Gait & Posture 72 (2019) 148–153

Contents lists available at ScienceDirect

Gait & Posture

journal homepage: www.elsevier.com/locate/gaitpost

Full length article

Stair climbing ability in patients with early knee osteoarthritis: Defining the clinical hallmarks of early disease

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ARTICLE INFO

Keywords:
Early knee osteoarthritis
Stair climb test
Receiver operating characteristic

ABSTRACT

Background: A growing clinical interest has been shown towards identifying knee osteoarthritis (OA) patients at earlier stages. The early detection of knee OA may allow for more effective interventions.
Research question: The aim of this study was to determine the discriminative ability of a stair-climb test (SCT) in identifying patients with early knee OA, and to determine if descending stair time during the SCT is better than ascending stair time for the identification of these patients.
Methods: This study was a secondary, cross-sectional analysis of baseline data from a randomized controlled trial. Adults with moderate to severe knee pain were enrolled (n = 57; mean age 58.9 years; 71.9% women). Each participant performed an 11-step SCT (11-SCT) while wearing shoes with a pressure sensor insole. A receiver operating characteristic analysis was used to examine the discriminative power of 11-SCT for identifying early knee OA (Kellgren and Lawrence grade 1). The discriminative power was also compared between the ascending and descending 11-SCT time as evaluated by the pressure sensor.
Results: The 11-SCT time in patients with early knee OA was 0.55 s longer than that in those with symptomatic non-radiographic OA. A one-second increase in the 11-SCT time was significantly associated with 1.9-fold increased odds of early knee OA being present. The 11-SCT value with the best balance of sensitivity and specificity for identifying early knee OA was 8.33 s (area under the curve: 0.711). The descending time was not significantly better than the ascending time for identifying early knee OA.
Significance: This study determined the time values of an 11-SCT that may be useful for identifying early knee OA patients. These preliminary findings may serve as the foundation for future studies investigating the clinical hallmarks associated with early knee OA.

1. Introduction

In the aging population, knee osteoarthritis (OA) is the most common chronic joint disease and a major cause of pain and functional impairment [1]. An increased clinical interest has been directed towards identifying knee OA patients at earlier stages of the disease. Since patients with less severe radiographic disease respond better to therapeutic interventions than those with severe disease [2], the early detection of knee OA may allow for interventions to be more effective before major structural damage has occurred [3].

Although several studies have focused on the walking mechanics of patients with early knee OA [4,5], it could be advantageous to explore if patients in the earliest stages of knee OA show limited mobility during more biomechanically demanding tasks such as weight-bearing activities with large knee flexion. Stair climbing is a common motion that is more challenging than level walking [6–8]. Stair climbing may be the first type of weight-bearing activity to be affected in individuals with knee OA [9,10]. A previous meta-analysis revealed that patients with knee OA exhibit altered lower limb biomechanics during stair climbing and lower stair climbing speed compared with age-matched healthy adults [11].

The stair climb test (SCT) is one of the Osteoarthritis Research

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https://doi.org/10.1016/j.gaitpost.2019.06.004
Received 5 November 2018; Received in revised form 1 June 2019; Accepted 4 June 2019

Society International (OARSI)-recommended performance-based tests to assess mobility limitations for patients with knee OA [12,13]. The SCT is low cost and easy to apply in clinical practice with a high reliability and validity in patients with early to mild knee OA [13]. Baert et al. showed that the 5-step SCT time in female patients with early knee OA (6.29 ± 1.60 s; n = 14) was 0.7 s longer than that in asymptomatic controls (5.59 ± 1.01 s; n = 14) [14], although this was statistically non-significant due to the small sample size. Thus, this may be an attractive option to predict early knee OA in clinical practice. Further investigation of mobility limitations detected by SCT in patients with early knee OA could be helpful in understanding the clinical hallmarks of this condition and the trajectory of disease onset [15].

