骨折部位分布

前屈

30	6	
1	1	1

単軸

Cranial

Anterior / Posterior

7(2)	17(3)	4
2(2)	5	6(3)

Caudal

立位

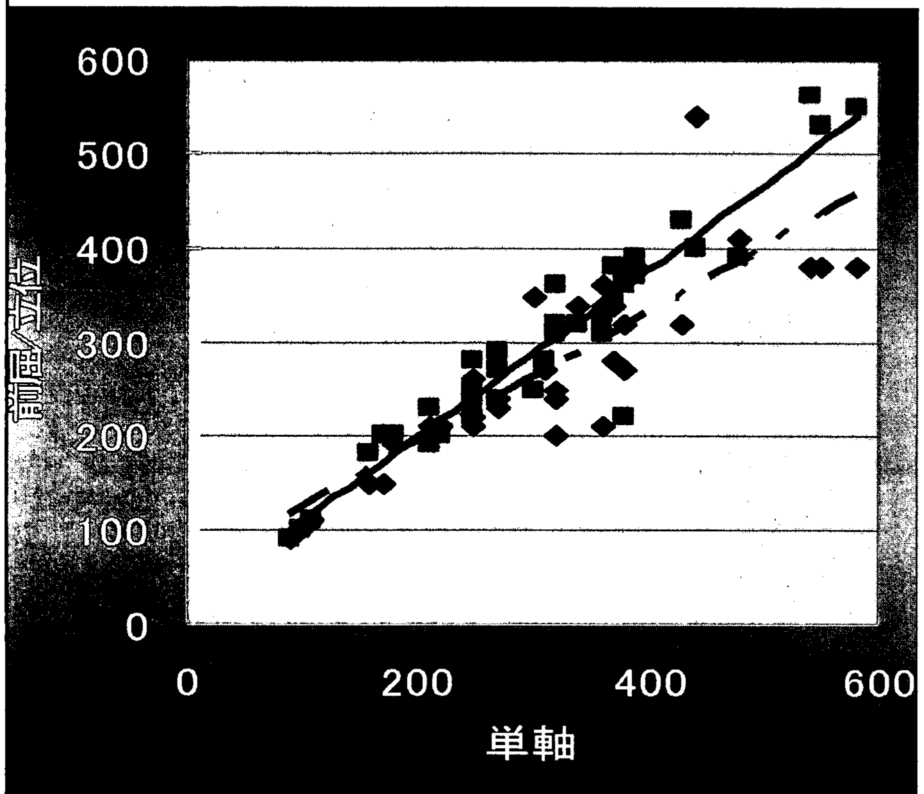
4	16(4)	7(1)
2(2)	3(2)	9(1)
		2

* () は同時に2ヶ所圧壊を起こしているため重複している症例数

骨折荷重比較

回帰直線・Friedman検定 多重比較

単軸 vs 前屈/立位



■単軸 vs 立位　$y = 0.894x + 19.338$

$R = 0.954$ ($p < 0.001$)

多重比較: P値 = 0.140

◆単軸 vs 前屈　$y = 0.6932x + 54.839$

$R = 0.853$ ($p < 0.001$)

