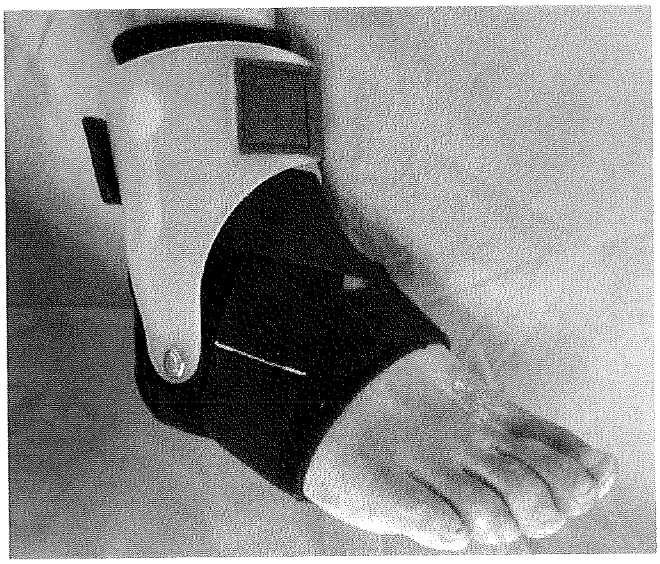

Figure 2. The Ever Step 6 (Nippon Sigmax Co Ltd, Tokyo, Japan) ankle brace is constructed of 2 polypropylene guards and an elastic band. The band is fastened in a figure-of-8 configuration.

First, the specimens were tested intact while inversion and eversion forces of 19.6 N were applied to the proximal tibia 30 cm from the distal fixation level. These traction forces were applied horizontally with a pulley-and-weight system. The traction force of 19.6 N was found to be suitable for biomechanical testing in a preliminary study.[32] Next, 2.0-N·m internal and external rotation torques were applied to the longitudinal axis of the femur. The apparatus for rotation torque consisted of a 10-cm-diameter acrylic tube fixed to the femoral diaphysis using a 3.0-mm-diameter pin, which provided a constant moment arm with weight at a tangent through a cable. The weight consisted of a water bag and a cable calibrated to apply 2.0 N·m of torque with the pulley-and-weight system.[27]

The movements of the talus were measured via the magnetic tracking system while each load was applied (Figure 1). The following angles and translation were calculated from the coordinates and the angles of the anatomical points. The angles of the talocrural and subtalar joints in the frontal plane and the rotational angles in the transverse plane were recorded while the inversion and eversion forces, as well as the internal and external rotation torques, were applied. The absolute anterior translations of the talus were also measured while the inversion and eversion forces were applied. Three trials were done for each loading condition, and the mean of the last 2 values was used. Each trial lasted 10 seconds, and a 5-second recovery period was allowed.[32]

The calcaneofibular ligament, cervical ligament, and interosseous talocalcaneal ligament were exposed before the trials by the lateral approach. The extensor retinaculum was kept intact. Trials were performed with intact ligaments and then with serial sectioning of the calcaneofibular ligament, cervical ligament, and interosseous talocalcaneal ligament. Each ligament was carefully sectioned to minimize disruption of surrounding soft tissues. After complete sectioning of these 3 ligaments (the calcaneofibular ligament, cervical ligament, and interosseous talocalcaneal ligament), the ankle brace (Ever Step 6, Nippon Sigmax Co Ltd, Tokyo, Japan) was applied, and trials were performed to investigate the stabilizing effects of the ankle brace on the subtalar joint.

The Ever Step 6 (Nippon Sigmax Co Ltd) is a semirigid orthosis constructed of medial and lateral polypropylene guards and one elastic band to prevent or treat ankle sprains. The band is fastened in a figure-of-8 configuration under the guards (Figure 2). In this study, we chose the M size of the brace, which fits the average Japanese foot and ankle.

TABLE 1
Angular Changes of the Talocrural Joints When Inversion and Eversion Forces Were Applied (deg, mean ± SD)[a]

	Inversion Force		Eversion Force	
	Angular Change	*P* Value	Angular Change	*P* Value
Intact	2.9 ± 1.5		1.5 ± 0.9	
CFL sectioning	11.1 ± 5.6	.036	1.3 ± 0.5	.997
CFL and CL sectioning	13.2 ± 6.4	.005	1.5 ± 0.8	.999
CFL, CL, and ITCL sectioning	13.7 ± 9.1	.003	1.2 ± 0.6	.994
Application of the brace	8.4 ± 5.8	.292	1.7 ± 1.0	.999

[a]CFL, calcaneofibular ligament; CL, cervical ligament; ITCL, interosseous talocalcaneal ligament. Statistical differences compared to the intact state were checked using the Tukey test.

TABLE 2
Angular Changes of the Talocrural Joints When Internal and External Rotation Torques Were Applied (deg, mean ± SD)[a]

	Internal Rotation		External Rotation	
	Angular Change	*P* Value	Angular Change	*P* Value
Intact	3.6 ± 1.4		7.3 ± 1.9	
CFL sectioning	4.3 ± 1.7	.864	8.7 ± 3.2	.768
CFL and CL sectioning	4.5 ± 1.5	.749	9.0 ± 3.3	.657
CFL, CL, and ITCL sectioning	4.7 ± 1.7	.579	8.8 ± 2.4	.765
Application of the brace	4.7 ± 0.9	.588	7.9 ± 2.5	.992

[a]CFL, calcaneofibular ligament; CL, cervical ligament; ITCL, interosseous talocalcaneal ligament. Statistical differences compared to the intact state were checked using the Tukey test.