Stair descending is supposed to be more challenging than stair ascending as stair descending requires larger external knee flexion moment than those during stair ascending [6,16,17]. As patients with early knee OA may attempt to avoid pain and minimize stress to the knee joint [18], patients with early knee OA may display greater mobility limitations during stair descending than when ascending. Separate analysis of stair ascending and descending in SCT would provide a more in depth understanding of the early knee OA-related mobility limitations.

The aims of this study were to determine (1) whether stair climbing ability was poorer in patients with early knee OA than those without radiographically identified knee OA; (2) the discriminative ability of the SCT time for the identification of patients with early knee OA; and (3) if descending stair time is more accurate for identifying early knee OA compared to ascending stair time.

2. Methods

2.1. Participants

This study was a secondary baseline cross-sectional analysis of data from a randomized controlled trial (RCT) examining the immediate effects of transcutaneous electrical nerve stimulation (TENS) on knee pain and physical function in people with painful knee OA [19]. Detailed information for participants was provided in the original RCT [19]. In brief, community-dwelling adults that reported knee pain within the last month were identified through a website. The inclusion criteria included (1) age ≥ 50 years; (2) Kellgren and Lawrence (K&L) grades ≤2 in one or both knees as evaluated using weight-bearing anteroposterior radiographs, and (3) an average pain experience of ≥4 but ≤9 on a numeric rating scale in the last month. All participants, including those without radiographically identified OA, felt knee pain for 1 month prior.

In this study, only index knee per participant was used for radiographic analysis. The index knee was defined as the knee with more pain in either the past or at present. If patients felt that both their knees were equally painful, the index knee was randomly selected using a computer-generated permuted block randomization scheme [20]. Patients who had a K&L grade of 0, 1, or 2 in their index knee were categorized into the control (without radiographically identified OA), early knee OA, or mild knee OA study groups, respectively.

2.2. Measurement

2.2.1. Radiographic osteoarthritis severity

The radiographic severity of the tibiofemoral joint in both knees was assessed by a trained examiner (HI) using the original version of the K&L grading system [21]. We previously reported excellent intra-examiner (κ: 0.876; 95% confidence interval [CI]: 0.829, 0.924) and inter-examiner (κ: 0.845; 95% CI: 0.793, 0.897) reliability scores [22].

2.2.2. Stair climbing test

2.2.2.1. Instrumentation. As footwear influences balance, performance [23,24], and walking speed [24], all participants wore standardized shoes (LD AROUND M, Mizuno, Tokyo, Japan) with the 15 sensors-mounted insole inserted in both shoes [25]. During stair climbing, forefoot contact without heel contact was expected. A pilot study for one healthy male adult (age: 30 years; height: 1.83 m; body mass: 75.0 kg) indeed confirmed forefoot initial contact when descending stairs which cannot be adequately captured by single foot switch (data not shown). The 15 sensors-mounted insole can detect foot contact more precisely than a single foot sensor. All subjects reported that the shoes were comfortable and caused no pain. Data were sampled at 100 Hz.

2.2.2.2. Procedure for eleven-step stair-climb test. Each participant underwent the SCT in accordance with the OARSI recommended method [26] while wearing the standardized shoes with pressure sensor-mounted insoles. Participants descended and ascended the flight of stairs which consisted of 11 steps with a step height of 17 cm, step width of 135 cm, and step tread of 29 cm. Although a standard SCT starts with stair ascent, the 11-step SCT (11-SCT) in this study started with stair descent because of environment constraints. A pilot study, performed in the same place and conditions as a validation study, confirmed that the 11-SCT time in six healthy adults (age: 24.3 ± 3.93 years; 1 female) did not significantly differ between an ascending stair start (9.31 ± 1.47 s) and descending stair start (9.17 ± 1.45 s) with a mean difference of 0.15 s (95% CI: -0.30, 0.60; p = 0.439). A trained physical therapist (KS) measured the time required to perform the 11-SCT during each participant's test and retest session using a stopwatch (TD-392, TANITA Corp., Tokyo, Japan). 11-SCT time in test and retest session was averaged and used for analyses. Detailed information for stopwatch-based SCT was provided in previous study [13].

