Introduction

Stroke is a leading cause of long-term disability [1], and the primary goal of stroke rehabilitation is to regain independence in performing activities of daily living (ADLs). The improvement of standing balance is an essential factor of ADL performance because activities while standing, such as transferring, walking, climbing stairs, toileting, and dressing, are frequently performed in daily life. Standing balance is also important in preventing falls in individuals with stroke [2].

The clinical guidelines of the Stroke Foundation suggested that the task-specific practice of standing balance is recommended for individuals with stroke who have difficulty standing [3]. Furthermore, performing standing practice early after stroke onset is essential for improving stroke care effectiveness [4, 5]. The current concepts of biological recovery after brain injury suggest that early task-specific intensive practice has a crucial contribution in improving stroke recovery [6]. To prevent or minimize secondary changes to the musculoskeletal and cardiorespiratory systems due to immobility, performing standing practice early after stroke onset is essential [7]. In individuals with severe stroke, standing and walking activities are affected by severe impairments, and balance recovery and independent walking are limited. Therefore, improving standing abilities, such as standing reach, early after stroke onset is required for individuals with severe stroke.

In the clinical setting, lower limb orthoses, such as...
as ankle-foot orthoses (AFOs) and knee–ankle–foot orthoses (KAFOs), have been used to improve standing abilities by compensating for the stability of the paretic lower limb. The therapeutic effects of lower limb orthoses are differentiated into immediate effects by wearing lower limb orthosis [8–15] and fixed-term effects by wearing and training with lower limb orthoses over a certain period [16]. The immediate effects refer to changes in performance that immediately occur after wearing lower limb orthoses. The fixed-term effects refer to the changes in performance that occur when individuals use lower limb orthoses over a specific period, and these effects include immediate effects. Therefore, to verify the fixed-term effects of using lower limb orthoses, the immediate effects need to be evaluated.

AFOs have been used to compensate for the stability of the paretic lower limb by stabilizing the ankle joint. Previous studies have shown that AFOs immediately improved walking abilities, such as walking independence [8], walking speed [9], walking endurance [10], and stride length [11], and standing abilities, such as weight bearing on the paretic lower limb [12] and body sway [13] in static standing. Furthermore, the use of AFOs improved walking speed over time [16].

Conversely, KAFOs have been used to compensate for the stability of the paretic lower limb by stabilizing the knee and ankle joints and improve the walking abilities of individuals with severe stroke [17]. However, little information has been reported on the immediate and fixed-term effects of KAFOs on the standing balance of individuals with stroke. Standing balance is divided into static and dynamic standing balance abilities [18, 19]. Previous study reported that KAFOs immediately improved the static standing of individuals with subacute stroke [15]. However, the immediate effects of KAFOs on the dynamic standing of individuals with subacute stroke have not been clarified. Dynamic balance is defined as the ability to maintain stability during weight shifting [19] and is assessed by performing reaching tasks while standing. A recent report showed that AFOs immediately improved reach distance while standing [14]. Although KAFOs are used for individuals with severe stroke instead of AFOs, KAFOs immediately improved static standing [15] similar to AFOs [12, 13]. Therefore, KAFOs can be one of the beneficial interventions for stabilizing unstable paretic lower limb and for improving the disabilities of individuals with stroke [17]; hence, the authors hypothesized that wearing KAFOs immediately improves the standing reach of individuals with stroke, similar to AFOs [14], by compensating for the stability of the paretic lower limb.

This study was to evaluate the immediate effects of KAFOs on the standing reach of individuals with subacute stroke. Identifying the immediate effects of KAFOs on standing reach could be useful for the establishment of therapeutic and rehabilitation programs with KAFOs that are designed to improve the standing reach of individuals with severe stroke.

**Methods**

**Study design**

A cross-sectional experimental design was adopted. This study was approved by the ethics committee of Kyorin University (28-4) and Hatsudai Rehabilitation Hospital (H27–85).

