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*Original article*

# Effect of special insole fitting on walking exercise: An open-label study.

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## Abstract

***Objective***: The aim of this study was to evaluate the effects of walking movements exerted while wearing insoles produced experimentally which simulate the characteristics of walking on a sandy beach. The examinations were conducted, comparing between groups who walked with and without insoles.

***Methods***: Research participants were 12 healthy females with a shoe size between 22.5 and 23.5 cm (age: 29.9 ± 3.3 years, BMI: 19.2 ± 2.6). A treadmill walking examination was conducted for the groups without specially processed insoles, and then after a washout period (1 week), an examination using the test insoles was conducted. Blood tests were performed before and after walking.

***Results***: Data results showed an increase in serum levels of growth hormones. However, differences in the hormones between the absence or presence of the insoles were not observed. There were no significant changes in cortisol, Triglyceride (TG), Plasma glucose (PG) and Immunoreactive insulin (IRI). Insole equipment enabled the prevention of a shoe blister.

***Conclusion***: Considering the effects of the test insoles in an electromyography from a prior examination recognized an increase in muscle force generation, this study suggested a possibility that this test product had scarce adverse events, and load training effects of the insoles on the lower thigh muscles were expected.

***KEY WORDS***: insole, walking, growth hormone, electromyography (EMG), coast walking

## Introduction

Lifestyle-related diseases with considerable glycative stress have been increasing recently in many countries, including Japan, such as visceral fat obesity, diabetes mellitus, metabolic syndrome and hyperlipidemia. Therapeutic exercises play an essential role as countermeasures against glycative stress. Among the exercises, walking is the most familiar physical activity. Ambulation extends beneficial effects not only to control glycative stress on the prediction and prevention of onset and the progression of diabetes mellitus but also to influence motor and neurological functions [1-6]. We hypothesized that focusing on footwear would recreate the remarkable effect of walking with the characteristics or images of a sandy beach; footwear must feel comfortable to wear and at the same time provide large loads on muscles. Based on this concept, we have developed a prototype of specially processed insoles fitting foot-shape and enabled a sole of foot to sink deeper while stepping or treading. A comparative examination was conducted to evaluate the physical effects of a 30-minute walking exercise with and without the specially produced insoles, focusing on the secretion of growth hormone (GH) as an indicator.

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## Methods

### Research participants

An open-label study was conducted to evaluate the physical effects of the specially produced insoles in walking with 12 healthy female research participants who belonged to or were related to the Urata Clinic or S-QOL Kanazawa and who were between the ages of 25 and 40 years with a shoe size between 22.5 and 23.5 cm.

After this study was approved by the Doshisha University Ethics Review Committee on Research involving Human Subjects, an information session for the research was conducted at Urata Clinic and S-QOL Kanazawa (Kanazawa City, Ishikawa Prefecture, Japan). Research participants were 12 individuals who agreed to participate in this study with a written consent and who did not meet the following exclusion criteria.

[1] Individuals with a chronic disease currently receiving drug treatment
[2] Individuals with a serious past medical history and/or present illness
[3] Individuals with serious anemia
[4] Individuals who are or may be pregnant
[5] Individuals with a disease currently receiving drug treatment

One subject who had participated in this trial was eliminated from analysis in the clinical conference after the completion of the research. The analysis target was 11 subjects (age: 29.9 ± 3.29 years).

### Clinical study design

This study was an open-label controlled trial. The test item was a pair of female pumps to which the newly developed insoles were attached. The insoles were developed as an academic-industrial collaboration by the Anti-Aging Medical Research Center, Doshisha University (Kyoto, Japan) and ASICS Trading Co., Ltd. (Kobe, Japan) and were characterized by recreating the sensation of sandy beach walking of sandy-beach walking with comfortability in walking and load training on muscles to enhance muscle activity. The control item was a pair of female pumps not equipped with insoles.

Wearing the control item, research participants performed 30 minutes of treadmill walking with an exercise intensity around 3 METs (Metabolic Equivalents) using a treadmill that had been set at the walking speed of 4.5 km (Life Fitness Discover Treadmill SE3, Brunswick Corporation, Illinois, USA). Glucose load had been provided by 40 g of glucose 75 minutes before the start of walking to temporarily inhibit GH secretion, which was the major assessment item. The first sample blood collection was performed 15 minutes before the walking exercise. Hematologic test and biochemical examination of blood were performed, examining growth hormone (GH), cortisol, triglyceride (TG), plasma glucose (PG) and immunoreactive insulin (IRI). The second collection of sample blood was performed after walking to observe and evaluate changes in GH, cortisol, TG, PG and IRI, comparing tests before and after walking. After a 1-week washout period, wearing the test item, another walking exercise examination with blood tests was conducted in the same manner for the controlled item case.

