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## Original Article

## Measurement Error for Hand-Held Dynamometer in Knee Osteoarthritis: Minimal Detectable Change to Monitor Time-Dependent Changes in Knee Strength in Older Individuals

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## SUMMARY

**Background:** Accurate measurement of quadriceps muscle strength is important for patients with knee osteoarthritis (OA) to evaluate intervention outcomes. As the prevalence of OA increases, due to aging of the population, understanding the time-dependent effects of aging-related decreases in muscle strength becomes necessary. This study evaluated the errors in measurement of knee flexion and extension strength using hand-held dynamometer (HHD) in individuals with knee joint OA, and to determine the minimal detectable change (MDC) over a 3-month follow-up.

**Methods:** This was a longitudinal, observational study of 52 individuals with knee OA treated on an outpatient basis, for whom the HHD measurements were obtained at baseline, and at the end of a 3-month follow-up. The time-dependent changes in muscle strength measurements were evaluated using a paired *t*-test for changes in strength between the two time points. A Bland-Altman analysis was used to identify systematic bias on strength measures. We calculated the intra-rater reliability using the intra-class correlation coefficient (ICC), and the MDC<sub>95</sub>.

**Results:** There were no differences in HHD measurements for knee extensors and flexors between the two time points. There was no evidence of fixed or proportional bias. The intra-rater reliability was high, with an ICC (1,1)  $\geq 0.85$ . The MDC<sub>95</sub> was 0.23 Nm/kg for knee extension and 0.17 Nm/kg for knee flexion.

**Conclusion:** HHD measurements can have good reliability for standardized strength testing methods, used in clinical practice. The MDC<sub>95</sub> values can be used to monitor change in knee strength over time and the efficacy of interventions.

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## 1. Introduction

Knee osteoarthritis (OA) is a gradually progressive degenerative joint disease.<sup>1</sup> Conservative treatment is recommended in the early stages of knee OA, with evidences of increase in quadriceps strength and decrease in knee joint pain through combined resistance training, stretching, and low-load aerobic exercise, which can slow the progression of OA.<sup>2,3</sup> Therefore, accurate measurement of quadriceps strength is necessary to tailor exercise prescription, and to evaluate the effectiveness of an intervention in a patient-specific way. This is important for healthcare professionals involved in the delivery of non-pharmacological interventions.

As the majority of patients with knee OA are older individuals, aging-related sarcopenia is an important clinical issue to consider when evaluating outcomes of an exercise regimen designed to improve muscle strength. A muscle mass loss of 1–2% per year has been reported in those > 50 years, increasing to approximately 3% per year after the age of 60 years.<sup>4,5</sup> This age-related decline in skeletal muscle mass and strength is accelerated in the absence of regular

exercise. Therefore, accurate assessment of the change in quadriceps muscle strength in older individuals must take into account these time-dependent effects on muscle strength, as they can lead to systematic errors in measurements of muscle strength, and negatively influence decision-making of clinical interventions.<sup>6,7</sup> However, previous reports on the measurement errors in muscle strength tests have been based on two measurements obtained on the same day.<sup>8,9</sup> As such, the measurement errors calculated from these same-day measurements do not include time-dependent effects. This could lead to a misinterpretation of outcomes of strength training programs in older individuals.

A recent systematic review on the clinical usefulness of resistance training exercises in individuals with knee OA identified the positive effects of increased knee muscle strength in improving physical function and reducing OA-related knee joint pain.<sup>10</sup> Generally, programs regimens of quadriceps strengthening for OA consisting 30–60 min/session, 2 to 3 sets of 8 to 12 repetitions, for an average of 2 or 3 months, have reported positive strength outcomes.<sup>10</sup> Accordingly, in our view, minimal detectable change (MDC) values should be calculated over this time period, rather than from same-day data. Therefore, this study aimed to evaluate the measurement error of muscle strength tests of knee flexion and extension, obtained by hand-held dynamometer (HHD), in individuals with knee joint OA

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and to determine the MDC using data over a 3-month follow-up.

