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ORIGINAL ARTICLE: EPIDEMIOLOGY, CLINICAL PRACTICE AND HEALTH

Estimation of appendicular muscle mass and fat mass by near infrared spectroscopy in older persons

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Aim: Near infrared spectroscopy has been reported to have a high reliability and accuracy in assessing the percentage of body fat. However, whether muscle mass can be accurately estimated using this method has not been established. This study examined whether a near infrared spectroscopy method could estimate appendicular muscle mass and fat mass, with dual-energy X-ray absorptiometry as the standard method for comparison.

Methods: A total of 20 orthopedic inpatients (mean age 73.2 ± 6.8 years) were recruited for this study. Their body composition was assessed using near infrared spectroscopy and dual-energy X-ray absorptiometry. Appendicular muscle mass and fat mass were estimated from height, weight and optical densities.

Results: The optical densities for the upper arm (biceps, triceps) and forearm (flexor carpi radialis) were significantly correlated with appendicular muscle mass ($r = 0.534$ to 0.623) or fat mass ($r = -0.483$ to -0.827). Estimated appendicular muscle mass and fat mass explained 89% and 80% of the variance in the dual-energy X-ray absorptiometry-derived muscle mass and fat mass estimates using height, weight and optical density values of the proximal flexor carpi radialis.

Conclusions: Near infrared spectroscopy is a useful method to assess not only fat mass, but also muscle mass in older adults. **Geriatr Gerontol Int 2012; 12: 652–658.**

Keywords: aged, body composition, body fat, sarcopenia, skeletal muscles.

Introduction

Age-related loss of muscle mass (so-called sarcopenia) can lead to functional decline in older persons.[1–5] Two published Health, Aging and Body Composition reports showed that sarcopenia, as determined by computed tomography (CT) in the mid-thigh, was a weak to modest predictor of loss of physical function over the following 2 to 3 years.[6,7] Furthermore, one study reported that older sarcopenic patients were twice as likely to contract infection during a hospital stay compared with older patients with a normal muscle mass.[8] This suggested that sarcopenic individuals might have decreased immunity, which might provide a mechanistic link between sarcopenia and mortality risk. In addition, reduced arm muscle area was reported to be an independent predictor of long-term mortality in community-dwelling older adults.[9] According to the

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New Mexico Elder Health Survey, the prevalence of sarcopenia increased from 13 to 24% in persons aged under 70 years to >50% in persons aged over 80 years.[1] To achieve successful aging, it is important to preserve muscle mass to maintain function.

Recently, some researchers reported that sarcopenic patients who were obese were at particularly high risk of functional impairment and physical disability.[10–13] The condition was termed sarcopenic obesity, and it was suggested that approximately 15% of those with sarcopenia were also obese.[10] This suggests that it is necessary to assess not only muscle mass, but also fat mass accurately in the elderly.

There are various methods for measurement of body composition. Total body and regional skeletal muscle mass can now be accurately quantified using imaging methods, including CT and magnetic resonance imaging (MRI).[14] However, CT and MRI are costly methods and access to the equipment can be limited. Dual-energy X-ray absorptiometry (DXA) has been widely used in clinical practice, not only for osteoporosis screening and diagnosis, but also for assessment of body composition, such as skeletal muscle mass and fat mass. DXA is less expensive and less invasive compared with MRI and CT. Previous studies have shown good correlations between DXA-derived lean soft tissue mass and skeletal muscle mass in the lower limb region when CT and MRI were used as the standards for comparison.[15,16] However, DXA methods take more time, although whole-body scanning by this method exposes the patient to minimal radiation.

Bioelectrical impedance analysis (BIA) is a non-invasive, portable, quick and inexpensive method for measuring body composition.[17] Previous studies have shown that there is a strong correlation between BIA resistance and skeletal muscle measurements in the arms[18] and legs.[19] In addition, one report suggested that BIA could provide rapid and accurate estimates of whole body skeletal muscle mass in adults.[20] There are some disadvantages with the BIA method. First, fat tissue also holds water, although the proportion is small.[21] Second, the volume of muscle derived by BIA might overestimate the actual volume. Third, there are a large proportion of older adults who have a changed distribution of body water, such as edema. One report showed that the expansion of extracellular water relative to intracellular water and to regional lean volume masks actual muscle cell atrophy during aging.[22] This suggested that it might be difficult to accurately assess body composition in older adults.

Another development that might have potential for use in older adults is near infrared spectroscopy (NIRS). NIRS is also a non-invasive, simple and rapid method of assessing the percentage of body fat. There are some reports that the NIRS method has a high reliability and accuracy in determination of the percentage of body fat.[23–25] In contrast, it has not been established whether muscle mass can be estimated accurately by NIRS.

The present study investigated whether a NIRS method could provide an accurate estimate of appendicular muscle mass (AMM) and appendicular fat mass (AFM) using DXA as the standard method for comparison.

Methods

Participants

A total of 20 orthopedic patients who were admitted to the National Hospital for Geriatric Medicine and who were aged 60 years or older were recruited for the present study. Patients with dementia or who had major laterality of muscle mass in the arms and legs, or who had surgery just before the study were excluded. All participants had their height (to the nearest 0.1 cm) and weight (to the nearest 0.1 kg) measured after admission. The details of the study were explained in advance and written consent was obtained from each participant. In addition, the present study was approved by the ethics committee of the National Center for Geriatrics and Gerontology.

