Should we use conventional or functional performance measures for evaluation of

immediate outcomes after TKA?

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Background: Recently, evaluation of outcomes following total knee arthroplasty (TKA) in the immediate postoperative period (\leq 12 weeks) has been frequently reported for efficiency of new surgical approaches or new pain management protocols. Several functional performance measures have been added to those of conventional tools. However, there has been no comparative evaluation of individual measures at a serial follow-up for immediate outcomes after TKA, in terms of time to significant improvement compared the preoperative period.

Methods: We prospectively evaluated 40 patients who had primary knee osteoarthritis and underwent uncomplicated TKA for immediate outcomes at postoperative 2nd week, 6th week, and 12th week, consecutively. All patients were evaluated for conventional outcome measures, including Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) index and SF-36, as well as functional performance measures, including Time up and go test (TUGT) and 6-min walk distance (6MWD). The improvement of individual tests at each evaluation was compared to the preoperative period.

Results: There were 37 females and 3 males. The patients' mean age was 70.1 years, and mean body mass index (BMI) was 27.26 kg/m². The majority of patients (97.5%) had ASA class I and II. At the 2nd week, several conventional measures, including WOMAC index and SF-36 provided significant improvement; however, all of the functional performance measures showed significantly worse parameters than those at the preoperative evaluation. Functional performance measures, including TUGT and 6MWD provided significant improved outcomes at the 12th week.

Conclusion: Conventional measures demonstrated faster outcome improvements after TKA than function performance.

Keywords: Total knee arthroplasty, functional performance measures, conventional measures, outcome, immediate

The Thai Journal of Orthopaedic Surgery: 40 No.3-4: 3-9

Full text. e journal: http://www.rcost.or.th, http://thailand.digitaljournals.org/index.php/JRCOST

Introduction

Total knee arthroplasty (TKA) is a definite surgical treatment for late stage knee osteoarthritis (OA). The goals of TKA are pain-free surgery, good mobility, and high functional activity. In the past, the patients undergoing TKA were older and sedentary, however, in the present they are younger and need more activity. Nowadays, many surgical approaches or surgical implants, and new pain management protocols are developed with the aim of improving the efficiency of the treatment.

Currently, there are several outcome measures following TKA which evaluate clinical signs and symptoms, functional activities, and postoperative radiographs. The outcome measures can be divided into conventional measures and functional performance measures.

The conventional measures included the patient reported outcome measures (PROMs) and the surgeon-based evaluation. The PROMs are based on patient self-evaluation that can be divided into 2 groups; 1) disease specific such as the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the Oxford Knee Score (OKS), and the Knee Injury and Osteoarthritis Outcome Score (KOOS) etc. 2) general health assessment such as SF-36, the EuroQol-5 dimensions (EQ5D), the UCLA activity score (UCLA), and visual analogue scale (VAS) for pain etc. The surgeon-based evaluations are composed of self-patient and surgeon assessments such as the Knee Society Score (KSS) clinical and function scores.

The functional performance measure is based on the patient's true functional activity. The

Osteoarthritis Research Society International (OARSI)⁽¹⁴⁾ 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⁽¹⁵⁾ representing ambulatory transitions 5) 6-min walk test⁽¹⁶⁾ representing aerobic capacity/walking long distances.

In the past, the several studies used PROMs to evaluate improvement post TKA, $^{(17-19)}$ but in recent years the trend of outcome measures changed to use functional performance measures. $^{(20-22)}$

However, there has been no comparative evaluation of individual measures at a serial follow-up (FU) for immediate outcome (less than 12 weeks) after TKA, in terms of time to significant improvement to the preoperative period. This study aims to determine the different patterns of improvement post-TKA of each measure when comparing the immediate period to the preoperative period. The hypothesis was that the pattern of improvement of each measure is not different.

Methods

Fifty patients who had late stage primary knee osteoarthritis and underwent TKA from October 2014 to April 2015 at King Chulalongkorn Memorial Hospital were enrolled. The inclusion criteria were the patient's age between 60-80 years, BMI < 40 kg/m², and normal psychological status. The exclusion criteria were infected TKA, revision TKA, previous knee surgery, bilateral TKA, and patients unwilling to attend the research protocol. Ethical approval was obtained from the Ethical Review Board. Faculty of Medicine. Chulalongkorn University. Ten patients were excluded because of failure to attend the research protocol.

All Forty patients were evaluated for conventional outcome measures, including WOMAC index⁽⁷⁾ and SF-36,⁽¹⁰⁾ as well as functional performance measures, including Time up and go test (TUGT)⁽¹⁵⁾ and 6-min walk distance (6MWD).⁽¹⁶⁾ The conventional measures were evaluated at the preoperative period (after admission, before surgery was done), and postoperatively at 2nd week, 6th week, and 12th week. The improvement of individual measures at each evaluation was compared to the preoperative period.