To determine the insole-based 11-SCT time, vertical ground reaction force (GRF) was calculated from sensor-mounted shoe data [25]. Subsequently, times of initial contact and toe-off in each foot were defined as the time point where vertical GRF exceeded and fell below the 1% threshold of estimated maximum ground reaction force using custom MATLAB code (MathWorks Inc., Natick, MA, USA, version R2017a). The insole-based 11-SCT time was defined as the time from the initial foot-off from the top platform to the point of foot contact with both feet on the top platform. Using the initial contact and foot-off data, the insole-based 11-SCT was further divided into three phases: descending, ascending, and transition phases. Transition phase was defined as time between the initial contact to the staircase landing after descending and the initial contact to the first step during ascending. Test-retest reliability was excellent for the stopwatch-based 11-SCT (intraclass correlation coefficient [$ICC_{1,1}$]: 0.952 s; 95% CI: 0.560–0.985 s) [13] and for the insole-based 11-SCT ($ICC_{1,1}$: 0.929 s; 95% CI: 0.883–0.957 s). The minimal detectable change (MDC_{95}) for stopwatch- and insole-based 11-SCTs was 0.102 s and 0.089 s, respectively.

2.2.3. Patient characteristics and covariates

Data on age, sex, and height were self-reported by the patients. Weight was measured on a digital scale with the participants clothed and without shoes. Body mass index (BMI) was calculated by dividing the patient's weight in kilogram by the height in meters squared. Knee pain severity and disability level were evaluated using the Japanese Knee Osteoarthritis Measure (JKOM) subcategories of "pain and stiffness" (8 questions, 0–32 points) and "daily living activities" (10 questions, 0–40 points) [27]. Knee pain during the 11-SCT was also evaluated using visual analog scale (VAS).

2.3. Statistical analyses

A binary logistic regression analysis was performed to calculate the odds ratios and their 95% CI with the stopwatch-based and insole-based 11-SCT or the insole-based ascending/descending SCT and their transition stair time, a continuous independent variable, and the presence of

early knee OA (0: absence [control]; 1: presence [early knee OA]), a dependent variable, after adjusting for age, sex, BMI, and VAS pain score during 11-SCT. These covariates were chosen a priori based on clinical judgment and their potential association with the 11-SCT time and presence of early knee OA. To identify the predictive value of the 11-SCT for early knee OA, the area under the receiver operating characteristic (ROC) curve (AUC) was also calculated. The ROC represents a curve of sensitivity, $q(c)$, against 1 – specificity, $p(c)$, at different cut-off points of the 11-SCT for identifying patients with early knee OA. Larger values of the ROC (ranging between 0 and 1) indicate satisfactory discriminative power [28]. Interpretation of AUC was based on inspection of the lower one-side 95% CI set at a clinically acceptable level of 0.750 [29]. We identified stopwatch- and insole-based 11-SCT values that correspond to 90% sensitivity and specificity. To identify a recommended cut-off time value for the 11-SCT, the Youden index was used to determine the 11-SCT value that best identifies patients with early knee OA (i.e. maximizing the sum of sensitivity and specificity) [30].

To examine which of the stair ascending and descending times evaluated by sensor-mounted shoes can best discriminate between control and early OA individuals, separate binary logistic regression analyses were performed as mentioned above. Delong's test was used to compare the AUC between stair ascending and descending SCT time. Since radiographic assessment for discriminating between K&L grade 1 and 2 may depend on the assessor in some cases, we performed sensitivity analyses repeated all analyses by extending our study samples to those with early to mild knee OA as a dependent variable (0: absence [control]; 1: presence [early to mild knee OA]) to assess whether the accuracy of the classification changed. All statistical analyses were performed using JMP Pro 13.0 (SAS Institute, Cary, NC, USA). A p value < 0.05 was considered statistically significant.