## 2. Materials and methods

### 2.1. Study design

This was a longitudinal, observational study approved by the Research Ethics Committee of Tokoha University (approval no: R-2021-504H). All participants provided written informed consent. Reporting of outcomes adhered to the Strengthening of Reporting of Observational Studies in Epidemiology (STROBE) Guidelines.<sup>11</sup>

### 2.2. Participants

Participants were recruited from three medical facilities across Japan, between February 2019 and September 2021. We used non-random sampling method for selection of eligible patients, who were diagnosed with knee OA and received conservative therapy < 3 days/week, which is less than the recommended frequency to obtain positive strength outcomes.<sup>10</sup> The exclusion criteria, which were chosen because the measurement error of muscle strength tests differs for each disease, were as follows: prior knee surgery or fracture of the knee with OA; other significant joint diseases, such as multiple-joint OA or rheumatoid arthritis; neurological impairments, such as sensory disturbances or motor paralysis; and other cognitive or psychiatric disorders, such as dementia.

### 2.3. Variables

Clinical and physical characteristics were obtained at the baseline. Clinical characteristics included sex; age; height and body weight, from which body mass index (BMI) was derived, Kellgren-Lawrence (K-L) grade, laterality (unilateral or bilateral) of the knee OA, pharmacotherapy, implementation period of conservative therapy, and frequency of hospital visits. Physical functions included knee extension (quadriceps) and flexion strength; knee extension and flexion range of motion (ROM); subjective knee pain; five times sit-to-stand test (FTSST); and 5-meter walk test (5mWT). Measurements of physical functions were repeated at the 3-month follow-up, which were assessed by the same rater, for each participant, respectively. Six physical therapists, with 5–20 years of clinical experiences, conducted every test. For the measurements of muscle strength, the physical therapists practiced the muscle strength test adhering to our method that we had prepared until they became proficient, before the data collection.

Measurements of muscle strength was obtained with HHD instead of manual muscle testing (MMT) and isokinetic testing for the following reasons: MMT is a qualitative assessment; thus, includes between-assessor variability,<sup>12,13</sup> and isokinetic testing, using systems such as the Cybex (Life Fitness, Franklin Park, IL, USA), provides quantitative and reliable measures of strength but is very expensive; thus, not viable for all real-world practice settings;<sup>14</sup> on the other hand, HHD, using standardized methods, provides an inexpensive, highly portable, easy-to-use, and reliable quantitative measure of muscle strength for patients with knee OA. Also, previous studies have reported excellent intra-rater (intra-class correlation coefficients (ICC): 0.92 to 0.96) and inter-rater (ICC: 0.96) reliability scores of muscle strength test using HHD.<sup>9,15</sup>

For participants with bilateral knee OA, measures for the knee with more severe OA defined by a more severe K-L grade; greater restriction of knee joint ROM; greater pain was included in the analysis. The maximum isometric muscle strength of the extensors and

flexors of the involved knee was measured using HHD (model:  $\mu$ Tas F-1, Anima, Tokyo, Japan), with a standardized method. First, the participants sat on a chair with arms crossed over their chest and hips, and knees flexed at 90° (Figures 1 and 2). Then, the opposite foot was placed on the floor or a raised platform to maintain a stable



**Figure 1.** Testing method for knee extension strength. The hand-held dynamometer was held against the distal anterior surface of the lower leg of the affected side, secured using a belt attached to a bed leg.



**Figure 2.** Testing method for knee flexion strength. The hand-held dynamometer was held against the distal posterior surface of the lower leg of the affected side, secured using a belt attached to the rater's leg.

sitting posture during measurements. The participants would then have enough opportunity to practice performing the HHD measurement before testing to eliminate effects of learning. Maximal isometric knee flexion and extension strength was obtained at two time points of measurement, baseline, and at the end of the 3-month follow-up. For inter-subject comparison, the maximal isometric muscle strength (torque) was normalized to body weight (Nm/kg).<sup>16</sup> Previous studies on measurement error for quadriceps muscle strength using HHD reported absolute measures of force, N, or kg, rather than torque, Nm.<sup>17,18</sup> However, as muscles produce moments of force around a joint, rather than an absolute force, we used the torque measurement, normalized to body weight (Nm/kg) as the unit of muscle strength in our analysis.