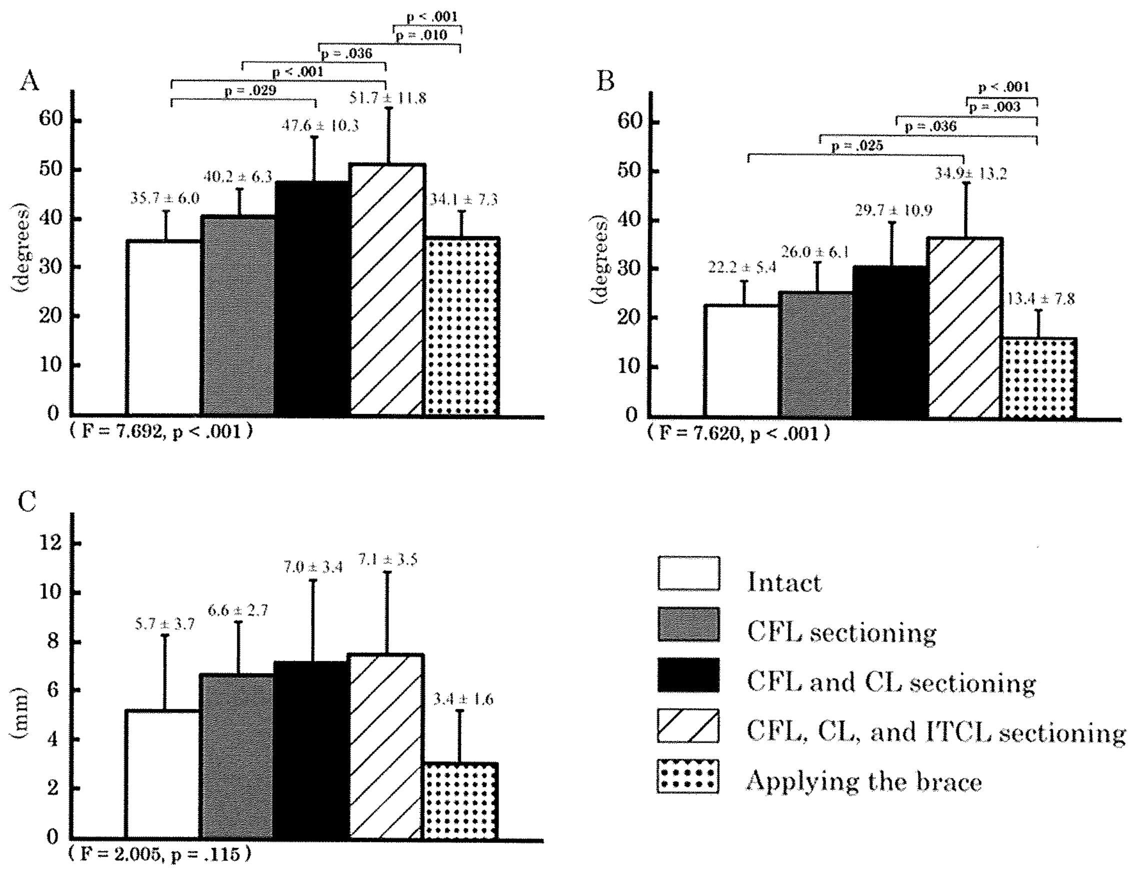

Figure 3. Change of the angles between the talus and calcaneus by sequential sectioning of the ligaments and application of the ankle brace when inversion force was applied. A, Change of the angles between the talus and calcaneus in the frontal plane when inversion forces were applied. B, Change of the angles between the talus and calcaneus in the transverse plane when inversion forces were applied. C, Anterior translation of the talus when inversion forces were applied. CFL, calcaneofibular ligament; CL, cervical ligament; ITCL, interosseous talocalcaneal ligament.

Statistical analysis was performed using SPSS for Windows (version 11.5J, SPSS Japan Inc, Tokyo, Japan). To evaluate instability, as well as the stabilizing effects of the ankle brace, 1-way repeated measures analysis of variance (ANOVA) was used. The subtalar instability and stabilizing effects of the ankle brace were assessed with the same 1-way ANOVA test. Statistical significance of the differences among the parameters was checked using the Tukey test. A P value of .05 was chosen as the level of significance.

RESULTS

Talocrural Joint

Angular changes of the talocrural joint in the frontal plane were significantly increased across sequential sectioning of the ligaments and application of the brace when inversion forces were applied (F = 5.065; P = .002). The calcaneofibular ligament sectioning increased the angle to 11.1° ± 5.6° compared with 2.9° ± 1.5° in the intact state. However, these angles remained almost constant after additional sectioning of the cervical ligament and interosseous talocalcaneal ligament. A significant difference was not found between the intact state and application of the brace when inversion forces were applied. Angular changes of the talocrural joint in the frontal plane while eversion forces were applied were very small (F = .123; P = .973) (Table 1). Changes in the rotational angles of the talocrural joint in the transverse plane while internal and external rotation torques were applied were increased little by sequential sectioning of the ligaments (Table 2). Significant differences were not found in the rotational angles of the talocrural joint across sequential sectioning of the ligaments and application of the brace when the internal (F = .677; P = .612) and external (F = .747; P = .567) rotation torques were applied.

Subtalar Joint

Applying the Inversion Force. Sequential sectioning of the ligaments increased the angle between the talus and calcaneus in the frontal plane when inversion force was applied. Complete sectioning of the ligaments increased

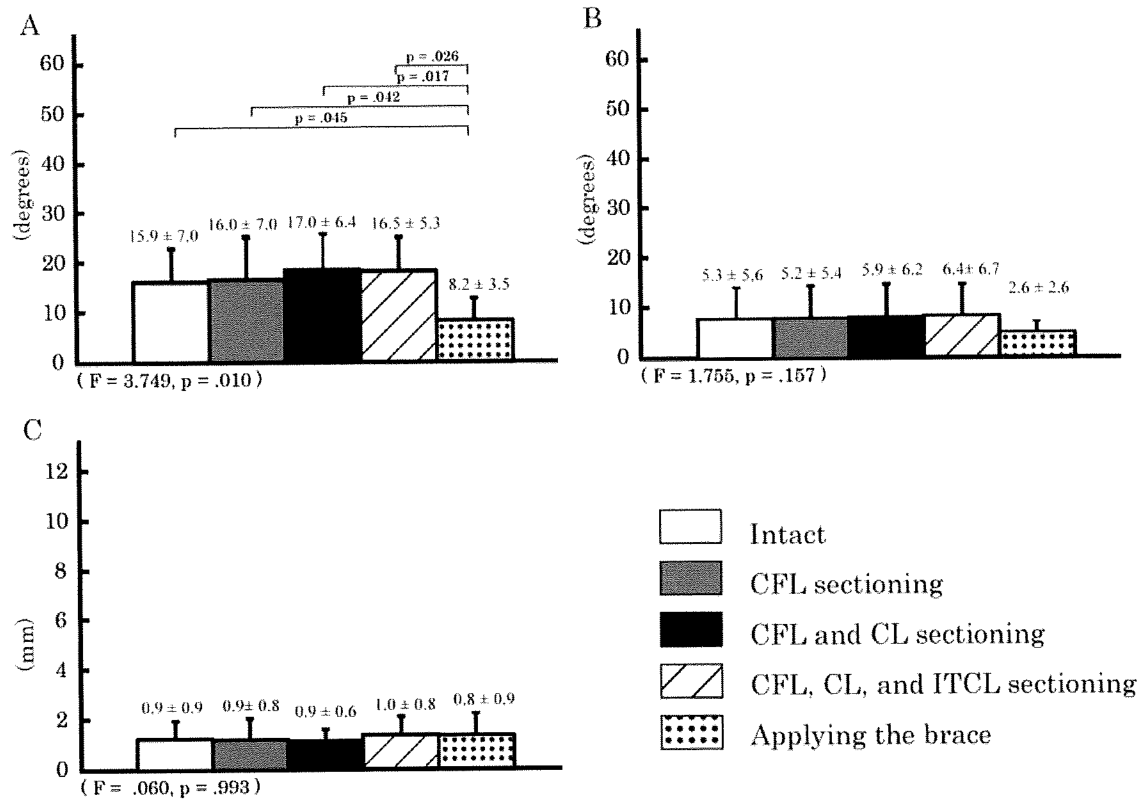

Figure 4. Change of the angles between the talus and calcaneus by sequential sectioning of the ligaments and application of the ankle brace when eversion force was applied. A, Change of the angles between the talus and calcaneus in the frontal plane when eversion forces were applied. B, Change of the angles between the talus and calcaneus in the transverse plane when eversion forces were applied. C, Anterior translation of the talus when eversion forces were applied. CFL, calcaneofibular ligament; CL, cervical ligament; ITCL, interosseous talocalcaneal ligament.

the angle between the talus and calcaneus in the frontal plane to 51.7° ± 11.8° compared with 35.7° ± 6.0° in the intact state. There was a statistically significant difference in the angles between complete sectioning of the ligaments and application of the brace (34.1° ± 7.3°), whereas statistical significance was not found between the intact state and application of the brace (Figure 3A). The rotational angles of the talus compared with the calcaneus in the transverse plane were also increased by sequential sectioning of the ligaments and were significantly increased after complete sectioning of the ligaments. There was a statistically significant difference in the angles between the calcaneofibular ligament sectioning (26.0° ± 6.1°) and application of the brace (13.4° ± 7.8°) (Figure 3B). The anterior translations of the talus were not significantly different between the intact state (5.7 ± 3.7 mm) and complete sectioning of the ligaments (7.1 ± 3.5 mm) when inversion forces were applied. Application of the brace decreased the anterior translation to 3.4 ± 1.6 mm, but this was not statistically significant (Figure 3C).

