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Original Article

Effectiveness of medial-wedge insoles for children with intoeing gait who fall easily

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ABSTRACT

Objectives: This study aims to investigate the effectiveness of orthosis therapy using a medial-wedge insole (MWI) with a height of 5 mm and an arch support for children with intoeing gait who are prone to falling.

Patients and methods: Between January 1997 and July 2014, a total of 51 children (24 males, 27 females; mean age 5.0 years; range, 3 to 8 years) who were treated for an intoeing gait symptom of easily falling using the MWI (toe-in gait group) were included. The effectiveness of the MWI was evaluated based on the scores reported by children and their parents on a scale. Physical findings of the study group were also compared with a control group consisting of seven healthy children (4 males, 3 females; mean age 5.2 years; range, 3 to 6.2 years). Foot stability with and without MWI were assessed.

Results: The MWI was found to be effective in 80.8% of the toe-in gait group. Bilateral sum of the internal rotation angle of the hip (IRAB) was significantly higher (136±17°) ($p=0.007$) and bilateral sum of thigh foot angle (TFAB) significantly lower (-27±21°) ($p<0.001$) before using MWI in the toe-in gait group, compared to the control group. The maximum range of motion of the foot in six children in the toe-in gait group significantly decreased from 14.1±5.0° without MWI to 8.2±3.0° with MWI ($p=0.002$) in the gait analysis.

Conclusion: These study results suggest that MWI is effective in reducing the risk of falling in children with intoeing gait, mainly due to the internal torsion of the tibia or femur. In addition, it appears to be effective in improving the maximum range of motion of the foot.

Keywords: Gait analysis, medial-wedge insole, orthosis therapy, toe-in gait.

In healthy children, alignment of the lower extremities changes as they grow until about the age of eight. The tibial torsion axis starts to rotate from internal to external from approximately age one to two years, while femoral anteversion gradually decreases from approximately age three years.[1,2] However, toe-in gait can be seen when femoral anteversion, internal tibial torsion or metatarsus adductus do not decrease sufficiently.[3,4] Toe-in gait is one of the gait abnormalities which is often confronted in pediatric orthopedics, which can cause children to easily fall, when they walk or run. The symptom of falling is followed without treatment in most cases, as it often resolves spontaneously as children grow up.[5-7] However, proactive treatment is required when the symptom persists, or may cause a risk of injury from falling or a delay in motor development.[8-10] As the patients are children and toe-in gait is not a severe disease, treatment methods need to be simple and less invasive. Given this condition, we conceive of orthotic treatment modalities using a medial-wedge insole (MWI) with a height of 5 mm and an arch support.

In the present study, we hypothesized that MWI would improve toe-in gait by limiting the rearfoot valgus when landing, and shifting the weight on the sole outward, thus reducing the excessive internal tibial rotation and forefoot turning inwards. It is important to prevent locomotion accidents to support normal development of children. From the viewpoint of preventing accidents, MWI may be useful. Medial-wedge insole is also highly safe and cost-effective,

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compared to treatment costs in case of any accident. In this study, therefore, we aimed to investigate the parent and child-reported effectiveness of MWI for children with intoeing gait who are prone to fall.

PATIENTS AND METHODS

Study population

Between January 1997 and July 2014, a total of 102 feet of 51 children (24 males, 27 females; mean age 5.0 years; range, 3 to 8 years) who were treated for an intoeing gait symptom of easily falling using the MWI (toe-in gait group) were included. All children were examined by a single pediatric orthopedic specialist in a single center. Children who had toe-in gait caused by paralysis, or had a history of treatment for congenital foot diseases were excluded from the study. Children aged less than three years old were also excluded, as they are prone to fall regardless of the toe-in gait, and it is difficult to confirm the intent in such young children. In addition, children aged ≥9 years were excluded from the point of view of developmental changes in the lower extremity alignment in childhood. Toe-in gait is reported to be a gait in which the foot progression angle (FPA) deviates from normal to internal rotation.[7,8,11] Normal angle of the FPA is suggested to be between -3° and +20°,[12] although as there is no clear definition of toe-in gait regarding FPA,[10,12] we diagnose toe-in gait as the condition when the forefoot turns inward to the gait direction at stance phase, while walking during examination. The time from starting to use MWI to evaluation was less than six months to minimize any effects of growing with a mean value of 1.8 months (range, 1 week to 5 months) among all children.

A written informed consent was obtained from each parent. The study protocol was approved by the Ethics Committee of Kyoto Prefectural University of Medicine (ERB-C-378). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Medial-wedge insole use

The MWI with a height of 5 mm and an arch support (Figure 1a-c) made of ethylene-vinyl acetate were made-to-order and customized to the foot of each child by a prosthetist (Rakuhoku Prosthetic and Orthotic Manufacturing Co. Kyoto, Japan). The MWIs were inserted into shoes and used, when the children went out.