The research period was from March of 2018 to April of 2018.

## Evaluation points

### Anthropometric measurements

Anthropometric measurements involved measurements of height, weight, body fat, body mass index (BMI), systolic and diastolic blood pressure, and pulse. Organization composition was examined using a body composition analyzer (InBody770; InBody Japan, Koto-ku, Tokyo, Japan).

### Blood test

A peripheral blood test and a biochemical test were performed using blood samples. Evaluation points in this study were GH, cortisol, TG, PG and IRI. Clinical examinations using blood samples were performed by ALP Academic Laboratory Pharmacy (Kanazawa City, Ishikawa Prefecture, Japan).

### Statistical analysis

Statistical analysis was conducted using SPSS (IBM Japan, Chuo-ku, Tokyo, Japan) statistical analysis software. Paired-t test was employed in this analysis, and a hazard rate less than 5 % was considered to be statistically significant. Outlier were not excluded from the analysis. However, in cases where data were unable to be obtained due to troubles in the test process or problems of unreliable data occurred, they were regarded as a missing value and a substitution value was not employed.

### Ethical consideration

This study was implemented in compliance with the Helsinki Declaration (amended by the 64th WMA General Assembly, Fortaleza, Brazil, 2013) and the Ethical Guidelines for Medical and Health Research Involving Human Subjects established by Japan's Ministry of Health, Labour and Welfare, and Ministry of Education. Further, the Doshisha University Ethics Review Committee on Research involving Human Subjects was held to deliberate ethics and validity for this study, which was approved (application number #17079). Clinical trial registration to UMIN was obtained in advance (UMIN #000031282).

## Results

### General background

The general background of 11 subjects for analysis are shown in ***Table 1*** as follows: age 29.9 ± 3.3 years, height 156.9 ± 4.3 cm, weight 46.9 ± 5.5 kg and BMI 19.2 ± 2.6.

### Growth hormone (GH)

In the group with the test article, GH levels before and after walking were 0.48 ± 0.31 ng/mL and 3.63 ± 3.83 ng/mL, respectively and GH level was significantly increased ($p = 0.018$, ***Fig. 1***). In the group with the control article, GH levels before and after walking were 1.12 ± 1.34 ng/mL and 5.61 ± 5.91 ng/mL, respectively and the GH level was significantly increased ($p = 0.030$). No significant difference was recognized between the test article group and the control article group (***Table 2***).

***Table 1. Anthropometry.***

| | | Average | | SD |
|---|---|---|---|---|
| Age | | 29.9 | ± | 3.29 |
| Height | cm | 156.9 | ± | 4.28 |
| Weight | kg | 46.9 | ± | 5.47 |
| Body fat | % | 24.2 | ± | 3.43 |
| BMI | − | 19.2 | ± | 2.57 |
| Blood pressure (systolic) | mmHg | 110.4 | ± | 6.54 |
| (diastolic) | mmHg | 67.8 | ± | 9.15 |
| Pulse | /min | 83.4 | ± | 11.19 |

n = 11. BMI, body mass index; SD, standard deviation.