Applying the Eversion Force. Angular changes of the talus were relatively small with sequential sectioning of the ligaments while the eversion force was applied. However, application of the brace significantly decreased the angle between the talus and calcaneus in the frontal plane compared to the intact state (Figure 4A). The rotational angles and the anterior translations were almost constant, even with sequential sectioning of the ligaments when the eversion force was applied (Figure 4B, C).

Applying the Internal Rotation Torque. The rotational angles of the subtalar joint in the transverse plane were not significantly different between the intact state (1.8° ± 1.0°) and complete sectioning of the ligaments (2.9° ± 1.5°) while the internal rotation torque was applied. Application of the brace decreased the rotational angle to 1.6° ± 1.4°, but this was not statistically significant (Figure 5).

Applying the External Rotation Torque. Each sequential sectioning significantly increased the rotational angles of the subtalar joint in the transverse plane while the external rotation torque was applied. The calcaneofibular ligament sectioning increased the angle to 1.8° ± 0.6° from 0.4° ± 0.5° in the intact state. Both the calcaneofibular ligament and cervical ligament sectioning increased the angle to 2.9° ± 0.9°. Statistical significance was not found among the application of the brace and each ligament sectioning state. However, there was a statistically significant difference in the angle between the intact state and application of the brace (2.2° ± 1.0°).

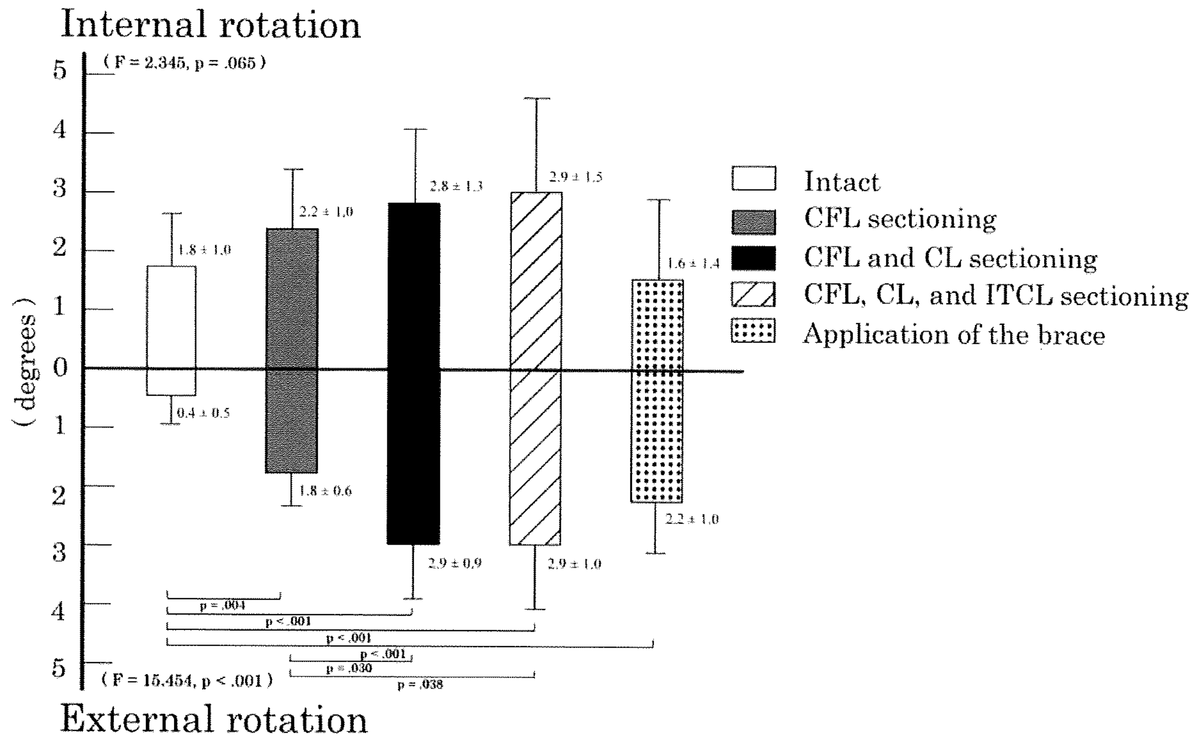

Figure 5. Change of the angles between the talus and calcaneus by sequential sectioning of the ligaments and application of the ankle brace when internal and external rotation torques were applied. CFL, calcaneofibular ligament; CL, cervical ligament; ITCL, interosseous talocalcaneal ligament.

DISCUSSION

The current study demonstrated the functional roles of the calcaneofibular ligament, cervical ligament, and interosseous talocalcaneal ligament with respect to the subtalar joint. The calcaneofibular ligament restricted excessive motion of the talus, especially when external rotation torque was applied. In the present study, there was a statistically significant difference in motion between the intact state and the calcaneofibular ligament sectioning in the transverse plane while the external rotation torque was applied. Kjaersgaard-Andersen et al[14] studied the role of the calcaneofibular ligament using lower leg–amputated cadaveric models. They reported that the increment of talus motion in external rotation after sectioning of the calcaneofibular ligament was significantly increased during the total range of plantar-dorsiflexion of the ankle joint. Stormont et al[25] concluded that the calcaneofibular ligament is the primary restraint in external rotation. Cahill[3] and Smith[24] performed anatomical studies that demonstrated that the cervical ligament limits inversion and prevents excessive motion of the subtalar joint. Martin et al[20] reported that the calcaneofibular ligament deficient state caused a significant increase in the length of the cervical ligament. In the present study, a significant increase of talus inversion was demonstrated after both the calcaneofibular ligament and cervical ligament were sectioned. While the external rotation torque was applied, a significant increase of talus motion was observed after the calcaneofibular ligament sectioning, and further instability was created by both the calcaneofibular ligament and cervical ligament sectioning. Kjaersgaard-Andersen et al[15] reported that the median increase in the total range of rotation after cutting the cervical ligament was 0.9° for the subtalar joint in the neutral position. The cervical ligament not only restricted excessive motion of talus inversion but also limited talus rotation under the external rotation torque.

Kjaersgaard-Andersen et al[15] demonstrated that interosseous talocalcaneal ligament sectioning increased total motion of the subtalar joint. Knudson et al[16] suggested that the interosseous talocalcaneal ligament contributed substantially to subtalar joint stability, particularly in supination. Tochigi et al[29] reported that interosseous talocalcaneal ligament failure causes inversion instability of the subtalar joint. The present study indicated that the calcaneofibular ligament, cervical ligament, and interosseous talocalcaneal ligament sectioning increased the motions of talus while the inversion force and external rotational torque were applied. These findings supported the previous reports[15,16,29] that the interosseous talocalcaneal ligament is important to stabilize the subtalar joint.

The present results showed that subtalar movement was well restricted by the Ever Step 6 (Nippon Sigmax Co Ltd) ankle brace, especially when the inversion and eversion forces were applied. However, no statistically significant difference was found while the internal and external rotation torques were applied. It appears that the 2 polypropylene guards of the ankle brace maintained the ankle in the neutral position and limited talus inversion and eversion. On the other hand, rotation of the subtalar joint was only partly restricted by these polypropylene supports and the band that was constructed in a figure-of-8.

Our study indicated that the brace worked as a mechanical restraint in the ankle and subtalar joint. We recommend that some improvement of the brace might be considered to restore better rotational stability, such as specially designed straps. However, the proprioceptive improvement on the ankle joint is also a key effect of the ankle brace. Application of the brace has been shown in other studies to facilitate ankle joint proprioception through the stimulation of cutaneous mechanoreceptors.[5,10] Furthermore, the proprioceptive effect on the subtalar joint should be investigated in the future to solve this question.

