

Clinical prediction rule for early recovery of knee range of motion after total knee arthroplasty: A prospective cohort study

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ABSTRACT. Objective: To derive a clinical prediction rule for early recovery of knee range of motion after total knee arthroplasty. Methods: This prospective cohort study evaluated the data of 273 individuals undergoing primary total knee arthroplasty. The individual factors, the physical and motor function data were assessed preoperatively upon admission as a baseline survey. The knee joint extension angle and knee joint flexion angle were re-evaluated on postoperative day 14 as a follow-up. The recovery group comprised individuals with a knee joint extension angle of more than -5 degrees and knee joint flexion angle of more than 110 degrees on postoperative day 14. The other patients constituted the non-recovery group. Multivariate logistic regression analysis was used for deriving a clinical prediction rule. Results: The results indicated that the use of a cane, knee joint extension and flexion angles, and Timed Up and Go test time were significant factors for predicting early recovery of knee range of motion after total knee arthroplasty. Furthermore, a clinical prediction rule was derived and included the use of a cane, knee joint extension angle ≥ -15 degrees, knee joint flexion angle ≥ 125 degrees, and a Timed Up and Go test time < 11.2 s. A total clinical prediction rule score ≥ 8 indicated a positive likelihood ratio of more than 10 for a successful outcome and the post-test probability was approximately 95%. Conclusions: The derived clinical prediction rule might be a useful screening tool for proper postoperative goal setting and the establishment of individualized physical therapy programs.

Key words: knee osteoarthritis, prognosis, screening tool, decision support techniques, physical and rehabilitation medicine

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The incidence of knee osteoarthritis (OA) is increasing along with the rate of obesity and the extension of average life expectancy. Knee OA is one of the leading causes of disability despite advances in treatment¹⁾. Conservative, non-surgical therapy is the first choice for the treatment of knee OA due to its effectiveness, as indicated by interna-

tional evidence-based clinical guidelines²⁻⁶⁾. On the other hand, surgical intervention is necessary when symptoms worsen despite conservative therapy. The most frequently performed surgery for knee OA is total knee arthroplasty (TKA). A previous study noted the validity and cost-effectiveness of TKA for individuals who have difficulty performing activities of daily living (ADL)⁷⁾. Physical therapy after TKA aims to improve functional outcomes in the individual. Therefore, scientific reports on functional prognosis are of special interest to physical therapists.

The most serious problems in individuals with knee OA are functional limitations, such as standing and walking, due to knee pain and range of motion (ROM) limitations in the knee joint. A previous cross-sectional study re-

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ported that the movable range of the knee joint required for ADL such as standing, walking, and stair climbing is 5 to 110 degrees⁸. The goal of TKA for knee OA is to improve functional ability through pain reduction and improved ROM in the knee joint. The target angle after surgery is a knee joint flexion angle of more than 110 degrees⁹. A previous cohort study reported that ROM limitations after TKA reduce patient satisfaction¹⁰. Thus, the recovery of knee ROM after TKA is one of the most important measurable outcomes in the field of rehabilitation.

Although individuals undergoing TKA can begin walking with a T-cane in the early postoperative phase, they need to perform physical therapy after discharge for complete recovery of knee ROM^{11,12}. In a previous study evaluating the recovery of knee joint function after TKA, the knee joint flexion angles measured on postoperative day (POD) 14 were significantly worse than the preoperative measurements¹³. POD 14 is a crucial time for individuals to resume ADL where the goal is to increase activity gradually. In addition, A previous observational study reported that C-reactive protein levels up to POD 11 were higher than the reference value, and a significant association was found between deep temperature around the operated knee and knee ROM recovery at POD 14¹⁴. Thus, because of inflammation of the knee joint, the joint angle takes longer to recover after TKA in some individuals, and it might take more than 2 weeks for functional ROM recovery after TKA. Conversely, some individuals successfully recover knee ROM in the early phase after TKA. Therefore, it is important to investigate significant preoperative factors that influence the early recovery of knee OA in patients to individualize rehabilitation goals.