3. Results

Fifty-nine participants were enrolled in the original RCT and two participants were excluded due to missing data. Fifty-seven participants (mean age 58.9 [range 50–69] years; mean BMI 22.7 kg/m^2; 71.9% female) were included in the final analyses of this study. Table 1 compares the participants' characteristics among control (n = 30), early knee OA (n = 22), and mild knee OA participants (n = 5).

Table 2 shows results of the logistic regression analyses. The adjusted difference between groups for the stopwatch- and insole-based 11-SCT was 0.552 s (95% CI: 0.178, 0.925 s) and 0.551 s (95% CI: 0.146, 0.956 s), respectively. A one-second increase in the stopwatch- and insole-based 11-SCTs was significantly associated with 1.9-fold and 1.7-fold increased odds of early knee OA being present, respectively. When the insole-based 11-SCT was divided into three phases (ascending, descending, and transition), a time increase in the ascending phase was significantly associated with higher prevalence of early knee OA. A time increase in the descending phase was also, but non-significantly, associated with higher prevalence of early knee OA. These results were similar when patients with mild knee OA were included as a dependent variable.

The stopwatch- and insole-based 11-SCT time with the best balance of sensitivity and specificity for the identification of early knee OA were 8.33 s and 9.28 s, respectively (Fig. 1A and B). The AUC in stopwatch- and insole-based 11-SCT was 0.711 (95% CI: 0.549, 0.833) and 0.666 (95% CI: 0.492, 0.804), respectively. Separate ROC curves for the ascending and descending stair times (Fig. 1C) revealed that the AUC value in the ascending stair time did not significantly differ (Delong's test, $p = 0.636$) from that of the descending stair time.

4. Discussion

This study examined the ability of an 11-SCT to identify early knee OA in fifty-seven adults with K&L grade 0-2. Patients with early knee OA had poorer stair climbing ability than those with symptomatic non-radiographic knee OA, and an increasing time in the 11-SCT was associated with a higher prevalence of early knee OA. Descending SCT time was similar to ascending SCT time for identifying early knee OA. Based on the lower one-side 95% CI of the AUC, 11-SCT time had poor to fair discriminative ability for identifying early knee OA; so, no strong conclusions can be drawn. Future biomechanical studies could use these finding to better define clinical hallmarks of early radiographic disease. Fig. 2 shows graphic abstract.

4.1. Interpretation of poor stair climbing abilities in patients with early knee OA

Patients with early knee OA had an 11-SCT time which was 0.55 s longer than those without radiographically identified knee OA. The between-group difference exceeds the MDC_{95} value of the 11-SCT time

Table 1
Participants' characteristics (n = 57).

Variable	All (n = 57)	Control (n = 30)	Early OA (n = 22)	Mild OA (n = 5)
Age, years	58.9 ± 6.10	58.6 ± 6.15	59.2 ± 6.03	59.8 ± 7.26
Female, no. (%)	41 (71.9)	20 (66.7)	17 (77.3)	4 (80.0)
Height, m	1.60 ± 0.08	1.60 ± 0.09	1.60 ± 0.07	1.64 ± 0.09
Mass, kg	58.6 ± 10.6	56.6 ± 8.61	60.5 ± 12.9	62.8 ± 9.42
BMI, kg/m^2	22.7 ± 3.56	21.9 ± 2.86	23.7 ± 4.42	23.3 ± 2.12
Index knee K&L grade, no. (%)				
Grade 0	30 (52.6)	30 (100.0)	0 (0.0)	0 (0.0)
Grade 1	22 (39.6)	0 (0.0)	22 (100.0)	0 (0.0)
Grade 2	5 (8.8)	0 (0.0)	0 (0.0)	5 (100.0)
Bilateral disease, no. (%)[†]	22 (38.6)	0 (0.0)	17 (77.3)	5 (100.0)
VAS pain score during 11-SCT, mm	15.8 ± 17.4; 10 [0, 67][*]	11.2 ± 11.1; 7 [0, 34][*]	19.5 ± 20.3; 11 [0, 63][*]	28.0 ± 27.6; 15 [0, 67][*]
JKOM, points				
Pain and stiffness	7.00 ± 3.94; 7 [0, 22][*]	5.97 ± 3.59; 5 [1, 16][*]	7.91 ± 4.43; 7 [0, 22][*]	9.20 ± 1.48; 9 [7,11][*]
Activities of daily living	2.98 ± 3.14; 2 [0, 14][*]	2.20 ± 2.47; 1 [0, 8][*]	3.82 ± 3.85; 3 [0, 14][*]	4.00 ± 2.45; 5 [1, 7][*]
Participation in social activities	2.46 ± 1.97; 2 [0, 9][*]	2.20 ± 1.65; 2 [0, 7][*]	3.14 ± 2.32; 3 [0, 9][*]	10.0 ± 10.0; 1 [0, 2][*]
General health conditions	1.95 ± 0.99; 2 [0, 4][*]	1.83 ± 1.02; 2 [0,3][*]	2.18 ± 0.96; 2 [0, 4][*]	1.60 ± 0.89; 2 [0, 2][*]
Total score	14.4 ± 7.69; 13 [3, 49][*]	12.2 ± 5.86; 12 [3, 25][*]	17.0 ± 9.59; 15 [6, 49][*]	15.8 ± 4.27; 16 [11, 20][*]