多重比較: P値 ＜ 0.05

考察

·単軸圧縮条件は前屈・立位荷重条件と高相関

·相関係数(R):単軸圧縮 vs 立位　0.954

単軸圧縮 vs 前屈　0.853

→骨強度予測としての単軸圧縮:有用

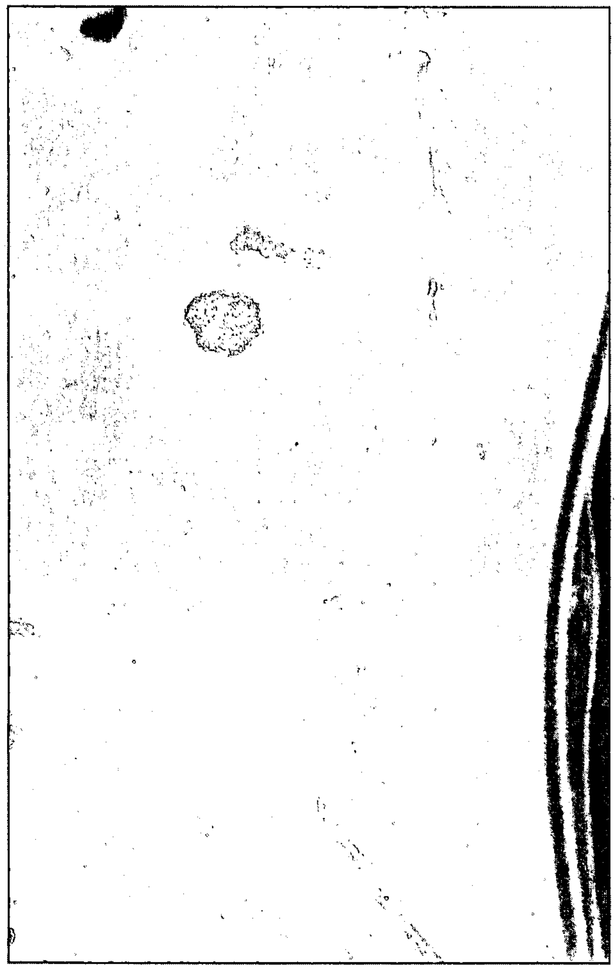
·Friedman検定 多重比較:単軸圧縮と前屈条件に有意差

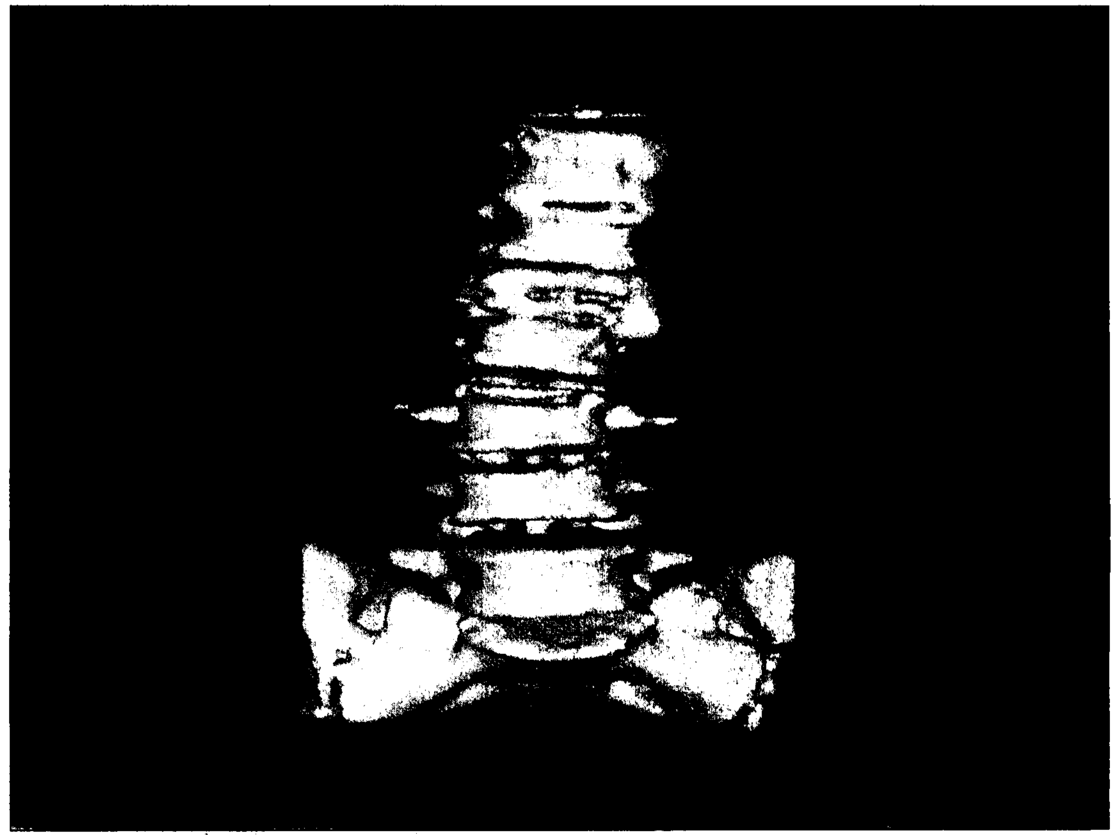
→日常生活動作リスク評価:前屈条件も必要

結語

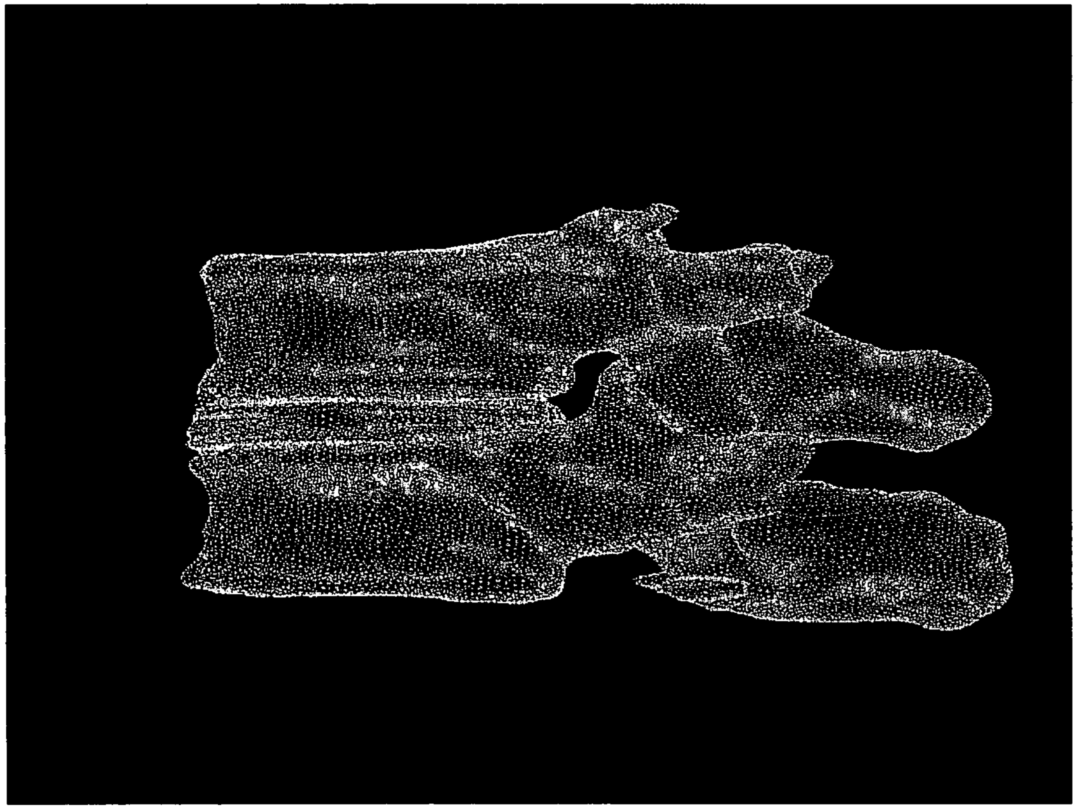
骨強度予測として単軸圧縮シミュレーションは有用だが日常生活動作リスク評価には前屈条件も考慮する必要がある

共同研究／高知医大





Spinal Unit model



椎間板、椎間関節を介在させたモデル

検討事項:

- 材料特性:
  椎間板・関節軟骨
- 荷重条件:
  椎体・椎間関節

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Original article

Diet and lifestyle associated with increased bone mineral density: cross-sectional study of Japanese elderly women at an osteoporosis outpatient clinic

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Abstract

Background. Several studies have already demonstrated that lifestyle characteristics, such as physical activity, smoking, and alcohol intake, are associated with bone mineral density (BMD). Coffee intake was shown to be negatively associated with BMD, whereas tea drinking was reported to be associated with increased BMD. A review of the literature, however, revealed that few studies have described the association between BMD and lifestyle, including characteristic Japanese foods such as fish, *natto*, and Japanese green tea. The aim of this study was to identify lifestyle factors associated with BMD.

Methods. A total of 632 women age ≥60 years were enrolled in this study. Subjects were interviewed about their lifestyle by means of a questionnaire regarding the consumption pattern of dietary items. BMD was measured at the lumbar spine by dual energy X-ray absorptiometry.

Results. The BMD was higher in subjects with the habits of alcohol drinking, green tea drinking, and physical activity and lower in those with the habits of smoking and cheese consumption. Multiple regression analysis showed that factors associated with BMD were smoking, alcohol consumption, green tea drinking, and physical activity after adjusting for age and body mass index (BMI).

Conclusions. In this cross-sectional study at an osteoporosis outpatient clinic, patients with the habits of alcohol drinking, green tea drinking, and physical activity had significantly higher BMD, and those who smoked had significantly lower BMD than patients without each habit after adjusting for age, BMI, and other variables regarding lifestyle.

Introduction

As the population ages in Japan, osteoporosis has become a serious threat to society. Hip fracture is the most severe consequence of osteoporosis, leading to reduced activities of daily living, lowered quality of life, and increased mortality of patients.[1,2] Studies have demonstrated that lifestyle characteristics such as physical activity,[3] smoking,[4] and excessive alcohol intake[5] are associated with bone mineral density (BMD). Coffee drinking was shown to be negatively associated with BMD,[6,7] whereas tea drinking was reported to be associated with increased BMD.[8] However, few studies described the association between BMD and lifestyle regarding characteristic Japanese foods such as fish, *natto*, and Japanese green tea. The aim of this study was to identify lifestyle factors associated with BMD.

Subjects and methods

A total of 632 women age ≥60 years attending the Osteoporosis Outpatient Clinic at the Tokyo Metropolitan Geriatric Medical Center were enrolled in this study. Their mean age was 71.8 ± 7.5 years. The patients and/or families were informed that data from the case would be submitted for publication and gave their consent. Women who had complications associated with BMD, such as a history of hysterectomy or ovariectomy before menopause, gastrectomy or colonectomy, thyroid disease, parathyroid disease, severe diabetes mellitus, and/or steroid and bisphosphonate usage were excluded from the study.