Measurement of body composition

Whole and regional body composition was measured using DXA (Lunar DPX, Madison, WI, USA). This system provided the mass of lean soft tissue, fat and bone mineral for both the whole body and specific regions. Appendages were isolated from the trunk and head by using a DXA regional computer-generated default line. AMM or AFM was derived as the sum of the fat-free soft tissues or fat tissue of the arms and legs. A previous study reported that total body skeletal muscle mass can be accurately predicted from DXA-estimated appendicular lean soft tissue mass.[26,27]

NIRS

The NIRS measurements were carried out with the Fitness Analyzer BFT-3000 (Kett Electrical Laboratory, Tokyo, Japan, Fig. 1), the Japanese version of the Futrex 5000 (Futrex, Gaithersburg, MD, USA; 1988), which has potential for estimating body composition.[22,28] This device uses optical densities (OD) at two wavelengths (OD1 = 937 nm, OD2 = 947 nm) measured at each site. The NIRS instrument was tested immediately before taking measurements on each patients by using an optical standard, which was provided with the instrument and situated in a flexible light shield, to ensure that its performance was consistent throughout the study.

OD values were obtained at six sites: distal biceps (5 cm from the olecranon), distal triceps (5 cm from the

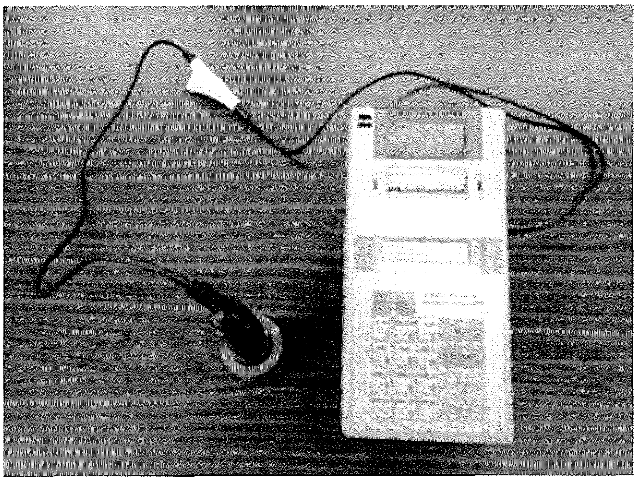

Figure 1 The near infrared spectroscopy instrument (Fitness Analyzer BFT-3000).

Figure 2 Method of measurement.

olecranon), proximal flexor carpi radialis (5 cm from the olecranon), distal quadriceps (5 cm from the upper edge of patella), proximal tibialis anterior (5 cm from the caput fibulae) and proximal calf (5 cm from the caput fibulae). The reliability was confirmed by test–retest. The test–retest reproducibility was excellent (intraclass correlation coefficient = 0.95–0.97, $P < 0.01$). Patients were required to maintain a seated position, with their arms relaxed at their sides (Fig. 2). NIRS measurements were carried out by a single trained physical therapist, and completed within a few minutes.

Statistical analysis

Pearson's correlation coefficient was used to determine the relationship between AMM or AFM and each OD value. Equations for estimation of AMM and AFM were developed with the use of multiple linear regression analysis. Potential explanatory variables included OD value, height and weight. DXA-measured AMM and AFM were set as the objective variable. The coefficient of determination (R^2) values were used to quantify the accuracy of model fit. The mean difference between DXA-measured AMM (AFM) and estimated AMM (AFM) was tested using the paired Student's *t*-test. Statistical analyses were carried out using PASW Statistics 18 for Windows (SPSS, Chicago, IL, USA) and the significance level was less than 5%.

Results

The characteristics of the patients are shown in Table 1. Mean age was 73.2 ± 6.8 years (range 62–84 years) and 70% were female. The subjects were diagnosed with the following: spinal canal stenosis ($n = 11$), disc herniation ($n = 1$), spinal tumor ($n = 2$), knee osteoarthritis ($n = 2$), compression fracture ($n = 1$), femoral neck fracture ($n = 1$) and others ($n = 2$).

The correlation coefficients between AMM or AFM and each OD value are listed in Table 2. AMM was significantly correlated with OD values at the distal triceps (OD1: $r = 0.623$; OD2: $r = 0.534$). AFM was significantly correlated with OD values at the distal biceps (OD1 $r = -0.570$; OD2 $r = -0.551$), distal triceps (OD1 $r = -0.483$; OD2 $r = -0.494$) and proximal flexor carpi radialis (OD1 $r = -0.827$; OD2 $r = -0.821$). In the correlation analysis between muscle mass or fat mass and the OD value, correlation coefficients were mostly higher with OD1 than with OD2. Thus, OD1 was used as the representative value of NIRS data for the estimation equation.

The results from linear regression analyses for the multivariate models are presented in Table 3. The multiple regression equations incorporated height, weight and OD1. Using anthropometric data (height and weight) as the explanatory variables, the R^2 value of AMM and AFM were 0.81 (standard error of the estimate [SEE] = 1.67 kg) and 0.50 (SEE = 1.77 kg), respectively (model 1). When OD1 was added to the explanatory variables, the R^2 values of AMM and AFM ranged from 0.85 to 0.89, and 0.58 to 0.80, respectively (models 2–5). The highest R^2 values of AMM and AFM were 0.89 (SEE = 1.33 kg) and 0.80 (SEE = 1.16 kg), respectively, when OD1 at the proximal flexor carpi radialis was added to the explanatory variables. For separate estimation equations (upper and lower limb), the accuracy of model fit was slightly less (muscle mass $R^2 = 0.82$–0.87, fat mass $R^2 = 0.53$–0.55). There were no significant differences between DXA-measured AMM and estimated AMM (mean difference 0.01, 95% confidence interval −0.56 to 0.58), or between DXA-measured AFM and estimated AFM (mean difference −0.25, 95% confidence interval −0.75 to 0.25).