In this study, we investigated the effect of one of the popular types of athletic ankle brace on subtalar instability. But further research is required to directly compare the effectiveness of ankle taping versus ankle brace on the ankle and subtalar joint stability.

The subtalar joint is stabilized by the bony configuration, especially under loading conditions. The present study was a nonweightbearing model, and the model did not simulate active muscle forces. When sudden inversion occurred in the ankle, the dynamic defense mechanism of the muscles was activated in an in vivo model.[12,17] However, the most unstable phase of the talocrural and subtalar joints in the gait cycle is the transition from the swing phase to the stance phase.[33] The body weight starts to add to the hindfoot from the initial contact. It is important for the stability of the subtalar joint to achieve correct alignment of the hindfoot at heel contact. The model used in the present study partially simulated initial contact in the gait cycle.

Clinically, severe inversion stress also causes anterior talofibular ligament injury. The role of the anterior talofibular ligament is to restrict excessive motion of the ankle inversion and anterior translation.[1,4,25,30] The purpose of the present study was to investigate the angular changes of the subtalar joint. Furthermore, the anterior talofibular ligament was kept intact in our experimental model, which may not be true in clinical cases of subtalar instability.

In conclusion, the roles of the calcaneofibular ligament, cervical ligament, and interosseous talocalcaneal ligament were investigated in the subtalar joint using fresh cadaveric specimens. These ligaments were found to restrict excessive motion of the talocrural joint when the inversion force and rotational torques were applied. Furthermore, the effects of the ankle brace on subtalar joint instability were also clarified. The ankle brace limited inversion and eversion of the subtalar joint, whereas it provided no significant restriction under rotational torques.

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RESEARCH PAPER

Characteristics of disabilities in patients with subacute myelo-optico-neuropathy living at home: Satisfaction in daily life and short form-36

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Abstract

Purpose. The aim of this study was to investigate the characteristics of disabilities in patients with subacute myelo-optico-neuropathy (SMON), and to reveal whether the satisfaction in daily life (SDL) or short form-36 (SF-36) correlated with these disabilities.

Method. The subjects consisted of 97 patients with SMON living at home, who were mailed a questionnaire concerning the patient's profile, SMON severity (disability scale for SMON), basic activities of daily living (self-rating Barthel Index, SR-BI), lifestyle (self-rating Frenchay Activities Index, SR-FAI), SDL and SF-36. A relationship with SDL, SF-36 and disabilities was analysed by using Spearman's rank correlation coefficient.

Results. Fifty-eight out of 97 patients with SMON responded, and their mean age was 76.1 years. The mean of SMON severity was 8.0; SR-BI, 70.8; SR-FAI, 11.1; SDL, 27.3; physical component summary of SF-36 (PCS), 26.3; mental component summary of SF-36 (MCS), 39.5. The SMON group had significantly lower scores for SDL than those for the age- and sex ratio- matched elderly persons. With respect to SDL, a significant correlation was observed with SMON severity, SR-BI, SR-FAI, SDL, and PCS and MCS of SF-36, but no significant correlation was observed regarding SMON severity and either the PCS or MCS.

Conclusions. The subjective domains of the quality of life in patients with SMON were observed to have decreased. SDL was considered to closely reflect the characteristics of the disabilities observed in patients with SMON.

Keywords: *SMON, satisfaction in daily life, SF-36*

Introduction

SMON is the name of a disease, being an acronym for subacute myelo-optico-neuropathy, which has a distinctive clinical course, symptoms and pathological findings, and in Japan, it occurred as drug poisoning in which clioquinol, an intestinal antibacterial drug, was normally the cause [1]. Following the onset of intestinal symptoms, the occurrence of visual impairment, paraparesis, paresthesia in the lower limb, bladder bowel disturbance, and so on, has been reported. The incidence of this disease was clustered from 1955 to 1970, and because a long period of time has passed after the onset of the disease, neurologic abnormalities associated with this disease have already become chronic. The effects of advancing age and its complications make overall disabilities of the patients with SMON more complicated [2]. For this reason, it is important to understand the disabilities, lifestyle, and quality of life (QOL) of the patients with SMON before teaching how to lead a daily life and providing information on welfare services, if rehabilitative intervention is carried out.

SMON is a condition that resembles paraparesis, and the disabilities and lifestyle of the patients with SMON may be appropriately evaluated using the Barthel Index (BI) and the Frenchay Activities Index (FAI) [3]. On the other hand, satisfaction in daily life (SDL) [4] was devised in 1989 as an evaluation of the subjective domain of QOL in SMON which was a simpler method than the sickness impact profile [5] and the Nottingham health profile [6]. SDL had

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seven items on a 5-point scale, and was revised to have 11 items on a 5-point scale in order to make this universally adaptable to elderly persons, based on the results of a random sampling study on the factors involved in the satisfaction of daily living for elderly individuals living at home [7]. Later, we also proved the validity of SDL in using for patients with stroke living at home [8], elderly persons living at home [9] and hemophiliacs [10].

Although there were few reports on the QOL of patients with SMON, Kuriyama et al. [11] and Fujii and Arakawa [12] carried out research using short form-36 (SF-36) [13], and Honaga et al. [14] used SF-8, which was a shortened version of SF-36. From these reports, all SF-36 scores in patients with SMON were lower than those of healthy elderly people. In the present research, the disabilities, lifestyle and QOL of patients with SMON were studied using self-rating Barthel Index (SR-BI), self-rating Frenchay Activities Index (SR-FAI), SDL and SF-36, in order to reveal: (1) what are the features of disabilities, lifestyle and QOL in patients with SMON and (2) whether SDL closely reflects the characteristic disabilities in patients with SMON.

Methods

Ninety-seven patients with SMON residing in Fukuoka prefecture (one of Japanese 47 prefectures, situated in north-eastern Kyushu, with a population of about 5.05 million people as of 1 March 2007) were registered with the Ministry of Health, Labor and Welfare. The study forms were mailed to the 97 patients with SMON, who were asked to fill in the forms and mail them back. Fifty-eight patients with SMON who responded were analysed as the subjects (SMON group), and their age distribution and sex ratio were described as follows: 50–59 years, 3 (males 0/females 3); 60–69 years, 16 (7/9); 70–79 years, 11 (3/8); 80–years, 28 (8/20).

To include age distribution and sex ratio-matched elderly persons as a control, 58 persons (control group) were randomly sampled from the database, using the RANDOM command of a statistical software package (SPSS 8.1J, SPSS Japan, Tokyo). The database derived from the measurements of 748 elderly people who were randomly selected from the list of voters for Yahatanishi-ku, Kitakyushu, to obtain standard values for SR-BI, SR-FAI and SDL [15]. The evaluation items were patient profile (age, sex, living arrangements), SMON severity, activities of daily living (ADL), lifestyle and QOL. Here is an outline of the evaluation items.

SMON severity was classified based on Disability Scale for SMON patients, which was devised by the SMON research committee of the Ministry of Health, Welfare and Labour [16]. The Disability Scale for SMON, consisting of three major neurologic disturbances, namely gait, sensation and vision, indicated a total score of three weighted disturbances as severity (from 0 for no sign to 21 for very severe sign of SMON), and they are considered to be the standard criteria for severity.

SR-BI [17], which was modeled after the Granger version of BI [18] and was a self-rating modification for epidemiological research, was used for evaluation of the personal ADL. The SR-BI consists of 13 items concerning basic daily activities, summed up on a 0–100 scale, and the validity and reliability of the self-entry form have been confirmed.

SR-FAI [19], which is a self-rating modification of FAI [20], was used for evaluation of lifestyle. The SR-FAI consists of 15 items concerning performance of applied ADL in four stages from 0 to 3, for a total of 0–45 points. The validity and reliability of a self-rating version have been confirmed [21].

