that the new Knee Society Scoring System should be broadly applicable and accurately characterizes patient outcomes after TKA.

3. Functional performance-based evaluation

This group of evaluations demonstrates patients' performance on activities determining knee functions which represent actual ability of the examined knee. However, the disadvantage of this evaluation is the risk of fall or accident during the test.

According to the systematic review of Dobson et al.[33] there are 21 common performance-based tests, including 15 single-activity (8 walk tests, 4 chair stand tests, 3 stair climb tests) & 6 multi-activity tests. However, the Osteoarthritis Research Society International (OARSI)[34] has recommended 5 performance-based tests of physical function after total joint replacement including 1) the 30-s chair-stand test representing sit to stand activity, 2) 40 m fast-paced walk test representing walking short distances, 3) a stair-climb test representing stair negotiation, 4) timed up-and-go test representing ambulatory transitions, and 5) 6-min walk test representing aerobic capacity/walking long distances.

The 30-s Chair-stand Test

This test measures the number of times that the patient rises from a chair to a full stand with body erect and straight, and then returns back to a seated position in 30 seconds (if more than halfway up at the end of 30 seconds, it is counted as a full stand).

Jones et al.[35] presented the 30-s chair stand test to indicate the lower body strength in generally active community dwelling older adults. The reliability was good (ICC of 0.84 for men and 0.92 for women) and moderately high correlations between chair-stand performance and maximum weight-adjusted leg-press performance for both men and women (r = 0.78 and 0. 71, respectively). The results supported the criterion-related validity of the chair-stand test as a measure of lower body strength. Gill and McBurney[36] showed ICC of this test was consistently high (intra-rater reliability = 0-97-0.98, and inter-rater reliability = 0.93-0.98) and concluded that the 30-s chair-stand test could be a reliable measurement for physical performance.

The 40 m Fast-paced Walk Test (40 m fast SPWT)

This test measures the time that the patient takes to walk as quickly, but safely, as possible to a mark at 10 m away, then return and repeat for a total distance of 40 m. Kennedy et al.[37] showed the ICC was 0.91 (95% CI, 0.81-0.97) that meant the test-retest estimate of the SPWT met the requisite standards for making decisions at the individual patient level.

The Stair-climb Test (SCT)

The test measures the time that the patient ascends and descends a flight of 9 steps (step height at 20 cm) in the usual manner at a safe and comfortable pace. Using the hand rail is not specified for this test. This test assesses lower extremity strength, power, and balance. Kennedy et al.[37] showed the ICC was 0.90 (95% CI, 0.79-0.96) which meant the test-retest estimate of the stair-climb test met the requisite standards for making decision at the individual patient level.

The Time-up-and-go Test (TUGT)

This measurement was initiated in 1991 by Podiadlo and Richardson[38] which was modified from the "get up and go test" by Mathisas et al. This test assesses quantifiable functional mobility. The test measures the time that the patient takes to rise from a chair and walk for 3 m. Then, he or she turns around and comes back to the seat at the initial position. According to Podiadlo and Richardson, the TUGT was a reliable and valid test for quantifying functional mobility. Kennedy et al.[37] showed the ICC of TUGT was 0.75 (95% CI, 0.51-0.89). The advantages are that it is fast, easy, and does not require special equipment or training.

The 6-minute Walk Distance (6MWD)

The 6MWD is modified from the 12-minute walking test to measure exercise tolerance and is simpler and more practical to define everyday disability than the 12-minute walking test. Although the 12-minute walking test is both time consuming for the investigator and exhausting

for the patient, Butland et al.[39] have showed that there was a high correlation between 6-minute vs 12-minute walk tests (r=0.955). Jakobsen et al.[40] represented the ICC of 6MWD was 0.97 and concluded the intra-tester reliability of the 6-min walk test was high in patients with TKA.

Although Oultet et al.[41] reported that, following TKA, the 6MWD decreased to 72% and 58% at immediate and 2 months, postoperatively, Ko et al.[42] showed a stronger constructed validity of the 6MWD in the TKA population than TUGT, 30MWD, and WOMAC. They suggested that the 6MWD was a strong predictor of patient-reported function after TKA.

Comparative studies on outcome measurements following TKA

According to studies on comparative outcome measurements following TKA[18, 43-46], there is no best measurement that covers all domains or aspects of outcomes. The study of Gandhi et al.[43] comparing patient-based (WOMAC and SF-36) and functional performance-based (TUGT) measurements suggested patient evaluation for level of disability should include a combination of self-reported and performance-based tests. In addition, the study on patient-based (WOMAC) and functional performance-based (6MWD and TUGT) measurements of Stratford et al.[44] showed that the dependence on self-reported measurements alone resulted in an overestimation of the ability of patients, postoperatively. Mizner et al.[45] reported that functional performance-based measurements (TUGT, SCT, and 6MWD) decreased after surgery then gradually increased in long-term follow ups, while patient-based measurements (SF-36 and KOS-ADLS) had excellent long-term responsiveness that were twice as large as functional performance-based measurements.

Medalla et al.[46] showed a good correlation of patient-based measurement (OKS) and surgeon-based measurement (AKS) at 2 years with moderate correlation at 5 and 10 years. Ko et al.[18] reported bodily pain (BP) and physical functioning (PF) were more responsive than the other subscales of SF-36 domains. On the other hand, among KS subscales, the KS-P was the most responsive, while the KS-F was the least responsive. Therefore, the measurement used should combine patient-based (disease specific and general health assessment), surgeon-based, and functional performance-based evaluations.