Time up and go test (**TUGT**)⁽¹⁵⁾ was the measured time that the patients took to stand up from a chair and walk 3 meters with or without gait aid. Then, he or she turned around and came back to the seat at the initial position. The high back chair with armrests was used with a seat height of

46 centimeters (18 inches) and armrest heights of 65 centimeters (26 inches).

6-min walk distance (6MWD) ⁽¹⁶⁾ was the measured distance that the patients could walk within 6 minutes with or without gait aid on 30 meters of solid ground with marks at 3 meter intervals.

All TKA operations were performed by one senior orthopaedist (A.T.) using a Cemented PS design (NexgenFlex, Zimmer & Vanguard, Biomet). Spinal anesthesia with morphine was administered. A tourniquet was applied at 320 mmHg. The midline longitudinal skin incision and mini-midvastus arthrotomy were performed. The distal femur was cut valgus 5 degrees with an The tibia intramedullary guide. was perpendicular with an extramedullary guide. The rotation of the femoral component was 3 degrees external rotation to the posterior condylar axis and parallel to the transepicondylar axis. The rotation of the tibial component was a parallel line from the posterior cruciate ligament (PCL)insertion to the mid-patellar tendon. Local joint infiltration was composed with 0.5% Marcaine 20 ml, morphine 5 mg, 0.3 ml of 1:1000 adrenaline diluted with normal saline to 40 ml, and was injected around the knee joint after the tibial and femoral components were applied. A drain was placed and removed before 24 hr postoperative. The postoperative pain was controlled with a COX-2 inhibitor (Celecoxib 400 mg OD \geq 2 wk), neuropathic pain control (Pregabalin 75 OD \geq 2 wk), and a pain killer (Ultracet $0.5X3 \ge 2$ wk). The rehabilitation protocol included start to sit bed side and range of motion exercises, and quadriceps and hamstring muscle strengthening at day 1, with start to walk with walker at day 2, and discharge at day 3.

Statistical analysis

This study was a prospective descriptive study. The qualitative data are presented as frequency and percent. The quantitative data was presented as the mean \pm SD. The paired t-test was performed for each improvement of outcome measure. All reported p values were 2-tailed with a p-value of less than 0.5 being considered statistically significant. Data were analyzed with Stata software version 11.2.

Results

The remaining forty patients consisted of 37 women and 3 men with a mean age of 70.1 ± 7.43 years and a mean body mass index of 27.26 ± 3.79 kg/m². The mean preoperative alignment was varus 4.78 ± 8.42 degrees and mean postoperative alignment was valgus 5.35 ± 2.45 degrees. The majority of patients (97.5%) had ASA class I and II. (Table 1)

The majority of the conventional measures including the WOMAC index and most domains of

SF-36 showed significant improvements at the 2nd week postoperative. Meanwhile all of the functional performance measures showed significantly worse parameters than those of the preoperative evaluations. At the 12th week after surgery, all tests of conventional and functional performance measures provided significant improvement outcomes compared to the preoperative period. The data are shown in Table 2.

The conventional measures WOMAC

The mean preoperative WOMAC score was 50.23. There was significant improvement at the $2^{\rm nd}$ week (mean 40.13, p < 0.001), $6^{\rm th}$ week (mean 30.85, p < 0.001), and $12^{\rm th}$ week (mean 29.68, p < 0.001).

SF-36

At the 2nd week, some domains of SF-36 were significantly improved, including general

health, physical function, and mental health, p = 0.004, 0.02, and 0.002, respectively. Bodily pain and role emotional were significantly improved at 6 weeks, p = 0.002 and 0.026, respectively. Role physical was significantly improved at the $12^{\rm th}$ week, p = 0.001. Vitality and social functioning were not significantly improved at the $12^{\rm th}$ week following surgery, p = 0.073 and 0.484.

The functional performance measures Time up and go test (TUGT)

The mean preoperative TUGT was 18.8 seconds and was significantly improved only at the 12^{th} week (mean 15.66 seconds, p < 0.001).

6-min walk distance (6MWD)

The mean preoperative 6MWD was 249.08 meters and was only significantly improved at the 12^{th} week (mean 286.15 meters, p = 0.001).