Clinical prediction rules (CPRs) are used to estimate a patient's prognosis after surgery. A previous study recommended the application of CPRs that combine individual factors and medical test scores as a tool for quantifying functional prognosis and treatment effects¹⁵. For example, there have been CPRs associated with pain¹⁶⁻¹⁸ and ADL¹⁹ in previous studies. However, there is no established CPR for individuals undergoing TKA to predict successful early recovery of knee ROM. Therefore, this study aimed to derive a CPR for early recovery of knee ROM after TKA.

Materials and Methods

Study design

This study used a prospective cohort study design. All participants were informed of the study's aims and provided written informed consent. This study was approved by the Research Ethics Committee of Tokoha University (approval no. R-2017-510H).

Setting

Participants were recruited and the data collected be-

tween July 2013 and December 2017 at 13 general hospitals.

Participants

Individuals included in the study: (1) were undergoing primary TKA for knee OA, (2) had a body mass index (BMI) more than 18.5 kg/m², and (3) were diagnosed with OA of Kellgren-Lawrence (K-L) grade III or IV. Exclusion criteria were as follows: (1) bilateral simultaneous TKA, (2) presence of significant functional joint disorders other than in the knee such as multiple-joint OA, (3) neurological impairment such as sensory disturbances or motor paralysis, and (4) cognitive or psychological disorder diagnosis.

The participants of this study started physical therapy on POD 1. The main physical therapy programs consisted of ROM exercises, muscle strengthening, walking, stair climbing, and icing. The protocol for all patients included in the study was for 40-minute/day of physical therapy every weekday until POD 14.

Assessments

Previous studies have reported that requisite knee joint ROM for ADL is 5 to 110 degrees⁸. The target angle after TKA is a knee joint flexion angle of more than 110 degrees⁹. Therefore, we defined a successful TKA outcome as individuals with a knee joint extension angle of more than -5 degrees and knee joint flexion angle of more than 110 degrees on POD 14. These individuals were considered part of the recovery group and the other participants were considered the non-recovery group.

The following factors were assessed by physical therapists upon preoperative admission as a baseline. Individual factors included sex, age, BMI, K-L grade, femorotibial angle, affected side (unilateral or bilateral knee OA), operative method (minimally invasive surgery [MIS]-TKA or conventional TKA), history of surgery (prior history of joint surgery for OA in the contralateral knee), exercise habits (yes or no to the following: do you usually exercise twice a week or more; for 30 minutes or more, and; for more than a year?)²⁰, and use of a cane (determined by whether the participant used a single-point cane during the motor function test measurement). Physical function data included muscle strength of knee extensors and flexors, knee joint extension angle and flexion angle, hip joint extension angle, and pain. The muscle strength test was performed using a handheld dynamometer (μ Tas F-1; Anima Corp., Tokyo, Japan). A fixed band was used to secure the sensor to the part of the body that was being evaluated. Individuals sat on a chair with their knee joints at 90 degrees of flexion. Measurement of the maximal isometric contraction of the muscle strength of the knee joint was performed on the operated side and was normalized by body weight (Nm/kg)²¹. ROM was measured as the maximum tolerable range of passive movement by using a goniometer. The

pain test was a self-assessment in reference to the knee joint of the operated side using a numerical rating scale that ranged from 0 (no pain) to 10 (worst possible pain) conducted upon preoperative admission²². Motor function data included a 5-meter walking test and Timed Up and Go test (TUG). The participants who were using a cane while walking in the hospital were permitted to use it when they performed the motor function test. The 5-meter walking test was conducted as an in-room test and consisted of an 11-meter straight line, which included an initial 3-meter acceleration zone, a central 5-meter timed zone, and a final 3-meter deceleration zone. The measurement included the time it took for the individuals to walk the entire 5-meter zone at maximum speed (walking time measured in seconds) and calculated the walking speed (m/s)²³. For the TUG, individuals rose to a standing position from a chair, walked 3 meters, turned, walked back, and sat back down in the chair as quickly as they could. The time it took for individuals to complete the test was recorded in seconds²⁴. The knee joint extension angle and knee joint flexion angle were re-evaluated on POD 14 as a follow-up.

