Table 1 Characteristics of participants, body composition and skeletal muscle mass index in both males and females

Characteristics	Females HF group (*n* = 304)	Females NF group (*n* = 1893)	*P* value	Males HF group (*n* = 53)	Males NF group (*n* = 618)	*P*-value
Age (years)	82.7 ± 9.3	70.5 ± 11.1	<0.001	80.3 ± 9.4	67.5 ± 12.9	<0.001
Height (cm)	146.2 ± 7.2	149.5 ± 6.9	<0.001	160 ± 8.7	163.1 ± 7	0.004
Weight (kg)	43.1 ± 9	50 ± 9.8	<0.001	51.4 ± 10.6	60.3 ± 12.2	<0.001
BMI (kg/m²)	20.1 ± 3.6	22.3 ± 3.7	<0.001	20 ± 3.3	22.6 ± 3.7	<0.001
Whole body BMD (g/cm²)	0.84 ± 0.09	0.93 ± 0.12	<0.001	0.86 ± 0.13	1.02 ± 0.2	<0.001
Whole-body T-score	−3.29 ± 1.29	−2.08 ± 1.51	<0.001	0.95 ± 0.11	1.09 ± 0.15	<0.001
Whole-body bone mineral content (kg)	1.25 ± 0.33	1.62 ± 0.40	<0.001	1.81 ± 0.36	2.33 ± 0.53	<0.001
Whole-body fat tissue mass (kg)	9.67 ± 6.68	15.11 ± 7.28	<0.001	8.55 ± 6.57	13.63 ± 7.18	<0.001
Whole-body lean mass (kg)	30.72 ± 3.77	32.61 ± 4.01	<0.001	39.35 ± 5.59	43.55 ± 6.52	<0.001
Arm bone mineral content (kg)	0.14 ± 0.05	0.18 ± 0.05	<0.001	0.25 ± 0.07	0.31 ± 0.08	<0.001
Arm fat tissue mass (kg)	0.95 ± 0.84	1.49 ± 0.88	<0.001	0.70 ± 0.66	1.11 ± 0.7	<0.001
Arm lean mass (kg)	2.98 ± 0.95	3.16 ± 0.67	<0.001	4.18 ± 1.16	4.67 ± 1.03	<0.001
Arm SMI (kg/m²)	1.40 ± 0.45	1.41 ± 0.28	0.001	1.64 ± 0.48	1.75 ± 0.35	0.006
Leg bone mineral content (kg)	0.40 ± 0.13	0.55 ± 0.15	<0.001	0.66 ± 0.18	0.84 ± 0.19	<0.001
Leg fat tissue mass (kg)	3.08 ± 2.02	4.51 ± 2.19	<0.001	2.69 ± 1.92	3.56 ± 1.85	<0.001
Leg lean mass (kg)	9.1 ± 1.72	10.11 ± 1.72	<0.001	11.48 ± 2.12	13.39 ± 2.59	<0.001
Leg SMI, kg/m² (kg)	4.27 ± 0.77	4.51 ± 0.65	<0.001	4.49 ± 0.82	5.01 ± 0.76	<0.001
Appendicular SMI† (kg/m²)	5.66 ± 1.04	5.92 ± 0.84	<0.001	6.13 ± 1.2	6.76 ± 1.01	<0.001

All data were expressed as mean ± SD. All *P*-values were from Mann–Whitney's *U*-test. †Appendicular skeletal muscle mass index (SMI) is defined as the sum of leg SMI and arm SMI. BMD, bone mineral density; BMI, body mass index; HF group, hip fracture group; NF group, non-fracture group; SD, standard deviation.

group for females and males. Whole-body lean mass and fat mass were significantly low in both men and women in the HF group.

For adjusting the differences of age and the ratio of females between the NF group and the HF group, general linear model analysis was used to compare the characteristics, body composition and skeletal muscle mass index of patients in both the study groups, after controlling for age and sex (Table 2). No differences were observed in height, after controlling for age and sex. The weight, BMI and whole-body BMD significantly decreased in patients in the HF group. No significant difference in the arm SMI was observed between the HF and NF groups. In contrast, the patients in the HF group had significantly lower leg SMI than those in the other groups. The appendicular SMI – which was the sum of the arm SMI and leg SMI – also decreased in patients in the HF group, even after controlling for age and sex. No difference was observed in the whole-body lean mass. The prevalence of sarcopenia was significantly higher in the HF group after adjusting by age and sex with the Mantel–Haenszel method.

A stepwise logistic regression analysis was carried out to identify predictive factors for the occurrence of a hip fracture. We found that the presence of sarcopenia, older age and lower whole-body BMD were significant factors for the occurrence of a hip fracture ($P = 0.002$, $P < 0001$ and $P < 0.001$, respectively; Table 3).

Table 4 shows the estimated prevalence of sarcopenia in each age group of the HF and NF group patients. The prevalence of sarcopenia was higher in every age group of the HF group, and there were significances in the females in the 70–74 years group and 74–80 years group ($P = 0.004$, $P = 0.001$, respectively).

Overall in the HF group, the prevalence of sarcopenia in women and men was 44.7% and 81.1%, respectively; overall in the NF group, it was 27.2% and 52.8%, respectively. Sarcopenia prevalence was significantly higher in both men and women overall in the HF group than in the NF group. For comparing the prevalence of sarcopenia between males and females, differences were not observed in the group aged less than 70 years ($P > 0.95$) and in the group aged between 70 and 74 years ($P = 0.598$) in the HF group. However, this prevalence was significantly higher in men than in women aged between 75 and 80 years ($P = 0.005$) and those aged more than 80 years ($P < 0.001$). In the NF group, sarcopenia prevalence was high in all patients from all age groups ($P < 0.001$).

The relationship between muscle volume and bone mineral density in each group is shown in Figure 1.

Table 2 Characteristics of participants, body composition, skeletal muscle mass index, and prevalence of sarcopenia in the fracture and non-fracture group controlled by the general linear model procedure

Characteristics	HF group	NF group	*P*-value
Height (cm)	152.5 ± 0.34	152.3 ± 0.14	>0.95
Weight (kg)	48.8 ± 0.54	51.9 ± 0.19	<0.001
BMI (kg/m^2)	20.7 ± 0.21	22.3 ± 0.081	<0.001
Whole-body BMD (g/cm^2)	0.93 ± 0.0061	0.97 ± 0.0024	<0.001
Whole-body T-score	−2.47 ± 0.77	−1.88 ± 0.30	<0.001
Whole-body bone mineral content (kg)	1.57 ± 0.020	1.77 ± 0.0079	<0.001
Whole-body fat tissue mass (kg)	11.31 ± 0.39	14.54 ± 0.15	<0.001
Whole-body lean mass (kg)	34.55 ± 0.24	35.02 ± 0.96	0.458
Arm bone mineral content (kg)	0.19 ± 0.003	0.19 ± 0.001	<0.001
Arm fat tissue mass (kg)	1.07 ± 0.046	1.39 ± 0.018	<0.001
Arm lean mass (kg)	3.48 ± 0.043	3.50 ± 0.017	>0.95
Arm SMI (kg/m^2)	1.48 ± 0.018	1.50 ± 0.070	>0.95
Leg bone mineral content (kg)	0.54 ± 0.007	0.61 ± 0.003	<0.001
Leg Fat tissue mass (kg)	3.50 ± 0.11	4.23 ± 0.045	<0.001
Leg lean mass (kg)	1.05 ± 0.099	1.08 ± 0.039	<0.005
Leg SMI (kg/m^2)	4.45 ± 0.038	4.64 ± 0.015	<0.001
Appendicular SMI (kg/m^2)	5.93 ± 0.020	6.13 ± 0.050	<0.001
Prevalence of sarcopenia (%)	47.4	31.9	<0.001†

All data were controlled with age and sex. All data except the prevalence of sarcopenia were expressed as mean ± SE. *P*-values were obtained using the general linear model procedure except for prevalence of sarcopenia. †A *P*-value was obtained using the Mantel–Haenszel method after adjusting for age and sex. BMD, bone mineral density; BMI, body mass index; HF group, hip fracture group; NF group, non-fracture group; SE, standard error; SMI, skeletal muscle mass index.

Table 3 Stepwise logistic regression analysis for a hip fracture

	B	OR	95% CI	*P*-value
Presence of sacopenia	0.389	1.476	1.154–1.888	0.002
Age	0.098	1.103	1.087–1.120	<0.001
Whole-body BMD	−3.587	0.082	0.009–0.087	<0.001

The dependent variable was the occurrence of a hip fracture. The presence of sarcopenia was conventionally attributed a value of 1, the absence of sarcopenia was attributed a value of 0. BMD, bone mineral density; CI, confidence interval; OR, odds ratio.