Table 1 Physical characteristics of the study participants

Variables	All subjects (n = 20)	Men (n = 6)	Women (n = 14)
Age (years)	73.2 ± 6.8	67.8 ± 8.1	75.5 ± 4.9
Height (cm)	153.2 ± 9.5	166.1 ± 3.2	147.8 ± 4.3
Weight (kg)	53.9 ± 10.3	64.3 ± 6.8	49.4 ± 8.2
BMI (kg/m^2)	22.8 ± 2.9	23.3 ± 2.1	22.6 ± 3.2
AMM (kg)	15.7 ± 3.7	20.5 ± 1.2	13.6 ± 2.0
AFM (kg)	4.8 ± 2.4	4.1 ± 2.2	5.1 ± 2.4
Diagnosis n (%)			
Spinal canal stenosis	11 (55%)		
Disc herniation	1 (5%)		
Spinal tumor	2 (10%)		
Knee osteoarthritis	2 (10%)		
Compression fracture	1 (5%)		
Femoral neck fracture	1 (5%)		
Others	2 (10%)		

Values are mean ± standard deviation or n (%).
AFM, dual-energy X-ray absorptiometry-derived appendicular fat mass; AMM, dual-energy X-ray absorptiometry-derived appendicular muscle mass; BMI, body mass index.

Table 2 Correlation coefficients between limb muscle mass or fat mass and each optical densities value

	Biceps OD1	Biceps OD2	Triceps OD1	Triceps OD2	Flexor carpi radialis OD1	Flexor carpi radialis OD2
Upper limb muscle mass						
Four limbs	0.369	0.350	0.623**	0.534*	0.343	0.324
Upper limb	0.292	0.286	0.572**	0.462*	0.279	0.267
Upper limb fat mass						
Four limbs	−0.570**	−0.551*	−0.483*	−0.494*	−0.827**	−0.821**
Upper limb	−0.423	−0.394	−0.403	−0.411	−0.723**	−0.705**

	Quadriceps OD1	Quadriceps OD2	Tibialis anterior OD1	Tibialis anterior OD2	Calf OD1	Calf OD2
Lower limb muscle mass						
Four limbs	0.332	0.190	0.139	0.118	0.297	0.327
Lower limb	0.383	0.248	0.138	0.125	0.346	0.373
Lower limb fat mass						
Four limbs	−0.348	−0.220	−0.421	−0.388	−0.426	−0.443
Lower limb	−0.333	−0.218	−0.434	−0.401	−0.458*	−0.472*

*$P < 0.05$; **$P < 0.01$. Optical density (OD)1 = 937 nm, OD2 = 947 nm.

Discussion

Recently, Sanada *et al.* reported prediction models for skeletal muscle index using body mass index (BMI) in Japanese adults.[29] The results showed that the R^2 values for the skeletal muscle index were 0.56 in men and 0.45 in women. Similarly, Gallagher *et al.* reported that height and weight accounted for 64% and 67% of the total variance of the appendicular skeletal muscle mass in African-American and Caucasian women, respectively, and 63% and 39% of the total variance in African-American and Caucasian men, respectively.[30] These results showed the difficulty in estimating the AMM accurately using only anthropometric measurements, and the need for an objective method for accurate measurement of body composition.

To address this problem, we investigated whether AMM and AFM could be estimated by a combination of height, weight and NIRS data (OD values). The present results showed that OD1 of the proximal flexor carpi

Table 3 Regression equation for estimating appendicular muscle mass and fat mass

Model	Equation	R^2	SEE
Appendicular muscle mass			
1	$y = 0.23 \times$ (height) + $0.13 \times$ (weight) − 26.35	0.81	1.67
2	$y = 0.17 \times$ (height) + $0.17 \times$ (weight) + $8.45 \times$ [OD1 [biceps]) − 28.97	0.89	1.34
3	$y = 0.13 \times$ (height) + $0.18 \times$ (weight) + $10.49 \times$ (OD1 [triceps]) − 23.19	0.85	1.55
4	$y = 0.10 \times$ (height) + $0.24 \times$ (weight) + $7.82 \times$ (OD1 [flexor carpi radialis]) − 21.42	0.89	1.33
5	$y = 0.20 \times$ (height) + $0.15 \times$ (weight) + $6.12 \times$ (OD1 [calf]) − 29.44	0.85	1.57
Appendicular fat mass			
1	$y = -0.22 \times$ (height) + $0.25 \times$ (weight) + 25.39	0.50	1.77
2	$y = -0.17 \times$ (height) + $0.21 \times$ (weight) − $7.89 \times$ (OD1 [biceps]) + 27.84	0.65	1.52
3	$y = -0.10 \times$ (height) + $0.20 \times$ (weight) − $12.11 \times$ (OD1 [triceps]) + 21.73	0.61	1.60
4	$y = -0.06 \times$ (height) + $0.12 \times$ (weight) − $10.01 \times$ (OD1 [flexor carpi radialis]) + 19.08	0.80	1.16
5	$y = -0.19 \times$ (height) + $0.23 \times$ (weight) − $6.55 \times$ (OD1 [calf]) + 28.70	0.58	1.66

R^2, coefficient of determination; SEE, standard error of the estimate.

radialis, in association with anthropometric data, can provide accurate estimates of both AMM and AFM in older adults, although the NIRS data alone did not reflect muscle mass except at the distal triceps. Furthermore, compared with the estimation equation that included only anthropometric data, the estimation equation that included both anthropometric and NIRS data had a higher coefficient of determination.

In the present study, the NIRS data were obtained at six sites to determine the best location for estimating AMM and AFM. As a result, OD values measured at the distal triceps and proximal flexor carpi radialis showed a good correlation coefficient with limb muscle mass and fat mass, respectively. Yasukawa *et al.* reported that the NIRS data (OD values) measured by BFT-2000 (old model of BFT-3000) had higher correlations with percentage fat at the thinner adipose sites than thicker adipose sites,[31] and similar results were observed by Futrex 5000 in another report.[25] Inconsistent strengths of the association of OD values with total body fat at the various sites might simply be a result of differences in the depth of penetration of the infrared radiation. These results suggested that it might be preferable to carry out measurements at sites where there is little subcutaneous fat, such as the flexor carpi radialis.