BMI, body mass index; JKOM, Japanese Knee Osteoarthritis Measure; K&L grade, Kellgren and Lawrence grade; OA, osteoarthritis; VAS, visual analog scale; 11-SCT, 11-step stair climb test.
Except where otherwise indicated, values are mean ± SD.
[*] Median [lower range–upper range] was also provided because of the scattered distribution of the answered items.
[†] Bilateral disease was defined as K/L grade ≥1 in both knees.

Table 2
Results of binary logistic regression analysis showing the association between 11-SCT time and presence of early (K&L grade 1: n = 22) knee OA or early to mild (K&L grade 1–2; n = 27) knee OA.

Independent variable	Control (n = 30)	Early OA (n = 22)	Mild OA (n = 5)	Control vs. Early knee OA		Control vs. Early to mild OA	
	Mean ± SD	Mean ± SD	Mean ± SD	OR (95% CI)†	*p*-value	OR (95% CI)†	*p*-value
Stopwatch							
11-SCT time, s	8.59 ± 1.14	9.62 ± 1.53	9.12 ± 1.12	**1.852 (1.067, 3.214)**	**0.019**	**1.759 (1.048, 2.953)**	**0.024**
Insole							
11-SCT time, s	8.96 ± 1.20	9.93 ± 1.65	9.57 ± 1.21	**1.697 (1.026, 2.805)**	**0.030**	**1.661 (1.028, 2.684)**	**0.030**
Ascending phase, s	4.57 ± 0.53	5.03 ± 0.92	4.77 ± 0.28	**3.378 (1.157, 9.860)**	**0.018**	**3.188 (1.134, 8.964)**	**0.020**
Descending phase, s	4.08 ± 0.62	4.47 ± 0.72	4.21 ± 0.66	2.494 (0.890, 6.992)	0.073	2.241 (0.847, 5.931)	0.095
Transition phase, s	0.32 ± 0.27	0.44 ± 0.33	0.59 ± 0.50	3.057 (0.302, 30.92)	0.334	4.276 (0.463, 39.45)	0.183

OA, osteoarthritis; OR, odds ratio; 11-SCT, 11-step stair climb test; 95% CI, confidence interval.
Bold type represents a statistically significant result.
† OR (95% CI) for a presence of early knee OA or early to mild knee OA was calculated to indicate the predictive ability of independent variables while simultaneously including (one-step model) age (continuous), female sex, body mass index (continuous), and VAS pain score during 11-SCT (continuous) in the binary logistic regression model.