Table 4 Prevalence of sarcopenia in both males and females from each age group

Age (years)	Females			Males		
	HF group	NF group	*P*-value	HF group	NF group	*P*-value
<70	37.5% (12/32)	22.7% (196/864)	0.051*	42.9% (3/7)	37.6% (120/319)	>0.95**
70–74	50.0% (11/22)	22.7% (80/352)	0.004*	75.0% (3/4)	55.7% (64/115)	0.631**
75–80	51.1% (23/45)	26.8% (77/287)	0.001*	92.9% (13/14)	70.7% (65/92)	0.107**
80<	43.9% (90/205)	41.3% (161/390)	0.539*	85.7% (24/53)	83.7% (77/92)	>0.95**
All Age	44.7% (136/304)	27.2% (514/1893)	<0.001*	81.1% (43/53)	52.8% (326/618)	<0.001*

P-values were obtained using the *χ^2-test and **Fisher's exact test. HF group, hip fracture group; NF group, non-fracture group.

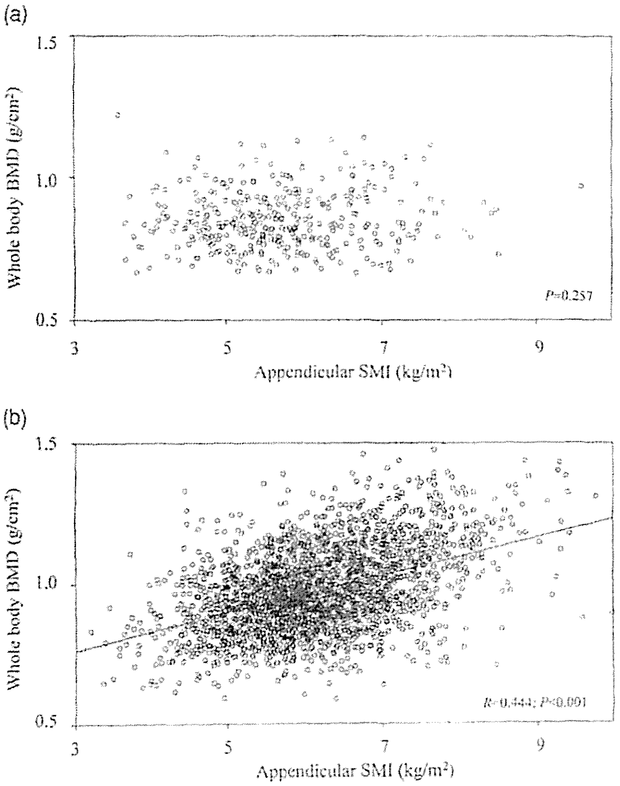

Figure 1 Correlation of appendicular skeletal muscle mass index (SMI) and whole-body bone mineral density (BMD) in (a) the hip fracture (HF) group and (b) the non-fracture (NF) group. *P*-values were from Pearson's test.

There was no significant difference in the HF group ($P = 0.257$). In contrast, there was a positive correlation between appendicular SMI and whole-body BMD in the NF group. ($R = 0.444$; $P < 0.001$).

Discussion

Sarcopenia, which is a barometer of disability and frailty, is one of the most crucial problems for the elderly. In contrast, hip fracture is already known to affect the morbidity and ADL of osteoporotic patients. The relationship between sarcopenia and hip fracture, however, has not been extensively examined. The present study examined the prevalence of sarcopenia in hip-fractured Japanese older adults diagnosed by DXA imaged within 48 h of their hip fracture occurrence, and hospital controls defined as appendicular muscle mass two standard deviations below the healthy normal young population.

The prevalence of sarcopenia in community-dwelling women aged more than 80 years in New Mexico, as reported by Baumgartner *et al.*, was 43.2% for Caucasians and 60% for Hispanics.[18] In the current study, the prevalence of sarcopenia in Japanese women aged more than 80 years without fracture was 41.3%. The prevalence of sarcopenia of women aged 70–80 years of age in New Mexico was 23.1–35.9% and that of Japanese women in the present study was 22.7–26.8%. These are consistent with Baumgartner's findings. An earlier study reported the prevalence of sarcopenia in 313 hip-fractured women whose average age was 79.7 years to be 58%.[21] These patients were diagnosed by DXA at an average of 21 days after occurrence. Estimation of muscle mass in the subacute phase of fracture was affected by surgical intervention and disuse atrophy, and had the possibility of overestimation of the prevalence of sarcopenia. Therefore, the prevalence of sarcopenia in their study might be higher than the real value. In contrast, the present results are regarded as more accurate, because we measured muscle mass in the short-term after the fracture.

In the present study, 44.7% of female and 81.1% of male patients with an acute phase of hip fracture were found to be sarcopenic; sarcopenia prevalence was significantly higher in patients with hip fractures than those without hip fractures, even when adjusted for age and sex. Sarcopenia prevalence was observed to be higher in men with hip fractures than in women with hip fractures. Men with hip fractures were found to have high mortality levels.[22,23] A high prevalence of sarcopenia might reflect the poor general health or frail condition of the patient. For example, the glucose tolerance was impaired, and elevated glycated hemoglobin was observed in sarcopenic patients.[17,24] The risk of nosocomial infection was doubled for patients with sarcopenia in geriatric wards.[25] Montano-Loza *et al.* recently mentioned in their paper that sarcopenia was an independent risk factor for mortality in patients with liver cirrhosis.[26] Szulc *et al.* reported that the loss of appendicular skeletal muscle mass was a predicting factor for mortality in older men.[27] Sarcopenia diagnosed using DXA should be considered as an important indicator of frailty in men.

Muscle volume and strength are the main factors to maintain the motor function of aged people. A number of studies have shown the relationship between sarcopenia and falls. Baumgartner *et al.* reported that people with lower appendicular SMI had a higher incidence of falls and lower body balance.[18] In a cohort study of 2148 English participants, Sayer *et al.* observed that patients with a history of falls presented with significantly lower muscle power.[28] According to a 5-year prospective study with 141 participants, the risk of deteriorated ADL doubled for those participants with decreased appendicular skeletal muscle.[29]

Furthermore, the muscle mass of the lower extremities was significantly decreased in patients with hip fracture in the present study. In contrast, the muscle mass of the arm did not differ regardless of hip fracture. This result supports previous reports about that the attenuation of leg muscle increasing the risk of falls and hence fractures.[30–32] The sarcopenic leg, or the muscle decrease and weakness of lower extremities, was already known to be associated with poor leg performance,[33,34] and to be a risk factor for recurrent falls and fracture.[35] Although handgrip strength instead of knee flexion/extension strength was recommended as a diagnosis tool in a European consensus on the definition and diagnosis of sarcopenia,[9] the measurement of muscle mass and strength of the lower extremities can be valuable for predicting the fracture risk of a hip.

In addition, there was a significant positive correlation between muscle mass and BMD in patients without a hip fracture in the present study, a finding that is compatible with past reports.[32,36,37] The mechanisms underlying disease, such as malnutrition, insufficiency of vitamin D and lack of physical activity, are common to sarcopenia and osteopenia.[38] In contrast, our study showed the BMD and appendicular SMI were not correlated significantly for the patients in the acute phase after occurrence of a hip fracture. Patients with a hip fracture had developed more severe sarcopenia and osteoporosis, as shown in Table 1. There was the speculation that the BMD and appendicular SMI were not correlated in patients who were especially frail. Furthermore, multivariate analysis showed that not only low BMD, but also the presence of sarcopenia, was a potential risk factor for an osteoporotic fracture. Simultaneous muscle and bone loss causes more severe instability in the frail elderly, which leads to falls and subsequent fracture.

Several ways to assess muscle volume have been established. Evaluation of the thigh muscle cross-sectional area by computed tomography or magnetic resonance imaging is the gold standard measurement for research,[9] but various limitations, such as high cost, the invasiveness of radiation and poor accessibility, have been reported. DXA is a precise and reproducible, as well as more accessible, less invasive and lower-costing alternative.[39] The technical errors of DXA compared with computed tomography were reported to be just 2.5%.[40] Anthropometric measurements, including calf circumference, are the traditional and convenient way to estimate skeletal muscle mass, but their accuracy is inadequate for the screening of sarcopenia.[41] Bioelectrical impedance analysis for sarcopenia is also a non-invasive and easy-to-use method. However, its validity has not been ascertained for those patients whose hydration status alters, such as the extremely elderly and fractured patients.[42] Currently, DXA is the preferred measurement method for clinical and research use.