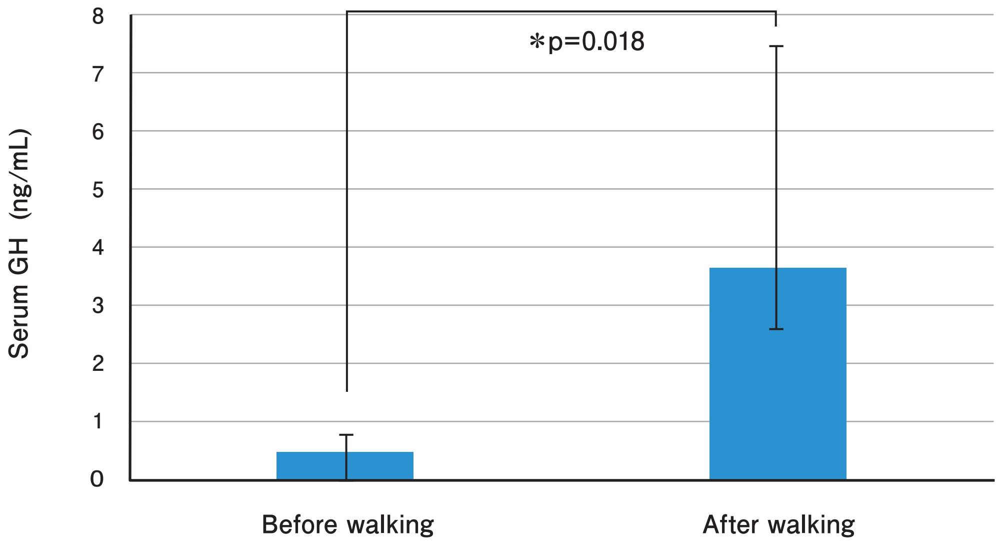


***Fig. 1.*** **GH (Test article)**

Data are expressed as mean ± SD, paired t test, n = 11. GH, growth hormone; SD, standard deviation.

***Table 2. Serum GH***

| | | Before walking | After walking | p value | Inter-group analysis |
|---|---|---|---|---|---|
| **Test article** | ng/mL | 0.48 ± 0.31 | 3.63 ± 3.83 | 0.018 | 0.299 |
| **Control article** | ng/mL | 1.12 ± 1.34 | 5.61 ± 5.91 | 0.030 | |

Data are expressed as mean ± SD, paired t test, n = 11. GH, growth hormone; SD, standard deviation.

### *Cortisol*

In the group with the test article, cortisol levels before and after walking were 11.1 ± 4.0 μg/dL and 9.5 ± 4.0 μg/dL, respectively. In the group with the control article, cortisol levels before and after walking were 10.6 ± 4.4 μg/dL and 7.9 ± 3.3 μg/dL, respectively. No significant difference was recognized in both comparisons, between before and after walking and between groups with the test article and with the control article (***Table 3***).

### *Triglyceride (TG)*

In the group with the test article, TG levels before and after walking were 62.4 ± 26.0 mg/dL and 52.8 ± 22.3 mg/dL, respectively. In the group with the control article, cortisol levels before and after walking were 65.4 ± 32.9 mg/dL and 50.5 ± 16.7 mg/dL, respectively. No significant difference was recognized in both comparisons, between before and after walking and between groups with the test article and with the control article (***Table 4***).

### *Plasma glucose (PG)*

In the group with the test article, PG levels before and after walking were 136.8 ± 41.1 mg/dL and 103.6 ± 23.1 mg/dL respectively, and PG level was significantly decreased (p = 0.038). In the group with the control article, PG levels before and after walking were 140.6 ± 35.7 mg/dL and 94.7 ± 29.0 mg/dL, respectively and PG level was significantly decreased (p = 0.005). No significant difference was recognized between groups with the test article and the control article (***Table 5***).

***Table 3. Serum cortisol***

| | | Before walking | After walking | p value: Before vs after | p value: Inter-group difference in % change |
|---|---|---|---|---|---|
| **Test article** | μg/dL | 11.13 ± 3.96 | 9.50 ± 4.04 | 0.374 | 0.426 |
| **Control article** | μg/dL | 10.59 ± 4.37 | 7.93 ± 3.31 | 0.140 | |

Data are expressed as mean ± SD, paired t test, n = 11. SD, standard deviation.

***Table 4. Serum TG***

| | | Before walking | After walking | p value: Before vs after | p value: Inter-group difference in % change |
|---|---|---|---|---|---|
| **Test article** | mg/dL | 62.36 ± 26.01 | 52.82 ± 22.34 | 0.389 | 0.657 |
| **Control article** | mg/dL | 65.36 ± 32.89 | 50.45 ± 16.72 | 0.216 | |

Data are expressed as mean ± SD, paired t test, n = 11. TG, triglyceride; SD, standard deviation.

***Table 5. PG***

| | | Before walking | After walking | p value: Before vs after | p value: Inter-group difference in % change |
|---|---|---|---|---|---|
| **Test article** | mg/dL | 136.82 ± 41.13 | 103.64 ± 23.14 | 0.038 | 0.449 |
| **Control article** | mg/dL | 140.64 ± 35.66 | 94.73 ± 28.97 | 0.005 | |

Data are expressed as mean ± SD, paired t test, n = 11. PG, plasma glucose; SD, standard deviation.