It was considered that 5 mm was an adequate medial-wedge height, based on the previous finding reporting that it is the most effective height in stabilizing feet among 3 sizes, 0, 5, and 10 mm.[13]

Evaluation of treatment

To evaluate the treatment, the children and their parents were asked to rate the MWI on a scale ranging between 1 and 5: 1 effective, 2 rather effective, 3 rather ineffective, 4 ineffective, 5 don't know (Table 1a). Among the five grades, 1 and 2 were determined to be effective, and 3 through 5 as ineffective.

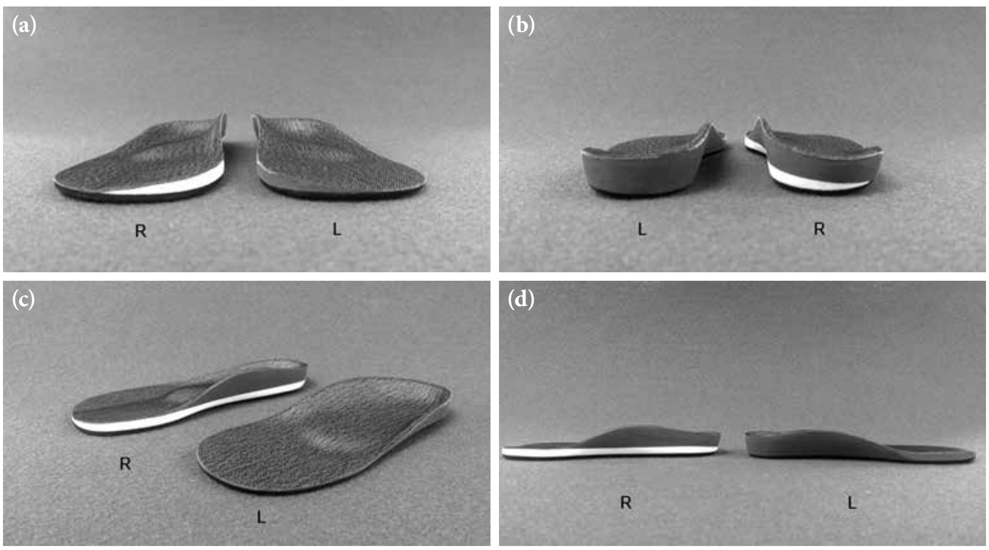

Figure 1. External appearance of medial-wedge insoles with a height of 5 mm and an arch support extending from heel to toe in a single block. **(a)** front, **(b)** rear, **(c)** oblique, **(d)** medial.

Table 1. Questionnaire for the evaluation of MWI[9]

a	Do you think MWI was effective to prevent falls?	
	Effective	1
	Rather effective	2
	Rather ineffective	3
	Ineffective	4
	I don't know	5
b	How often did you fall before wearing MWI?	
	Never fell	1
	Less than one time/week	2
	Less than one time/day	3
	One to less than five times/day	4
	Five to less than 10 times/day	5
	10 times or more/day	6
c	How often did you fall while wearing MWI?	
	Never fell	1
	Less than one time/week	2
	Less than one time/day	3
	One to less than five times/day	4
	Five to less than 10 times/day	5
	10 times or more/day	6

MWI: Medial-wedge insole; 2 and 3 were adopted from a report by Redmond.
(a) Questionnaire for the effectiveness of MWI
(b) Frequency of falling before using MWI
(c) Frequency of falling while using MWI

In addition, effectiveness in terms of falling was classified into six grades in 40 children who had reported frequency of falling, using a questionnaire based on a report by Redmond[9] (Table 1b and 1c). Some of the participants from before the year 2000 were evaluated from inquiry by phone call in addition to their medical records.

Physical findings of toe-in gait group compared to control group

The range of internal and external rotation in the hip internal rotation angle (IRA), external rotation angle (ERA), thigh foot angle (TFA), femorotibial angle (FTA), and metatarsus adductus index (MAI) were measured as physical findings of the toe-in gait group by a goniometer before using MWI. The IRA, ERA, TFA, FTA, and MAI were calculated by adding values for the left and right lower limbs and defined as IRAB, ERAB, TFAB, FTAB, and MAIB to evaluate the physical characteristics of both sides together. For MAI modifying Bleck's classification,[14] numbers were assigned from hallux to the fifth toe in the order 1-5, from each interdigital area in the order 1.5-4.5 and a line was extended from the central axis of the hind foot to determine with which toe it connected with and, then, was converted to a numerical value. The control group consisted of 14 feet of seven healthy children (4 males, 3 females; mean age 5.2 years; range, 3 to 6.3 years) without any symptom of being prone to falling easily (control group). Each item of physical findings was assessed and compared between the toe-in gait and control groups.