The present study had several limitations. The participants in the NF group were neither randomly selected residents nor healthy volunteers. They were those patients who were suspected to be osteoporotic at our outpatient clinic. Because there is positive relationship between muscle mass and BMD, the patients with osteoporosis were estimated to have a higher prevalence of sarcopenia. We probably underestimated the difference of skeletal muscle mass between the hip fracture patients and the normal population. The second limitation is that we did not assess the function of the muscle, menopause status, comorbidities, the degree of pre-injury daily activity and energy expenditure in the present study. Recent reports mentioned that bed rest and low energy intake of inpatients might affect sarcopenia and hospitalization-associated disability.[43,44] However, the present study estimated the muscle mass within only 48 h from admission and the effect was limited. It is also well known that muscle strength declines much more rapidly than muscle mass, and sometimes the declines of muscle mass and strength were different between elderly individuals.[45] In future studies, we need to take into account a larger number of such covariates, which might confound the muscle mass–fracture relationship. There is another limitation about the sample size to evaluate the prevalence of sarcopenia in the each age group (Table 4). Our sample size analysis carried out with G*Power software (version 3.1.3, Faul *et al.*;[46] Heinrich-Heine-University, Dusseldorf, Germany) showed that statistical power for the female group aged <70 years, 70–74 years, 75–80 years, >80 years and all ages were 17.4%, 90.0%, 95.6%, 15.0% and 100%, respectively. Statistical power for the male age groups were <70 years, 70–74 years, 75–80 years, >80 years and all ages were 8.8%, 18.8%, 55.2%, 8.2% and 99.2%, respectively. Although adequate sample size was not mandatory, because the present study was an exploratory study, calculated statistical power over 80% was generally optimal for a significant result. A further study is required to validate the results in another dataset with a sufficient number of cases in the groups with inadequate statistical power, such as all age groups of the male and female group aged less than 70 years.

In conclusion, the present study showed that a higher prevalence of sarcopenia in Japanese patients in the acute phase of hip fracture than those patients from outclinics who did not have hip fractures, and that leg muscles of patients with a hip fracture were more sarcopenic. The diagnosis of sarcopenia and the evaluation of leg muscle by DXA can be the key to estimating patients at risk of a hip fracture.

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Disclosure statement

The authors or the members of their immediate families did not receive payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity. No commercial entity paid or directed, or agreed to pay or direct, any benefits to any research fund, foundation, division, center, clinical practice, or other charitable or non-profit organization with which the authors, or a member of their immediate families, are affiliated or associated

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ORIGINAL ARTICLE

Why not use your own body weight to prevent falls? A randomized, controlled trial of balance therapy to prevent falls and fractures for elderly people who can stand on one leg for ≤15 s

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Abstract

Background Maintaining or improving motor (balance) ability is essential to extending the healthy lifespan of elderly people, and developing effective and efficient strategies to prevent falls of elderly people is an urgent. The purpose of this study was to determine the effects of balance exercise on fall and fracture prevention for elderly people with poor balance.

Methods A 6-month, randomized controlled trial was conducted to verify whether one-leg standing with eyes open for a total of 1 min, three times a day (dynamic flamingo exercise) prevents falls and fractures. Setting and participants were elderly people ≥75 years of age and one-leg standing time ≤15.0 s living in their own home. They were visiting orthopaedic clinics for orthopaedic handicaps. Subjects with poor balance were allowed to hold on to something. If a subject's lifted leg touched the ground during the exercise, they were allowed to lift it again and continue so that they stood on one leg for a total of 60 s.

Results The dynamic flamingo exercise group (410 people; 86 men, 324 women) and the no exercise group (455 people; 78 men, 377 women) were compared. After dynamic flamingo exercise for 6 months, significant differences were seen in the increase in one-leg standing time with eyes open (men right/left, women right/left), in the improvement in independence in daily living (women), number of people who fell during the 6 months (women),

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and adverse events (women). The number of fractures was not significantly different for men or women.
Conclusions Dynamic flamingo exercise prevents falls but no significant difference was demonstrated in fracture prevention in elderly women with poor balance.

Introduction

As the aging of society accelerates, a very important question is how to maintain daily living functions in elderly people so that they can spend their remaining life comfortably. Elderly people with underlying osteoporosis are susceptible to fractures of the proximal femur, and their mortality 1 year after a fracture is high (10–27 %) [1–3]. Prevention of proximal femur fractures is believed to be beneficial for extending the healthy life span of elderly people. One-third of elderly people ≥65 years of age are said to fall once a year [4], and more than half of these need to be hospitalized for trauma accompanying the fall [5]. Strategic development and implementation of effective and cost-efficient means of preventing falls of elderly people is a pressing global health challenge. Sherrington et al. [6]. conducted a systematic review and meta-analysis of the most effective methods for fall prevention, and concluded that effective methods are training for ≥50 h during trials, training in standing on both legs with narrow bases of support, or center of gravity balance control training standing on one leg. Walking training was not included among the most effective methods. Selection of methods with superior cost performance must also be considered in exercise training [7].

Haeney [8] listed three elements related to the growth and deterioration of bone: genetics, endocrine activity, and mechanical stress. As seen from this, mechanical stress is a crucial element for bone metabolism. Bone density of the proximal femur of astronauts returning to earth after a space flight of 6 months, during which time there is little mechanical stress, requires a long period of approximately 900 days to return to its original level [9]. Various kinds of exercise therapy are recommended, but this exercise therapy must combine three basic rules:

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1. dynamic loading;
2. short duration; and
3. customary mechanical loading environment [10].

To prevent fractures of the proximal femur caused by minor trauma when osteoporosis is a background factor, it is necessary not only to prevent falls but also to apply loads to the proximal femur to increase its density and to improve bone quality and strengthen the bone.

Standing on one leg with the eyes open for 1 min 3 times a day (dynamic flamingo (DF) therapy [11]), uses the fact that one-leg standing places a load on the femoral head that is 2.75 times greater than the load on one leg when standing on two legs. This exercise theory is based on the finding, for the elderly, that the total load on the femoral head when standing on one leg with eyes open for 1 min is equivalent to the total load placed on the femoral head on one side from walking for 53.3 min (160/3 min) [12]. DF therapy has points in common with Tai Chi exercise, which is reported to be effective in preventing falls [13, 14]. It is also reported to be effective in increasing bone density in the proximal femur [15, 16]. DF therapy is exercise that uses the body's own weight as mechanical stress, and it requires no special equipment. It is also a very simple exercise therapy that does not require special exercise instruction. A randomized trial was conducted for 6 months to determine whether this DF therapy is, in general, effective in preventing falls and fractures for elderly people with an orthopedic handicap who live at home. If this therapy were to be effective in fall prevention, it may be beneficial in preventing femoral neck fractures by increasing bone density in the femoral neck and preventing falls.

Subjects

The subjects were men and women ≥75 years of age who lived at home and visited an orthopedic clinic or hospital for an orthopedic handicap and who could stand on one leg, both right and left, with the eyes open for ≤15 s (the Ministry of Health, Labor, and Welfare of Japan designates men and women ≥75 years of age who can stand on one leg with eyes open for ≤15 s as having musculoskeletal ambulation disability symptom complex). The time of one-leg standing with eyes open for the left and right legs is measured with the subject standing on one leg with both hands placed at the hips until the subject takes a hand off his or her hip or the other leg hits the floor. The subject is first allowed one attempt as practice, and the second attempt is measured using a stopwatch to the first decimal place. The time of one-leg standing with eyes open was measured for up to 20 s for each leg for elderly individuals aged ≥75 years, and those with a time ≤15 s for both legs were allocated to the Entry group. To ensure accuracy in judgments of the effect of one-leg standing exercise training, subjects were usually people with the ability to communicate and those who could continue training. It had been recommended to these people that they participate in exercise without DF therapy. After presenting a written explanation, consent was obtained from the subjects in writing for participation in the clinical study. People with Parkinson's disease or other conditions that made them susceptible to falls, people with artificial joints, and people with cognitive disorders were excluded. From April 2007 until March 2010, 1,788 subjects were recruited (exercise group 889, non-exercise group 899; Fig. 1; flow diagram: trial profile [17]). Those who did not meet the stipulations were excluded, as were subjects with no responses for dominant leg, weight, height, and other items on a questionnaire. Next, those for whom there was no report at the end of the 6 months were excluded. Final reports were collected for 483 people in the exercise group and 524 in the no exercise group. Of these, those with items with no responses in the report were excluded. The comparative