*Table 6. Serum IRI*

| | | Before walking | After walking | p value: Before vs after | p value: Inter-group difference in % change |
|---|---|---|---|---|---|
| **Test article** | µU/mL | 24.88 ± 8.25 | 12.78 ± 8.57 | 0.004 | 0.836 |
| **Control article** | µU/mL | 29.97 ± 10.95 | 12.56 ± 9.48 | 0.001 | |

Data are expressed as mean ± SD, paired t test, n = 11. IRI, immunoreactive insulin; SD, standard deviation.

### *Immunoreactive insulin (IRI)*

In the group with the test article, IRI levels before and after walking were 24.9 ± 8.3 µU/mL and 12.8 ± 8.6 µU/mL, respectively and IRI level was significantly decreased (p = 0.004). In the group with the control article, IRI levels before and after walking were 30.0 ± 11.0 µU/mL and 12.6 ± 9.5 µU/mL, respectively and IRI level was significantly decreased (p = 0.001). No significant difference was recognized between groups with the test article and the control article (*Table 6*).

### *Safety*

Neither adverse events nor effects occurred in the group with the test article, while shoe sores or blisters were recognized as an adverse event (7 out of 12 subjects, incident rate 58.3 %) in the group with the control article.

## Discussion

### *Overviews of results*

This study examined the effects of walking exercise wearing a pair of shoes equipped with specially produced insoles as the test product in an open label trial with 12 healthy female research participants with a shoe size 22.5 - 23.5 cm (age: 29.9 ± 3.3 years, BMI 19.2 ± 2.6). The clinical conference after the completion of the tests eliminated one subject from the analysis. Data of 11 subjects were analyzed and the following results were obtained:

GH levels were significantly decreased from the tests before walking compared to after walking in both groups with the test and the control product. Furthermore, levels of PG and IRI were significantly decreased between the before and after walking tests. There was no significant difference in pre- and post-walking change rates between the two groups. In the test product group, neither adverse events nor effects occurred, while shoe sores or blisters were recognized as an adverse event (7 out of 12 subjects, incident rate 58.3 %) in the group with the control product.

An examination of the effects of the test product was conducted with 6 female subjects (age: 40.2 ± 7.6 years, BMI 19.2 ± 1.8), who were not precipitants of this test. Employing a multipurpose telemetry electromyography DL-5000 (S&ME, Nakano-ku, Tokyo, Japan), eight sites were examined: erector spinae, gluteus medius, vastus medialis, vastus lateralis, soleus, tibialis anterior, tibialis posterior and peroneus brevis. Among these sites, erector spinae muscle measurement value of the test article was significantly higher in average rectified values and integrated value of electromyogram (EMG) than in those of the control article (*Table 7*). That is, the usage of the insoles enabled the enhancement of the physical activities of erector spinae muscle.

Judging from the above findings, it has been suggested that the test products, the specially produced insoles, were comfortable to wear, were unlikely induce adverse events, and were assumed to have motional effects due to load training on erector spinae muscles.

## *Effects of walking exercise*

In this rapidly aging society, people developing problematic symptoms with their legs and feet have been drastically increasing in number. The elderly people tend to have problems of diabetes or arteriosclerosis. Reduced or loss of walking function or ability could be the biggest impact [7], which hinders opportunities of going out. A reduction of opportunities for social contact could induce social isolation. Consequently, not only walking function but also entire physical activities functions are increasingly diminished [8]. In order to break this vicious cycle, continuous walking exercise is effective for maintaining functional gait to improve walking speed with eyes closed, extend stride length and shorten double leg supporting time [9, 10].

Remarkably beneficial effects can be exerted by walking intervention programs to middle and senior patients with high blood pressure, metabolic disorder, locomotor disease and neurological disorder. Walking exercise has been reported to have diverse effects such as the reduction of blood pressure [11, 12], the prevention of osteoporosis [13], the prevention of frailty or "frail" in Japanese [14], the maintenance of a beautiful posture [15], the improvement in leg muscle strength [9, 16], the maintenance of good functional sense of balance [9, 17], fall prevention [18, 19], relaxing effect [20], the improvement of subjective symptoms related to quality of life (QOL) [21], the improvement of sleep quality and daytime sleepiness [22], as has been reported.