Sample size

In a previous study investigating joint function recovery in individuals undergoing MIS-TKA²⁵, 75 out of 123 individuals (61.0%) had successful recovery of knee ROM by POD 14. Based on this result, the ratio of positive to negative individuals (i.e., recovery group to non-recovery group) was assumed to be 3 (60.0%) to 2 (40.0%). The alpha value was set at 0.05, and the power was set at 0.80. The area under the ROC curve was set at 0.60. As a result of the sample size calculation, the total number of required cases was estimated to be 259 (positive, 155 cases; negative, 104 cases).

Statistical analysis

We classified the subjects into two groups (recovery group=1 and non-recovery group=0). Qualitative data were converted to dummy variables as follows: sex (male=1; female=0), K-L grade (grade III=1; grade IV=0), affected side (unilateral knee OA=1; bilateral knee OA=0), operative method (MIS-TKA=1; conventional TKA=0), history of surgery, exercise habits, and use of a cane (yes=1; no=0). Cases with missing values were excluded.

To derive a CPR, we identified potential predictive factors for early recovery of knee ROM after TKA using multivariate logistic regression analysis. According to a previous study, the sample size of multivariate logistic regression analysis requires the number of the small category of outcomes per explanatory variables of 10 or greater²⁶. From sample size calculated in this study, the sample size of the small category of outcomes (non-recovery group) was 104 individuals, thus we considered that the appropriate number of explanatory variables to be included in multi-

variate logistic regression analysis would be less than 10 items. Since there were 18 explanatory variables included in this study, univariate logistic regression analysis was performed to eliminate non-significant variables, ensuring the stability of results in the multivariate logistic regression analysis. Multivariate logistic regression analysis was performed with explanatory variables that reached $P < 0.25$ in the univariate logistic regression analysis²⁷. Akaike's information criterion was used in the multivariate logistic regression analysis with forward and backward stepwise selection. Among the explanatory variables adopted in the final model, quantitative variables underwent receiver operating characteristic (ROC) analyses using Youden's index and were converted to binary values at the cut-off points. The effect on outcome was weighted based on the standardized partial regression coefficient (SPRC) of variables extracted by the multivariate logistic regression analysis. Finally, the CPR was obtained using binary variables and called the "knee joint angle recovery screening tool." We performed ROC analyses with the outcome and total score from the CPR. We calculated the sensitivity, specificity, positive likelihood ratio (PLR), and post-test probability of the CPR. The stats, DAAG, pROC, and OptimalCutpoints packages in R version 3.2.4 (R Foundation for Statistical Computing, Vienna, Austria) was used for all statistical analyses and the significance level was set at $P = 0.05$.

Results

Three hundred and forty-one individuals (281 females and 60 males, mean age=74.6±7.3 years) participated in this study. After exclusion because of missing values, data from 273 individuals were analyzed (222 females and 51 males, mean age=74.8±7.1 years). The characteristics of the individuals are summarized in Table 1. There were no individuals who used walking assistive devices other than a single-point cane in this study.

According to the univariate logistic regression analysis, explanatory variables satisfying the $P < 0.25$ alpha level were BMI, femorotibial angle, operative method, use of a cane, knee joint extension and flexion angles, hip joint extension angle, and TUG time (Table 2). After the multivariate logistic regression analysis using extracted explanatory variables, the variables adopted for the final model (Akaike's information criterion=342.9, area under the ROC curve=0.712) were use of a cane (odds ratio [OR]=3.15; 95% confidence interval [CI]=1.67, 5.95; $P < 0.001$), knee joint extension angle (OR=1.03; 95% CI=0.99, 1.07; $P = 0.098$), knee joint flexion angle (OR=1.05; 95% CI=1.03, 1.08; $P < 0.001$), and TUG time (OR=0.91; 95% CI=0.84, 0.98; $P = 0.015$) (Table 3). It was revealed that individuals who used a cane before surgery, individuals who had good preoperative knee joint angles, and individuals with short TUG times had a high probability of successful early recovery.