There are several reports of NIRS being a valid method to assess the percentage of fat or fat mass. For example, Sawai *et al.* reported that the correlation coefficient between percentage body fat as predicted by the NIRS method and as predicted by the hydrostatic weighing technique was 0.88 ($P < 0.001$, SEE = 3.2).[24] Fuller *et al.* also suggested that NIRS methods using Futrex 5000 have the potential to replace skinfold thickness (SFT) for estimation of body composition.[25] The BFT-3000 used in the present study was developed for Japanese patients, and the principle of measurement was the same as for Futrex 5000. Our findings that NIRS data could accurately reflect fat mass are consistent with a previous study.[25] These results suggest that NIRS is a valid method for the estimation of AFM.

Other reports (by Futrex 5000) showed that NIRS might have little or no advantage over SFT in determining body composition.[32,33] One of the reasons for this controversy is that the degree of obesity differs in each patient. Elia *et al.* concluded that NIRS might underestimate body fat in very obese patients.[32] In the present study, the mean BMI of the patients was 23.3 ± 2.1 kg/m^2 in men and 22.6 ± 3.2 kg/m^2 in women, and there was no patient whose BMI was over 30 kg/m^2. Previous studies of older Japanese patients also reported a BMI ranging from 19.9 to 23.3 kg/m^2.[21,22] These results imply that NIRS data might be less affected by subcutaneous fat in older Japanese patients, and that NIRS is a valid method to assess their percentage fat and fat mass.

In contrast, NIRS data were not correlated significantly with whole and regional muscle mass except in the distal triceps. It is possible that quantitative assessment of skeletal muscle mass might be difficult using only NIRS data, because near infrared light might not reach the deeper muscle layer. However, when bodyweight is divided into fat mass and fat-free mass, skeletal muscle constitutes the largest fraction of appendicular fat-free mass. Previous investigators also proposed several models for predicting skeletal muscle mass with DXA. Lean body mass consists mostly of skeletal muscle. If we obtain an accurate bodyweight and the fat mass, the lean body weight (i.e. skeletal muscle mass) can be calculated automatically. The results in the present study suggest that AMM might be estimated indirectly by using NIRS data and bodyweight.

The present study is limited by the small sample size and orthopedic patients who were mostly women. The estimation equations of AMM and AFM developed in the present study might have high specificity. In addition, we did not confirm the validity of these estimation equations. Thus, further studies are required to check the validity of these equations in other older adults (cross-validity) and longitudinally monitored populations (predictive validity) in the future. Furthermore, these equations will be developed for each sex using larger samples. Finally, to our knowledge, it is unclear whether the OD value (wavelength 937–947 nm) is influenced by blood flow and oxygen saturation. In the previous study, investigators did not mention this point. However, all patients were maintained in a resting position before and during the measurement in the present study. We think that the influence of blood flow and oxygen saturation is not likely to be marked, but this should be considered in a future study.

In conclusion, NIRS data can provide reliable and accurate estimates of AMM and AFM in older adults with the use of anthropometric data (height and weight). The estimation equations of AMM and AFM suggest the possibility that NIRS is a convenient method to assess body composition and to screen sarcopenic (or sarcopenic-obesity) patients. For further adjustment of this equation, it might be expected that sarcopenia or sarcopenic-obesity patients can be screened easily.

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Disclosure statement

The authors have no financial disclosures or other conflicts of interest to report.

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Research Article

Divergent Significance of Bone Mineral Density Changes in Aging Depending on Sites and Sex Revealed through Separate Analyses of Bone Mineral Content and Area

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Bone mineral density (aBMD) is equivalent to bone mineral content (BMC) divided by area. We rechecked the significance of aBMD changes in aging by examining BMC and area separately. Subjects were 1167 community-dwelling Japanese men and women, aged 40–79 years. ABMDs of femoral neck and lumbar spine were assessed by DXA twice, at 6-year intervals. The change rates of BMC and area, as well as aBMD, were calculated and described separately by the age stratum and by sex. In the femoral neck region, aBMDs were significantly decreased in all age strata by an increase in area as well as BMC loss in the same pattern in both sexes. In the lumbar spine region, aBMDs decreased until the age of 60 in women, caused by the significant BMC decrease accompanying the small area change. Very differently in men, aBMDs increased after their 50s due to BMC increase, accompanied by an area increase. Separate analyses of BMC and area change revealed that the significance of aBMD changes in aging was very divergent among sites and between sexes. This may explain in part the dissociation of aBMD change and bone strength, suggesting that we should be more cautious when interpreting the meaning of aBMD change.

1. Introduction

Bone mineral density (aBMD) decreases with age [1] and it is the most significant and widely used index for the diagnosis of osteoporosis and for considering the effects of medication in its treatment [2]. When an aBMD decrease is found, the cause is usually considered to be a decrease in bone mineral content (BMC) in the region measured. ABMD is equivalent to BMC divided by an area. Since areal BMD depends both on bone mineral content and bone dimensions, it is difficult to interpret unambiguously [3]. Dimensional changes occur in long bone by aging [4–6], the shape of the bone, and conditions like osteophytes or vertebral fracture in lumbar spine [7–9] are well known. These can affect the measuring area of DXA examinations, and naturally their results. However, a longitudinal epidemiological DXA study on aging considering the effect of the area has not been carried out on a large scale, although there have been cross-sectional studies [10–17]. This study was performed in order to reconsider the significance of aBMD change and aging in different anatomical locations, by analyzing the longitudinal changes of both components of aBMD, namely, BMC and the area, and comparing the differences in sex. A large cohort for longitudinal studies of local inhabitants was used for this study.