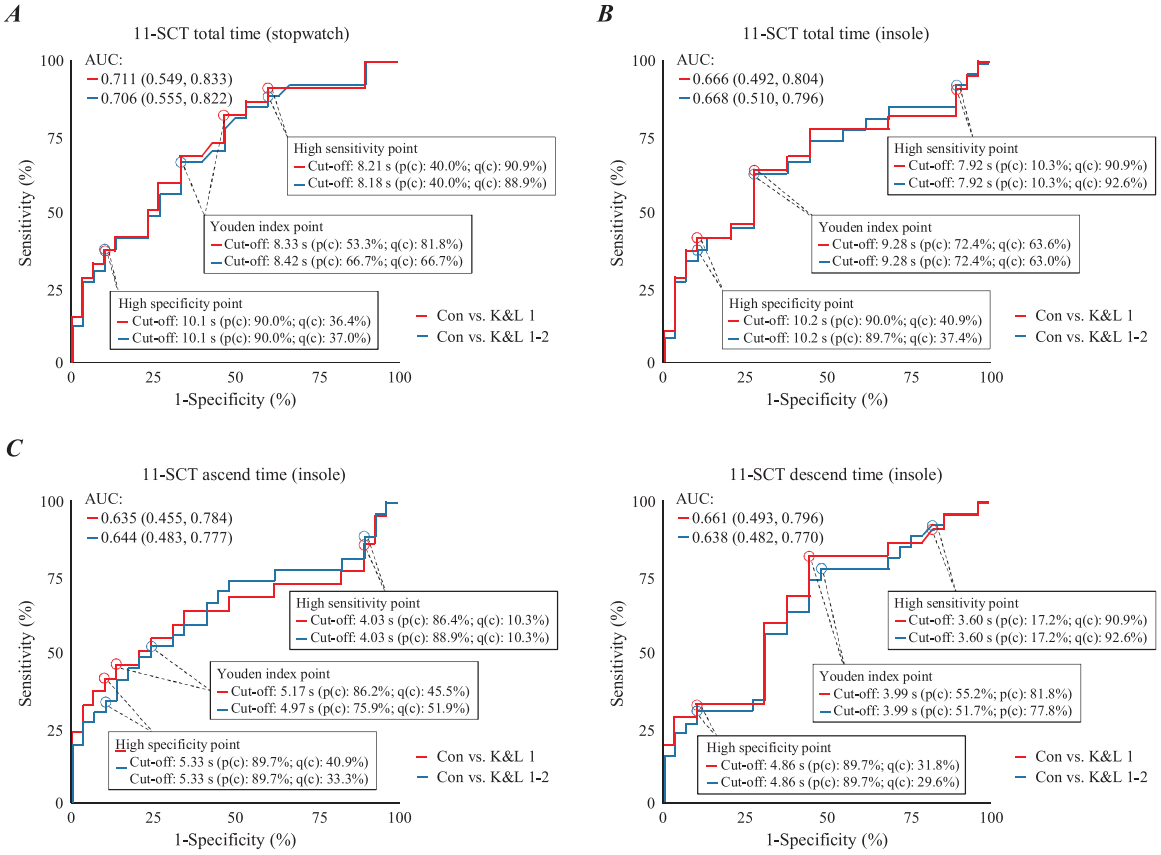

Fig. 1. Receiver operating characteristics curves to classify non-radiographic OA (K&L grade 0) and early OA (K&L grade 1) or early to mild OA (K&L grade 1–2) individuals correctly. **A,** 11-SCT time measured by a stopwatch. **B,** 11-SCT time measured by an insole. **C,** Stair ascend time measured by an insole. **D,** Stair descend time measured by an insole. The area under the curves (AUCs) and their 95% confidence intervals are provided. Sensitivity, p (c), and specificity, q (c), in each cut-off point (high sensitivity, high specificity, and Youden index points) are also provided.

(0.10 s) [13], indicating that the between-group difference would be considered a true difference. Such findings reinforce the previous finding that early knee OA had non-significant but longer time to perform 5-step SCT compared to asymptomatic controls [14]. The mechanisms of poor stair climbing ability in patients with early knee OA are unclear from this study. Such patients showed more inter-limb asymmetry in the sensor-estimated first peak GRF which is associated with the 11-SCT time (see Supplemental Fig. 1), although this data was from a post-hoc analysis. Larger inter-limb loading asymmetry would place relatively greater joint loads on one side [18], affecting multi-articular OA changes. Since 77% patients with early knee OA displayed bilateral disease, close attention to the inter-limb asymmetry in addition to poor stair climbing ability might help clarify clinical hallmark of early knee OA and the trajectory of disease onset.