Table 1. Characteristics of the study participants

Characteristic		Total (n=273)	Recovery group (n=157)	Non-recovery group (n=116)
Individual factors	Sex, female	222 (81.3)	134 (85.4)	88 (75.9)
	Age (years)	74.8±7.1	74.5±6.9	75.2±6.9
	BMI (kg/m ²)	25.9±3.7	25.7±3.7	26.2±3.6
	K-L grade, grade IV	142 (52.0)	86 (54.8)	56 (48.3)
	FTA (degrees)	184.5±7.5	185.1±7.4	183.8±7.6
	Affected side, bilateral	165 (60.4)	100 (63.7)	65 (56.0)
	Operative method, MIS	250 (91.6)	144 (91.7)	106 (91.4)
	History of surgery, yes	86 (31.5)	50 (31.8)	36 (31.0)
	Exercise habits, yes	80 (29.3)	49 (31.2)	31 (26.7)
	Use of a cane, yes	145 (53.1)	92 (58.6)	53 (45.7)
Physical functions	Muscle strength of knee extensors (Nm/kg)	0.75±0.32	0.74±0.33	0.76±0.32
	Muscle strength of knee flexors (Nm/kg)	0.41±0.18	0.41±0.17	0.41±0.19
	Knee joint extension angle (degrees)	-10.1±7.0	-9.1±5.8	-11.5±8.2
	Knee joint flexion angle (degrees)	118.9±12.1	121.8±10.8	115.0±12.7
	Hip joint extension angle (degrees)	11.8±7.0	12.5±6.1	10.9±8.0
	NRS (points)	2.0±2.7	2.3±2.8	1.7±2.5
Motor functions	5mWT (m/s)	1.02±0.33	1.04±0.36	1.00±0.28
	TUG time (s)	11.78±4.02	11.49±4.00	12.17±4.04

Data are presented as the mean ± SD or n (%).

Abbreviations: BMI, body mass index; K-L, Kellgren-Lawrence; FTA, femorotibial angle; MIS, minimally invasive surgery; NRS, numerical rating scale; 5mWT, 5-meter walking test; TUG, timed up and go test.

Table 2. Screening of explanatory variables

Variable	RC	OR	95% CI		P-value
			lower	upper	
Sex	-0.31	0.73	0.42	1.28	0.278
Age	<0.01	1.00	0.97	1.03	0.805
BMI	-0.04	0.96	0.91	1.02	0.187
K-L grade	-0.14	0.87	0.57	1.33	0.509
FTA	0.02	1.02	0.99	1.05	0.183
Affected side	-0.06	0.94	0.60	1.47	0.792
Operative method	0.77	2.15	1.24	3.73	0.006
History of surgery	0.04	1.04	0.66	1.64	0.860
Exercise habits	0.18	1.20	0.74	1.93	0.459
Use of a cane	0.26	1.30	0.85	2.00	0.225
Muscle strength of knee extensors	<0.01	1.00	0.52	1.94	0.995
Muscle strength of knee flexors	0.57	1.76	0.53	5.82	0.353
Knee joint extension angle	0.04	1.04	1.01	1.08	0.012
Knee joint flexion angle	0.05	1.05	1.03	1.07	< 0.001
Hip joint extension angle	0.03	1.03	1.00	1.07	0.092
NRS	0.01	1.01	0.94	1.09	0.817
5mWT	0.36	1.44	0.73	2.82	0.296
TUG	-0.03	0.97	0.92	1.02	0.221

Abbreviations: RC, regression coefficient; OR, odds ratio; 95% CI, 95% confidence interval; BMI, body mass index; K-L, Kellgren-Lawrence; FTA, femorotibial angle; NRS, numerical rating scale; 5mWT, 5-meter walking test; TUG, timed up and go test.

Table 3. Predictors for identifying early recovery of knee ROM after TKA

Variable	RC	β	OR	95% CI		P-value
				lower	upper	
Use of a cane	1.15	0.57	3.15	1.67	5.95	<0.001
Knee joint extension angle	0.03	0.22	1.03	0.99	1.07	0.098
Knee joint flexion angle	0.05	0.61	1.05	1.03	1.08	<0.001
TUG	-0.10	-0.39	0.91	0.84	0.98	0.015

Akaike's information criterion=342.9. Hosmer-Lemeshow test: $p=0.858$.