In the evaluation of QOL, SDL and SF-36 were used. The SDL is an evaluation of the subjective domain of QOL in daily life, and consists of 11 important items shared by the elderly persons living at home (physical health, mental stability, self care, ambulatory mobility, household work, living environment, living arrangements with spouse/family, hobbies/recreation, local/social interaction, pension/income and work), using a 5-stage satisfaction level, from 1 for 'dissatisfied' to 5 for 'satisfied', with the total score being within the range of 11 for the most dissatisfied and 55 for the most satisfied [7].

SF-36 is a standard evaluation indicator of health-related QOL, comprising 36 items generally related to health, as reported by Ware et al. [13] in 1992. These items are arranged into eight sub-scales (physical functioning, role physical, bodily pain, social functioning, general health perceptions, vitality, role emotional and mental health), and are put together into two summary measures (physical component summary (PCS) and mental component summary (MCS)).

A relationship between disabilities, lifestyle and QOL in SMON patients was statistically analysed by using Spearman's rank correlation coefficient (SPSS 8.1J). *p*-values of less than 0.05 were considered to be significant.

Results

The SMON group comprised 58 patients (18 males and 40 females), and the mean age was 76.1 ± 10.6 years (mean $\pm$ SD). The control group also consisted of 58 (18 males and 40 females), and the mean age was 75.3 ± 8.7. There was no significant difference in age between both groups (NS, *t*-test).

A total score of the SMON severity was 8.0 ± 4.8 (3.3 ± 2.6 for gait, 2.2 ± 0.9 for sensation and 2.5 ± 2.6 for vision). The living arrangements were as follows: living alone, 11 persons (19.0%); living with a spouse, 13 persons (22.4%); living with a spouse and another family member (son, daughter, daughter-in-law and/or son-in-law), 16 persons (27.6%); living with another family member, 10 persons (17.2%); and other arrangements, 8 persons (13.8%).

The total score and all items of SR-BI of the SMON group were significantly lower than those of the control group (Table I), and the total score and all items, except for preparing meals, washing clothes, and gainful work of SR-FAI were significantly lower than those of the control group (Table II). Table III shows that the total score and all items of SDL of the SMON group were significantly lower than those of the control group. PCS and MCS of SF-36 in the SMON group were 26.3 ± 7.8 and 39.5 ± 11.0, respectively.

Table IV shows the correlation coefficients between SMON severity, SR-BI, SR-FAI, SDL, PCS and MCS. SDL had significant correlations with SMON severity, SR-BI, SR-FAI, PCS and MCS; PCS, with SR-BI and SDL; MCS, with SDL.

Discussion

The number of subjects in this study was not large, but we believe our data reflect the situation for all

Table I. Scores of Self-Rating Barthel Index.

	SMON (*N*=58)	Control (*N*=58)
Self-care		
Eating (0–10)	8.8 ± 2.9*	10.0 ± 0.0
Grooming (0–5)	4.4 ± 1.3*	5.0 ± 0.0
Washing or bathing (0–5)	3.7 ± 1.9*	5.0 ± 0.0
Dressing upper body (0–7)	5.6 ± 2.3*	7.0 ± 0.0
Dressing lower body (0–8)	6.0 ± 2.8*	8.0 ± 0.0
Toileting (0–5)	4.2 ± 1.6*	5.0 ± 0.0
Controlling urination (0–10)	5.3 ± 3.5*	10.0 ± 0.0
Controlling bowel movements (0–10)	6.5 ± 3.7*	9.9 ± 0.7
Mobility		
Getting in and out of chairs (0–5)	3.8 ± 1.8*	5.0 ± 0.0
Getting on and off a toilet (0–5)	4.0 ± 1.8*	5.0 ± 0.0
Getting in and out of tub or shower (0–5)	3.3 ± 2.0*	5.0 ± 0.0
Walking 50 m on level ground (0–15)	10.7 ± 5.2*	15.0 ± 0.0
Walking up/down the stairs (0–10)	4.5 ± 4.4*	9.1 ± 2.4
Total score (0–100)	70.8 ± 28.0*	99.0 ± 2.4

The numbers in brackets are theoretical ranges, and measured values are presented as means ± SD.
*$p < 0.05$, Mann–Whitney test, SMON *vs.* control.

Table II. Scores of Self-Rating Frenchay Activities Index.

	SMON (*N*=58)	Control (*N*=58)
1. Preparing meals (0–3)	0.9 ± 1.2	1.4 ± 1.4
2. Washing up (0–3)	1.0 ± 1.2*	1.9 ± 1.2
3. Washing clothes (0–3)	1.2 ± 1.3	1.7 ± 1.3
4. Light housework (0–3)	1.2 ± 1.3*	2.3 ± 1.0
5. Heavy housework (0–3)	0.6 ± 1.0*	2.0 ± 1.1
6. Local shopping (0–3)	0.9 ± 1.2*	2.2 ± 1.1
7. Social occasions (0–3)	0.8 ± 1.1*	1.9 ± 1.0
8. Walking outside (0–3)	0.9 ± 1.2*	2.5 ± 0.8
9. Actively pursuing hobby (0–3)	0.7 ± 1.1*	1.6 ± 1.3
10. Driving car/bus travel (0–3)	1.2 ± 1.2*	2.1 ± 1.0
11. Travel outings/car rides (0–3)	0.3 ± 0.7*	0.8 ± 0.8
12. Gardening (0–3)	0.3 ± 0.7*	1.1 ± 1.1
13. Household/car maintenance (0–3)	0.2 ± 0.5*	0.7 ± 1.1
14. Reading books (0–3)	0.8 ± 1.2*	1.3 ± 1.3
15. Gainful work (0–3)	0.2 ± 0.6	0.4 ± 1.0
Total score (0–45)	11.1 ± 11.0*	23.9 ± 7.7

The numbers in brackets are theoretical ranges, and measured values are presented as means ± SD.
*$p < 0.05$, Mann–Whitney test, SMON *vs.* control.

Table III. Scores of satisfaction in daily life.

SDL items	SMON (*N*=58)	Control (*N*=58)
Physical health (1–5)	1.6 ± 0.9*	3.2 ± 1.2
Mental stability (1–5)	2.2 ± 1.1*	3.7 ± 1.2
Self care (1–5)	2.4 ± 1.3*	4.4 ± 0.8
Ambulatory mobility (1–5)	2.3 ± 1.3*	4.4 ± 1.0
Household work (1–5)	2.1 ± 1.2*	4.1 ± 1.1
Living environment (1–5)	3.1 ± 1.4*	4.3 ± 1.0
Living arrangements with spouse/family (1–5)	3.5 ± 1.2*	4.4 ± 0.9
Hobbies/recreation (1–5)	2.4 ± 1.1*	3.4 ± 1.2
Local/social interaction (1–5)	2.5 ± 1.2*	3.5 ± 1.0
Pension/income (1–5)	2.4 ± 1.3*	3.3 ± 1.2
Work (1–5)	2.8 ± 0.7*	3.1 ± 0.5
Total (11–55)	27.3 ± 8.6*	41.8 ± 7.0

The numbers in brackets are theoretical ranges, and measured values are presented as means ± SD.
*$p < 0.05$, Mann–Whitney test, SMON *vs.* control.

Table IV. Correlation with SDL and SF-36 in patients with SMON.