From the viewpoint of glycative stress, it has been reported that walking exercise interventions enable the reduction of postprandial hyperglycemia [23] and improved neutral fat levels in blood [24]. Specifically, walking exercise greatly contributes to the reduction of glycative stress.

*Table 7. EMG*

| | | article | n | Average ± SD | p value |
|---|---|---|---|---|---|
| ① **Erector spinae muscle** | Average Rectified Value | Test article | 6 | 0.333 ± 0.611 | ***0.046** |
| | | Control article | 6 | 0.235 ± 0.398 | |
| | CV | Test article | 6 | 0.837 ± 0.364 | 0.938 |
| | | Control article | 6 | 0.831 ± 0.316 | |
| | Integrated value | Test article | 6 | 39.974 ± 73.364 | ***0.046** |
| | | Control article | 6 | 28.163 ± 47.804 | |
| ② **Gluteus medius muscle** | Average Rectified Value | Test article | 6 | 0.124 ± 0.042 | 0.109 |
| | | Control article | 6 | 0.099 ± 0.055 | |
| | CV | Test article | 6 | 1.682 ± 1.303 | 0.463 |
| | | Control article | 6 | 1.646 ± 1.106 | |
| | Integrated value | Test article | 6 | 14.824 ± 5.041 | 0.109 |
| | | Control article | 6 | 11.891 ± 6.645 | |
| ③ **Vastus medialis** | Average Rectified Value | Test article | 6 | 0.184 ± 0.121 | 0.127 |
| | | Control article | 6 | 0.148 ± 0.108 | |
| | CV | Test article | 6 | 1.386 ± 0.337 | 0.916 |
| | | Control article | 6 | 1.432 ± 0.480 | |
| | Integrated value | Test article | 6 | 22.116 ± 14.535 | 0.127 |
| | | Control article | 6 | 17.819 ± 12.939 | |
| ④ **Vastus lateralis** | Average Rectified Value | Test article | 6 | 0.060 ± 0.028 | 0.240 |
| | | Control article | 6 | 0.053 ± 0.018 | |
| | CV | Test article | 6 | 1.296 ± 0.317 | 0.443 |
| | | Control article | 6 | 1.356 ± 0.261 | |
| | Integrated value | Test article | 6 | 7.236 ± 3.330 | 0.240 |
| | | Control article | 6 | 6.387 ± 2.146 | |
| ⑤ **Soleus** | Average Rectified Value | Test article | 6 | 0.117 ± 0.028 | 0.262 |
| | | Control article | 6 | 0.131 ± 0.039 | |
| | CV | Test article | 6 | 1.547 ± 0.207 | 0.532 |
| | | Control article | 6 | 1.516 ± 0.138 | |
| | Integrated value | Test article | 6 | 13.994 ± 3.419 | 0.262 |
| | | Control article | 6 | 15.750 ± 4.643 | |
| ⑥ **Tibialis anterior** | Average Rectified Value | Test article | 6 | 0.085 ± 0.031 | 0.916 |
| | | Control article | 6 | 0.086 ± 0.036 | |
| | CV | Test article | 6 | 1.091 ± 0.246 | 0.916 |
| | | Control article | 6 | 1.173 ± 0.279 | |
| | Integrated value | Test article | 6 | 10.193 ± 3.764 | 0.916 |
| | | Control article | 6 | 10.302 ± 4.261 | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| ⑦ **Tibialis posterior** | Average Rectified Value | Test article | 6 | 0.086 | ± | 0.013 | 0.427 |
| | | Control article | 6 | 0.092 | ± | 0.024 | |
| | CV | Test article | 6 | 1.437 | ± | 0.193 | 0.463 |
| | | Control article | 6 | 1.479 | ± | 0.145 | |
| | Integrated value | Test article | 6 | 10.371 | ± | 1.519 | 0.427 |
| | | Control article | 6 | 11.063 | ± | 2.902 | |
| ⑧ **Peroneus brevis** | Average Rectified Value | Test article | 6 | 0.085 | | 0.033 | 0.770 |
| | | Control article | 6 | 0.083 | | 0.030 | |
| | CV | Test article | 6 | 1.400 | | 0.193 | 0.674 |
| | | Control article | 6 | 1.374 | | 0.172 | |
| | Integrated value | Test article | 6 | 10.161 | | 3.906 | 0.770 |
| | | Control article | 6 | 9.929 | | 3.618 | |

Data are expressed as mean ± SD, Wilcoxon signed-rank test, n = 6. EMG, electromyography; CV, coefficient of variation; SD, standard deviation.