Upon entry into the study, body height and weight were measured, and the body mass index (BMI) was calculated. Subjects were interviewed about their lifestyle by means of a questionnaire regarding the consumption pattern of nine dietary items including milk, cheese, yogurt, fish, vegetable, tofu, *natto* (which contains a large amount of vitamin K), coffee, and green tea as well as their history of smoking and alcohol con-

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sumption and their level of physical activity. For each dietary item, subjects were divided into two groups: those consuming the food item ≥5 days per week and those consuming it <5 days per week. Subjects were categorized according to their history of smoking as nonsmokers or smokers, their history of alcohol consumption as nondrinkers or drinkers, and their level of physical activity as exercising ≥1 day a week or <1 day a week.

The BMD was measured at the lumbar spine by dual-energy X-ray absorptiometry with the Expert-5000 instrument (<1% CV; Lunar, Madison, WI, USA). Measurements were obtained from anteroposterior projections of the second to fourth lumbar vertebrae. Bone turnover markers and other serum levels such as serum osteocalcin, alkaline phosphatase, calcium (Ca), phosphorus (P), intact parathyroid hormone (iPTH), 1,25-vitamin D, and urine deoxypyridinoline were measured.

Table 1. Characteristics and the ratio of subjects with habits of each variable regarding lifestyles among 632 women aged ≥60 years

Age (years)	71.8 ± 7.5
Body height (cm)	148.5 ± 6.7
Body weight (kg)	48.7 ± 7.7
BMI (kg/m^2)	22.1 ± 3.2
BMD (g/cm^2)	0.802 ± 0.198
T score	−1.634 ± 1.633
Smoking (%)	20.6
Alcohol (%)	19.7
Milk (%)	30.9
Cheese (%)	16.8
Yogurt (%)	36.8
Fish (%)	31.0
Vegetables (%)	70.9
Tofu (%)	30.2
Natto (%)	24.2
Coffee (%)	28.3
Green tea (%)	91.8

BMI, bone mass index; BMD, bone mineral density

Table 2. Bone mineral density of lumbar spine according to lifestyle

	BMD at lumbar spine			
	Yes		No	
Lifestyle item	BMD (g/cm^2)	T score	BMD (g/cm^2)	T score
Smoking	0.772 ± 0.176**	−1.89 ± 1.45**	0.808 ± 0.194	−1.59 ± 1.60
Alcohol	0.842 ± 0.199*	−1.31 ± 1.65*	0.792 ± 0.198	−1.72 ± 1.64
Milk	0.802 ± 0.191	−1.64 ± 1.58	0.802 ± 0.207	−1.64 ± 1.71
Cheese	0.767 ± 0.209*	−1.93 ± 1.72*	0.812 ± 0.191	−1.56 ± 1.58
Yogurt	0.800 ± 0.205	−1.66 ± 1.70	0.805 ± 0.195	−1.61 ± 1.61
Fish	0.791 ± 0.192	−1.73 ± 1.59	0.809 ± 0.201	−1.58 ± 1.66
Vegetables	0.793 ± 0.191	−1.71 ± 1.58	0.818 ± 0.208	−1.50 ± 1.71
Tofu	0.799 ± 0.186	−1.66 ± 1.54	0.804 ± 0.204	−1.62 ± 1.69
Natto	0.797 ± 0.191	−1.68 ± 1.58	0.803 ± 0.201	−1.63 ± 1.66
Coffee	0.809 ± 0.199	−1.62 ± 1.64	0.805 ± 0.198	−1.58 ± 1.65
Green tea	0.807 ± 0.187*	−1.59 ± 2.70*	0.733 ± 0.182	−2.17 ± 2.08
Physical activity	0.856 ± 0.203*	−1.19 ± 1.68*	0.794 ± 0.198	−1.70 ± 1.64

Student's *t*-test was used to compare BMD between subjects with the habit and without the habit of each variable
* $P < 0.05$
** $P < 0.1$

Table 3. Lifestyles associated with BMD in women aged ≥60 years

	Coefficient of variation	SE	*P*
Age (year)	−0.002	0.001	<0.05
BMI (kg/cm^2)	0.017	0.003	<0.0001
Smoking (yes vs. no)	−0.058	0.034	<0.05
Alcohol (yes vs. no)	0.054	0.022	<0.05
Cheese (yes vs. no)	−0.032	0.024	NS
Green tea (yes vs. no)	0.064	0.033	<0.05
Physical activity (yes vs. no)	0.060	0.030	<0.05

SE, standard error
Variables were chosen according to the results of Student's *t*-test (Table 2, $P < 0.01$)
Multiple regression analysis was used to determine the lifestyles associated with BMD after adjusting for age and BMI

Table 4. Bone turnover markers according to the lifestyles associated with BMD

Marker	Smoking		Alcohol		Green tea		Physical activity	
	Yes	No	Yes	No	Yes	No	Yes	No
Osteocalcin	8.65 ± 3.71	9.08 ± 5.31	8.38 ± 3.82	9.00 ± 5.12	8.95 ± 5.09	8.86 ± 3.60	7.51 ± 2.93	9.13 ± 5.24
Alkaline phosphatase	308.0 ± 153.2*	264.5 ± 93.8	271.8 ± 90.3	268.2 ± 103.1	268.8 ± 106.6	275.1 ± 98.9	243.1 ± 79.9	273.2 ± 107.5
Deoxypyridinoline	7.11 ± 3.22	6.91 ± 3.32	6.81 ± 2.66	6.95 ± 3.36	6.89 ± 3.28	7.28 ± 2.34	5.76 ± 1.81	7.07 ± 3.38
Intact PTH	43.1 ± 35.7*	31.7 ± 22.2	32.3 ± 18.7	32.4 ± 24.7	32.0 ± 23.0	31.0 ± 16.8	26.9 ± 8.7	32.8 ± 25.1
Ca	9.65 ± 0.47	9.56 ± 0.72	9.50 ± 0.69	9.59 ± 0.71	9.58 ± 0.69	9.55 ± 0.59	9.55 ± 0.38	9.59 ± 0.69
P	3.59 ± 0.55	3.59 ± 0.49	3.56 ± 0.51	3.59 ± 0.50	3.59 ± 0.49	3.57 ± 0.45	3.63 ± 0.45	3.58 ± 0.50
1,25-Vitamin D	51.5 ± 19.2	50.7 ± 16.4	52.2 ± 18.3	50.2 ± 15.9	50.6 ± 16.3	50.4 ± 15.2	49.3 ± 15.3	50.5 ± 15.8

PTH, parathyroid hormone

Student's *t*-test was used to compare bone turnover markers between subjects with the habit and without the habit for each variable

$*P < 0.05$

Statistical analyses were performed using the statistical software package Statview 5.0 (Abacus Concepts, Berkeley, CA, USA). Student's *t*-test was used to compare the BMD and bone turnover markers between subjects with habits of each variable and those without the habit. The effects of the lifestyles associated with BMD by using Student's *t*-test ($P < 0.1$) were subsequently analyzed using multiple regression analysis after adjusting for age and BMI. Statistical significance was defined as $P < 0.05$.