Area under the curve=0.712. β : Standardized partial regression coefficient.

Abbreviations: ROM, range of motion; TKA, total knee arthroplasty; RC, regression coefficient; OR, odds ratio; CI, confidence interval; TUG, timed up and go test.

Table 4. Quantitative evaluation cut-off values

Variable	Cut-off value	AUC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)	PLR (95% CI)	NLR (95% CI)
Knee joint extension angle	≥ -15 degrees	0.57	91.1	21.6	1.16	0.41
		(0.50, 0.64)	(85.5, 95.0)	(14.5, 30.1)	(1.04, 1.29)	(0.23, 0.76)
Knee joint flexion angle	≥ 125 degrees	0.66	51.6	70.7	1.76	0.69
		(0.59, 0.72)	(43.5, 59.6)	(61.5, 78.8)	(1.28, 2.43)	(0.56, 0.84)
TUG	<11.2 s	0.56	57.3	57.8	1.36	0.74
		(0.49, 0.63)	(49.2, 65.2)	(48.2, 66.9)	(1.06, 1.75)	(0.58, 0.94)

Cut-off value is the optimal cut-off value based on Youden's index methods.

Abbreviations: AUC, area under the curve; CI, confidence interval; PLR, positive likelihood ratio; NLR, negative likelihood ratio; TUG, timed up and go test.

ery of knee ROM after TKA.

Among explanatory variables adopted in the final multivariate logistic regression model, ROC analyses were performed for the quantitative variables. As a result, cut-off values were -15 degrees for knee joint extension angle, 125 degrees for knee joint flexion angle, and 11.2 s for TUG (Table 4). The SPRC for each test was 0.57 for use of a cane, 0.22 for knee joint extension angle, 0.61 for knee joint flexion angle, and -0.39 for TUG. The SPRC for the use of a cane was 2.6 times that for the knee joint extension angle, which was the lowest SPRC value and was therefore set to 3 points in the CPR. Similarly, a knee joint flexion angle of more than 125 degrees was 2.8 times that of the lowest SPRC value, and it was set to 3 points. Additionally, a TUG time less than 11.2 s was 1.8 times that of the lowest SPRC and set to 2 points. Finally, a knee joint extension angle of more than -15 degrees was scored as 1 point. Thus, the knee joint angle recovery screening tool ranged from 0 (minimum) to 9 (maximum), where total scores were calculated for each individual and a higher score meant better results (appendix). ROC analyses using the total score from the knee joint angle recovery screening tool and patient outcomes were performed to calculate the diagnostic characteristics of the CPR. Of the 273 participants, 157 were in the recovery group, yielding a pre-test probability of 57.5%. A total CPR score of more than 8 points indicated a PLR of

more than 10 for a successful outcome, with a post-test probability of around 95% (Table 5).

Discussion

This study was conducted to derive a CPR for identifying individuals with a high probability for early recovery of knee ROM after TKA. Our CPR indicates that the use of a cane, knee joint extension angle, knee joint flexion angle, and TUG time significantly predicted early recovery of knee ROM by POD 14. In other words, it was shown that individuals who use a cane, have good preoperative knee joint angles, and fast TUG times before surgery had a high probability of acquiring good knee joint ROM by POD 14.