2. Materials and Methods

2.1. Subjects. The subjects were selected among people who participated in both the 1st and 4th waves of the National Institute for Longevity Sciences Longitudinal Study of Aging (NILS-LSA). Details of the NILS-LSA are presented elsewhere [18]. It is a biannual examination checking the physical and mental condition of ordinary Japanese people, so as to clarify the effect of aging. It is conducted by the National Center for Geriatrics and Gerontology (NCGG), in Japan. The National Institute for Longevity Sciences (NILS) is a research section of NCGG. The participants were chosen randomly from the residents of Obu city and Higashiura-cho, in Aichi prefecture, Japan. For this study, data from 1167 persons were analyzed (59.2 ± 10.9, mean ± SD). Participants were 594 men and 573 women, whose ages ranged from 40 to 79 at the time of the 1st wave. The 1st and 4th waves were from November 1997 to April 2000, and June 2004 to July 2006, respectively.

2.2. Measurements of Bone Mineral Density. Areal bone mineral densities (aBMD) were measured using Hologic QDR4500, both at the 1st and 4th wave. Only one DXA scanner was used. Data on the right femoral neck (Figure 1) and the lumbar spine (L2–4) were used for the analysis. Coefficients of variance of the DXA instrument for aBMD were 1.3% (femoral neck), 1.0% (trochanter), and 0.9% (L2,1–4) [19]. ABMD is equivalent to BMC divided by an area, so the following formula was used for the theoretical calculation: aBMD (g/cm^2) = BMC (g)/Area (cm^2). Therefore, not only aBMD values but also those of BMC and the area measured were used for the analysis in the three different regions above. The annual change rates (CR) were calculated by the following formula. CR (%) = (the values in the 4th−the values in the 1st)/the values in the 1st × 100/6. The CRs of aBMD, BMC, and the area measured were calculated and described separately by the age stratum of 40s, 50s, 60s, and 70s and by sex. All who were 40 to 49 years at baseline belonged to the 40's age stratum, and so forth. Data are presented as the mean ± SD, including those in figures. The study protocol was approved by the Committee on Ethics of Human Research of the National Institute for Longevity Sciences. Written informed consent was obtained from each subject.

2.3. Statistical Analyses. The statistical analyses were made to test for significance of change (versus no change) in each subgroup defined by age decade and sex, using paired t-tests. Also, the trend analyses according to the increase of the age stratum were made for each subgroup using a general linear model procedure. Gender difference was checked for each subgroup. All analyses were conducted using SAS Ver. 8.2 (SAS Institute, Cary, NC, USA).

3. Results

Characteristics of subjects were shown in Table 1.

The change rates (CR) from the first to fourth what were expressed as an annual rate. Mean variation between the two DXA measurements was 6 years.

3.1. Femoral Neck Region. ABMDs significantly decreased in all age strata both in women (−1.1 ± 1.1% in 40s, −1.2 ± 0.9% in 50s, −1.0 ± 0.9% in 60s, and −0.8 ± 1.1% in 70s, all $P < 0.01$) and in men (−0.4 ± 0.8% in 40s, −0.5 ± 0.7% in 50s, −0.6 ± 0.9% in 60s, and −0.6 ± 1.0% in 70s, all $P < 0.01$) (Figures 2(a) and 2(b)). These declines were caused not merely by the decrease of BMC in most of the age strata (in women, −0.7 ± 1.4% in 40s, −0.8 ± 1.2% in 50s, and −0.4 ± 1.2% in 60s, all $P < 0.01$, and in men, −0.2 ± 0.9% in 50s and −0.2 ± 1.1% in 70s, with $P < 0.01$ and $P < 0.05$, resp.), but also by the constant or significant increase of the area measured (in women, 0.4 ± 1.1% in 40s, 0.5 ± 1.1% in 50s, 0.6 ± 1.2% in 60s, and 0.5 ± 1.5% in 70s, all $P < 0.01$, and in men, 0.4 ± 0.6% in 40s, 0.3 ± 0.8% in 50s, 0.4 ± 0.8% in 60s, and in 0.4 ± 0.8% in 70s, all $P < 0.01$). This trend was the same in both sexes. The change rates (CR) of the aBMD and BMC, however, were different between women and men in their 40s, 50s, and 60s (Table 2). The CR became higher (in absolute value) only in women according to age in aBMD and BMC (P trend = 0.0126 and 0.0027, resp.). As for the CR of the area, no significant trend according to age was observed in both sexes, and no sex difference was observed (Table 2).