	SDL	PCS	MCS
SMON severity	−0.387*	−0.204	0.049
SR-BI	0.464*	0.417*	−0.075
SR-FAI	0.442*	0.343	−0.019
SDL	–	0.373*	0.459*

SMON severity, disability scale for SMON; SR-BI, Self-Rating Barthel Index; SR-FAI, Self-Rating Frenchay Activities Index; PCS of SF-36, physical component summary of short form-36; MCS of SF-36, mental component summary of short form-36.
*$p < 0.05$, Spearman's correlation coefficient (with Bonferroni correction for multiple testing).

patients with SMON living at home to some extent. The officially approved number of patients with SMON in Japan is 2504 in April 2006. Because patients with SMON are receiving a special health allowance from the pharmaceuticals and medical devices agency and all such patients are known to receive the payments, the officially approved number of SMON is presumably accurate. Although Kuriyama et al. [11], Fujii and Arakawa [12], Honaga et al. [14] investigated 23, 17 and 7 patients with SMON, respectively, we examined 58 subjects in this study who were thus equivalent to 2% of all patients with SMON in our country.

We have developed SDL in order to evaluate the subjective domains of QOL in patients with SMON, and have studied the similarities and differences between the measurement concepts of SDL and SF-36 in the patients with stroke living at home and the elderly persons living at home [8]. As a result, we demonstrated that SDL could detect the subjective domains of QOL in patients with stroke that were similar to the psychological scales of SF-36.

As mentioned before, there have been few reports on the QOL of patients with SMON, and moreover, there are no reports of research on disease-specific QOL scales for patients with SMON. In the present study, we have investigated the characteristics of disabilities in patients with SMON based on the research to date, and we have examined the similarities and differences between SDL and SF-36. We found that significant correlations were observed between SMON severity and SR-BI, SR-FAI and SDL. It is believed that the subjective domains of QOL in patients with SMON are reduced, along with a decrease in independence of basic ADL and performance of applied ADL, when the SMON severity is severe. In addition, from the fact that correlations were observed between SDL and SMON severity, basic and applied ADL, and PCS and MCS of SF-36, SDL would reflect well the characteristics of disabilities in patients with SMON. On the other hand, no relationship has been observed between SF-36 and SMON severity.

Significant correlations were observed between SMON severity and SDL, but not between SMON severity and SF-36. SDL was originally developed to evaluate the subjective domains of QOL specific to patients with SMON, and the questionnaire consisted of the items related to satisfaction of elderly people living at home and disabilities of patients with SMON. SF-36 is a comprehensive evaluation scale that does not specify the disease or symptoms, and its items are constructed to broadly measure, across eight areas, comprehensive health concepts. It is believed that SDL reflects the disabilities in SMON better than SF-36. Fujii and Arakawa evaluated patients with SMON using Disability Scale for SMON, BI and SF-36, but reported that no correlation with the PCS and MCS of SF-36 could be found. The reason for this was stated as the possibility that QOL of a patient with SMON is not simply correlated with the extent of the disability, and that other factors are involved [12]. However, the results of our research show that SDL, a QOL scale disease-specific to SMON, can detect subtle changes of living conditions which are difficult to accurately determine using SF-36.

In our previous research which included a comparison between patients with SMON and stroke, patients with SMON showed high values in applied ADL and low values in SDL. Those results also indicated that SDL was able to differentiate the characteristics between patients with SMON and stroke [22].

The limitations of our research can be stated as follows. The first is that 39 non-respondents may have affected the results. The male–female ratio of respondents and non-respondents was about 1:2 in both groups, and there was no disparity. The questionnaires were designed to be anonymous, so there was little information on the non-respondents. Patients with SMON who were bedridden or had very severe disabilities might not have either wanted or be able to respond the questionnaire. However, such patients are less than 5% according to the annual medical checkup administered by the local members of the SMON research committee of the Ministry of Health, Welfare and Labour, and it is unlikely that there was any definite bias toward the respondents. The second is that the values of correlation coefficients with significance were not high. Although the SDL was associated with SMON severity, basic and applied ADL, and QOL, SDL could not explain all of the symptoms and disabilities of patients with SMON, and other factors, including victims of drug poisoning might be involved as Fujii and Arakawa had previously described [12].

In conclusion, the subjective domains of the QOL in patients with SMON were observed to decrease, and SDL was found to closely reflect the characteristics of disabilities in patients with SMON. As a result, SDL is therefore considered to be an appropriate scale for the subjective domains of QOL in patients with SMON.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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[Technical note]

A Walker with a Device of Partial Suspension for Patients with Gait Disturbance: Body Weight Supported Walker

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***Abstract*:** We developed a walker, the Body Weight Supported (BWS) Walker, with a device of partial suspension for patients with gait disturbance. It consists of a light frame with casters, a harness, and a winch system. One therapist alone can perform gait training safely with the BWS Walker without any additional physical load, even if a patient has severe gait disturbance, and the therapist can concentrate on evaluating and improving the patient's standing balance and gait pattern. Because the BWS Walker is less expensive, simpler, and easier to operate than other BWS systems, we believe the BWS Walker can be widely applicable in training for patients with severe and moderate gait disturbance.

***Key words*:** stroke, gait training, walker, body weight-supported training, rehabilitation.

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Introduction

A stroke patient with severe gait disturbance may require intensive and safe gait training from the acute stage, to gain a successful result in rehabilitation. Recently, several researchers have reported that manual-assisted or robotic-assisted body weight-supported (BWS) treadmill training enhanced the gait function of patients suffering from spinal cord injury, stroke, or other neurological conditions [1]. Although the manual-assisted BWS treadmill training has benefits of functional recovery and independence of gait, the physical burden on the therapist is considerably heavy, and a patient cannot walk freely on the floor. Robotic-assisted BWS devices reduce the burden, but they are too big and too expensive. A gait training device which is less expensive, simpler, and easier to operate is desirable, but there are few reports about such a device [2]. We therefore developed a walker with an apparatus of partial suspension for patients with gait disturbance, the BWS Walker.

BWS Walker

The BWS Walker consists of a frame made of aluminum with four locking casters, a parachute harness, and a winch system (Fig. 1). It is 900 mm wide, 1,000 mm deep, 1,800–2,200 mm high and weighs 24.5 kg. The height of the BWS Walker is adjustable, and the frame and winch system can endure the weight of patients up to 100 kg. A weight measure is attached to the winch system, by which we can easily measure the suspended body weight. The frame has a horizontal bar and a central bar (Fig. 2), which support the upper extremities. The central bar is removable, and the horizontal bar is adjustable. The harness is also adjustable to fit the waist and hips. The BWS Walker costs about $3,000, and is far less expensive than robotic devices.

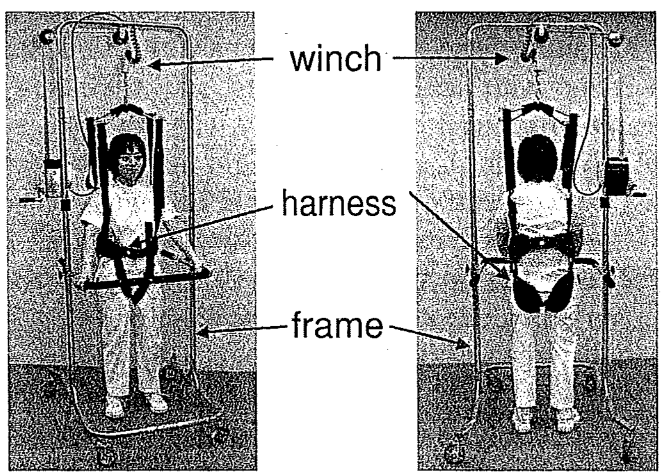

Fig. 1. Body Weight Supported (BWS) walker. The BWS walker consists of a frame made of aluminum with four locking casters, a parachute harness, and a winch system. It is 900 mm wide, 1,000 mm deep, and 1,800–2,200 mm high, and weighs 24.5 kg.