Table 1 Demographic data

Variables	All patients (n=40)		
Age	70.10 ± 7.43		
Gender			
- Female	37 (92.50%)		
- Male	3 (7.50%)		
Side			
- Right	24 (60.00%)		
- Left	16 (40.00%)		
Height (cm)	154.19 ± 7.70		
Weight (kg)	64.73 ± 9.72		
BMI (kg/m^2)	27.26 ± 3.79		
preop. Alignment (degrees) varus	4.78 ± 8.42		
postop. Alignment (degrees) valgus	5.35 ± 2.45		
preop. Arc of motoion (degrees)	113.38 ± 22.49		
postop. Arc of motion (degrees)	127.38 ± 9.20		
ASA			
- I	6 (15.00%)		
- II	33 (82.50%)		
- III	1 (2.50%)		
- IV	0 (0%)		
- V	0 (0%)		
Diagnostic			
- HT	25 (62.50%)		
- DLP	20 (50.00%)		
- DM	9 (22.50%)		
- Other; MR, CKD	9 (22.50%)		

Table 2 Conventional and Functional performance outcome data

	Pre-op	2 nd	6 th	12 th		<i>p</i> -value	
	3.6	Week	Week	Week	2 nd	6 th	1.0th
	Mean ±	Mean ±	Mean ±	Mean ±	_		12 th
	SD.	SD.	SD.	SD.	week ^(a)	week ^(a)	week ^(a)
Conventional measure	e						
WOMAC	50.23 ±	40.13 ±	30.85 ±	29.68 ±	<0.001*	<0.001*	<0.001*
	11.46	12.03	11.17	14.64			
SF-36							
General health	46.35 ±	$55.94 \pm$	$58.98 \pm$	$59.06 \pm$	0.004	< 0.001*	0.001
	17.15	18.39	17.68	19.74			
Physical function	$29.34 \pm$	$31.75 \pm$	$44.38 \pm$	$47.13 \pm$	0.02	0.001	< 0.001*
•	25.28	19.63	22.45	21.45			
Role physical	$26.87 \pm$	20 ±	$31.25 \pm$	$52.50 \pm$	0.243	0.513	0.001
	32.71	30.06	37.45	42.67			
Bodily pain	$43.81 \pm$	$48.13 \pm$	$55.87 \pm$	$63.19 \pm$	0.266	0.002	< 0.001*
	18.95	20.91	17.97	19.04			
Role emotional	$40.83 \pm$	$52.50 \pm$	$56.67 \pm$	$63.33 \pm$	0.09	0.026	0.003
	37.35	36.89	38.64	39.80			
Social functioning	$40.00 \pm$	$41.88 \pm$	$40.31 \pm$	$42.19 \pm$	0.504	0.909	0.484
	15.56	12.52	9.17	10.47			
Vitality	$55.50 \pm$	$58.41 \pm$	$60.06 \pm$	$61.38 \pm$	0.342	0.165	0.073
	19.67	17.45	18.45	17.76			
Mental health	$69.20 \pm$	$76.50 \pm$	$75.80 \pm$	$76.83 \pm$	0.002	0.026	0.003
	19.70	14.1	17.52	16.68			
Functional performance measure							
TUGT (seconds)	$18.80 \pm$	$32.42 \pm$	$17.43 \pm$	$15.66 \pm$	< 0.001*	0.261	0.01
	6.01	18.63	7.21	7.34			
6MWD (meters)	$249.08 \pm$	$170.33 \pm$	$261.41 \pm$	$286.15 \pm$	< 0.001*	0.292	0.001
	60.96	78.12	69.72	71.09			
·							

Values presented as mean±SD. P-value corresponds to paired t-test^(a)

Table 3 Improvement of each measure after TKA

Improved after TKA	2 nd week	6 th week	12 th week	
Measure				
Conventional measure	WOMAC	SF-36: Bodily pain	SF-36: Role physical	
	SF-36: General health	SF-36: Role emotional		
	SF-36: Physical function			
	SF-36: Mental health			
Functional performance			TUGT	
measure			6MWD	

Discussion

There are several outcome measures following TKA. The conventional measures included in PROMs are simple to use⁽⁷⁾, take a short time to complete⁽²³⁾, and have high internal consistency⁽²⁴⁾, but have limitations with representing true functional activities⁽²⁵⁾, and cannot evaluate psychologically-impaired patients.⁽²⁶⁾ The functional performance measures represent true functional activities, but have the risk of accident during the test. In this study, we

used WOMAC and SF-36 from the conventional measures, and TUGT and 6MWD from the functional performance measures.