Fig. 1 Flow diagram trial profile

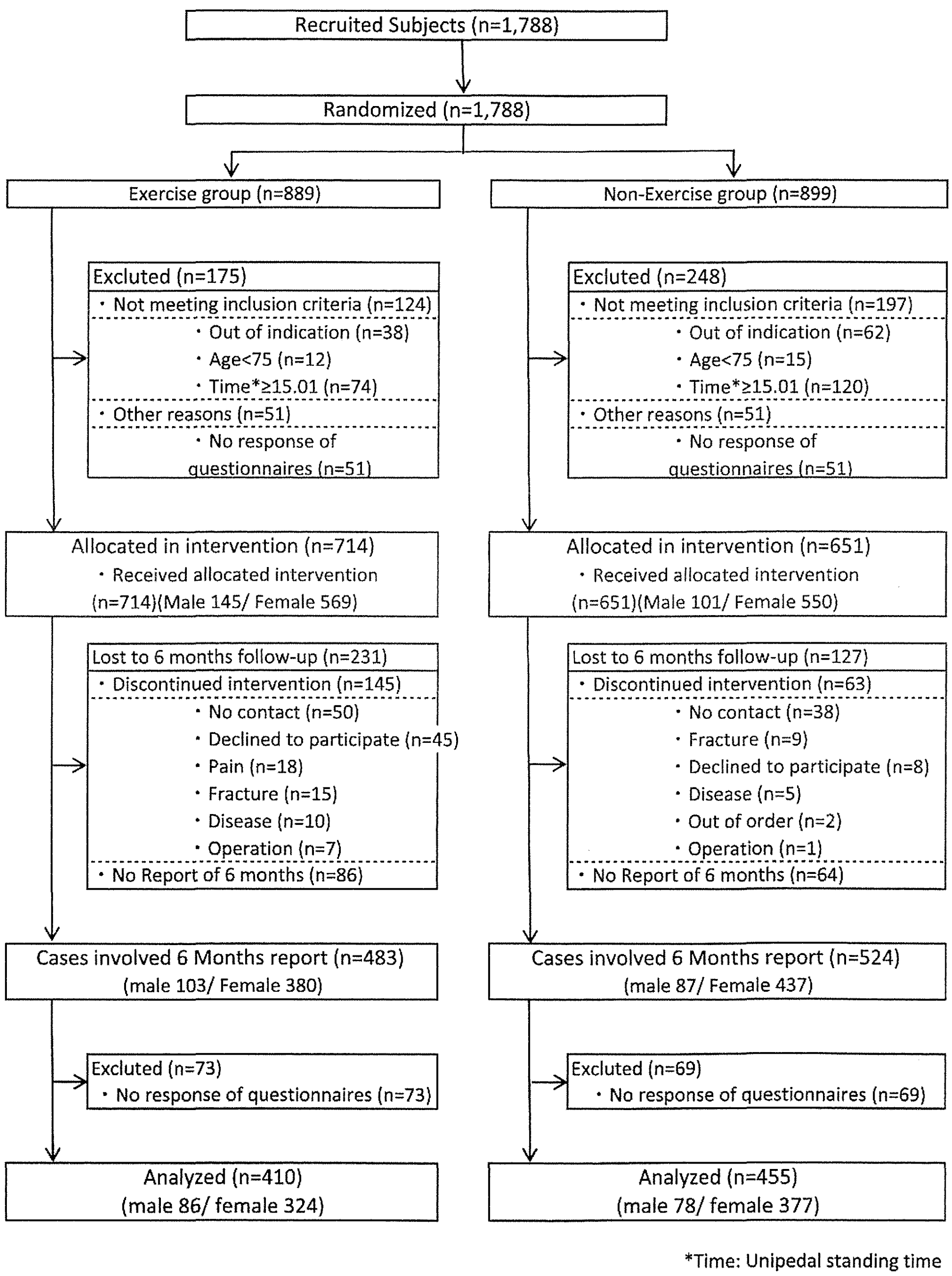

Table 1 Diagnosis of subjects at baseline survey between exercise group and non-exercise group (the first diagnosis name described on report sheet)

Female				Male	
Exercise group		Non-exercise group		Exercise group	
Diagnosis	*N*	Diagnosis	*N*	Diagnosis	*N*
OA (knee)	97	OA (knee)	97	Spondylosis deformans	24
Osteoporosis	72	Osteoporosis	90	LCS	14
LSD	31	LCS	45	OA (knee)	13
LCS	30	LSD	40	Osteoporosis	6
Spondylosis deformans	18	Vertebral fracture	22	Cervical spondylosis	5
Painful shoulder	10	Cervical spondylosis	21	LDD	4
Cervical spondylosis	8	Non-vertebral fracture	12	Diabetes meritis	4
Hypertension	7	Rheumatic arthritis	10	Lumbar spondylosis	3
Vertebral fracture	6	Painful shoulder	8	Painful shoulder	3
MAD	5	LDD	7	Vertebral fracture	2
Low back pain	4	Heart disease	4	etc.	8
CTS	4	OA (shoulder)	3	Total	86
Non-vertebral fracture	4	MAD	2		
LDD	3	OA (hip)	2	Non-exercise group	
Lumbar disc hernia	3	Low back pain	2	Diagnosis	*N*
Cranial infarct	3	etc.	13	LCS	16
Rheumatic arthritis	2	Total	378	OA (knee)	15
CDD	2			Spondylosis deformans	13
Scoliosis	2			Osteoporosis	8
Rotator cuff injury	2			Cervical spondylosis	8
etc.	11			Painful shoulder	4
Total	324			Lumbar disc hernia	3
				Rheumatic arthritis	3
				Gout	2
				etc.	6
				Total	78

Exercise group versus non-exercise group

OA osteo arthritis, *LSD* lumbar spondylosis deformans, *LCS* lumbar canal stenosis, *MAD* musculoskeletal ambulation disability symptom complex, *CTS* carpal tunnel syndrome, *LDD* lumbar disc degeneration, *CDD* cervical disc degeneration, *N* number

analysis was finally conducted with 410 people from the exercise group (86 men, 324 women) and 455 people from the no exercise group (78 men, 377 women).

The ailments diagnosed in each group are listed in Table 1. Among women in both groups, osteoarthritis of the knee was the most common ailment (97 subjects). Among men, spondylosis deformans was the most common in the exercise group (24 subjects), and lumbar canal stenosis was the most common in the no exercise group (16 subjects).

Methods

Application for approval of this study was made to the Ethics Committee of the School of Showa University, and the randomized, controlled trial (RCT) was conducted for 6 months after approval was obtained. To prevent feelings of unfairness among participants, random allocation to the intervention group (exercise group) or control group (non-exercise group) was conducted at the institution level, meaning that all participants attending the same institution belonged to the same group. The following randomization method was applied. The 10 × 5 (= 50) random number tables with 5 × 5 (25) numbers were prepared and 2 ten-faced dice (one green, one yellow) were thrown to decide which table to use. Two six-faced dice were then thrown to select the number within the chosen random number table to decide whether the institution would be designated an exercise or non-exercise institution. Dice were repeatedly thrown in this manner until the target number of facilities had been allocated to each group.

Subjects were recruited with the cooperation of the Japanese Orthopaedic Association and the Japanese Society for Musculo-skeletal Rehabilitation over 3 years from April 2007 to March 2010. They were patients undergoing outpatient orthopedic treatment or rehabilitation who could stand on one leg with eyes open for ≤15 s with both the left and right leg. They were divided into a group that did one-leg standing exercise with eyes open for 1 min 3 times a day and a group that did not do this exercise. The effectiveness of exercise training in preventing falls and fractures was then examined.

In the DF exercise, people with poor balance held on to a table, chair, bar, or other object while standing on one leg (when they became accustomed to this, they stood on one leg without holding on to anything). If their free leg touched the ground, they lifted it once more so the total one-leg standing time was 60 s. They stood on one leg for a total of 1 min in this way 3 times a day with each leg. The basic position for one-leg standing was to have one leg swung slightly forward with the knee bent, but the subjects were free to adopt any one-leg standing position. However, when standing on one leg, precautions such as a table, chair, or bar were in place to prevent falls, in case the person lost his or her balance. The exercise was done as a home exercise so that it could be continued daily. To confirm the exercises were done, every day subjects were asked to complete a "Flamingo Record" with a "●" when the exercises were done 3 times a day, a "Δ" on days of falls, and an "x" for fracture (fracture was confirmed and recorded by a doctor). Exercises were continued every day, but 2 days off a week were allowed, and the Flamingo Record was checked at the time of examination at a clinic once a month.

The initial survey items for the subjects were: 1. sex, 2. date of birth, 3. dominant leg, 4. age at the start of exercise, 5. weight, 6. height, 7. one-leg standing time with eyes open (right, left), 8. name of primary disease, 9. medical history, 10. history of fracture, 11. complications, 12. presence or absence of osteoporosis, 13. medications, 14. number of falls in past year, 15. exercise habit, 16. use of cane or walking aid, and 17. level of ADL independence*. At the end of 6 months, items 5, 6, 7, 10 (fracture), 14 (falls or no falls, and number), 19 (ADL*), and 20 (adverse events) were surveyed.

*ADL: by Long-Term Care Insurance Act (The Ministry of Health, Labor and Welfare of Japan, December 17th 1997) (Table 2).

Statistical analysis was conducted by consulting statisticians (Hamano Statistical Analysis). The software used was SAS System 91.3 (SAS Institute), with the paired t test used for means and McNemar's test used for proportions.