Conclusion

Based on the literature review and our clinical experience, patient-based evaluation with disease-specific assessment (WOMAC and OKS) is simple while it provides good validity and reliability. Regarding patient-based evaluations with general health assessment, the SF-12 is less time consuming than the SF-36, while providing similar validity and reliability. Although the surgeon-based evaluation (AKS) is still commonly used in outcome measurement following TKA, it has less responsiveness on the function subscale. Functional performance-based evaluation may not be a sufficient measurement at the immediate-term (< 3 months) follow up, as studies have shown poor improved function performance. However, to perform functional performance-based evaluation, the TUGT or 30-s chair stand test for performance functional-based evaluation are reliable and less time consuming assessments. On the other hand, the immediate post-surgery use of the 6MWD is somewhat questionable, as it takes a long evaluation time which may cause the patient to become exhausted.

At our institution, we currently perform combined patient-based, surgeon-based, and performance functional-based evaluations including WOMAC, SF-36, AKS, TUGT, and 30-s chair stand test for outcome measurements following TKA.

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การประเมินผลหลังการผ่าตัดเปลี่ยนข้อเข่าเทียม

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การผ่าตัดเปลี่ยนข้อเข่าเทียมเป็นการรักษาผู้ป่วยที่มีข้อเข่าเสื่อมระยะรุนแรงหรือไม่ตอบสนองการรักษาด้วยวิธีไม่ผ่าตัด ผลลัพธ์ของการผ่าตัดเป็นที่น่าพอใจและสามารถเพิ่มคุณภาพชีวิตให้กับผู้ป่วยส่วนใหญ่ โดยผู้ป่วยส่วนน้อยไม่พึงพอใจหลังผ่าตัด เนื่องจากอาการปวดหรือไม่ดีขึ้นตามที่คาดหวัง ทั้งนี้ในปัจจุบันการประเมินผลลัพธ์การผ่าตัดเปลี่ยนข้อเข่าเทียมมีหลายวิธี ซึ่งแต่ละวิธีมีหัวข้อในการประเมินที่แตกต่างกันไป ตามความเห็นของผู้ประเมิน ความเห็นของผู้ถูกประเมิน หรือตามความสามารถในการใช้งานข้อเข่า

วิธีการประเมินผลลัพธ์การผ่าตัดเปลี่ยนข้อเข่าเทียมสามารถแบ่งเป็น 3 กลุ่มใหญ่ คือ กลุ่มที่ 1: ผู้ป่วยทำแบบสอบถามประเมินตนเอง ซึ่งสามารถแบ่งกลุ่มย่อยเป็น 1.1) การประเมินที่เป็น disease specific เช่น The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), The Oxford Knee Score (OKS), The Knee Injury and Osteoarthritis Outcome Score (KOOS) และ Lysholm Knee scale เป็นต้น และ 1.2) การประเมินสุขภาพทั่วไป เช่น The 36-item short-form health survey (SF-36), The 12-item short-form health survey (SF-12), The EuroQol (EQ-5D) และ The UCLA Activity Score เป็นต้น กลุ่มที่ 2: แพทย์ผู้รักษาเป็นผู้ประเมินหลัก โดยพิจารณาถึงความมั่นคงของข้อเข่า พิสัยการขยับของข้อ อาการปวด และปัจจัยอื่นๆ เช่น The American Knee Society Score (AKS) และ The New Knee Society Score (New KSS) เป็นต้น และกลุ่มที่ 3: ผู้ป่วยได้รับการประเมินความสามารถในการใช้งานจริง เช่น The 30-s Chair-stand Test, The 40 m Fast-paced Walk Test (40 m fast SPWT), The Stair-climb Test (SCT), The Time-up-and-go Test (TUGT) และ The 6-minute Walk Distance (6MWD) เป็นต้น

ในปัจจุบัน การประเมินผลลัพธ์การผ่าตัดเปลี่ยนข้อเข่าเทียมแต่ละกลุ่มวิธีมีทั้งข้อดีและข้อด้อย แต่ไม่มีการประเมินผลลัพธ์วิธีใดวิธีหนึ่งที่สามารถครอบคลุมอย่างดีที่สุด ดังนั้น เพื่อให้การประเมินผู้ป่วยทุกรายมีความครอบคลุมอย่างเหมาะสมและทำได้คล่องตัวทุกครั้งที่ประเมิน คณะผู้เขียนบทความนำเสนอการใช้ทั้ง 3 กลุ่มใหญ่ในการประเมินผลลัพธ์การผ่าตัดเปลี่ยนข้อเข่าเทียมโดยคณะผู้เขียนบทความใช้การประเมินดังนี้ กลุ่ม 1 (ผู้ป่วยทำแบบสอบถามประเมินตนเอง): กลุ่มย่อย 1.1 ใช้การทดสอบ WOMAC และกลุ่มย่อย 1.2 ใช้การทดสอบ SF-36, กลุ่ม 2 (แพทย์ผู้รักษาเป็นผู้ประเมินหลัก) ใช้การทดสอบ AKS, และกลุ่ม 3 (ผู้ป่วยได้รับการประเมินความสามารถในการใช้งานจริง) ใช้การทดสอบ TUGT และ 30-s chair stand test