| Table 1. Characteristics of participants. |
|-------------------------------------------|
|                                           |
| **Group 1 (n = 22)**                      |
| **Group 2 (n = 9)**                       |
| **Statistic**                             |
| **p**                                     |
| **Age, year**                             |
| 72.3 (11.8) [67.1, 77.5]                 |
| 52.4 (9.8) [44.9, 60.0]                  |
| -3.31<sup>c</sup>                        |
| <0.001                                    |
| **Gender (male/female), n<sup>c</sup>**   |
| 12 (55)/10 (45)                          |
| 6 (67)/3 (33)                            |
| 0.39<sup>c</sup>                         |
| 0.534                                    |
| **Stroke type (hemorrhage/infarction), n<sup>c</sup>** |
| 7 (32<sup>b</sup>/15 (68)<sup>c</sup>    |
| 8 (89<sup>e</sup>/1 (11)<sup>c</sup>     |
| 8.33<sup>c</sup>                         |
| 0.004                                    |
| **Affected side (right/left), n<sup>c</sup>** |
| 10 (45)/12 (55)                          |
| 5 (56)/4 (44)                            |
| 0.26<sup>c</sup>                         |
| 0.609                                    |
| **Period from stroke onset to admission, day<sup>d</sup>** |
| 28.2 (10.0) [23.8, 32.7]                 |
| 21.2 (8.9) [14.4, 28.0]                  |
| -1.72<sup>c</sup>                        |
| 0.085                                    |
| **Period from stroke onset to KAFO prescription, day<sup>d</sup>** |
| 37.6 (12.9) [31.9, 43.3]                 |
| 29.1 (12.5) [19.5, 38.7]                 |
| -1.72<sup>c</sup>                        |
| 0.085                                    |
| **BRS of the paretic lower limb (II/III/IV), n<sup>c</sup>** |
| 16 (73<sup>c</sup>/6 (27)<sup>b</sup>/0<sup>c</sup>   |
| 1 (11<sup>c</sup>/5 (56)<sup>c</sup>/3 (33)<sup>c</sup> |
| 13.20<sup>c</sup>                        |
| 0.001                                    |
| **SIAS knee extension strength item (2/3), n<sup>c</sup>** |
| 6 (27<sup>c</sup>/16 (73)                |
| 0 (0)/9 (100)                            |
| 3.04<sup>c</sup>                         |
| 0.081                                    |
| **Type of KAFO (1/2), n<sup>c</sup>**     |
| 20 (91<sup>c</sup>/2 (9)                 |
| 9 (100)/0 (0)                            |
| 0.88<sup>c</sup>                         |
| 0.349                                    |

Note. BRS = Brunnstrom recovery stage; SIAS = Stroke impairment assessment set; KAFO = knee–ankle–foot orthosis. Type of KAFO, 1 = KAFO with spring assisted extension knee joint and Klenzak ankle joint, 2 = KAFO with ring lock knee joint and Klenzak ankle joint.

<sup>a</sup>Continuous variables were analyzed with Mann-Whitney U test, and the data were shown as M (SD) [95% confidence interval].<sup>b</sup>Nominal variables were analyzed with chi-square test, and the data were showed as n (%).<sup>c</sup>Adjusted residual > |1.96|. <sup>d</sup>Z-score was based on Mann-Whitney U test. <sup>e</sup>χ²-score was based on chi-squared test.
Participants
This study enrolled 31 patients with subacute stroke (mean age, 66.5 ± 14.4 years; mean poststroke interval at admission, 26.2 ± 10.1 days) admitted to a rehabilitation hospital (Table 1). The inclusion criteria were as follows: (1) patients who have stroke for the first time, (2) those whose poststroke intervals at admission were within 60 days, (3) those not using lower limb orthoses (KAFOs were provided for the first time after stroke onset), and (4) those who can follow simple verbal commands or instructions. All participants provided written informed consent.

Experimental protocol
The demographic and physical characteristics of the participants were recorded within 1 week before receiving KAFOs (Table 1). Demographic characteristics, such as age, sex, stroke type, lesion side, time from stroke onset to admission or KAFO provision, and type of KAFO were investigated. As physical characteristics, paretic and nonparetic lower limb function were assessed by physical therapists. The motor paralysis severity of the paretic lower limb was evaluated using Brunnstrom recovery stage [20]. The BRS is classified under six categories (from I [flaccidity with no movement] to VI [individual joint movement with little awkwardness]) as per the motor recovery process of hemiparesis after stroke. The nonparetic lower limb function was evaluated using the quadriceps muscle strength item of the unaffected side function subcategory in stroke impairment assessment set (SIAS) [21]. This item is rated from 0 (severely impaired) to 3 (normal).

All participants were provided with KAFOs after admission for the first time. A doctor, physical therapist, and prosthetist determined whether to provide inpatients with KAFOs after early admission. KAFOs were provided on the basis of standing and walking performances and the presence or absence of knee collapse while standing and walking with or without the use of lower limb orthoses. Specifically, lower limb orthoses were...
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provided when the participants (1) could undergo standing or walking training but have unstable knee and ankle joints due to severe motor impairments, (2) exhibited spasticity patterns predominantly in the flexor muscles and could not keep a knee extension position while standing or walking, and (3) displayed insufficient knee control or instability or have an AFO that inadequately controlled knee instability [22]. All participants were provided with traditional KAFOs equipped with bilateral metal struts that could be used as AFOs by removing the parts for the knee joint and thigh (Kawamura Gishi Co., Ltd., Osaka, Japan; MEDX. Co., Ltd., Tokyo, Japan).