Knee extension and flexion ROM was measured as the maximum tolerable range of passive movement using a goniometer. Subjective knee pain was rated on the visual analogue scale (VAS) that ranged from 0 (no pain) to 100 (worst possible pain).<sup>19</sup> FTSST was defined as the time taken by the participants to stand up from a chair (chair height: 43–45 cm) and sit down for five repetitions as quickly as possible.<sup>20</sup> The 5mWT measured the time the participants took to walk the designated in-room walkway as fast as they could. The walkway for the in-room 5mWT was an 11-meter straight line, which consisted of an initial 3-meter acceleration zone, a central 5-meter timed zone, and a final 3-meter deceleration zone.<sup>21</sup>

#### 2.4. Sample size

The sample size was calculated using the Fisher z-transformation, with the following values: minimum tolerance of the reliability coefficient of the muscle strength test, 0.70; assumed value of the reliability coefficient, 0.85; number of measurements, 2;  $\alpha$  error, 0.05; and  $\beta$  error, 0.70. The target sample size was 41 participants.

#### 2.5. Analysis

The changes in the physical function measurements at the baseline and the 3-month follow-up were evaluated using a paired *t*-test. The outcome measure was knee muscle strengths. Bland-Altman plot analysis was conducted to confirm the presence or absence of systematic disagreement in muscle strength scores, including both fixed and proportional bias. The ICC, model 1,1, of strength measures were calculated at baseline, and follow-up to examine intrarater reliability. Standard error of measurement (SEM) and  $MDC_{95}$  were calculated as follows:

$$SEM = \text{standard deviation of measurements} \times \sqrt{1 - ICC}$$

$$MDC_{95} = SEM \times 1.96 \times \sqrt{2}$$

**Table 2**

Comparison of physical function tests of the baseline and the 3-month follow-up.

Variable	Unit	Baseline	Follow-up	<i>p</i> -value	95% confidence interval	
					Lower	Upper
Knee extension strength	Nm	48.8 ± 16.0	49.2 ± 16.6	0.636	-1.42	2.30
	Nm/kg	0.87 ± 0.30	0.87 ± 0.30	0.761	-0.03	0.04
Knee flexion strength	Nm	28.5 ± 9.8	28.1 ± 9.1	0.523	-1.67	0.86
	Nm/kg	0.50 ± 0.16	0.50 ± 0.15	0.704	-0.03	0.02
Knee extension ROM	degrees	-6.3 ± 4.8	-6.5 ± 4.8	0.261	-0.80	0.22
Knee flexion ROM	degrees	134.5 ± 12.3	136.4 ± 12.1	0.011*	0.46	3.39
Visual analogue scale	mm	33.8 ± 22.9	30.1 ± 21.5	0.002*	-14.26	-3.24
Five times sit-to-stand test	s	8.98 ± 2.53	8.35 ± 2.34	0.001*	-1.00	-0.26
5-meter walk test	s	3.68 ± 0.98	3.67 ± 1.17	0.830	-0.17	0.14

Data are presented as mean ± SD. \* *p* < 0.05. ROM, range of motion.

All analyses were performed using R4.1.2 (CRAN, freeware for Windows). The significance level was set at *p* < 0.05.

### 3. Results

Our analysis included 52 individuals (46 women; mean age, 72.7 ± 9.7 years); the clinical characteristics of the study sample at baseline are provided in Table 1. The participants underwent a course of conventional physical therapy for 20 min/day, 1–2 days/week, within the follow-up period. The main physical therapy programs consisted of quadriceps strengthening, ROM exercises, and low-impact aerobic exercises.