Furthermore, walking exercise contributes to sustaining cognitive activity and mental function [1, 2, 25-28]. Research of exercise effects on young people demonstrated that a greater number of steps in walking induced greater effects on cognitive function with a higher concentration of oxygenated hemoglobin and a higher full-scale intelligence quotient, as was shown by a near infrared spectroscopy examination for cerebral blood flow [26]. A research advocated *Cognicise* and/or *Cogniwalk* to sustain cognitive function and prevent cognitive decline [29].

Transcervical fractures caused by falls have an adverse effect on convalescence. Falls are likely to happen while walking. There are risk factors of fear for having a fall among aged persons, especially women [30]. It is important to remove fear, which requires starting to establish a walking habit prior to senescence.

The research participants of this study were residents in or around Kanazawa City. Epidemiological data indicates that the number of daily steps in walking is different, depending the scale of cities; in both males and females, which were age-adjusted. Persons living in a smaller-sized city tend to have the smaller number of steps [31]. To specify some negative determinants of physical function, there is low population density, low land use mix score, and fewer daily life-related destinations such as community centers, medical facilities and recreational facilities [32]. Furthermore, public transportation systems are difficult to develop in smaller cities, which generally has a car-dependent community. The research participants of this study were persons living in an area where the number of daily steps is rather small.

## *Exercise and growth hormone (GH)*

Health-promoting lifestyle behavior involves the improvement of dietary, physical and intellectual education. Physical education, which means exercise therapy, contains stretching exercises, aerobic exercises and muscle training. The points of attention in the exercises are to keep balance without inclination in practicing these exercises and to avoid an excessive amount of exercise. One of the exercise effects is to promote GH secretion [33-36]. The secretion of GE is frequently applied as an index to evaluate the amount of exercise or physical activity [37-42]. Compression Strength Training, or KAATSU training has been developed to obtain efficient GH secretion [35, 43-45].

This research was conducted, referring our previous research, successfully to employ glucose load; 40 g of glucose oral load was provided to subjects approximately 1 hour before walking. In the previous research regarding a dumbbell exercise, a problem occurred where female subjects had shown a GH stimulated secretion before the test and no increase of GH level had been shown from the exercise in the GH stimulation test. In the present research, glucose load enabled to set GH values at a low level prior to the walking exercise. The function of GH stimulated secretion was recognized even due to a low-load exercise of a 30-minutes of walking. Cases where GH values were not recovered with glucose load were eliminated. However, possibilities of GH hypersecretion due to hypophyseal adenoma or hyperplasia cannot be excluded and further minute examinations such as MRI will be requested.

## *Anti-aging medical checkup*

Anti-aging medical checkups or examinations are an effective method to evaluate physical conditions of the elderly, not only as indicators of aging-related of whole body, but also as a balance among diverse functions [46-48].

We provided a 6-month walking intervention program to workers of an enterprise, lending a pedometer and confirming the total number of steps every month. Two anti-aging checkups were performed before and after the intervention. Results of the checkups indicated the reduction of weight, body mass index (BMI), blood pressure, LDL-C, fasting insulin level (improvement in insulin resistance), and IGF-I [49]. The decrease of IGF-I was interpreted to be triggered where the increase of insulin resistance had induced the condition of the compensatory increase in insulin secretion, but the exercise intervention resulted in a compensatory reduction in IGF-I. We also conducted a similar intervention and research in another factory, examining the effectiveness of the walking exercise [50].