Results

Table 1 shows the characteristics and lifestyles of the subjects. The BMD was higher in subjects with the habits of alcohol drinking, green tea drinking, and physical activity; it was lower in those with the habits of smoking and cheese consumption (Table 2). Table 3 shows the result of multiple regression analysis of BMD with age, BMI, and the aforementioned variables regarding lifestyle. Factors associated with BMD were age, BMI, smoking, alcohol consumption, green tea drinking, and physical activity. No significant associations were found between any serum or urinary levels and the aforementioned factors regarding lifestyle, except alkaline phosphatase and iPTH, between smokers and nonsmokers (Table 4).

Discussion

In this study, lifestyle habits such as smoking, alcohol consumption, green tea drinking, and physical activity were associated with increased BMD. According to multiple regression analysis, smoking was associated with low BMD, which agreed with findings in previous studies.[4] In contrast, alcohol consumption was associated with an increased BMD. Excessive alcohol consumption was reported to lower BMD,[5] although moderate alcohol consumption has been shown to be associated with increased BMD.[9] The amount of alcohol consumption was not examined, although it may be moderate in most alcohol drinkers. Japanese green tea was also associated with increased BMD.

To the best of the authors' knowledge, this study is the first to investigate the relation between consumption of Japanese green tea and BMD. An epidemiological case-control study suggested that Japanese green tea drinking was a factor in protecting against hip fracture.[10] The reason was unclear, although flavonoids that are contained in Japanese green tea have been shown to have a weak estrogenic effect,[11] which may increase BMD. Recent evidence suggests that (−)-epigallocatechin-3-gallate, which is one of the major flavonoids contained in green tea, induces apoptosis of osteoclasts.[12] This inhibits bone resorption, which may lead to increased BMD.

In this study, however, subjects were recruited only at one osteoporosis outpatient clinic and interviewed not about their history of green tea consumption but about the current level of their green tea consumption. Hence, this study did not indicate that green tea drinking increased BMD among a general Japanese population, but that green-tea drinkers had higher BMD than non-green-tea drinkers among subjects at one osteoporosis outpatient clinic. To clarify the effect of green tea drinking on BMD, a prospective randomized study regarding the quantity of green tea drinking and BMD among population-based cohorts is necessary.

In this study, BMD was measured at the lumbar spine. Degenerative spinal diseases are reported to be associated with increased lumbar spine BMD measurements in the elderly.[13] Lumbar spine BMD is currently the gold standard for estimating osteoporosis.

There are many kinds of Japanese green tea that may have different effects on bone metabolism, but this study was not performed on the basis of different types of green tea. However, the results of multiple regression analysis showed that the effect of green tea on BMD was independent of age, BMI, and other variables. Up to now, there have been no reports relating green tea drinking and BMD, so this is the first study to indicate the possible effect of green tea drinking on BMD.

Conclusions

This cross-sectional study was performed at an osteoporosis outpatient clinic. The results indicated that patients with the habits of alcohol drinking, green tea drinking, and physical activity had significantly higher BMD and those who were smokers had significantly lower BMD than patients without each habit after adjusting for age, BMI, and other variables regarding lifestyles.

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In Vivo Assessment of Lumbar Vertebral Strength in Elderly Women Using Computed Tomography-Based Nonlinear Finite Element Model

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and Kozo Nakamura, MD, PhD*

Study Design. *In vivo* study of a computed tomography (CT)-based nonlinear finite element model (FEM).

Objective. To establish an FEM with the optimum element size to assess the vertebral strength by comparing analyzed data with those obtained from mechanical testing *in vitro,* and then to assess the second lumbar (L2) vertebral strength *in vivo.*

Summary of Background Data. FEM has been reported to predict vertebral strength *in vitro,* but has not been used clinically.

Methods. Comparison among the 3 models with a different element size of 1 mm, 2 mm, and 3 mm was performed to determine which model achieved the most accurate prediction. Vertebral strength was assessed in 78 elderly Japanese women using an FEM with the optimum element size.

Results. The optimum element size was 2 mm. The L2 vertebral strength obtained with the FEM was 2154 ± 685 N, and the model could detect preexisting vertebral fracture better than measurement of bone mineral density.

Conclusion. The FEM could assess vertebral strength *in vivo.*

Key words: vertebral strength, osteoporosis, finite element model, elderly women, *in vivo* assessment. **Spine 2008;33:27–32**

Osteoporotic vertebral fractures have become a major social problem because the elderly population continues to increase. Vertebral fractures affect approximately 25% of postmenopausal women.[1] Measurement of the bone mineral density (BMD) by quantitative computed tomography (QCT) and dual energy radiograph absorptiometry (DXA) have been used to predict the risk of vertebral fracture. However, the correlation between vertebral bone strength and BMD measured by QCT is reported to be only 0.37 to 0.74,[2–7] while the correlation achieved with DXA is reported to be 0.51 to 0.80.[5–9] Therefore, such methods only explain 37% to 80% of vertebral strength. Bone strength primarily reflects the bone density and bone quality, which are influenced by bone architecture, turnover, accumulation of damage, and mineralization.[10]

It has been reported that a CT-based nonlinear finite element model (FEM) could predict vertebral strength and fracture sites accurately *in vitro.*[11] To predict quantitative strength and fracture sites is essential for the clinical application of an FEM because both parameters are important indicators of vertebral fracture risk. Prediction by an FEM with a smaller element size using the data from computed tomography (CT) scans with a thinner slice thickness and a smaller pixel size is thought to be more accurate. On the other hand, thinner CT slices lead to more radiation exposure in the clinical situation. To decrease radiation exposure as much as possible during CT scanning, optimization of the element size of the FEM was performed by assessing the accuracy of the FEM simulation.

The purposes of this study were to establish a CT-based nonlinear FEM with the optimum element size to predict the vertebral fracture load by evaluating the accuracy of our model from a comparison between predictions and data obtained by mechanical testing of human cadaver specimens *in vitro*, and then to assess lumbar vertebral strength in elderly women using the optimized CT-based nonlinear FEM.

Materials and Methods

Optimization of the Element Size of the FEM. This study used CT data and mechanical testing data obtained previously.[11] Twelve thoracolumbar vertebrae (T11, T12, and L1) with no skeletal pathology were collected within 24 hours of death from 4 men (31, 55, 67, and 83 years old). The vertebrae were disarticulated, and the discs were excised. Then the posterior element of each vertebra was removed by cutting through the pedicles. The vertebrae were immersed in water and axial CT scans with a slice thickness of 1 mm and a pixel width of 0.351 mm were obtained using a Lemage SX/E (GE Yokokawa Medical System, Tokyo, Japan) with a calibration phantom containing hydroxyapatite rods.