Table 2 Classification of the disability of elderly people

ADL independent (people have some disability but ADL are independent and they go out without help)
J1: Able to go out using public transport
J2: Able to go out to visit neighbors only
ADL dependent (requires assistance to leave home)
A. Lives independently indoors but requires assistance to go out
A1: Goes out with assistance, stays out of bed most of the day
A2: Seldom goes out, has several rests in bed during the day
(Nearly bedridden)
B. Requires some assistance living indoors and spends most of the day in bed, although sitting up
B1: Uses a wheelchair to move about, but gets up for meals and to go to the toilet
B2: Moves about in a wheelchair with assistance
(Completely bedridden)
C. Spends all day in bed requires assistance to urinate/defecate
C1: Can turn over in bed unassisted
C2: Cannot turn over in bed unassisted

By Long-Term Care Insurance Act (The Ministry of Health, Labor and Welfare of Japan, December 17th 1997)

Results

A comparison of men and women in the DF exercise group and the no exercise group at the start of the RCT (Table 3) revealed that, in men, there were more users of canes and aids in the no exercise group. Other than that, there were no significant differences in items from dominant leg to level of ADL independence. In women, one-leg standing time was increased with both legs, number of falls in the past year was greater, level of independence in activities of daily living (ADL) was higher in the exercise group. No significant differences were seen in other items between the groups. No significant differences were seen between the groups other than in sex, height, weight, and history of fracture. In a comparison of the DF exercise group and the no exercise group at the completion of the 6-month RCT (Table 4), one-leg standing time on both the right and left legs was clearly and significantly increased in the exercise group. However, no significant difference was seen other than in one-leg standing time in men. In women, on the other hand, in the exercise group, one-leg standing time with both the right and left legs was increased, there were fewer people who fell, and the level of ADL independence was higher. However, no significant difference was seen between the groups in the mean number of falls. There were also significantly more adverse events in the exercise group.

Data for men at the time of baseline for the RCT and after 6 months were compared (Table 5). In the DF exercise group, body weight decreased after 6 months of exercise training, and one-leg standing time with both the right and left legs was increased approximately 3 times. In

Table 3 Comparison of clinical data at baseline survey between exercise group and the non-exercise group

	Male			Female		
	Exercise group (%)	Non-exercise group (%)	Statistical p value	Exercise group (%)	Non-exercise group (%)	Statistical p value
Number	86	78		324	377	
Dominant leg: right	77 (89.5)	72 (92.3)	0.538#	283 (87.3)	331 (87.8)	0.856#
Age (years)	80.5 ± 4.1	80.7 ± 4.0	0.3548§	80.1 ± 4.0	80.5 ± 4.1	0.199§
Weight (kg)	58.8 ± 9.8	58.5 ± 10.6	0.849§	49.8 ± 8.2	49.6 ± 8.9	0.755§
Height (cm)	158.9 ± 6.1	159.7 ± 6.7	0.458§	147.0 ± 5.9	146.4 ± 6.1	0.191§
One leg time (right)	5.8 ± 4.2	5.6 ± 3.8	0.836§	5.9 ± 4.1	5.1 ± 3.8	0.013§
One leg time (left)	5.2 ± 3.7	5.4 ± 3.6	0.731§	5.9 ± 4.0	5.2 ± 3.8	0.025§
History of fracture	25 (29.1)	27 (34.6)	0.446#	134 (41.4)	167 (44.3)	0.433#
Complication	78 (90.7)	73 (93.6)	0.446#	285 (88.0)	318 (84.4)	0.169#
Osteoporosis	17 (19.8)	14 (17.9)	0.766#	251 (77.5)	276 (73.2)	0.193#
Falls yes/no	23 (26.7)	27 (34.6)	0.274#	120 (37.0)	114 (30.2)	0.057#
No. of falls	0.5 ± 1.3	1.3 ± 3.8	0.09§	1.1 ± 2.2	0.6 ± 2.0	0.005§
Exercise habit yes/no	41 (47.7)	39 (50.0)	0.766#	127 (39.2)	186 (49.3)	0.007#
Use of aids yes/no	16 (18.6)	31 (39.7)	0.003#	114 (35.2)	159 (42.2)	0.059#
ADL Independence	81 (94.2)	71 (91.0)	0.438#	310 (95.7)	344 (91.2)	0.019#

Dominant leg, leg to kick a ball, number of right leg (%); age, average (Av) years ± standard deviation (SD); weight, Av ± SD; height, Av ± SD; one leg time, one leg standing time (seconds) with eyes open, Av ± SD; history of fracture, number with fracture history (%); complication, number of people who had complications (%); osteoporosis, number of people who had osteoporosis (%); falls yes/no, number of people (yes) who had a fall in past year (%); No. of falls, number of falls in 1 year, Av ± SD; exercise habit yes/no, number of people (yes) who have exercise habit (%); use of aids, number of people (yes) who use of cane or walking aid (%); level of ADL, number of people who are independent in activities of daily living (J*1 + J*2)

J*1, J*2: criteria for independence in ADL by the Ministry of Health, Labour and Welfare of Japan

The paired t test for means

§ McNemar's test used for proportions

the no exercise group, on the other hand, one-leg standing time on the left side increased significantly, but there were no other significant differences.

In a comparison of the data at the time of RCT registration and after 6 months for women (Table 6), after 6 months, weight and height decreased and one-leg standing time with both the right and left leg increased significantly in the DF exercise group. Because the survey period differed for fractures (history), number of people who fell, and number of falls, tests of significance were not conducted. For the women in the no exercise group, on the other hand, one-leg standing time with both the right and left legs was significantly increased, but the increase in the number of seconds was small. It was supposed all participants had some physical treatment at their clinics or hospitals and their therapy was apparent as good effects on time dependence. For both men and women, the one-leg standing time with eyes open in the no exercise group increased significantly after 6 months compared with the time of entry, but the increase in the one-leg standing time with eyes open was much larger in the DF exercise group. The number of fractures, which is viewed as the most important outcome, was 10 in the no exercise group in women (5 compression fractures of the spine, 3 rib fractures, 1 fracture of the scaphoid bone, and 1 fracture of the proximal femur) versus 3 in the DF exercise group (2 fractures of the distal radius and 1 fracture of the fifth metacarpal bone). The number was larger in the no exercise group, but there was no significant difference. Among men, there was one compression fracture of the spine in the DF exercise group and one fracture of the distal radius in the no exercise group. No significant difference was seen between the groups. There was one adverse event (knee pain) in men and four (knee pain 1, lower limb pain 1, palpitations 1, fall during training 1) in women in the DF exercise groups.

Discussion

Methods to prevent proximal femur fractures include treatment for osteoporosis, which is a background factor that is a risk for proximal femur fractures, and fall prevention. Currently, many drugs, including bisphosphonates [18, 19], alfacalcidol [20, 21], and selective estrogen receptor modulators (SERM) [22, 23], are widely used for treatment of osteoporosis. Many reports on exercise

Table 4 Comparison of clinical data at 6-month survey between exercise group and non-exercise group

	Male			Female		
	Exercise group (%)	Non-exercise group (%)	Statistical *p* value	Exercise group (%)	Non-exercise group (%)	Statistical *p* value
Number	86	78		324	377	
Weight (kg)	58.4 ± 9.8	58.8 ± 10.9	0.815§	49.3 ± 7.9	49.6 ± 9.1	0.641§
Height (cm)	158.2 ± 7.9	159.4 ± 6.8	0.290§	146.6 ± 6.1	146.2 ± 6.1	0.401§
One leg time (right)	17.7 ± 35.1	6.4 ± 5.0	0.004§	16.2 ± 21.6	7.2 ± 7.9	<0.000§
One leg time (left)	19.3 ± 44.4	6.7 ± 6.0	0.011§	15.0 ± 21.2	6.1 ± 6.1	<0.000§
Cases of fracture	1 (1.2)	1 (1.3)	0.945#	3 (0.9)	10 (2.7)	0.091#
Falls yes/no	10 (11.6)	14 (17.9)	0.253#	46 (14.2)	78 (20.7)	0.025#
No. of falls	0.2 ± 0.8	0.5 ± 1.7	0.183§	0.3 ± 1.2	0.3 ± 0.7	0.687§
ADL independence	82 (95.3)	72 (92.3)	0.416#	313 (96.6)	345 (91.5)	0.005#
Adverse event	1 (1.2)	0 (0.0)	0.339#	4 (1.2)	0 (0.0)	0.031#

Weight, average ± standard deviation (Av ± SD); height, Av ± SD; one leg time, one leg standing time (seconds) with eyes open, Av ± SD; cases of fracture, number of fracture cases (%); falls yes/no, number of people (yes) who had a fall in past 6 months (%); No. of falls, number of falls in 6 months, Av ± SD; ADL independence, number of people who are independent in activities of daily living (J*1 + J*2), (%); adverse event, number of adverse events, (%)

J*1, J*2: criteria for independence in ADL by the Ministry of Health, Labour and Welfare of Japan

The paired *t* test for means

§ McNemar's test used for proportions

therapy with the objective of preventing falls have also been published. However, they include reports that such therapy is both ineffective [24, 25] and effective [13, 26, 27]. A common point among reports that exercise therapy is effective in preventing falls is that the exercise is not short, vigorous exercise but slow, sustained mechanical load. Balance control by standing on both legs with a narrow base of support or standing on one leg is also recommended [6, 10].