Our research center started to conduct a walking intervention program with pedometer-based management in the Yurin area of Shimogyo-ku, Kyoto, Japan in December of 2008 and evaluated their physical conditions through anti-aging medical checkups [51-53]. The research participants of this exercise program, including people who joined midway, were provided with a pedometer and instruction sheets to be motivated by the intervention. A cohort study [52] was conducted for the participants for two and a half years to examine the physical influences of the walking program employing a pedometer [51]. Our project clarified the importance of physical activities for the elderly. Our research center had conducted preceding research examining the association between the number of steps and the amount of physical activities [53]. It was demonstrated that the elderly participants of this program were maintaining a physical level of activity which was almost identical to the level of adult physical activity recommended by the Ministry of Health, Labour and Welfare guidelines. It was also shown that independently-living elderly people were significantly younger in neural functional age than support- or nursing-requiring elderly people [48]. It is important to lead a mentally and physically active life, remaining healthy in neural function, in order to be an elderly person requiring no nursing care.

From the viewpoint of anti-aging, it can be recognized that walking exercise contributes to the health promotion for workers or the elderly, the prevention of dementia and the reduction of glycative stress.

## *Research on footwear, shoes and insoles*

Research on the influences of footwear or foot care has been actively conducted in Japan recently. However, little interest or awareness on foot care was shown in a consciousness survey by the elderly [54]. Other than the accumulation of research findings, publicity is necessary to promote walking exercise. To encourage elderly persons to be aware of the importance of foot care, concrete methods of care for the sole and toe of the foot must be introduced through mass media.

Biomechanics of the feet is a matter of concern and interest to all people related to insole therapy. Conventionally, the foot was regarded as a single segment in the field of biomechanics. However, state of the art technologies have enabled more precise measurement to divide a foot into multiple zones and to acquire information that is distinguished from the conventional measurement. As a matter of fact, what is important for healthy walking, from the viewpoint of three-dimensional motion analysis, is the movement of the sagittal plane rather than pronation/ supination and adduction/ abduction [55]. It has been recognized that important factors are not only movement of the rearfoot, which is frequently regarded as an observation point clinically, but also the forefoot and midfoot.

It is important to establish an assessment method to compare and examine the effects of shoes [56-59]. This study examined the amount of muscle movement of lower limbs employing a multi-channel surface EMG, though subjects were different. Characteristics of muscle activities can be evaluated in various parts of the legs [60-62].

Matched or mismatched shoes influence standing posture or walking [63, 64]. The functions of legs, especially in elderly persons, are reduced and are more likely to be influenced by shoes. Appropriate selection and wearing of shoes could prevent the elderly from falling or having disorders of the leg and feet [64]. Many females experience foot pain due to high-heeled shoes. Even low-heel shoes could cause pain when they are mismatched to feet. Many females seek a pair of ideal shoes that meet their conflicting desires. Shoes must be stylish and fashionable and at the same time, functional and comfortable. However, to prevent foot trouble, it is necessary to chose suitable shoes for their own use and to wear them in an appropriate manner. The keys to choosing shoes are as follows: To know how to measure feet, foot length and foot circumference, to confirm whether pressure is intense on the hallux (first toe) or the metatarsophalangeal (MTP, little toe) joint, which is likely to induce pain when wearing shoes, to confirm whether space is left in the toe of a shoe, to confirm whether the arch of the shoe fits the medial longitudinal arch of foot, and to confirm whether heels are stable. It is important to select shoes depending on the situation [63, 64].

One of the methods to solve a problem of mismatched shoes is to use insoles. Insoles are used to feel comfortable, to prevent shoe sores or blisters and to relieve arthralgia pain of the knees or ankles. It is possible to be closer to the ideal shoes by fixing a mismatch with the appropriate insoles.

Shoes consist of the upper and the sole. The upper requires proper fitting and durability, and diverse materials for the upper have been developed. A heel counter functions to support calcaneal and to prevent excessive pronation. The sole contacts the ground, which requires shock absorption and durability. A shank of the sole enhances stability. It is vital to understand the structures of shoes and the relation to human functions and diseases [65]. Insoles are placed between the upper and the sole.

Insoles are used for the conservative treatment of hallux rigidus [66], the increase of plantar and dorsal flexor muscle strength [67], the improvement of muscular activity and balancing sense, the relief of plantar region pain [68], the correction of floating toe [69], the relief of sacroiliac pain of patients with sacroiliac joint dysfunction [70] and the correction of flatfoot [71], as reported. In walking of a patient with osteoarthritis (OA), the movement distance of the reverse response phenomenon at the start of the walking motion is shorter than a healthy person and waveform pattern has different tendencies [71]. Research demonstrated that usage of appropriate therapeutic insoles is effective for patients with osteoarthritis (OA), as a center of pressure (COP) movement distances tend to alter in the crosswise and anterior directions [72]. In cases where insoles are not matched well, effects cannot be detected [61].