The 3-dimensional FEM was constructed from CT data using Mechanical Finder software (Mitsubishi Space Software Co., Tokyo, Japan). Three models with a different element size were created for each vertebra using 1 mm, 2 mm, or 3 mm tetrahedral elements. To the outer surface of the tetrahedral elements, triangular plates were attached as to form a cortical

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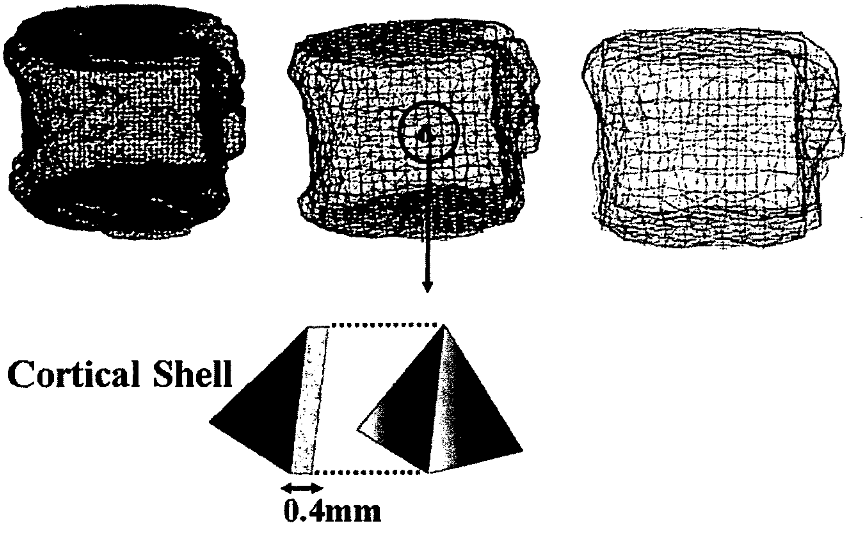

Figure 1. Finite element models of a whole vertebral body constructed with 1 mm, 2 mm, or 3 mm tetrahedral elements. The cortical shell was modeled by using triangular plates with a thickness of 0.4 mm. The model on the left consists of 104,205 nodes with 585,784 tetrahedral elements and 15,800 triangular plates constructed using 1-mm size elements. The middle model consists of 12,938 nodes with 70,022 tetrahedral elements and 3586 triangular plates constructed using 2-mm elements. The model on the right consists of 3476 nodes with 18,103 tetrahedral elements and 1330 triangular plates constructed using 3-mm size elements.

shell (Figure 1). The thickness of this shell was set as 0.4 mm based on the previous papers.[12–14]

To allow for bone heterogeneity, the mechanical properties of each element were computed from the Hounsfield unit value. Ash density of each voxel was determined from the linear regression equation created by these values of the calibration phantom. Ash density of each element was set as the average ash density of the voxels contained in one element. Young's modulus and the yield stress of each tetrahedral element were calculated from the equations proposed by Keyak *et al.*[15] Young's modulus of each triangular plate was set as 10 GPa and Poisson's ratio of each element was set as 0.4.

A uniaxial compressive load with a uniform distribution was applied on the upper surface of the vertebra and all the elements and all the nodes of the lower surface were completely restrained. Each model was analyzed using Mechanical Finder software as reported previously.[11]

A nonlinear FEM by Newton-Raphson method was used. To allow for the nonlinear phase, mechanical properties of the elements were assumed to be bilinear elastoplastic, and the isotropic hardening modulus was set as 0.05. Each element was assumed to yield when its Drucker-Prager equivalent stress reached the element yield stress. In the postyield phase, failure was defined as occurring when the minimum principal strain of an element was less than −10,000 microstrain.

The predicted fracture load was defined as the load that caused at least one element failure, while the measured fracture load was defined as the ultimate load that was achieved by mechanical testing. Pearson's correlation analysis was used to evaluate correlations between the fracture load predicted by FEM simulation and the measured fracture load. To optimize the element size of the FEM, the accuracy of prediction of the fracture load was compared among the 3 models with different element sizes. To assess the relationship between the models with a different element size, linear regression analyses were performed.

In addition, we also created models using 1.4 mm and 4.5 mm elements as well as 1 mm, 2 mm, and 3 mm elements to investigate the model convergence. For each of the models, total strain energy was calculated at a load of 1000 N, under which all specimens were in the elastic phase. Data on the total strain energy were compared among the 1 mm (average 403,033 tetrahedral elements), 1.4 mm (average 143,367 tetrahedral elements), 2 mm (average 47,687 tetrahedral elements), 3 mm (average 11,903 tetrahedral elements), and 4.5 mm (average 2719 tetrahedral elements) models.

In Vivo Assessment of Lumbar Vertebral Strength. The subjects were ambulatory postmenopausal Japanese women aged 60 to 85 years. Excluded from participation were women with disorders of bone and mineral metabolism other than postmenopausal osteoporosis, those who had any recent or current treatment with the potential to alter bone turnover or bone metabolism, and those with a history of second lumbar vertebral (L2) fracture. The study protocol was approved by our ethics committee and each participant provided written informed consent. A total of 78 eligible participants were enrolled in this study.

In all the participants, the BMD (g/cm^2) of the lumbar spine (L2–L4) was measured by DXA (DPX; Lunar, Madison, WI) in the supine position and axial CT scans of L2 were obtained with a slice thickness of 2 mm and pixel width of 0.35 mm using Light Speed QX/i (GE Yokokawa Medical System, Tokyo, Japan) with a calibration phantom containing hydroxyapatite rods. The 3-dimensional FEM was constructed from the CT data using Mechanical Finder with 2 mm tetrahedral elements and 2 mm triangular plates, and the fracture load was analyzed using this software as described above.

Results are expressed as the mean ± standard deviation (SD). Statistical analysis was performed with the Mann-Whitney *U* test and the Kruskal-Wallis test. Differences were considered significant at $P < 0.05$.

■ Results

Optimization of the FEM Element Size

There was a strong linear correlation between the fracture load predicted by the FEM with 1 mm tetrahedral elements and the measured loads ($r = 0.938$, $P < 0.0001$), and the slope of the regression line was 0.934 (Figure 2A). With 2 mm elements, the correlation was even stronger ($r = 0.978$, $P < 0.0001$), and the slope of the regression line was 0.881 (Figure 2B). With 3 mm elements, the correlation was slightly weaker ($r = 0.866$, $P < 0.0001$), and the slope of the regression line was