For standing balance, the maximal forward reaching distance was measured using the functional reach test (FRT) [23] with and without a KAFO on the paretic lower limb (Fig. 1). A tape measure was placed at the level of the participants’ acromion process. Before the reaching movement, the measuring tool was leveled so that it was horizontal to the floor. Reaching was performed using the nonparetic arm because it is difficult for individuals with stroke to maintain the paretic arm above shoulder level. The participants lifted their outstretched nonparetic arm to shoulder height, paused for initial reading, and reached as far forward as possible. They were instructed to “reach as far forward as they can without moving their feet or taking a step and to try keeping their hands along the tape measure.” The start and end positions of the index finger of the outstretched hand were recorded, and the positional difference represented the total reach for that direction. During the examination, the participants stood in a comfortable upright posture without physical assistance and raised their unaffected arm to the height of the acromion process. Their feet were maintained flat on the floor, and the test was discarded and repeated if the feet were moved. The FRT was performed on the same day within 1 week after providing KAFOs. In tests with and without KAFOs, participants wore shoes on their nonparetic lower limb and were barefoot, respectively. In this study, the KAFOs used were those that were provided to the participants after admission. The FRT was performed three times, and the maximal reach distance was adopted as the representative value.

To assess whether the participants can perform standing reach, the “reaching forward while standing” item of the functional balance scale (FBS) [24, 25] was scored on the basis of the FRT results. The FBS is a 14-item scale that assesses the balance of individuals with stroke and has good reliability and validity [25]. The items are scored from zero points to four points. A score of zero points represents an inability to complete the task, and a score of four points represents the ability to independently complete the task. In the present study, the “reaching forward while standing” item of the FBS was scored from zero points to four points.

Data analysis

To evaluate the immediate effects of KAFOs on the FRT results, the participants were divided into the following groups on the basis of the results of the “reaching forward while standing” item of the FBS without KAFOs: participants who were unable to undergo the FRT or require assistance (zero points) were categorized as participants who were unable to reach (group 1), whereas participants who were able to undergo FRT with or without supervision (≥1 point) were categorized as participants who were able to reach (group 2) (Fig. 2). The Mann-Whitney U test was performed to compare age and time from stroke onset to admission or KAFO provision between groups. The chi-squared test
was also performed to compare sex, stroke type, lesion side, the BRS of the paretic lower limb, quadriceps muscle strength items of the SIAS, and type of KAFO between groups. In group 1, the chi-squared test was used to compare the proportion of participants who were able to reach with KAFOs. In group 2, the data of reach distance during the FRT with or without KAFO followed normal distribution. However, the Wilcoxon rank-sum test was used to examine the differences in reach distance with and without KAFOs, because sample size in this study was small.

The significance level was set at $p \geq 0.05$, and all analyses were conducted using Statistical Package for the Social Sciences version 23.0 (IBM Corp., Chicago, IL, USA).

**Results**

The results of the “reaching forward while standing” item of the FBS without KAFOs showed that the numbers of participants in groups 1 and 2 were 22 and 9, respectively.

The Mann-Whitney $U$ test showed that group 2 was significantly younger than group 2 (Table 1). The chi-squared test showed that the proportions of participants who had infarction or BRS IV in group 2 were higher than those in group 1 (Table 2). In addition, the chi-squared test also showed that the proportion of participants who had BRS II in group 2 was lower than that in group 1. There were no significant differences in gender, affected side, quadriceps muscle strength items of the SIAS, type of KAFO, period from stroke onset to admission, and period from the stroke onset to KAFO prescription between groups.

The chi-squared test showed that the proportion of participants in group 1 who were able to reach significantly increased with KAFO use (Table 2). Among the participants in group 1 who were able to reach with KAFOs, the mean reach distance in the FRT was $11.0 \pm 6.2$ cm.