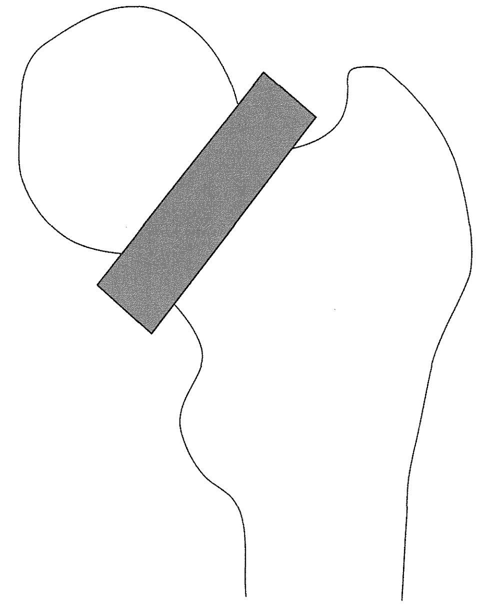
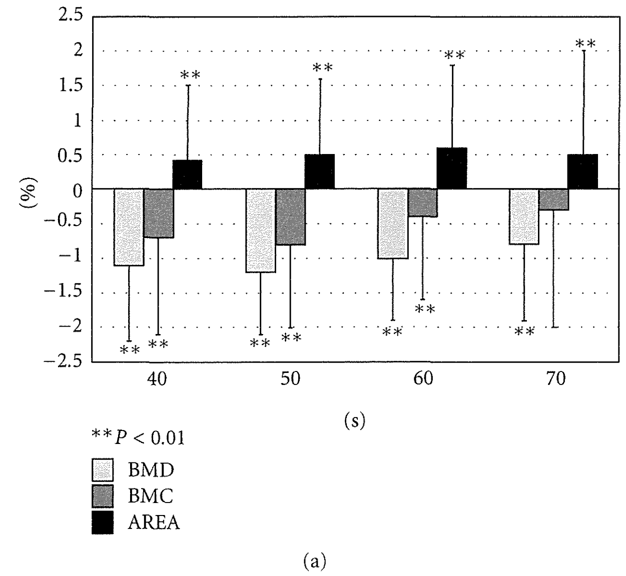


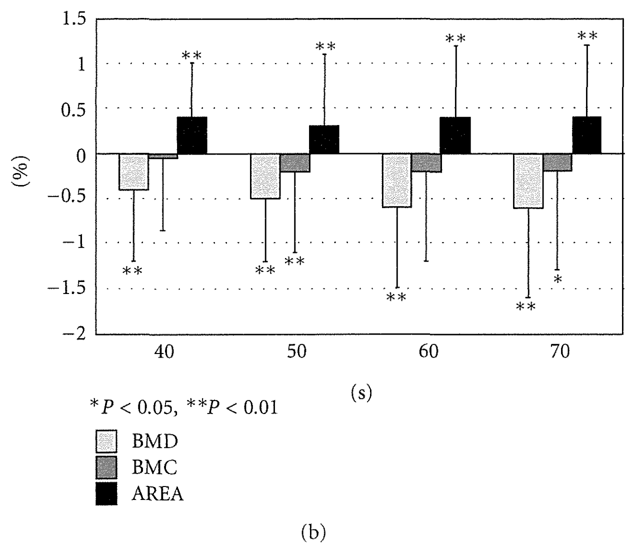
FIGURE 1: Femoral neck region of interest, derived from the Hologic QDR 4500 Operator's Manual.

3.2. Lumbar Spine Region. ABMDs significantly decreased in women in their 40s, 50s, and 60s (−1.1 ± 1.2% in 40s, −1.0 ± 0.9% in 50s, and −0.2 ± 1.1 in 60s, with $P < 0.01$, $P < 0.01$ and $P < 0.05$, resp.) (Figure 3(a)). At earlier ages, these declines were caused by a significant decrease in BMC (−1.2 ± 1.5% in 40s and −1.2 ± 1.2% in 50s, both $P < 0.01$) accompanied by a small but significant decrease in the area. After their 60s, however, no further decrease in BMC occurred, and the small but significant increase of aBMD was caused by the significant increase in the area.

The patterns of aBMD changes were much different in men. BMDs significantly increased in the 50s, 60s, and 70s (0.3 ± 0.8%, 0.5 ± 1.5%, and 0.3 ± 1.0%, all $P < 0.01$) due to



(a)



(b)

Figure 2: (a) Changes in the femoral neck region by age group in women. Results are the mean (±SD) CR of four different age strata. $^{**}P < 0.01$. (b) Changes in the femoral neck region by age group in men. Results are the mean (±SD) CR of four different age strata. $^{*}P < 0.05$, $^{**}P < 0.01$.

the significant increase of BMC (0.5 ± 1.0% in 50s, 1.0 ± 3.4% in 60s, and 0.4 ± 1.2% in 70s, all $P < 0.01$) (Figure 3(b)). The areas significantly increased in every age stratum (0.1 ± 0.5% in 40s, 0.2 ± 0.5% in 50s, 0.4 ± 1.2% in 60s, and 0.2 ± 0.6% in 70s, all $P < 0.01$). Since the increase of BMD occurred after the 50s, the rates of BMC increase surpassed those of the area. The change rates (CR) of the aBMD, BMC, and area were different between women and men in their 40s, 50s, and 60s (Table 2). And in women the CR increased according to age in aBMD, BMC, and area (P trend <0 .0001, P trend <0.0001, and P trend = 0.0115, resp.). The CR increased in men according to age in aBMD and BMC (P trend= 0.006 and P trend = 0.027, resp.), but not in area (Table 2).

Table 1: Characteristics of subjects.