Although DF exercise is a method of repeating one-leg standing exercise with eyes open for the short time of 1 min, 3 times a day, it is thought to satisfy the three basic rules stated by Turner [10]. DF exercise is a profoundly superior exercise in that it is a means of placing a mechanical load on the femoral head. It is also useful in balance training. In this RCT, the increase in one-leg standing time in the DF exercise groups in both men and women compared with the time of entry (men 3.1–3.7 times, women 2.5–2.7 times longer) was striking. In a study using Cybex II [28], the one-leg standing time with eyes open for elderly people ≥65 years of age reflected the strength of the quadriceps femoris muscle of that person. When knee extensor muscle strength dropped below 0.60 Nm/kg, one-leg standing for 30 s was impossible, and when it dropped below 0.40 Nm/kg, one-leg standing for 5 s was impossible. The increase in one-leg standing time with eyes open resulted in strengthening of that person's quadriceps femoris muscle. One-leg standing with eyes open also reflects a person's ADL and mortality [29]. Elderly people who can stand on one leg for ≥30 s are judged to be active people. For elderly people ≥70 years old, those who can stand for a long time on one leg with eyes open are reported to have high bone density [30]. Increase in one-leg standing time with eyes open leads to a larger total mechanical stress load on the femoral head, and is advantageous for improving bone density of the proximal femur. There is a good correlation between one-leg standing time with eyes open and the timed up-and-go test, which is used to assess motor ability in elderly people. Measurements of one-leg standing time with eyes open can be used as a simple means of judging the vitality of elderly people.

Looking at the results of this RCT, it can be seen that, while the increase in one-leg standing time with eyes open was marked for both men and women in the DF exercise group, there was a male–female difference in the decrease in the number of people who fell. A significant difference was not seen among men, but a significant difference was seen among women. Comparison of the number of people who were independent in ADL, which is thought to best reflect improvement in the level of vitality from DF exercise, revealed no significant difference between the DF exercise group and the no exercise group in men, but showed that there were significantly more independent people in the exercise group in women. However, no significant difference was seen in either men or women in the mean number of falls.

Table 5 Comparison of data between baseline and at 6 months (male)

	Male					
	Exercise group (%)			Non-exercise group (%)		
	Baseline	6 months	Statistical p value	Baseline	6 months	Statistical p value
Number	86	86		78	78	
Dominant leg: right	77 (89.5)	–	–	72 (92.3)	–	–
Age (years)	80.5 ± 4.1	–	–	80.7 ± 4.3	–	–
Weight (kg)	58.8 ± 9.8	58.4 ± 9.8	0.028§	58.5 ± 10.6	58.8 ± 10.9	0.353§
Height (cm)	158.9 ± 6.1	158.2 ± 7.9	0.246§	159.7 ± 6.7	159.4 ± 6.8	0.313§
One leg time (right)	5.8 ± 4.2	17.7 ± 35.1	0.002§	5.6 ± 3.8	6.4 ± 5.0	0.089§
One leg time (left)	5.2 ± 3.7	19.3 ± 44.4	0.004§	5.4 ± 3.6	6.7 ± 6.0	0.019§
History of fracture	25 (29.1)	1 (1.2)	–‡	27 (34.6)	1 (1.3)	–‡
Complication	78 (90.7)	–	–	73 (93.6)	–	–
Osteoporosis	17 (19.8)	–	–	14 (17.9)	–	–
Falls yes/no	23 (26.7)	10 (11.6)	–‡	27 (34.6)	14 (17.9)	–‡
No. of falls	0.5 ± 1.3	0.2 ± 0.8	–‡	1.3 ± 3.8	0.5 ± 1.7	–‡
Exercise habit yes/no	41 (47.7)	–	–	39 (50.0))	–	–
Use of aids yes/no	16 (18.6)	–	–	9.7	–	–
ADL Independence	81 (94.2)	82 (95.3)	0.564#	71 (91.0)	72 (92.3)	0.564#
Adverse event	–	1 (1.2)	–	–	0 (0.0)	–

Dominant leg, leg to kick a ball, number of right leg (%); age, average years ± standard deviation (SD); weight, average ± SD; height, average ± SD; one leg time, one leg standing time (seconds) with eyes open, average ± SD; history of fracture, number with fracture history (%); complication, number of people who had complications (%); osteoporosis, number of people who had osteoporosis (%); falls yes/no, number of people (yes) who had a fall in past year (%); no. of falls, number of fall times in 1 year, average ± SD; exercise habit yes/no, number of people (yes) who have exercise habit (%); use of aids, number of people (yes) who use of cane or walking aid (%); level of ADL, number of people who are independent in activities of daily living (J*1 + J*2); adverse event, number of people (%)

J*1, J*2: Criteria for independence in ADL by the Ministry of Health, Labour and Welfare of Japan

The paired t test for means

§ McNemar's test used for proportions

‡ No statistical analysis because of different observation period

One-leg standing with eyes open for 1 min 3 times a day can be continued daily without undue effort or the use of special equipment. It is effective not only in the prevention of falls, but also in improving bone density in the femoral neck [30], and it is also expected to be effective in preventing fractures of the proximal femur. In this 6-month RCT, however, no significant difference was seen in prevention of proximal femur fractures (DF exercise group 0 fractures, no exercise group 1 fracture). From these results, it is thought that, although DF exercise is an effective exercise therapy for improving leg muscle strength in men and women who can stand on one leg with eyes open for ≤15 s, in intervention to reduce the number of people who fall, DF exercise results in too small an exercise load for men but is effective exercise therapy for preventing falls in women. In addition, one-leg standing with eyes open may tend to induce pain in the knees or legs because it increases the load on the standing side. It is necessary to prevent falls during training, and adequate fall prevention instruction (to hold on to a bar or how to put the free leg down on the floor, to fall forward, etc.) is required before implementing the exercise training. For adverse events during DF training, it is thought that leg alignment can be corrected by providing wedge-shaped foot plates to prevent knee and leg pain.

In conclusion, DF exercise is effective exercise therapy for increasing one-leg standing time and improving leg muscle strength in men and women ≥75 years of age who can stand on one leg with eyes open for ≤15 s. DF exercise did not seem to prevent falls in elderly men, but a significant difference in falls was seen in women ≥75 years of age. However, no significant difference was demonstrated for fracture prevention. Even so, an increase in one-leg standing time with eyes open is thought to lead to prevention of fractures of the proximal femur for 75-year-old women with osteoporosis.

Table 6 Comparison of data between baseline and 6 months (female)

	Female					
	Exercise group (%)			Non-exercise group (%)		
	Baseline	6 months	Statistic p value	Baseline	6 months	Statistic p value
Number	324	324		377	377	
Dominant leg: right	283 (87.3)	–	–	331 (87.8)	–	–
Age (years)	80.1 ± 4.0	–	–	80.5 ± 4.1	–	–
Weight (kg)	49.8 ± 8.2	49.3 ± 7.9	0.001§	49.6 ± 8.9	49.6 ± 9.1	0.781§
Height (cm)	147.0 ± 5.9	146.6 ± 6.1	0.001§	146.4 ± 6.1	146.2 ± 6.1	0.011§
One leg time (right)	5.9 ± 4.1	16.2 ± 21.6	<.000§	5.1 ± 3.8	7.2 ± 7.9	<.000§
One leg time (left)	5.9 ± 4.0	15.0 ± 21.2	<.000§	5.2 ± 3.8	6.1 ± 6.1	0.002§
History of fracture	134 (41.4)	3 (0.9)	–‡	167 (44.3)	10 (2.7)	–‡
Complication	285 (88.0)	–	–	318 (84.4)	–	–
Osteoporosis	251 (77.5)	–	–	276 (73.2)	–	–
Falls yes/no	120 (37.0)	46 (14.2)	–‡	114 (30.2)	78 (20.7)	–‡
No. of falls	1.1 ± 2.2	0.3 ± 1.2	–‡	0.6 ± 2.0	0.3 ± 0.7	–‡
Exercise habit yes/no	127 (39.2)	–	–	186 (49.3)	–	–
Use of aids yes/no	114 (35.2)	–	–	159 (42.2)	–	–
ADL Independence	310 (95.7)	313 (96.6)	0.366	344 (91.2)	345 (91.5)	0.796#
Adverse event	–	4 (1.2)	–	–	0 (0.0)	–

Dominant leg, leg to kick a ball, number of right leg (%); age, average years ± standard deviation (SD); weight, average ± SD; height, average ± SD; one leg time, one leg standing time (seconds) with eyes open, average ± SD; history of fracture, number with fracture history (%); complication, number of people who had complications (%); osteoporosis, number of people who had osteoporosis (%); falls yes/no, number of people (yes) who had a fall in past year (%); ʲno. of falls, number of falls in 1 year, average ± SD; exercise habit yes/no, number of people (yes) who have exercise habit (%); use of aids, number of people (yes) who use of cane or walking aid (%); level of ADL, number of people who are independent in activities of daily living (J*1 + J*2); adverse event, number of people (%)

J*1, J*2: Criteria for independence in ADL by the Ministry of Health, Labour and Welfare of Japan

The paired t test for means

§ McNemar's test used for proportions

‡ No statistical analysis because of different observation period

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Conflict of interest The authors declare no conflict of interest related to this study.