The Osteoarthritis Research Society International guidelines recommend the use of a cane for individuals with knee OA if they do not have multiple-joint OA⁴). Our results support this guideline, and the use of a cane might be recommended for early recovery of postoperative knee ROM. Also, previous research has shown that flexion contracture of the knee joint before TKA increases the incidence of flexion contracture after TKA¹⁰). Furthermore, functional levels before TKA have been reported to affect postoperative functional recovery²⁸⁻³⁰). Similarly, individuals who had better knee joint angles and TUG times before TKA were more likely to achieve early recovery of knee

Table 5. Diagnostic characteristics of the knee joint angle recovery screening tool

Total score	All (n=273)	Recovery group (n=157)	Non-recovery group (n=116)	Sensitivity (95% CI)	Specificity (95% CI)	PLR (95% CI)	Post-test probability (95% CI)
≥1 point	267 (97.8)	156 (99.4)	111 (95.7)	99.4 (96.5, 100.0)	4.3 (1.4, 9.8)	1.04 (1.00, 1.08)	58.4 (52.3, 64.4)
≥2 points	252 (92.3)	151 (96.2)	101 (87.1)	96.2 (91.9, 98.6)	12.9 (7.4, 20.4)	1.11 (1.02, 1.19)	59.9 (53.6, 66.0)
≥3 points	245 (89.7)	151 (96.2)	94 (81.0)	96.2 (91.9, 98.6)	19.0 (12.3, 27.3)	1.19 (1.08, 1.30)	61.6 (55.2, 67.8)
≥4 points	194 (71.1)	126 (80.3)	68 (58.6)	80.3 (73.2, 86.2)	41.4 (32.3, 50.9)	1.37 (1.15, 1.63)	64.9 (57.8, 71.6)
≥5 points	124 (45.4)	91 (58.0)	33 (28.4)	58.0 (49.8, 65.8)	71.6 (62.4, 79.5)	2.04 (1.48, 2.80)	73.4 (64.7, 80.9)
≥6 points	115 (42.1)	85 (54.1)	30 (25.9)	54.1 (46.0, 62.1)	74.1 (65.2, 81.8)	2.09 (1.49, 2.94)	73.9 (64.9, 81.7)
≥7 points	50 (18.3)	41 (26.1)	9 (7.8)	26.1 (19.4, 33.7)	92.2 (85.8, 96.4)	3.37 (1.71, 6.65)	82.0 (68.6, 91.4)
≥8 points	20 (7.3)	19 (12.1)	1 (0.9)	12.1 (7.4, 18.3)	99.1 (95.3, 100.0)	14.04 (1.91, 103.37)	95.0 (75.1, 99.9)
=9 points	19 (7.0)	18 (11.5)	1 (0.9)	11.5 (6.9, 17.5)	99.1 (95.3, 100.0)	13.30 (1.80, 98.10)	94.7 (74.0, 99.9)

n (%). Pre-test probability=57.5%.

Abbreviations: CI, confidence interval; PLR, positive likelihood ratio.

ROM after TKA in our study. Thus, the CPR derived from this study has the potential to serve as a new prognostic tool, particularly in clinical settings, where it can be used to help guide the physical therapist's clinical decision making.

The CPR derived from our data is composed of 4 indices, including the use of a cane, knee joint extension angle more than -15 degrees, knee joint flexion angle more than 125 degrees, and TUG time less than 11.2 s. As the total score increased, the PLR and post-test probability increased, meaning the prognostic accuracy likewise increased. In addition, cases with more than 8 points on the knee joint angle recovery screening tool had approximately 95% probability of knee joint angle recovery by POD 14. This study is the first to derive a CPR for predicting early recovery of knee ROM after TKA. This is clinically important since the CPR might be a useful screening tool for proper postoperative goal setting and the establishment of individualized physical therapy programs.

This study had some limitations. First, we excluded individuals who underwent bilateral simultaneous TKA and individuals diagnosed with multiple-joint OA. Therefore, the findings of this study cannot be generalized to these individuals. Second, the findings cannot be used to predict functional recovery in individuals with a BMI of less than 18.5 kg/m², mild knee OA of K-L grade I or II. Third, we had no information on the onset of knee OA and commencement of conservative therapy in this study, thus the effect of these factors is unclear. Finally, we cannot estab-

lish the causal association for certain because our present study was an observational study. However, our CPR could be useful for future experimental studies to test causal association more directly. It is necessary for future studies to examine the cross-validity of this CPR and to compare the treatment results using this CPR to results without a CPR.

Conflict of Interest: The authors have no conflicts of interest to declare.

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Appendix

Knee joint angle recovery screening tool