The physical function data at the baseline, and at the 3-month follow-up are shown in Table 2. The mean follow-up period was 90.7 ± 4.0 days. There was no difference in knee extension and flexion

**Table 1**

Summary statistics of clinical characteristics (n = 52).

Characteristics	All
Sex	
Men	6 (11.5)
Women	46 (88.5)
Age, years	72.7 ± 9.7
Height, cm	152.6 ± 7.4
Body weight, kg	57.4 ± 11.5
BMI, kg/m <sup>2</sup>	24.6 ± 4.2
K-L grade	
Grade I	18 (34.6)
Grade II	20 (38.5)
Grade III	11 (21.2)
Grade IV	3 (5.8)
Laterality	
Unilateral	20 (38.5)
Bilateral	32 (61.5)
Pharmacotherapy	
Intra-articular injection of hyaluronic acid	16 (30.8)
Intra-articular steroid injection	8 (15.4)
NSAIDs	
Adhesive skin patch	30 (57.7)
Oral agent	13 (25.0)
Ointment	8 (15.4)
Implementation period of conservative therapy	
New	6 (11.5)
1–5 months	16 (30.8)
6–11 months	10 (19.2)
≥ 12 months	20 (38.5)
Frequency of hospital visits	
1 day/week	28 (53.8)
2 days/week	24 (46.2)

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

BMI, body mass index; K-L grade, Kellgren-Lawrence grade; NSAIDs, nonsteroidal anti-inflammatory drugs.

strength, knee extension ROM, and 5mWT between the two time points ( $p \geq 0.05$ ). In contrast, there was a significant difference in knee flexion ROM, VAS, and FTSST between the baseline and follow-up values ( $p < 0.05$ ).

In addition, there was no evidence of fixed or proportional bias on HHD measurements at the two time points (Table 3, Figure 3). These results made it possible to calculate the intra-rater ICC (1,1) and MDC<sub>95</sub>, considering the time-dependent effects on muscle strength. The reliability of HHD measurements were high, with intra-rater ICC (1,1) values  $\geq 0.85$  (Table 4). The MDC<sub>95</sub> of HHD values for our study sample was 0.23 Nm/kg (13.1 Nm) for knee extension and 0.17 Nm/kg (8.9 Nm) for knee flexion.

**4. Discussion**

To the best of our knowledge, this study is the first to determine the MDC<sub>95</sub> for measurements of knee extension and flexion strengths using HHD, taking into consideration time-dependent effects over a 3-month period, which are important in older adults with knee OA. For precise interpretation of the changes in muscle strengths of patients with knee OA, one should ideally examine the measurement errors in muscle strength test in patients who did not take any resis-

tance training exercises 3 months after the baseline. However, ethical reasons had not allowed us to exclude resistance training exercises from physical therapies. Therefore, we studied the patients who did not show any changes in lower limb muscle strength despite certain period of physical therapy, including resistance training exercises. There was significant difference in knee flexion ROM, VAS, and FTSST between the baseline and follow-up in this study, suggesting that physical functioning ability of the participants may have changed. In contrast, previous studies had reported MDC of knee flexion ROM, VAS, and FTSST to be 7.9 degrees, 28 mm, and 1.71 s in patients with knee OA, respectively.<sup>22-24</sup> The 95% confidence intervals of knee flexion ROM, VAS, and FTSST shown in Table 2 were smaller than the MDC of each test mentioned above. Thus, we considered the differences in measurements of knee flexion ROM, VAS, and FTSST between the baseline and follow-up in this study to be the changes within the measurement error of each test, and there were no clinically significant differences.