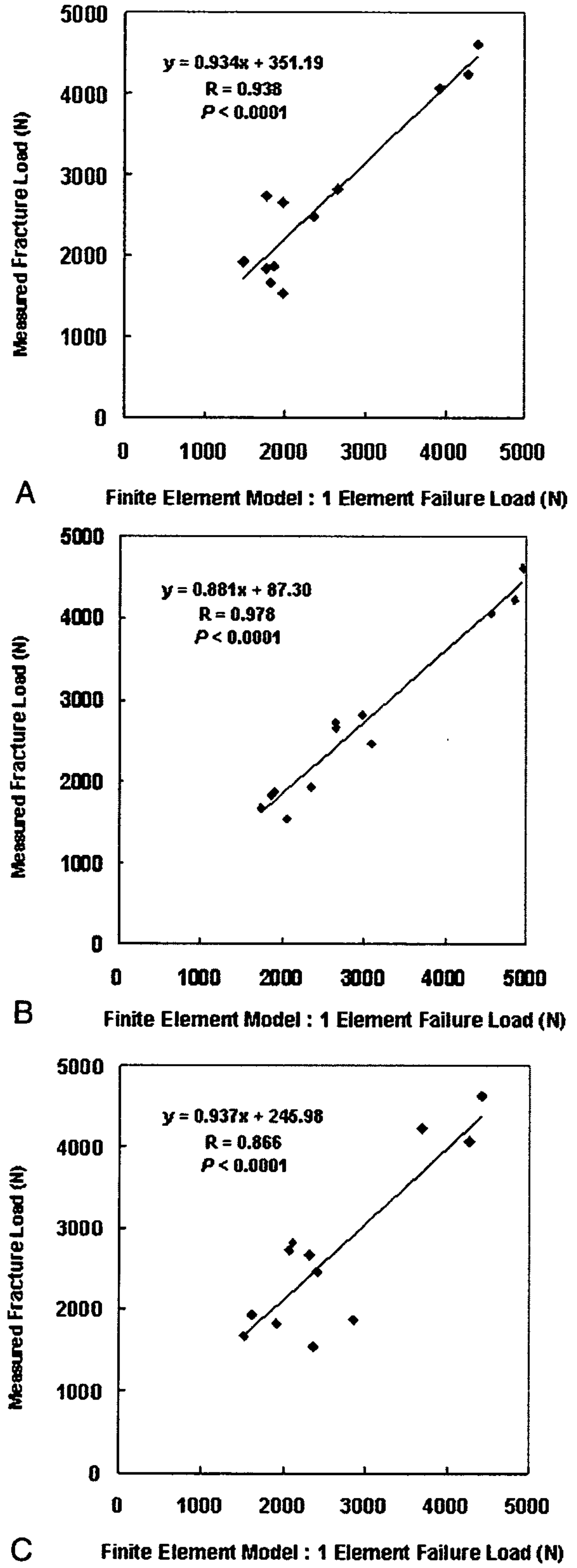

Figure 2. The measured fracture load *versus* the fracture load predicted by the finite element model (FEM). **A**, FEM with-1 mm tetrahedral elements. **B**, FEM with-2 mm tetrahedral elements. **C**, FEM with 3-mm tetrahedral elements. Strong correlations ($r > 0.90$) were obtained with elements of 1 mm and 2 mm in size, while a moderate correlation ($r = 0.866$) was obtained with 3-mm elements.

0.937 (Figure 2C). There was a strong linear correlation between the fracture load predicted by the 1 mm element model and that by the 2 mm ($r = 0.959$, $P < 0.0001$), and the slope of the regression line was 0.868. With the 1 mm and 3 mm models, the correlation was slightly weaker ($r = 0.912$, $P < 0.0001$), and the slope of the regression line was 0.839. With the 2 mm and 3 mm models, the correlation was much weaker ($r = 0.878$, $P < 0.0001$), and the slope of the regression line was 0.730.

In the convergence study, total strain energy decreased by 9.1% (4.0%–22.9%), with an increase of the element size from 1 mm to 1.4 mm. With an increase from 1.4 mm to 2 mm, it decreased by 10.0% (6.5%–17.3%), and decreased by 9.5% (2.9%–13.2%) from 2 mm to 3 mm. With an increase from 3 mm to 4.5 mm, total strain energy increased in some vertebrae although it decreased by an average of 38.6%.

In Vivo *Assessment of Lumbar Vertebral Strength*

The 78 women enrolled in the study had a mean age of 74.4 ± 5.6 years, a mean height of 148.4 ± 6.0 cm, and a mean weight of 50.3 ± 7.7 kg. The measured BMD of the lumbar spine was 0.808 ± 0.181 g/cm^2 and the strength of L2 predicted by the model was 2154 ± 685 N.

The subjects were classified into 5-year age groups, as summarized in Table 1. Height and vertebral strength showed a significant decrease in the older age groups, but weight and BMD did not change significantly (Kruskal-Wallis test, $P < 0.05$).

Next, the subjects were classified on the basis of prior vertebral fracture. Among the 78 women, 42 did not have any vertebral fractures (nonfracture group) and 36 subjects already had vertebral fractures (fracture group). Thus, vertebral fractures were present in 46.1% of the total study population. The characteristics of the 2 groups are summarized in Table 2. The nonfracture group was significantly younger than the fracture group (Mann-Whitney U test, $P < 0.001$). Height ($P < 0.05$) and weight ($P < 0.005$) were significantly greater in the nonfracture group than in the fracture group.

The average spinal BMD of the nonfracture group was 0.849 ± 0.146 g/cm^2, which was greater than that of the fracture group at 0.759 ± 0.207 g/cm^2 ($P < 0.05$) (Figure 3). The predicted vertebral strength of L2 was 2489 ± 580 N in the nonfracture group, which was greater than in the fracture group at 1764 ± 588 N ($P < 0.0001$) (Figure 3). The L2 strength to weight ratio was 4.80 ± 1.20 in the nonfracture group, and this was significantly greater than in the fracture group at 3.77 ± 1.36 ($P < 0.005$) (Figure 4).

■ Discussion

Assessing vertebral strength by using the FEM has been difficult because of the complex geometry, elastoplasticity, and thin cortical shell of the vertebra. The vertebrae have an elaborate architecture and geometry with curved surfaces, which cannot be modeled properly by using

Table 1. Summary of the Subjects' Height, Weight, BMD, and Analyzed Vertebral Strength (Mean ± SD)

Age (yr)	N	Height (cm)	Weight (kg)	BMD (g/cm^2)	Vertebral Strength (N)
60–64	6	153.5 ± 4.5	54.0 ± 6.1	0.850 ± 0.180	2592 ± 497
65–69	10	152.3 ± 7.8	50.9 ± 8.2	0.848 ± 0.112	2665 ± 528
70–74	21	148.1 ± 5.0	51.3 ± 7.4	0.744 ± 0.169	2050 ± 752
75–79	26	147.8 ± 6.2	48.5 ± 8.7	0.800 ± 0.200	2069 ± 706
80–85	15	145.1 ± 3.8	50.3 ± 6.3	0.867 ± 0.191	1933 ± 512

8-noded hexahedral elements. Previous mechanical tests have shown that there is a difference between the tensile and compressive strength of bone,[16–18] with compressive strength showing nonlinear behavior. Therefore, a nonlinear FEM should be used to predict the clinical fracture load. The cortical shell of each vertebra is estimated to have a thickness of approximately 0.4 mm.[12–14] In comparison, the resolution of clinically available CT scanners is fairly low, with a pixel spacing of larger than 0.25 mm. This means that the currently available CT data do not allow the thin cortical shell to be precisely modeled. The cortical thickness tends to be overestimated and its density is underestimated.[19,20] Therefore, it is necessary to construct a thinner model cortical shell from non-CT data. Shell elements of triangular plates with a uniform thickness of 0.4 mm were used to construct a cortical shell.

The characteristics of the present FEM in this study were as follows: adoption of the tetrahedral elements to model the surface curvature of the entire vertebra, utilization of nonlinear analysis to match the elastoplasticity of the vertebra during compression, and construction of a cortical shell as the surface of the model. It has been reported that the thin cortex of a vertebra contributes 12%–75% to its overall strength and the contribution of the cortex is estimated to be significantly larger in osteoporotic individuals.[21,22] Thus, the importance of the strength of the cortical shell should be taken into consideration when predicting the fracture load for osteoporosis patients.

The limitation of our model is that the cortical shell was treated as a homogenous material because the pixels of CT scans were too large to model the thin cortex. In addition, with the limited resolution of currently available CT scanners, the microarchitecture of the bone cannot be precisely assessed. Micro-CT and synchrotron micro-CT can visualize bone microstructure.[23] Therefore, an FEM based on micro-CT data may show more accurate simulation because it would be possible to model a cortical shell with heterogeneous properties and also to assess the microarchitecture. However, obtaining micro-CT scans of a whole vertebra *in vivo* would be impossible with the currently available scanners. Also, use of thinner CT slices to obtain images leads to more radiation exposure. To decrease radiation exposure for clinical use, somewhat thicker slices would be more appropriate.