Interestingly, the descending SCT time was not significantly better than the ascending SCT time for identifying early knee OA. This does not support the theory that stair descending is more challenging than stair ascending [6,16,17]. It should be noted that stair descending was done first before stair ascending which is in contrast with protocol for 11-SCT. Patients with early knee OA may have had some fatigue while performing stair ascent after completing the challenging stair descent. Furthermore, this study is a secondary analysis of data from a RCT; type

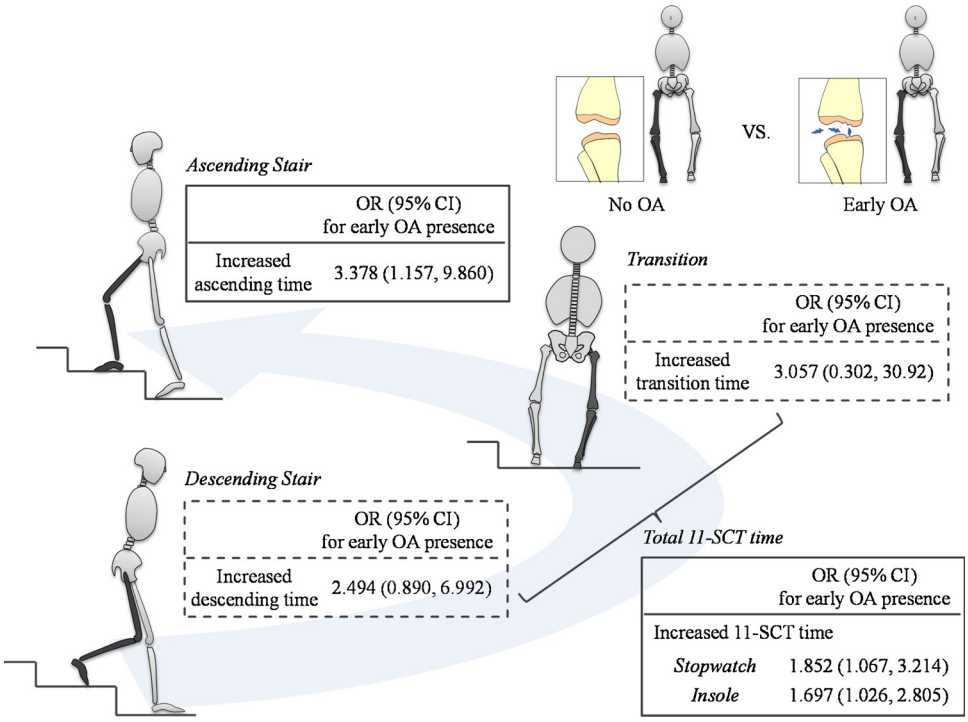

Fig. 2. Graphic abstract. A one-second increase in the stopwatch- and insole-based 11-SCTs was significantly associated with 1.9-fold and 1.7-fold increasing odds of the presence of early knee OA, respectively. When the insole-based 11-SCT was divided into three phases (ascending, descending, and transition), an increase in time in the ascending phase was significantly associated with a higher prevalence of early knee OA. Solid and dotted black squares represent statistically significant and non-significant results, respectively.

II error may exist and caution is required when interpreting non-significant data of stair descending time. Although this study might add new evidence that stair climbing ability, particularly in ascending stairs, might be impaired from the earliest stage of knee OA, direct comparison between ascending and descending stairs is needed.