A study of 1,093 patients with knee OA reported that the median of quadriceps strength in the non-surgical side was 58.5 Nm.<sup>25</sup> Another study of 273 knee OA patients reported the knee extension and knee flexion strength were  $0.75 \pm 0.32$  Nm/kg and  $0.41 \pm 0.18$

**Table 3**  
Systematic bias of muscle strength testing using hand-held dynamometer.

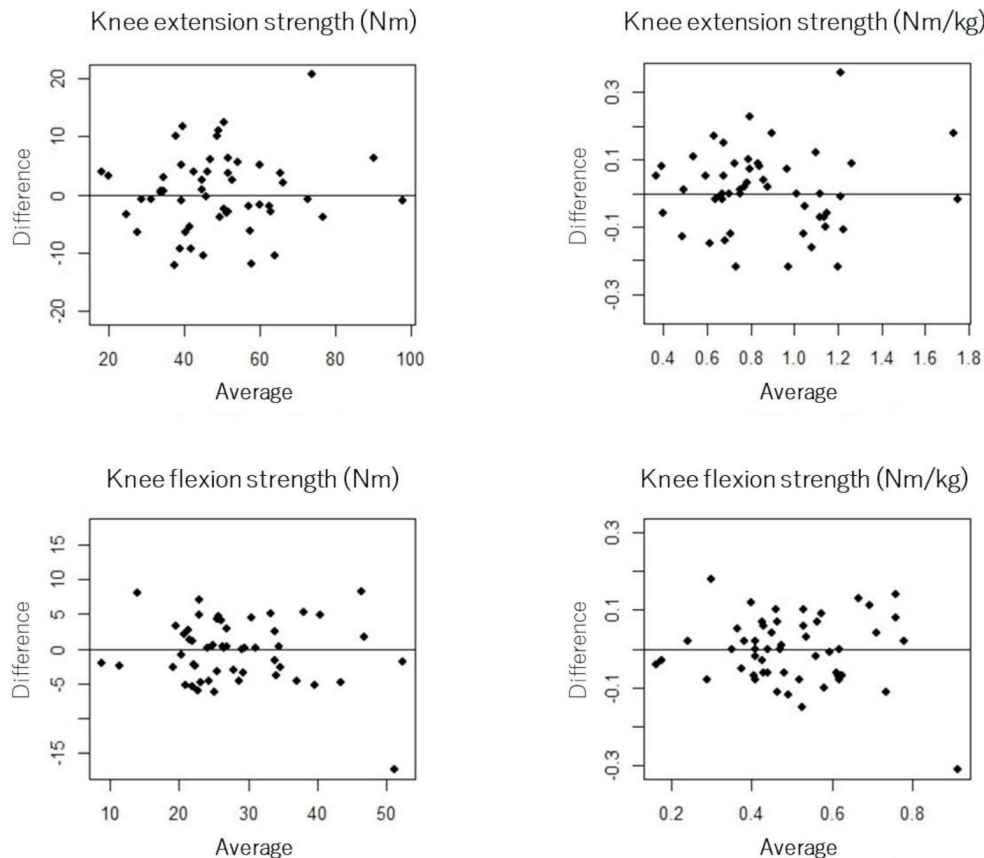
Variable	Unit	Constant bias		Proportional bias	
		95% CI	p-value	r	p-value
Knee extension strength	Nm	-1.42 to 2.30	0.636	0.09	0.531
	Nm/kg	-0.03 to 0.04	0.761	-0.01	0.962
Knee flexion strength	Nm	-1.67 to 0.86	0.523	-0.15	0.301
	Nm/kg	-0.03 to 0.02	0.704	-0.11	0.432

CI, confidence interval.

**Table 4**  
Intra-rater reliability and minimal detectable change of muscle strength testing using hand-held dynamometer.

Variable	Unit	ICC (1,1)	95% CI	SEM	MDC <sub>95</sub>
Knee extension strength	Nm	0.92	0.86-0.95	4.7	13.1
	Nm/kg	0.93	0.87-0.96	0.08	0.23
Knee flexion strength	Nm	0.89	0.81-0.93	3.2	8.9
	Nm/kg	0.85	0.75-0.91	0.06	0.17

CI, confidence interval; ICC, intraclass correlation coefficients; MDC, minimal detectable change; SEM, standard error of measurement.