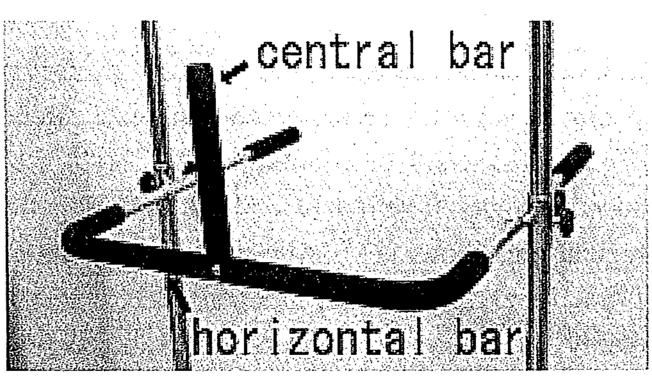

Fig. 2. Central bar and horizontal bar. A patient grasps the bars to keep his/her body straight. The central bar is removable, and the horizontal bar is adjustable.

Patients

We used the BWS Walker for 12 stroke patients with severe gait disturbance who could hardly train themselves for gait because of the severity of their hemiplegia or agnosia (eg. Pusher syndrome). It took about five minutes to put on the harness the first time, but took less time from the second time on. The rate of unloaded body weight, which was preferable from 0 to 40%, was adjusted based on the weight measure in relation to the patients' ability to swing their paretic limbs. While a therapist controlled the BWS Walker, a patient could walk freely on the floor at his own comfortable speed.

All patients could stand in a symmetrical posture with the BWS Walker, could walk straight on the floor for more than 10 m comfortably, and could turn smoothly. They did not complain of pain in their waist or inguinal areas because the harness fitted well. Ten of those using the BWS Walker could swing their paretic limb with the assistance of a therapist even if they couldn't swing it with a knee ankle foot orthosis (KAFO) or ankle foot orthosis (AFO) in the parallel bars with a therapist's assistance.

There were no accidents of falling down while the patients walked with the BWS Walker. One therapist alone could perform gait training with the BWS Walker on the floor safely, and could concentrate on evaluating and improving the stand and gait pattern.

Discussion

We developed the BWS Walker, which may be just as useful as a BWS treadmill for training a patient with gait disturbance and is definitely less expensive than a manual-assisted BWS treadmill or robotic-assisted BWS gait trainer [3, 4].

Because the BWS Walker has a structure as simple as ordinary walkers and is not equipped with a personal computer or complicated control unit, it is very easy for all physical therapists to operate the BWS Walker during gait training. The BWS treadmill or robotic-assisted BWS gait trainer can be operated properly only by specialists in the field of physical therapy and rehabilitation engineering. On the other hand nurses in the ward, assistants in welfare facilities, or even family members at home can fit the BWS Walker to a patient within a few minutes and manage it with ease. All the patients in this study could perform gait training comfortably, freely and safely with the BWS Walker, and gait training with the BWS Walker was not limited to a fixed place in the training room. When a patient puts on the BWS Walker by his bed in the ward, he can walk comfortably with the BWS Walker in the corridor, freely get in and out of an elevator, and safely arrive at the training room on a different floor. The features of the BWS Walker are comfort, freedom of movement, and safety in gait training.

The BWS Walker has two bars to support the upper extremities: a central bar and a horizontal bar. We set the central bar to the BWS Walker for patients who have a less stable standing balance; for example, a patient with pusher syndrome or visuospatial neglect. In this study, a patient with pusher syndrome who could barely stand still and walk in the parallel bars without putting a heavy physical burden on a therapist could stand still in a symmetrical posture with the BWS Walker, holding the central bar, and could walk safely having his paretic lower extremity swung by a physical therapist. The central bar is also a good mark for a patient with visuospatial neglect, indicating the center of field, because the patient is asked to grasp the central bar and look at it during gait.

Although the BWS Walker has several advantages compared with BWS treadmill or robotic-assisted BWS gait trainer, one disadvantage is that the BWS Walker has no system to control the paretic lower extremity. If a patient suffers from complete paralysis of both lower extremities, the BWS Walker is less applicable, and a robotic-assisted BWS gait trainer may be superior for such a patient. When a patient cannot walk volitionally or cannot follow commands, the BWS Walker is not useful.

We consider that the BWS Walker is useful for hemiplegic patients with severe or moderate gait disturbance and with agnosia, ataxia, or rigidity, but this remains to be further studied, because there are no data indicating that gait training by using the BWS Walker is objectively superior to ordinary gait training without any assistant device, BWS treadmills, or robotic-assisted BWS gait trainers.

Conclusion

We developed the BWS Walker, which consists of a frame made of aluminum with four locking casters, a parachute harness, and a winch system for partial body weight suspension. The BWS Walker is less expensive, simpler, and easier to operate than other BWS systems.

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歩行障害患者のための懸垂機構付き歩行器の開発

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要　　旨：懸垂機構付きの部分免荷歩行器(Body Weight Supported(BWS) walker)を開発した．BWS walkerはアルミ製の軽量フレーム，キャスター4個，ハーネス，ウィンチを用いた懸垂機構からなり，1人の療法士でハーネスの装着，ウィンチによる懸垂，歩行器を操作しながら歩行訓練を行うことができ，重度の歩行障害をもつ患者に安全に歩行訓練を行うことができ，かつ訓練を担当する療法士の負担が少ない．この歩行器による歩行訓練では，介助をすることよりも起立歩行の評価や指導に，より集中することができる．既存の部分免荷システムに比べ簡便かつ安価であり，扱いやすい点が優れている．重度から中等度の歩行障害患者に広く適応があると考えている．

キーワード：脳卒中，リハビリテーション，歩行器，歩行訓練，部分免荷歩行訓練．

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[Original]

Change in Lower Limb Isokinetic Muscle Strength of Polio Survivors over 5-Year Follow-up

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Abstract: To evaluate the muscle strength of the lower limbs over time in polio survivors during 5 years of follow-up and to examine the rate of change in their muscle strength, we performed a prospective, longitudinal study of polio survivors (n = 63: 61 with postpolio syndrome) living in the community who participated voluntarily. Their isokinetic knee-extensor and knee-flexor muscle strength (peak torque) at angular velocities of 60 and 120 deg/sec, using a fixed dynamometer (Biodex) were measured over a 5-year period. At 5-year follow-up, approximately 90% of the subjects had decreased knee extensor strength at both angular velocity of 60 and 120 deg/sec: similarly, at both angular velocities, approximately 80% of the subjects had decreased knee flexor strength. The annual average rate of decrease in the peak torque of the knee extensors was significantly greater than that of the flexors at both angular velocities, and the difference in the rates between the extensors and the flexors was marked at the faster angular velocity. The polio survivors had a progressive decrease in lower limb isokinetic muscle strength over time. In addition, the annual rate of decrease of the knee-extensor, the so-called weight bearing muscle, was greater than that of the knee-flexor.

Key words: muscle strength, isokinetic force, polio, rehabilitation.

(Received 12 February 2009, accepted 31 March 2009)

Introduction

Post-polio syndrome (PPS) is generally defined as a clinical syndrome of new muscle weakness, fatigue, and pain in individuals who have previously recovered from acute paralytic poliomyelitis [1, 2]. In recent years, PPS has become a serious issue for Japanese polio survivors, and it appears that Japan is following approximately 10 years or more behind the USA. We performed an epidemiological survey of PPS in an area with one million inhabitants in Japan and found that the prevalence of PPS was 18.0 per 100,000 population [3]. We also found that progressive muscle weakness had limited their daily and social activities [4].