Table 2. Background of the Subjects in No Fracture Group and Fracture Group

Group	N	Age (yr)	Height (cm)	Weight (kg)
No fracture group	42	72.3 ± 5.7	149.9 ± 5.7	52.6 ± 7.4
Fracture group	36	76.8 ± 4.6	146.6 ± 6.0	47.8 ± 7.3

We assessed 3 models each with a different element size of 1 mm, 2 mm, and 3 mm. With an element size of 1 mm and 2 mm, the correlation between the fracture load predicted by the FEM and that measured experimentally was very strong ($r > 0.90$). With an element size of 3 mm, the correlation was slightly weaker ($r < 0.90$). Although all of 3 FEM were generated using CT data obtained with a 1 mm slice thickness, these results suggested that the elements with a size of 1 mm or 2 mm could be used to accurately predict the fracture load. There was a stronger correlation ($r = 0.978$) with 2 mm tetrahedral elements than with either 1 mm or 3 mm elements. The correlation of the fracture load between the prediction and the experiment was better than that in the previous FEM studies ($r = 0.89–0.95$).[24–27] The slope of the regression line obtained with 2 mm tetrahedral elements was 0.881, which was also better than that in the previous FEM studies (0.569–0.86).[24–27] The previous FEM studies had failed to model the surface curvature of the vertebra, match the elastoplasticity of the vertebra, or model a cortical shell. These results indicated that our FEM predicted compressive vertebral strength more accurately.

The correlation between the fracture load with 1 mm and 2 mm elements ($r = 0.959$) was stronger than both of the correlations between 1 mm and 3 mm ($r = 0.912$), and between 2 mm and 3 mm ($r = 0.878$). The slope of the regression line relating 1 mm and 2 mm (0.868) was also better than that relating 1 mm and 3 mm (0.839), and that relating 2 mm and 3 mm (0.730). These results indicated that the prediction by the FEM with the 1 mm and 2 mm elements achieved more accurate result than the 3 mm elements.

The results obtained by the convergence study with the 1 mm, 1.4 mm, 2 mm, 3 mm, and 4.5 mm models suggested the model with 1 mm elements was the most accurate among the 5 models. However, the 2 mm model was thought to achieve sufficiently accurate prediction compared with the 1 mm model. In the previous FEM study using the models with 8-noded hexahedral elements, stiffness of the model with $3 \times 3 \times 3$ mm^3 elements was on average only 4% greater than that with

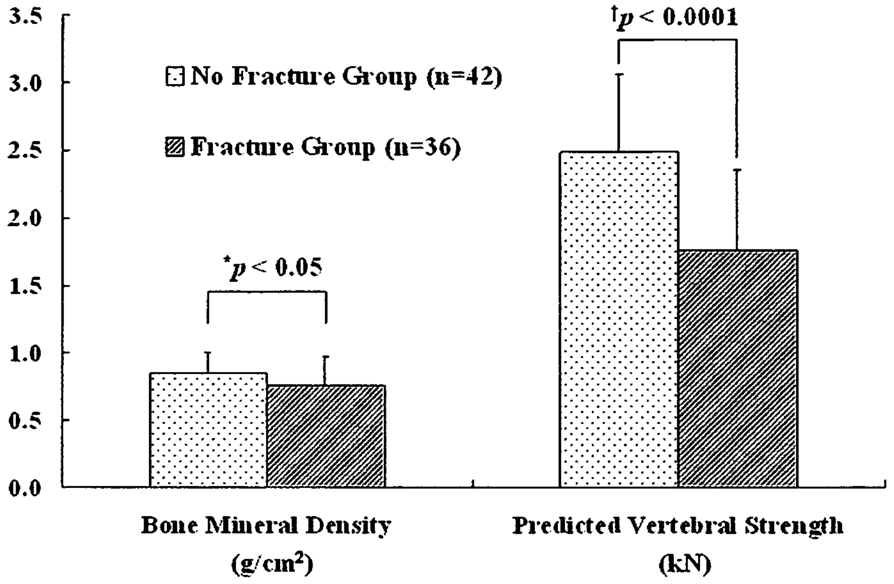

Figure 3. Bone mineral density of the lumbar spine (L2–L4) and predicted vertebral strength of the L2 vertebra in the nonfracture group (n = 42) and in the fracture group (n = 36). The error bars represent one standard deviation from the mean. Bone mineral density of the nonfracture group was greater than that of the fracture group. The difference was significant ($P < 0.05$). Predicted vertebral strength in the nonfracture group was also significantly ($P < 0.0001$) greater than that of the fracture group.

$1 \times 1 \times 1.5$ mm^3 elements, and there was a high correlation between the stiffness and the experimentally measured ultimate strength values in both $3 \times 3 \times 3$ mm^3 element model ($r^2 = 0.94$) and $1 \times 1 \times 1.5$ mm^3 element model ($r^2 = 0.92$).[28]

Based on these *in vitro* data, an *in vivo* study was performed using CT scans with a 2-mm slice thickness and a nonlinear FEM with an element size of 2 mm. There have been few reports about predicting vertebral strength *in vivo*, although some authors have assessed vertebral strength *in vitro* by mechanical testing. In the elderly, McBroom *et al* reported that among 10 specimens from subjects with an average age of 78 years, the average failure load for the L1 vertebral body was 3160 ± 424 N and it was 3385 ± 485 N for L3.[3] Eckstein *et al* reported that the average failure load for L3 was 3016 ± 149 N when they tested 102 specimens from the subjects with an average age of 80.6 years.[29] These 2 reports included both men and women. In the present study, however, all of the subjects were Japanese women. This might be one of the reasons why our predicted vertebral strength was smaller than that reported elsewhere.

The limitation in our study was that the prediction was made under a uniaxial compressive loading condition. In an *in vivo* situation, the loading and boundary conditions are completely different. However, one of the advantages of FEM simulation is that it allows us to set an arbitrary load magnitude or direction to simulate loading in various activities of daily living. If predicted strength by FEM was proved to be accurate in a uniaxial compressive loading condition, we could assume that we might be able to apply this method to predict accurately the strength under various other loading and boundary conditions. Nevertheless, the accuracy of our method in predicting strength under different loading and boundary conditions should be validated by conducting another mechanical testing and it would be one of our assignments in the future study.