**Figure 3.** Bland-Altman plots for the knee extension and flexion strength.

Nm/kg, respectively.<sup>26</sup> Since the muscle strength values between previous studies and this study were similar, our study participants could well represent the regular population. Additionally, with no systematic bias in measures identified, the MDC<sub>95</sub> values calculated over a 3-month interval could provide a useful index to evaluate the effectiveness of a program of resistance training, performed at a frequency expected to increase muscle strength. Therefore, the MDC<sub>95</sub> of muscle strength obtained by HHD in our study could assist physical therapists and other professionals, involved in the strength training of individuals with knee OA, in appropriately evaluating outcomes of strength interventions as well as in tailoring programs in patient-specific ways.

Reliable methods to quantify knee extension strength are necessary to evaluate the pathophysiological effect of quadriceps strength on knee OA. This reliability cannot be achieved with MMT, with the knee extension strength in patients with knee OA performing a program of resistance training generally reported as a grade of 4 or 5.<sup>15</sup> Thus, precise detection of actual change in their muscle strength is not possible by MMT. Decreased quadriceps strength is associated with progression in knee OA.<sup>27</sup> Moreover, an increase in quadriceps strength of 30–40% can decrease OA-associated knee pain.<sup>28</sup> Interestingly, 0.23 Nm/kg for the MDC<sub>95</sub> of quadriceps strength in this study was 26.4% of 0.87 Nm/kg for the quadriceps strength at baseline, representing a change of < 30%. The previous study reported the MDC<sub>90</sub> of quadriceps strength measured by Biodex was 0.33 Nm/kg, 18.2% of mean quadriceps strength of 1.81 Nm/kg in patients with knee OA.<sup>16</sup> That ratio of the MDC<sub>90</sub> to the mean quadriceps strength seemed to be a bit smaller than that of our present study, however, the difference of the ratio between the previous study and our present study would still be considered negligible. The use of MDC<sub>95</sub> of quantitative HHD of knee extension strength addresses this gap in practice, allowing accurate clinical interpretation of the effects of resistance training exercises in patients with knee OA.

Our MDC<sub>95</sub> values of 13.1 Nm and 8.9 Nm for knee extension and flexion strength, respectively, are comparable to values of 14.0 Nm and 11.2 Nm calculated for two sets of HHD data obtained on the same day for patients with OA.<sup>8</sup> Of note, the individuals of that study had a higher BMI than the participants in our study (mean, 28.9 kg/m<sup>2</sup>), and greater knee extension and flexion strength of 74.3 Nm and 42.4 Nm, respectively. Reporting MDC<sub>95</sub> values as a torque normalized to body weight (Nm/kg) allows for between-subject comparisons.

It has been reported that the reliability of HHD measures decreases as the force exceeds 200 N, with the use of a belt to tightly secure the dynamometer to the lower leg recommended to improve reliability at these higher force values.<sup>29</sup> A previous study reported a high intra-rater reliability of measures of muscle strength among patients with knee OA when the HHD was tightly secured to leg.<sup>30</sup> The ICC (1,1) in our study was  $\geq 0.85$ , with a reliability  $\geq 0.81$  and considered almost perfect.<sup>31</sup> Based on these findings, HHD can be considered as an inexpensive and highly reliable measure of muscle strength, with excellent portability, can be useful in various context, including home care.

The limitations of our study need to be acknowledged. First, the study findings were limited to the MDC<sub>95</sub> of the muscle test using HHDs in patients with knee OA who underwent conservative therapy and cannot be generalized to muscle test assessment of any other diseases such as multiple-joint OA, rheumatoid arthritis, and psychiatric disorders. Second, only intra-rater reliability was evaluated; inter-rater reliability is also needed to be determined with the standard HHD methods used.

## 5. Conclusions

The HHD measurements have good reliability using standardized methods for clinical practice. The MDC<sub>95</sub> values can be used to monitor change in knee strength over time and the effects of an intervention. The MDC<sub>95</sub> values also have clinical utility to tailor programs of resistance strength training to optimize outcomes in patient-specific way, as well as to determine the benefits of continuing a program or to justify cessation.

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## Conflicts of interests

The authors declare no conflicts of interest.

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