	Women	Men
Age (years)	56.5 ± 9.9	57.9 ± 9.9
Height (cm)		
All	152.2 ± 5.7 (n = 573)	165.4 ± 5.9 (n = 594)
40s	154.9 ± 5.0 (n = 168)	168.7 ± 5.5 (n = 148)
50s	153.3 ± 4.8 (n = 179)	166.3 ± 5.7 (n = 183)
60s	150.4 ± 5.6 (n = 147)	164.0 ± 4.7 (n = 162)
70s	147.0 ± 5.0 (n = 79)	161.0 ± 5.2 (n = 101)
Weight (kg)		
All	53.0 ± 8.0 (n = 573)	62.8 ± 8.5 (n = 594)
40s	54.1 ± 8.0 (n = 168)	66.4 ± 8.8 (n = 148)
50s	53.7 ± 7.4 (n = 179)	63.5 ± 8.1 (n = 183)
60s	53.0 ± 8.0 (n = 147)	61.2 ± 7.8 (n = 162)
70s	49.1 ± 7.9 (n = 79)	58.8 ± 7.5 (n = 101)
BMI (kg/m^2)		
All	22.9 ± 3.2 (n = 573)	22.9 ± 2.6 (n = 594)
40s	22.5 ± 3.3 (n = 168)	23.3 ± 2.6 (n = 148)
50s	22.9 ± 3.2 (n = 179)	23.0 ± 2.5 (n = 183)
60s	23.4 ± 3.1 (n = 147)	22.8 ± 2.7 (n = 162)
70s	22.7 ± 3.1 (n = 79)	22.6 ± 2.5 (n = 101)
BMD at 1st wave		
Femoral neck (g/cm^2)	0.7 ± 0.1	0.8 ± 0.1
Trochanter (g/cm^2)	0.6 ± 0.1	0.7 ± 0.1
Lumbar spine (L2–4) (g/cm^2)	0.9 ± 0.2	1.0 ± 0.2
BMC at 1st wave		
Femoral neck (g)	3.2 ± 0.6	4.0 ± 0.7
Trochanter (g)	6.0 ± 1.3	8.7 ± 1.6
Lumbar spine (L2–4) (g)	38.1 ± 9.3	50.7 ± 10.0
Area at 1st wave		
Femoral neck (cm^2)	4.6 ± 0.3	5.3 ± 0.3
Trochanter (cm^2)	10.2 ± 1.2	12.8 ± 1.4
Lumbar spine (L2–4) (cm^2)	42.3 ± 3.9	51.3 ± 4.5

Values are mean ± SD.

4. Discussion

ABMD is equivalent to BMC divided by an area, but when we encounter cases of BMD decline, we simply consider the decline of the BMC at the measured sites without

Table 2: P trend according to age strata and P value of sex difference analyses of subgroup.

		P trend according to age strata		Sex difference analysis			
		women	men	40s	50s	60s	70s
Femoral neck	BMD	0.0126	0.1682	<0.0001	<0.0001	<0.0001	0.0982
	BMC	0.0027	0.2519	<0.0001	<0.0001	0.0298	0.7122
	Area	0.2084	0.9947	0.9436	0.0434	0.0987	0.2391
Lumbar spine	BMD	<0.0001	0.006	<0.0001	<0.0001	<0.0001	0.815
	BMC	<0.0001	0.027	<0.0001	<0.0001	<0.0001	0.4277
	Area	0.0115	0.3383	<0.0001	<0.0001	0.0052	0.0986

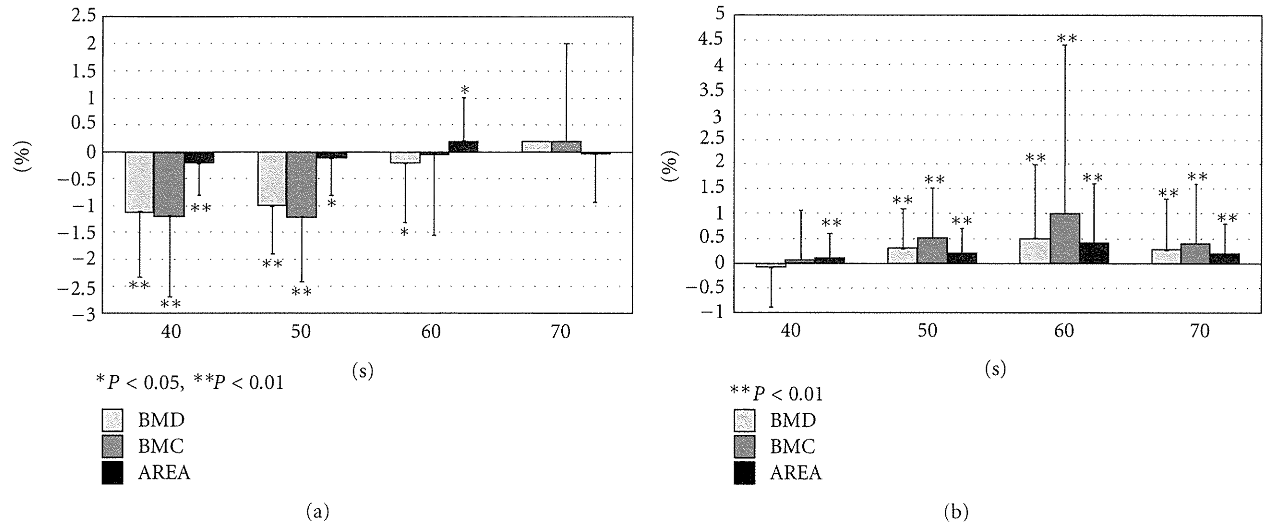


Figure 3: (a) Changes in the lumbar spine region by age group in women. Results are the mean (±SD) CR of four different age strata. $^*P < 0.05$, $^{**}P < 0.01$. (b) Changes in the lumbar spine region by age group in men. Results are the mean (±SD) CR of four different age strata. $^{**}P < 0.01$.

incorporating the change of the area (or size), which may represent the change of the shape in the region. The present study demonstrated that in the femoral neck, the aBMD decline in aging occurs not only due to the decline of BMC, but also due to the increase in the area, for both men and women. In fact, the increase of the femoral neck area represents the physiological compensating effect of the weakened bone tolerance [4, 20–23], caused by BMC decline. This may be one of the reasons for the dissociation between the strength of the bone and aBMD values. The widening (or enlargement) of the femoral neck in elderly persons has been demonstrated by the hip structure analyses of DXA [10, 13–15], by computed tomography [23–26], or utilizing both [27, 28]. The annual change rates of aBMD in our study in the femoral neck region were around −1% in women (Figure 2(a)) and 0.5% in men (Figure 2(b)). This is almost equal to the level of the large population-based cohort in Hiroshima Japan, −1.14% in women, and −0.38% in men [29]. In the lumbar spine, however, a sexual difference was observed in the changes of aBMD and those of BMC or the area as well. The increase in BMC together with the area may be explained by the osteophyte formation found to be more marked in elderly men [7, 9]. This type of change, osteophyte formation, occurs also in women but later. The significant area increase in women may derive from the osteophyte formation in advanced age. The reason for the significant decrease in the areas in women in their 40s and 50s is unclear at the moment. More detailed studies, using CT scans, are warranted to elucidate the mechanism of the sex difference in the spinal region.