The muscle strength of polio survivors generally decreases over time [1, 5–12], and reduction of muscle strength has been thought to be greater than that which occurs with normal aging. One of the proposed mechanisms for progressive muscle weakness in PPS is distal degeneration of massively enlarged motor units from axonal sprouting after acute paralytic poliomyelitis. However, there have been contradictory reports that patients with PPS had increased [13, 14] or constant [15–17] muscle strength. The reason for the above contradictory results is mainly methodological differences between studies, such as subjects' criteria, measurement of muscle strength, and follow-up periods. In particular, manual muscle testing (MMT) [1, 12, 14, 15] and the hand-held dynamometer (HHD) [9, 12, 14] are limited in detecting changes in muscle strength, and their interexaminer reliabilities are poor [18, 19]. Furthermore, deterioration in muscle strength cannot be detected in a short follow-up period of less than 2 years [19]. Therefore, quantitative muscle strength testing using a fixed dynamometer and a long-term follow-up period of at least 4 years are needed to study the muscle strength of polio survivors.

The purpose of the present study was: 1) to evaluate the lower extremity muscle strength using a reliable measurement method, the fixed dynamometer, in polio survivors over a 5-year period; and 2) to examine the rate of change in their knee-extensor and knee-flexor muscle strength.

Methods

Subjects

The subjects were recruited from the support group for polio survivors living in the North-Kyushu area of Japan (population of one million), where approximately 340 polio survivors were identified [3]. A total of 110 polio survivors voluntarily participated in the annual health examination for PPS and visited our hospital between 2001 and 2006. They were part of the polio survivors' population that we had previously surveyed. Inclusion criteria for the present study were: 1) a history of previous polio that was confirmed by the subjects' physically disabled persons' certificates; and 2) physical examination consistent with past paralytic polio. Most of the polio survivors with paralysis had physically disabled persons' certificates that had been issued based on the law for the Welfare of Physically Disabled Persons in Japan.

Study design

Subjects were evaluated prospectively over a 5-year period between 2001 and 2006. Data for this study were obtained at the time of presentation to our hospital. The outcome variable was isokinetic muscle strength of the lower limbs, which was obtained using an isokinetic strength dynamometer (described in the next section). Data on the following variables were also obtained by interview and examination: age, sex, age at the time of acute polio, general muscle weakness evaluated by MMT of the four extremities, personal activities evaluated using the Barthel ADL index (BI) [20], and instrumental activities evaluated using the Frenchay Activities Index (FAI) [21] at the time of presentation. An MMT sum score, ranging between 0 and 110, was obtained by adding the values of all 11 muscle groups bilaterally: shoulder flexion, elbow flexion and extension, wrist extension, finger abduction, hip flexion and extension, knee flexion and extension, and ankle dorsiflexion and plantarflexion. The details of the BI and FAI scales that evaluate mobility-related activities have been described previously [22]. Each subject was followed up every year at the annual health examination for polio survivors in the study area, and isokinetic muscle strength testing was repeated (Fig. 1).

Isokinetic muscle strength testing

Isokinetic muscle strength of the lower limbs was measured in subjects whose MMT scores for both knee-extension and knee-flexion were 4 or 5. This allowed subjects with mildly affected lower limbs to be included in the study (Fig.1).

We used the Biodex® System 3 Isokinetic Dynamometer to measure isokinetic knee-extension and knee-flexion strength at angular velocities of 60 and 120 deg/sec. The subject was positioned according to the standard knee testing procedures outlined in the Biodex System 3 Operations Manual. At each angular velocity, the subject performed 3 trial repetitions prior to the actual test to become familiar with the procedure. Following the trial repetitions, the subject performed 5 repetitions of maximal knee extension and flexion isokinetic contractions. While performing knee extension and flexion, the subject was verbally directed with the words "kick" and "bend", respectively. The highest torque values for each subject were recorded as the peak torque (PT) for subsequent analyses.

Statistical analysis

The JMP®7 (SAS Institute Inc) statistical analysis program was used to obtain descriptive statistics and perform univariate and survival analyses. First, we evaluated the proportion of subjects with decreased PT during follow-up, using the method of survival analysis, i.e. the time-to-failure or Kaplan-Meier analysis. This analysis takes different follow-up periods in each case into consideration. Second, secular change of the PT values was analyzed using ANOVA. Finally, each percent change of the PT values in the two directions at the two angular velocities was calculated from the PT values at baseline (PTbase), at the last visit (PTlast), and at the follow-up years (Y) during the study according to the formula: % change of PT per year = $(PTlast - PTbase) \times 100 / (PTbase \times Y)$ (%). Student t-test was used to compare the percent change of the PT values between the two directions.

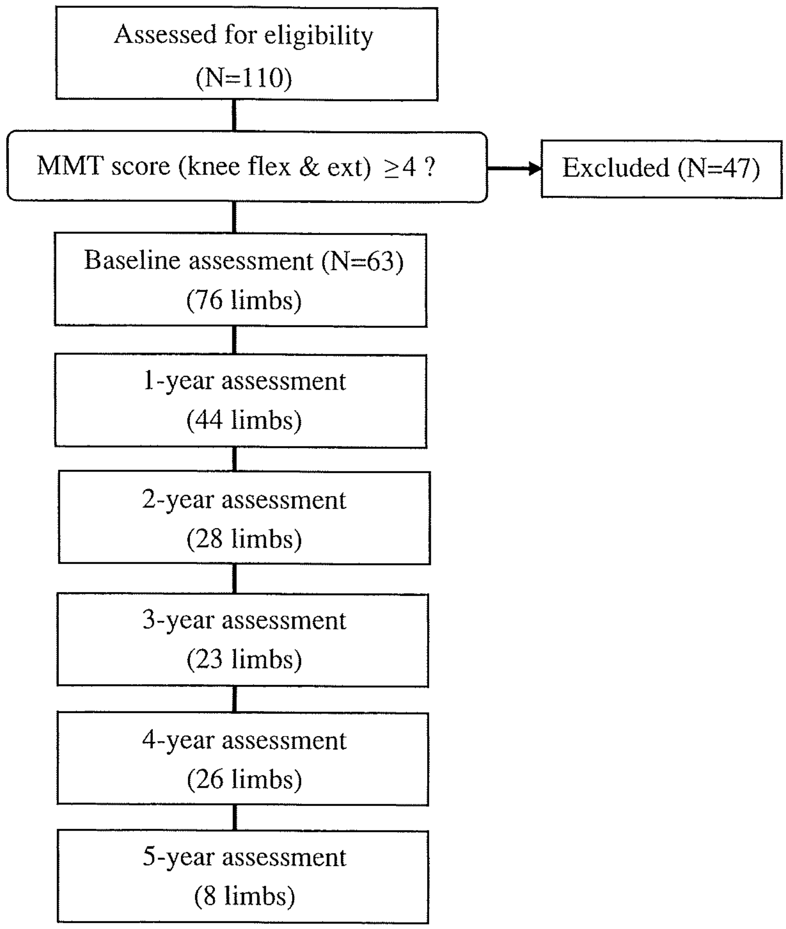

Fig. 1. Flow chart of the follow-up.

Results

Some of the study subjects' characteristics are presented in the Table 1. A total of 63 subjects (27 men and 36 women) with 76 affected lower limbs completed the requirements at the baseline of the study. Their mean age was 54.5 years, and 57% were women. The mean age at the time of acute polio onset was 2.3 years. Ninety-seven percent of the subjects (61 subjects) met Halstead's criteria of PPS [23]: 1) a history and physical examination compatible with paralytic polio; 2) at least 15 years of functional stability following initial recovery; 3) new symptoms of increased or new muscular weakness, and fatigue (muscular and/or general); and 4) no other neurological or medical conditions that could produce weakness and fatigue. Most of the subjects had a normal weight (mean body mass index score, 22.8). Forty percent of the subjects were using either a knee-ankle-foot orthosis or an ankle-foot orthosis. They were independent in personal and instrumental activities (mean total BI 98.4,