We determined preliminary values for the 11-SCT that may be considered as clinical recommendations to identify patients with early knee OA sooner. Specifically, a stopwatch-based 11-SCT time of 8.3 s may be an ideal target for detecting patients with early knee OA, as this cut-off value best discriminated between patients with early knee OA and those without radiographically identified knee OA. This cut-off value was decreased slightly to 8.2 s, which had a high sensitivity for identifying early knee OA and may be useful for screening patients for early knee OA. It should be acknowledged that the lower one-side 95% CI of all AUC values was below 0.750 which is considered as clinically acceptable [29]. Future studies such as biomechanical analysis during stair climbing is of interest to improve diagnostic ability for identifying early knee OA.

4.2. Significance and clinical impact of the study

The practical relevance of this study is that patients with early knee OA have climb stairs slower compared to those without radiographically identified knee OA. As kinematic parameters during level walking cannot identify patients with early knee OA [14], activities involving weight-bearing bending of the knee might be the first to be limited in those people at a high risk for knee OA because of relatively high knee joint loading [6–8]. These preliminary findings warrant additional validation of whether monitoring for stair climbing ability can identify patients in the earliest stage of knee OA among high risk people as causation cannot be established from this study.

Despite an increased interest, there has been limited research investigating whether or not early knee OA is associated with limited mobility in more biomechanically demanding tasks such as weight-bearing activities that involve large knee flexion motion. A previous study showed that stair climbing ability in patients with early knee OA is poorer but statistically non-significant than those without early knee OA, although it was not primary outcome [14]. Functional limitations in tasks involving deep knee bending in patients with early knee OA were not adequately assessed.

4.3. Study limitations

There were several limitations to this study. First, control patients with a K&L grade 0 also felt some knee pain in prior 1 month. This point should be considered during data interpretation, as previous studies examining early OA-related biomechanical changes included asymptomatic patients as control subjects [4,5,14]. Second, the 11-SCT in this study was performed while wearing standardized shoes which may not be used in clinical practice. These data should be interpreted with caution since most clinicians would perform the stopwatch-based 11-SCT with participants wearing their own footwear which might influence the SCT time. Finally, this study included relatively high female participants which might cause some selection bias. As gender differences in stair ambulation pattern [31] and muscle strength [32] are documented, generalization of results is questionable, although female sex was not significantly associated with early knee OA.

4.4. Conclusion

This study demonstrated that patients with early knee OA have a reduced speed to climb stairs compared to those without radiographically identified OA and with knee pain. Moreover, stair descent, which is supposed to be a biomechanically more demanding task, was not a significantly superior test for evaluating early knee OA. We determined the time values of an 11-SCT that may be useful for identifying early knee OA patients, although its discriminatory ability for identifying early knee OA was poor to fair. These preliminary findings may serve as the foundation for future studies investigating the clinical hallmarks associated with early knee OA.

Author contributions

All authors made substantial contributions to: (1) study conception and design, data acquisition, or data analysis and interpretation; (2) drafting the article or revising it critically for important intellectual

content; and (3) providing final approval of the manuscript for submission.

The specific contributions of the authors are as follows:

(1) Study conception and design: HI and KS;
(2) Data analysis and interpretation: HI, KS, RE, TA, and MT;
(3) Article drafting: HI, KS, RE, TA, and MT;
(4) Critical revision of the article for important intellectual content: HI, KS, and TA;
(5) Final approval of the article: HI, KS, RE, TA, and MT;
(6) Statistical expertise: HI;
(7) Obtaining funding: HI;
(8) Data collection and assembly: HI, RE, KS, TA, and MT.

Declaration of Competing Interest

The authors did not receive financial support or other benefits from commercial sources for the work reported in this manuscript, or any other financial support that could create a potential conflict of interest or the appearance of a conflict of interest with regard to the work.

Acknowledgments

This study was supported in part by (1) a funding from Omron healthcare Co., Ltd; and (2) a Grant-in-Aid from the Japan Society for the Promotion of Science (https://www.jsps.go.jp/) for Research Fellows to HI. The authors thank the members of the Aoyama laboratory (Kyoto University, Kyoto) for their assistance with the data collection. We also thank Editage (www.editage.jp) for the English language editing.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.gaitpost.2019.06.004.

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