In the immediate postoperative period (≤ 12 weeks) after TKA commonly used indirect outcomes for evaluation include length of hospital stay, VAS for pain, and amount of analgesic drugs. (27,28) However, some studies report the clinical outcomes. Gandhi et al. (29) reported the improvement of WOMAC, SF-36, and TUGT after postoperative 12 weeks in 142 TKA and 58 total

hip arthroplasty (THA) patients. Stratford et al. (30) demonstrated the improvement of WOMAC, but no significant improvements of 6MWD and TUGT after postoperative 9-13 weeks in 47 knee arthroplasty and 38 hip arthroplasty patients. Mizner et al. (31) studied the outcome at 1st and 12th month after 100 unilateral TKA. They showed 6MWD, TUGT, stair climb test, and SF-36 physical component summary worsened at 1st month, however, all improved by the 12th month. In this study, we collected data at the 2nd, 6th and 12th week to show improvements in the immediate postoperative period in more detail. At the 2nd week, some of the conventional measures improved, but all of the functional performance measures were worsened. At the 12th week, all tests of the conventional and functional performance measures provided significantly improved outcomes compared to the preoperative period. The data are shown in Table 3.

The strength of this study is the higher frequency of data recordings and number of measures. We collected the data three times at postoperative 2nd, 6th and 12th week which shows the improvement in more detail.

However, this study had some limitations. First, almost of the patients (92.5%) were female and may have different physiological responses from males. The improvement of functional performance might be affected by gender. Subgroup analysis should be done in the future. Second, this study had only 2 measures in each measure group. Third, the study had the small sample size. Fourth, the limited time of follow up was 12 weeks with no further correlation at longer follow ups.

Conclusion

Both conventional and functional performance measures are proper and effective to evaluate the outcome after TKA. All of measures significantly improve at the 12th week post-surgery. The conventional measures improve at the 2nd week, earlier than the functional performance measures. We concluded that the conventional measures demonstrate faster outcome improvements than functional performance in the immediate term after TKA.

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ควรใช้วิธีการประเมินแบบดั้งเดิมหรือการประเมินความสามารถในการใช้งานสำหรับการประเมินผลการ ผ่าตัดเปลี่ยนข้อเข่าเทียมในระยะฉับพลันหลังผ่าตัด

ชวรินทร์ อมเรศ, พบ, อารี ตนาวลี, พบ, ปฐมพร วีระเศรษฐ์ศิริ, พบ, นพ. สีหรัช งามอุโฆษ, พบ

วัตถุประสงค์: เพื่อศึกษาลักษณะการเปลี่ยนแปลงของการประเมินแต่ละชนิคในช่วงระยะฉับพลันหลังผ่าตัด (12 สัปคาห์ แรก) เมื่อเทียบกับก่อนผ่าตัด

วิธีการศึกษา: การศึกษานี้ได้ทำการศึกษาในผู้ป่วย 40 รายที่ได้รับการวินิจฉัยโรคข้อเข่าเสื่อมแบบปฐมภูมิและได้รับการ รักษาด้วยวิธีผ่าตัดเปลี่ยนข้อเข่าเทียม โดยประเมินผลลัพธ์ในระยะฉับพลันหลังผ่าตัดที่ 2 สัปดาห์ 6 สัปดาห์ และ 12 สัปดาห์หลังผ่าตัด ผู้ป่วยทุกรายได้รับการประเมินด้วยวิธีการประเมินแบบคั้งเดิม ได้แก่ WOMAC index และ SF-36 การ ประเมินความสามารถในการใช้งาน ได้แก่ Time up and go test (TUGT) และ 6-min walk distance (6MWD) ผลลัพธ์ที่ได้ ทั้งหมดถูกนำไปเปรียบเทียบกับการประเมินก่อนผ่าตัดเพื่อดูถึงลักษณะการเปลี่ยนแปลงของแต่ละวิธีประเมิน

ผลการศึกษา: ในการศึกษานี้ มีผู้หญิง 37 ราย ผู้ชาย 3 ราย มีค่าเฉลี่ยอายุ 70.10 ปี ค่าเฉลี่ยของคัชนีมวลกาย 27.26 กิโลกรัม/ตารางเมตร การประเมินผลลัพธ์ที่ 2 สัปคาห์หลังผ่าตัดพบว่าการประเมินค้วยวิธีแบบคั้งเดิมหลายชนิด ได้แก่ WOMAC index และ SF-36 มีผลลัพธ์ที่ดีขึ้น ในขณะที่การประเมินความสามารถในการใช้งานทุกชนิดนั้นลดลง ความสามารถในการ ใช้งานเท่านั้นที่มีผลลัพธ์ที่ดีขึ้นที่การประเมินผลลัพธ์ที่ 12 สัปดาห์หลังผ่าตัด

สรุป: ผลลัพธ์จากการประเมินด้วยวิธีดั้งเคิมพบการพัฒนาที่ดีขึ้นได้เร็วกว่าวิธีประเมินด้วยความสามารถในการใช้งาน