In this study, the vertebral strength predicted by FEM could detect preexisting vertebral fractures better than

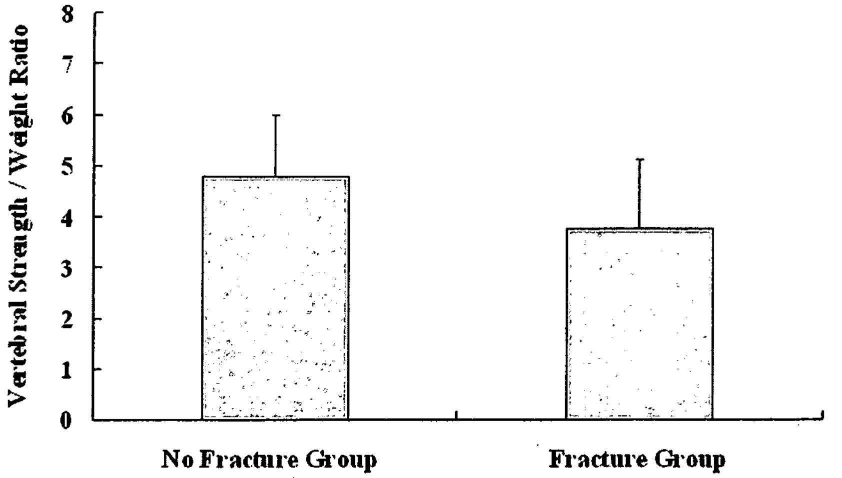

Figure 4. The ratio of L2 vertebral strength to weight in the nonfracture group (n = 42) and in the fracture group (n = 36). The difference was also significant ($P < 0.005$).

BMD. CT-based FEM assesses bone geometry and heterogeneous bone mass distribution as well as the BMD. It is hoped that CT-based FEM will become useful for estimating the risk of vertebral fracture in osteoporotic individuals.

Key Points

- *In vivo* assessment of lumbar vertebral strength in elderly Japanese women was performed using a CT-based nonlinear finite element model that was established and initially evaluated *in vitro*.
- The average L2 vertebral strength of the 78 subjects was 2154 ± 685 N according to this model.
- The present FEM could detect preexisting vertebral fracture more accurately than measurement of the bone mineral density.

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高齢者の腰痛症に係る効果的な診断、治療、リハビリテーション等の確立

分担研究報告書

高齢者の腰痛症に係る効果的な診断、治療、リハビリテーション等の確立に関する研究

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研究要旨：我々は、前向き derivation study を行い、腰部脊柱管狭窄を診断するための自記式問診票を作成し報告してきた。今回は、腰部脊柱管狭窄を診断するための精度のさらに高い自記式診断サポートツールを開発を行ったので、報告する。

A. 研究目的

高齢化社会に伴い腰部脊柱管狭窄の症例は増加しており、高齢者の QOL を制限する最も多い原因の一つと考えられる。しかし、いまだにその診断基準すら存在していない。我々は、前向き derivation study を行い、腰部脊柱管狭窄を診断するための自記式問診票を作成し報告してきた。本研究の目的は、腰部脊柱管狭窄を診断するための精度のさらに高い自記式診断サポートツールを開発することである。

B. 研究方法

東北6県の54施設の腰痛または下肢症状を有する患者で、解析が可能であった 345 例を検討の対象とした。対象疾患の内訳は腰椎椎間板ヘルニア 122 例、腰部脊柱管狭窄 109 例、閉塞性動脈硬化症 34 例、糖尿病性神経障害 27 例、その他 53 例であった。以上の症例に対し、15 項目からなる質問表を患者に配付した。各質問項目の単変量解析を行って、Odds 比から臨床上重要な質問項目を選択した。選択した因子に対し Logistic 解析による多変量解析を行い、β相関係数から各因子の重み付けを行った。最後にカットオフ値、感度、特異度、陽性尤度比、および陰性尤度比を求めた。

倫理面での配慮

本研究は、福島県立医科大学医学部倫理委員会の承認を得て行った。対象者に対してプロトコールを開示し、医師がその目的や危険について説明を行い、同意を得たうえで行った。

C. 研究結果

多変量解析を行い、各因子のβ相関係数を算出した。β相関係数で 0.5 以上あるいは -0.5 以下の 10 因子を clinical prediction rule として選出した。β相関係数から、診断に重要な因子の重み付けを行った。その結果、以下の clinical prediction rule が得られた。1.

しびれや痛みはしばらく歩くと強くなり、休むと楽になる。2. しばらく立っているだけで、太ももからふくらはぎやすねにかけてしびれたり痛くなる。3. 年齢(60 歳以上)。4. 両あしの裏側にしびれがある。5. おしりのまわりにしびれがでる。6. しびれや痛みはあしの両側(左右)にある。7. 前かがみになると、しびれや痛みは楽になる。8. しびれはあるが痛みはない。9. しびれや痛みで、腰を前に曲げるのがつらい。10. しびれや痛みで、靴下をはくのがつらい。カットオフ値と感度、特異度、陽性尤度比、および陰性尤度比の関係から、カットオフ値を 13 点と決定した。感度は 92.7%、特異度 84.7%、陽性尤度比 6.074、陰性尤度比 0.087 であった。すなわち、本ツールは、疾患のスクリーニングのみならず除外診断にも有用であるといえる。腰部脊柱管狭窄の識別力を示す ROC 曲線を示した。ROC 曲線下面積は 0.928 であり、疾患の識別力が充分高いといえる。

D. 考察

腰部脊柱管狭窄を診断するための精度の高い自記式診断サポートツールを開発した。今後、さらに外的妥当性の検討を行い、信頼性を評価する必要がある。本サポートツールを用いることにより、腰部脊柱管狭窄の大規模な疫学調査や患者の自己診断による早期治療ができるようになる可能性がある。

E. 結論

腰部脊柱管狭窄を診断するための精度の高い自記式診断サポートツールを開発した。

F. 研究業績

1. 論文発表

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2. 学会発表

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2) 紺野慎一，菊地臣一，国分正一，田中靖久，島田洋一，嶋村　正，山崎　建，横山　徹，武井　寛：腰部脊柱管狭窄の診断-自記式問診票の開発-. 第 80 回日本整形外科学会学術総会　一般演題　5 月　神戸

G. 知的財産権の出願・登録状況

予定していない。

研究の背景

- Clinical prediction rule
  - EBMの実践のための道具
  - エビデンスを臨床現場でより生かしやすい形にして使用するのが目的

腰部脊柱管狭窄診断サポートツール

当てはまる項目をチェックし、チェックした()内の数字の合計点を求めて下さい。ただし、アンダーラインの項目の数字は点数がマイナスですので注意して下さい。

病歴

年齢	□ 60 才 未満 (0)	
	□ 60～70 才 (1)	
1. 71 以上 (2)		
糖尿病の既往	□ あり (0)	□ なし (1)

問診

間欠跛行	□ あり (3)	□ なし (0)
立位で下肢症状悪化	□ あり (2)	□ なし (0)
前屈で下肢症状が軽快	□ あり (3)	□ なし (0)

身体所見

前屈による下肢症状出現	□ <u>あり(-1)</u>	□ なし (0)
後屈による下肢症状出現	□ あり (1)	□ なし (0)
ABI *0.9	□ 以上 (3)	□ 未満 (0)
ATR** 低下・消失 □ あり (1)	□ 正常 (0)	
SLR*** テスト	□ <u>陽性(-2)</u>	□ 陰性 (0)

合計点　　点

*ABI (Ankle brachial pressure index)

**ATR (Achilles tendon reflex) アキレス腱反射

***SLR (Straight Leg Raising)

Konno S. Eur Spine J. 2007:1951-7

7点以上の場合は、腰部脊柱管狭窄である可能性が高いといえます。専門医へ紹介し、診断を確定してください。