From this perspective, the meaning or significance of aBMD change should be diverse depending on the sites measured and gender. Moreover, the apparent decrease of aBMD may not simply represent the weakness of that measured region (e.g., in the femoral neck), since the greater diameter can make the cylindrical structure stronger [21].

The limitation of this study is that the measurements were carried out by the ordinary DXA method without using elaborate software like hip structure analysis or CT. DXA has an inherent inaccuracy [30–32]. If body composition or weight changed during the followup, it is possible that BMD is inaccurately measured, namely, it may be over- or underestimated. Also, the size measuring by DXA was not very accurate for volumetric analysis. But our method disclosed the differences among sites and between sexes, particularly in terms of longitudinal effect, which have been little investigated.

The strength of our study is its random selection of our samples from people in the local community with very little bias in the process. NILS-LSA is one of the few major epidemiological studies investigating the aging mechanism that is designed to select subjects in a completely random manner. The results of this study should therefore reveal characteristics of the entire Japanese population.

In summary, we investigated the meaning of aBMD changes in aging through separate analyses of BMC and area change. The results revealed that the significance of aBMD changes were very divergent among the sites measured, and between sexes. This may explain the dissociation of aBMD change and bone strength, which encourages one to be more cautious when interpreting the meaning of aBMD change.

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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

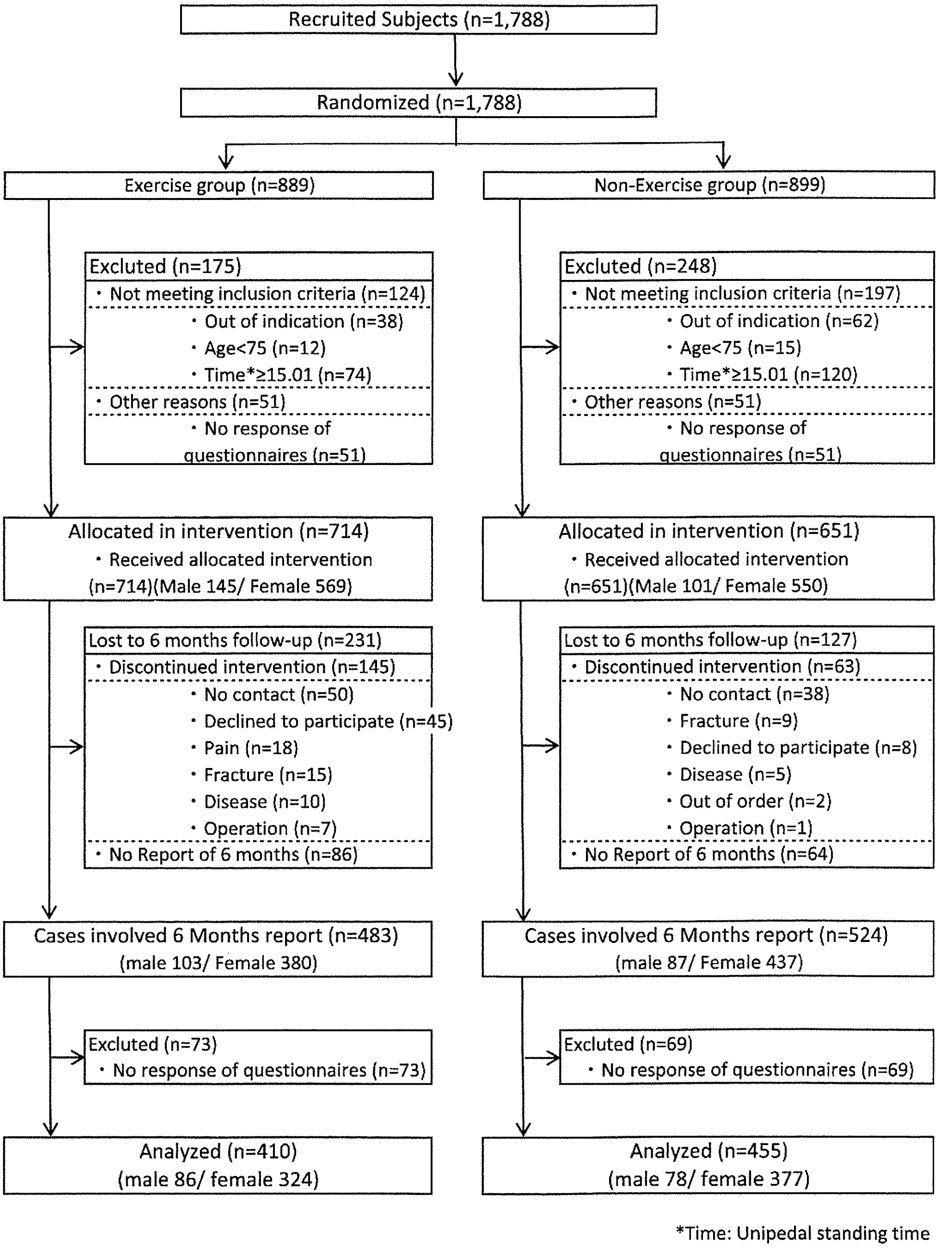

Table 1 Diagnosis of subjects at baseline survey between exercise group and non-exercise group (the first diagnosis name described on report sheet)

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.