Appendix: Principal Clinical sites

Furukawabashi Hospital, Kimuramorokado Hospital, Takatsu Chuoh Hospital, Kamiitabashi Dai2 Hospital, Nishikamata Clinic, Kyoudou Clinic, Kuchiishi Hospital, Kobayashi Clinic, Tsurumaki Orthopaedic Clinic, Sawatari Clinic, Kayama Orthopaedic Clinic, Musashiyamato Orthopaedic Clinic, Suzuki Orthopaedic Clinic, Sekimizu Orthopaedic Clinic, Central Hospital, Sakura Orthopaedic & Rehabilitation Hospital, Fukuzawa Orthopaedic Clinic, Furuoka Orthopaedic Clinic, Maeda Hospital, Yoshimura Orthopaedic Clinic, Chouritu Ogano Central Hospital, Tomakomai Hospital, Toyooka-Central Hospital, Hirosaki City Hospital, Iwate Medical University, Tokyo Kyousai Hospital, Yonehara-Central Hospital, Tokyo Jikeikai Medical University, Toho University Oohashi Hospital, Tokyo Metropolitan Rehabilitation Hospital, Kugayama Hospital, Washiya Hospital, Dokyou Medical University, Rounenbyo-Kenkyusyo Hospital, Shirogane Orthopaedic Hospital, Kikkouman Clinic, Shinnkawabashi Hospital, Yamanashi Prefectural Hospital, Nirasaki City Hospital, Fukui University, Gifu University, Ohgaki Central Hospital, Kouritu Morinomachi Hospital, Mie University, Yamada Orthopaedic Hospital, Maizuru Red-Closs Hospital, PL Hospital, Saiseikai Suita Hospital, Kinki University Sakai Hospital, Kobe 100 Nen Kinen Hospital, Kouritu Toyo-oka Hospital, Hyougo Medical University, Mimuro Prefectural

Hospital, Nara Rehabilitation Centre, Misasa Onsen Hospital, Sanin Rosai Hospital, Kaike Onsen Hospital, Okayama University, Cyugoku Denryoku Hospital, Kosei Sogou Hospital, Kagawa Rosai Hospital, Tosa City Hospital, University of Occupational and Environmental Health, Sinal Cord Injury Centre, Kawashima Orthopaedic Hospital, Ohita Orthopaedic Hospital, Kumamoto University, Miyazaki University, Nichinan Hospital, Komaki Hospital, Iida Hospital, Showa University, Kouritsu Tan-Nan Hospital, Showa University Yokohama Hokubu Hospital, Hiraosaki Kinenn Hospital, Teikyou University Chiba Medical Centre, Shiota Sogo Hospital, Sekigawara Hospital, Tsusima City Hospital, Minamikawa Orthopaedic Hospital, Isahaya Sogo Hospital, Tkachiho-Mmachi Hospital, Kusimaoto Hospital, Momotake Orthopaedic Hospital, Kumamoto Kino Hospital, Kitade Hospital, Uguisu-Yado Onsen Hospital, Hachiya Orthopaedic Hospital, Yonago Medical Centre, Seibu Shimane Medical Centre, Hiroshima Tetsudo Hospital, Moji Rosai Hospital, Kimachi Rehabilitation Hospital, Ohta Sogo Hospital, Sapporo Eikeigeka-Jyunkanki Hospital, Aomaori Prefectural Hamanasu Medical Centre, Edogawa Hospital, Gamagouri City Hospital, Suga Orthopaedic Hospital, Tamana Central Hospital, Kijima Orthopaedic Clinic, Seigo Clinic, Niigata Rehabilitation Hospital, Nakamura Orthopaedic Clinic, Murai Orthopaedic Hospital, Noto Orthopaedic Clinic, Nakayama Orthopaedic Clinic, Asai Orthopaedic Clinic, Yanagi Orthopaedic Clinic, Kojima Orthopaedic Clinic, Ishizaka Orthopaedic Clinic, YUkiyoshi Clinic, Takahashi Orthopaedic Clinic, Ohkawa Clinic, Motomachi Hospital, Iwate Medical University Hanamaki Onsen Hospital, MIzuhara-Go Hospital, Nissan Tamagawa Hospital, National Center for Geriatrics and Gerontology, Tomizawa Hospital, Sato Hospital, Ehime National Hospital, Ishikawa Prefectural Central Hospital, Chikuma Central Hospital, Ohta Hospital, Mazda Hospital, Ube Kyouritu Hospital, Yokohama City University, Kusunoki Orthopaedic Clinic, Nezu Orthopaedic Clinic, Kubota Orthopaedic Clinic, Saiseikai Otaru Hospital, National Hirosaki Hospital, Sanai Hoppital, Yamanaka Onsen Hospital, Sakasita Hospital, Yoshida Orthopaedic Clinic, Jinsen Onsen-Kaigo Rehabilitation, Suzuka Central Hospital, National Kochi Hospital, Ohita Jyunkannki Hospital, Honma Orthopaedic Clinic, Ishii Clinic, Niigata Prefectural Kamo Hospital, Kuwana Hospital, Nishi Niigata Central Hospital, Akishima Hospital, Namekawa Hospital, Kita Orthopaedic Clinic, Sanyudo Hospital, Yonago Higashi Hospital, Tama Hokubu Medical Centre, Ohdate City Hospital, Mirai Orthopaedic & Pain Clinic, Saku-Daira Orthopaedic Clinic, Minano Hospital, Hiramatu Orthopaedic Clinic, Kurata Hospital, Yourou Orthopaedic Clinic, Takeda Orthopaedic Clinic, Nakane Orthopaedic Clinic, Kanematsu Orthopaedic Clinic, Ebihara Hospital, Tama Medical Rehabilitation Clinic, Nasu Orthopaedic Clinic, Kichikawa Orthopaedic Clinic, Nagata Clinic, Hirose Clinic, Honda Orthopaedic Clinic, Mikami Orthopaedic Clinic and Mori Orthopaedic Clinic.

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ORIGINAL ARTICLE: EPIDEMIOLOGY, CLINICAL PRACTICE AND HEALTH

Relationship between near-infrared spectroscopy, and subcutaneous fat and muscle thickness measured by ultrasonography in Japanese community-dwelling elderly

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Aim: Near-infrared spectroscopy (NIRS) allows estimation of the percentage of body fat (%BF) regardless of the patient's posture; thus, it is useful for assessment of elderly patients with severe decline of basic activity who cannot hold a standing position. However, the accuracy by which the near-infrared light emitted from NIRS reflects subcutaneous tissue is unknown. The aim of this study was to assess how correctly NIRS reflects the subcutaneous fat and muscle thickness derived from ultrasonography in community-dwelling elderly.

Methods: A total of 93 community-dwelling older adults aged 65 years and older were enrolled in this study (mean 75.8 years, 6.7 SD). Participants were assessed according to optical density (OD) measurements by NIRS, subcutaneous fat and muscle thickness by ultrasonography, and muscle strength. Pearson's correlation coefficients were calculated for each sex. Stepwise multiple regression analysis was used to identify factors that contributed to OD for each sex.

Results: OD measured at the forearm and thigh were significantly correlated with subcutaneous fat thickness. In stepwise multiple regression analyses, subcutaneous fat thickness was found to be a significant determinant of OD in men (forearm $\beta = -0.37$, $P = 0.01$; thigh $\beta = -0.63$, $P < 0.001$) and women (forearm $\beta = -0.50$, $P < 0.001$; thigh: $\beta = -0.52$, $P < 0.001$).

Conclusions: These results suggest that NIRS can appropriately estimate fat-free mass. By adding other variables to OD as the predictive variable, skeletal muscle mass might be estimated in the elderly population. **Geriatr Gerontol Int 2013; 13: 351–357.**

Keywords: near-infrared spectroscopy, older adults, sarcopenia, subcutaneous fat thickness, subcutaneous muscle thickness.

Introduction

Sarcopenia is the loss of muscle mass and function related to aging[1–5]. A study reported that older sarcopenic patients are twice as likely to contract infection during a hospital stay compared with older patients with a normal muscle mass.[6] This suggests that sarcopenic individuals might have decreased immunity, which might provide a mechanistic link between sarcopenia and mortality risk. In fact, a low corrected arm muscle area independently predicts long-term mortality in community-dwelling older adults.[7] According to the New Mexico Elder Health Survey, the prevalence of sarcopenia increased from 13% to 24% in persons aged less than 70 years to >50% in persons aged more than 80 years.[8] To achieve successful aging, it is important to preserve a certain amount of muscle mass.