## *Effects of sand beach walkings*

The first thing that we did for the development of the insole is to have an image or a concept of sand beach walking. While your foot sinks into sand and your foot and leg muscles work extra hard with load, you feel comfortable and you are lifted up. We intended to develop insoles for this goal.

Effects of sand-walking are to improve metabolic-syndromes-related factors [73], which are indicated by triglyceride and visceral fat, insulin resistance and arterial stiffness. Other than that, sand walking can reduce mental and physical stress [74, 75] and lower blood pressure [75], as has been reported.

Previous research demonstrated that in comparison to walking on a paved street, sand walking has diverse effects such as the promotion of cardiac rate and calorie consumption, the decrease in body fat percentage, hypotensive action, the increase in plantar flexor muscle strength and knee extension force, the improvement of balance-function and the improvement of aerobic work ability [77, 78].

Some research indicated that psychological influences of walking intervention, such as entertainment [79] or fulfilment [80], could be encouraging to enhance social adaptability and sociability rather than the amount of exercise load in walking. Sand-walking would apparently be more entertaining than walking on a paved street.

These days a multi-channel surface EMG analysis enables us to clarify conditions of various muscle group activities showing how the activity amounts of walking-related muscles change along with changes in steps per minute, how a forward-inclining-posture gait influences walking and what differences are between the elderly and the young [81-83]. In the gait-patterning mechanisms of humans, their comfortable steps per minute and walking speed are naturally determined [82]. There has not yet been reported research information on electromyogram of sand-walking, which is anticipated and would be very interesting.

What would the EMG waveform of sand-walking be? The following is our hypothesis. Sand-walking is fatiguing, which is induced by muscle fatigue. The amount of muscle activity of walking in sand must be greater than walking on paved ground. The sinkages both in landing and kicking up are the key factor. Extra load is imposed on the muscle group of the lower limbs. Furthermore, unstable sandy soil adds extra load on erector spinae muscle (tension of muscle) for postural stability. However, walking around a beautiful beach is pleasant and entertaining. Satisfaction and fulfilment are gained. People feel comfortable due to these types of stimuli to the brain reward system, even though sand walking is an exercise with heavy load on muscles, which is not energy efficient.

This study revealed that the amount of activity in the erector spinae muscle was greater when using the test product through analysis results of multi-channel surface EMG. Erector spinae muscles play an important role for postural stability and is a large mass consisting of three groups, spinalis muscle, longissimus muscle and the iliocostalis muscle.

Although it was conjectured that the effects of sinkage in walking were reflected by the usage of insoles, there was no significant difference in the amount of muscle activity in the lower thigh. However, it was recognized that a load was imposed on musculus erector spinae for posture stability. There is a possibility that effects similar to sand-walking were obtained. More mental effects with pleasure could be achieved when shoes are both comfortable and fashionable. Direction of our attempt with the concept and goal of “walking on a sandy beach” is in a proper course to develop comfortable insole products.

### *Safety assessment*

There were no adverse events attributable to this study with using the test article. It was shown that there were no problems in safety. Contrarily, shoe sores or friction blisters were recognized as an adverse event (7 out of 12 subjects, incident rate 58.3 %) in the group with the control article. It was assumed that using the test article, the proper insoles enabled the reduction of frictional force against foot skin and prevented adverse events.

### *Research limitation*

This was study conducted as an open trial to examine the same subjects twice. The production of specially processed insoles was time and energy consuming, which requires fine tuning until just before the start of the test. Thus, a crossover trial was unable to be performed. Influences from the examination timing could be contained in the data. It was possible that the GH secretion activity by the exercise load was weaker in the test article in the second term of the examination than in the control article in the first term of examination. It is assumed that the second effect (the response reaction to stimuli is weaker in the second time than in the first time) resulted in the influence where GH secretion tended to be smaller in the second term of wearing the test article than in the first term of wearing the control article.

## *Conclusion*

The examination of exercise effects of the test article, specially processed insoles, which performed in an open trial with 12 healthy female subjects, suggested a possibility that this insole test product had a load training effect on lower thigh muscles and few adverse effects are expected from its use.

## *Conflict of interest statement*

The present study was sponsored by ASICS Trading Co. Ltd.

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