### Table 2. Comparisons of the proportion of participants who were able to reach with KAFOs among participants who were unable to reach without KAFOs.

|                  | Unable to reach |          | Able to reach |          |
|------------------|----------------|----------|---------------|----------|
|                  | n (%)          | Adjusted residual | n (%)       | Adjusted residual |
| Without KAFOs    | 22 (100)       | 3.13     | 0 (0)         | -3.13    |
| With KAFOs       | 14 (64)        | -3.13    | 8 (36)        | 3.13     |

Note. KAFOs = knee–ankle–foot orthoses. $\chi^2 = 9.78, p = 0.002$. Effect size (Cramer’s $V$) = 0.47.
In group 2, mean reach distance during the FRT with KAFOs and without KAFOs were 25.4 ± 6.7 cm, 95% confidence interval (CI) [20.2, 30.5] and 20.3 ± 7.0 cm, 95% CI [14.9, 25.7]. The Wilcoxon rank-sum test showed that the mean reach distance during the FRT with KAFOs was significantly longer than that during the FRT without KAFOs, \( p = 0.021 \), \( Z = -2.31 \), effect size \( r = 0.77 \), mean amount of change = 5.1 ± 4.6 cm, 95% CI for the difference [1.6, 8.7] (Fig. 3).

Discussion

This study evaluated the immediate effects of KAFOs on the standing reach of individuals with subacute stroke. There was a significant improvement in standing reach when the participants wore KAFOs. Among the participants who were unable to reach without KAFOs, the proportion of those able to reach significantly increased after wearing KAFOs. Furthermore, among the participants who were able to reach without KAFOs, standing reach significantly improved after using KAFOs. To the best of our knowledge, this is the first study to evaluate the immediate effects of KAFOs on the standing reach of individuals with subacute stroke. Regarding orthotic treatment for improving the standing reach of individuals with severe subacute stroke, this study provides information on the estimated effects of KAFOs on standing reach.

Among the participants who were unable to reach without KAFOs, the number of participants who were able to reach increased immediately after wearing KAFOs. Among the participants who were able to reach without KAFOs, wearing KAFOs improved the reach distance in the forward direction. Duncan et al. [21] reported that the reach distance during the FRT was highly correlated with the center of pressure (COP) displacement, which determines the limit of stability (LOS) [26]. The LOS of people with stroke is narrow because of instability of paretic lower limb affected by motor paralysis, and the upright standing of people with stroke is characterized by weight-bearing asymmetry with more weight on the nonparetic lower limb [27]. Narrow LOS restricts the COP displacement in the anterior-posterior and medial-lateral directions and makes it more difficult to control the COP movement and to perform the FRT. Participants in group 1 might be unable to reach because motor paralysis of paretic lower limb was more severe and the LOS was narrower than those of group 2. In group 2, most participants had moderate motor paralysis of paretic lower limb, and motor paralysis of paretic lower limb might decrease the LOS and reach distance during the FRT. In each group, the use of KAFO might increase the LOS by compensating for the stability of the paretic lower limbs, and make it easier to control the COP movement, resulting in immediately improvement of the FRT. On average, KAFO use increased the forward reach distance by 5.1 cm. In best of our knowledge, there were no previous studies on minimal clinically important change for FRT in people with severe stroke to compare the change of the forward reach distance in this study. However, in recently systematic review, exercise training improved the forward reach distance, and the mean difference in the forward reach distance before and after training was 3.1 cm in individuals with stroke [28]. The results of this study indicated that KAFOs immediately made positive changes in the forward reach distance equivalent to exercise training. In addition, the effect size \( r \) calculated for the change of the forward reach distance was large. Therefore, wearing KAFOs may lead to the considerable improvement for standing reach of individuals with subacute stroke.

Individuals with severe stroke have impaired abilities to perform standing activities and have decreased physical activity overall because of the severe impairments and disabilities. Decreased physical activity can induce secondary changes in the musculoskeletal [29] and cardiorespiratory systems [30] and may be harmful for rehabilitation. The early use of KAFOs in these individuals after stroke onset may improve the ability to perform standing activities and increase physical activity by immediately improving standing balance. Additionally, task-specific balance exercises improved the standing balance of individuals with stroke [31]. KAFOs can be used anywhere and allow individuals to perform task-specific standing exercises. Performing practical standing exercises with KAFOs during daily living may be useful for adaptations to the living environment and the reorganization of the brain after stroke. Further studies are needed to verify the fixed-term effects of additional exercises with KAFOs on standing reach that exceeds the immediate effects of KAFOs.

Limitation

This study used a small convenience sample. Caution is required when interpreting the results of this study for generalization and application.

Conclusion

The standing reach of individuals with subacute stroke can be improved immediately by wearing KAFOs.
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Author contributions

All authors contributed equally in the preparation of this manuscript.

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