Some researchers recently showed that sarcopenic obese persons are at a particularly high risk for functional impairment and physical disability.[8–11] A previous report suggested that approximately 15% of sarcopenic persons are also obese.[8] Thus, not only muscle mass, but also fat mass, should be accurately assessed in older adults.

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Protein energy malnutrition (PEM) is related to various risk factors (pressure sores, pneumonia, postoperative complications, anemia, loss of bone mineral, femoral neck fracture, cognitive impairment, low activities of daily living, low quality of life and sarcopenia).[12] Furthermore, PEM independently predicts long-term mortality in hospitalized older adults.[13] These individuals should have increased protein consumption, because energy uptake is insufficient in PEM; thus, the body protein (particularly in skeletal muscle) decreases. Therefore, sarcopenic patients might also have PEM. PEM has been reported to be prevalent in hospitalized older adults and nursing home residents,[14–16] whose physical functions often decrease severely. Therefore, body composition should be evaluated in patients with severe decline in physical function.

The most highly accurate method for measuring limb composition is whole-body dual-energy X-ray absorptiometry (DXA).[17] DXA can simultaneously measure body fat mass and bone mineral density. However, whole-body DXA is costly and time intensive. This scan also involves some exposure to radiation. Therefore, the use of bioelectrical impedance analysis (BIA) instruments has gained increasing attention both in the clinic and among the general population. However, few reports have been published about the measurement of body composition in lean elderly patients with severe decline in physical function.

BIA is a non-invasive, portable, quick and inexpensive method for measuring body composition.[18] It is the most common method for measuring body composition in Japan. However, many BIA instruments require patients to maintain a standing position for the measurement. Therefore, BIA instruments are often not used for elderly patients with severe decline in basic activity who cannot hold a standing position. Another method that might have potential for use in older adults is near-infrared spectroscopy (NIRS). NIRS is also a non-invasive, portable, simple and rapid method for assessing the percentage of body fat (%BF). The NIRS instrument allows estimating a patient's %BF simply by placing the tip of the probe against the center of the front side of the arm, regardless of the patient's posture.

Some reports showed that NIRS has a high reliability and accuracy in assessing %BF.[19–22] However, there has been no report on how correctly the near-infrared light emitted from NIRS reflects the subcutaneous tissue, particularly the muscle, at the irradiation point. Therefore, whether NIRS accurately estimates fat and muscle mass is unknown. Regional fat and muscle thickness can be accurately quantified with ultrasonography.[23,24] A previous study reported that the muscle cross-sectional area measured by ultrasonography is related to muscle strength.[25] If NIRS can reflect regional muscle mass, then there might be a relationship between the variable derived from NIRS and muscle strength.

The aim of the present study was to assess how correctly NIRS reflects the subcutaneous fat and muscle thickness derived from ultrasonography in community-dwelling older adults.

Methods

Participants

The participants were recruited from two volunteer databases ($n = 1543$), which included elderly individuals aged 65 years and older who were selected either by random sampling, or from those who attended a health check in Obu City near Nagoya in Japan. Among the 165 participants who responded to the eligibility assessments, 125 completed the strength, NIRS and ultrasound measurements. The inclusion criteria for the present study required that the participants be aged 65 years or older, living independently in the community, Japanese speaking, and with sufficient hearing and visual acuity to participate in the examinations. The exclusion criteria included a history of major psychiatric illness (e.g. schizophrenia or bipolar disorder), other serious neurological or musculoskeletal diagnoses, and clinical depression (Geriatric Depression Scale [GDS] score ≥10). A total of 93 out of 125 participants satisfied the inclusion criteria and were analyzed in the present study.

The present study was approved by the ethics committee of the National Center for Geriatrics and Gerontology. All participants provided written informed consent.

Near-infrared spectroscopy

The NIRS measurements used the Fitness Analyzer BFT-3000 (Kett Science, Tokyo, Japan), the Japanese version of Futrex 5000 (Futrex, Hagerstown, MD, USA), which can estimate body composition.[20,26] This device measures optical densities (OD) at two wavelengths (OD1 = 937 nm, OD2 = 947 nm). The NIRS instrument was tested immediately before obtaining measurements for each patient by using the optical standard provided with the instrument, which is situated in a flexible light shield to ensure its consistent performance throughout the study.

OD values were obtained at two sites: the forearm (flexor carpi radialis) and thigh (quadriceps). Participants were required to maintain a seated position, with their hands dropped to their sides. A single trained physical therapist carried out the NIRS measurements, which were completed in a few minutes.

Ultrasonography

The Miru Cube ultrasound scanning system (Global Healt, Kanagawa, Japan) with a 6-MHz linear array transducer, a portable instrument developed for measuring subcutaneous fat and muscle thickness outside the clinic,[27] was used for measuring the thicknesses of two kinds of subcutaneous soft tissue: fat and muscle. Measurements were taken in longitudinal directions. Participants were required to maintain a seated position, with their hands dropped to their sides. Scans were taken at the same sites (forearm and thigh) as those in NIRS measurements. A single trained physical therapist carried out the scans, which were completed in a few minutes.

The images were transferred to a computer for quantification. Subcutaneous fat and muscle thicknesses were automatically measured using software for exclusive use.

Muscle strength

Grip strength and isometric knee-extension strength were evaluated. The grip strength was measured using a Smedley-type digital hand dynamometer (model TKK5401; Takei Scientific Instruments, Niigata, Japan). The participants were instructed to apply as much hand-grip pressure as possible with their dominant hand in a standing position.

Isometric knee-extension strength was tested on a dynamometer (model MDKKS; Molten, Hiroshima, Japan). For the knee extension test, the right leg was used unless contraindicated by pain or a history of joint replacement. Knee extension was measured while the participant was sitting (knee joint angle of 90°) on a chair by placing a strap around the leg just proximal to the ankle joint. In two experimental trials, the participant pulled against the strap assembly with maximal force; the greatest force was recorded. Isometric knee-extension torque was normalized against the moment arm and body mass (N m/kg) in the data analysis.

Statistical analysis

Student's *t*-tests were used to compare the demographic data, OD, subcutaneous soft tissue thicknesses, and muscle strengths between men and women.

Pearson's correlation coefficients were calculated for each sex to assess simple relationships between OD and subcutaneous soft tissue thicknesses or strengths. Stepwise multiple regression analysis was used to identify factors that contributed to OD for each sex and each measurement site (forearm or thigh). Because there were high correlation coefficients between OD1 and OD2 ($r > 0.969$) and all correlation coefficients were higher at OD1 than at OD2, OD1 was used as the representative value. For the analysis of variables measured in the forearm, OD1 in the forearm was considered the dependent variable, and subcutaneous soft tissue thicknesses in the forearm and grip strength were considered independent variables. For the analysis of variables measured in the thigh, OD1 in the thigh was considered the dependent variable, and subcutaneous soft tissue thicknesses in the thigh and knee-extension strength were considered independent variables.

We considered a value of 5% to be significant. We analyzed the data using IBM SPSS Statistics version 19 for Windows (SPSS, Chicago, IL, USA).

Results

The mean (SD) age of all participants was 75.8 years (6.7). Table 1 summarizes the characteristics and the sex differences of the participants.

The correlation coefficients between subcutaneous soft tissue thicknesses or strengths and each OD value are listed in Table 2. In both men and women, subcutaneous fat thickness in the forearm was significantly correlated with OD in the forearm or the thigh (both OD1 and OD2). In men, subcutaneous fat thickness in the thigh was significantly correlated with OD in the forearm or the thigh (both OD1 and OD2). In women, subcutaneous fat thickness in the thigh was significantly correlated with OD in the thigh (both OD1 and OD2). In men, knee-extension strength was significantly correlated with OD in the forearm (both OD1 and OD2). In the correlation analysis between subcutaneous fat thickness and OD value, all correlation coefficients were higher at OD1 than at OD2 (Figure 1).

In stepwise multiple regression analyses, subcutaneous fat thickness was found to be a significant determinant of OD1 in men (forearm $\beta = -0.37$, $P = 0.01$; thigh $\beta = -0.63$, $P < 0.001$) and women (forearm $\beta = -0.50$, $P < 0.001$; thigh $\beta = -0.52$, $P < 0.001$; Table 3).

Discussion

The power with which light enters the body is called penetrability. The penetrability of light is proportional to the wavelength. Electromagnetic waves with a short wavelength, such as visible light or near-infrared light, have low penetrability and can only warm the surface of the skin. The NIRS instrument used in the present study also measures the amount of subcutaneous soft tissue by means of such near-infrared light; thus, the light might not reach a deep subcutaneous point. A previous study reported that the deviation in optical path length in NIRS becomes large when there is a big difference in the skinfold thickness among participants.[28]

A previous study showed that the distances from the skin surface to muscle measured using an ultrasonography image scanner were 1.0–2.5 cm in participants whose body mass index was 20–24.[29] The NIRS instrument has been used to measure subcutaneous soft