Evaluation of foot stability by gait analysis

The conditions of 12 feet of six children both with and without MWI (2 males, 4 females) in the toe-in gait group in whom MWI was effective were evaluated by gait analysis. The children, with markers affixed, were instructed to walk a short course, until we obtained adequate foot data from several gait cycles for each side both with and without MWI and, then, the mean degree of the maximum range of motion of the foot was calculated from the 10 feet whose width could be measured completely.

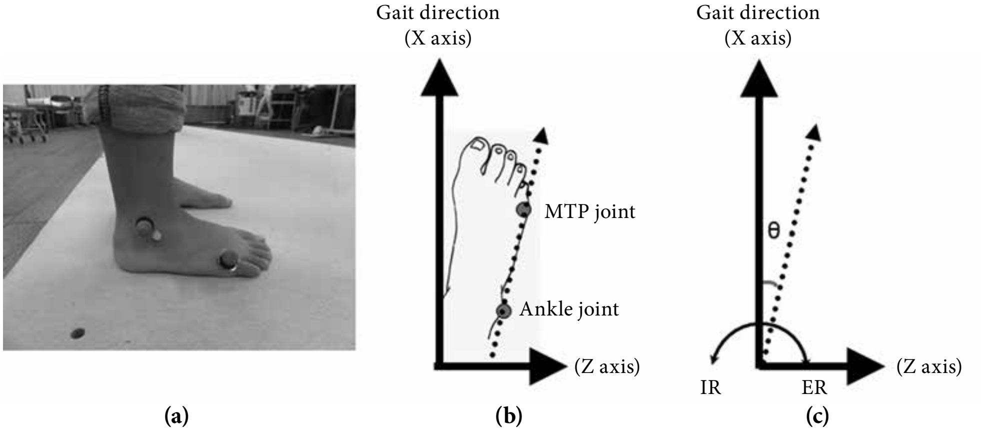

Figure 2. **(a)** Positions of markers, lateral. **(b, c)** Foot progression angle (θ). MTP: Metatarsophalangeal. IR: Internal rotation; ER: External rotation.

The VICON-MX (VMS) (Vicon Motion Systems Ltd., Oxford, UK)[13,15] was used in gait analysis, with gait direction labeled as X axis and the direction vertical to the X axis from the floor as Y axis, the direction orthogonal to X axis and parallel to the floor as Z axis on a coordinate plane. Cube-shaped infrared reflection markers in 15 mm diameter were affixed to the ankle joint and first metatarsophalangeal (MTP) joint of the little toe of both feet (Figure 2a). While the children walked unaided both with and without MWI, the courses of the markers were recorded using eight three-dimensional cameras. The courses with and without MWI were compared and the data analyzed using the workstation (VMS). Then, we examined the maximum range of motion of the foot during stance phase, which was calculated as the difference between the maximum and minimum value of FPA, which is an angle consisting of the line connecting the ankle joint and MTP joint of the little toe, and the gait direction on the XZ coordinate (Figure 2b). The distance between the two joints on both X and Z coordinates during stance phase were calculated respectively and Tanθ was determined as (distance on Z axis) / (distance on X axis). The given θ was determined as FPA as the gait direction was on X axis (Figure 2c). The FPA during stance phase were calculated each time, and the maximum range of motion of the foot was identified as the maximum angle minus the minimum angle. The maximum range of motion of the foot during stance phase of 10 feet of five cases (2 males, 3 females) in the control group was measured using gait analysis, replicating the method used for the toe-in gait group, but the control group did not use MWI.

Statistical analysis

Statistical analysis was performed using the OMS Statcel (OMS Statcel, Japan). Descriptive data were expressed in mean and standard deviation (SD), or number and frequency. The Students' t-test was used to compare physical findings between the toe-in gait and control groups, and age and physical characteristics of the toe-in gait MWI between MWI-effective and ineffective groups. The t-test was used to compare the maximum range of motion of the foot of toe-in gait group with and without MWI in the gait analysis. The chi-square test was used to compare the results according to gender. A p value of <0.05 was considered statistically significant.

RESULTS

Effect of MWI use in reducing risk of falling

Of a total of 41 children and their parents who reported that MWI was effective, 25 rated them as 1 and 16 as 2, whereas of 10 children and their parents who reported MWI was ineffective, one rated them as 3, seven as 4, and two as 5 on a scale ranging between 1 and 5, indicating that MWI was effective for 80.8% of the children with intoeing gait. The numbers of grades of frequency of falling before using MWI were as follows: 0 for Grades 6 and 1, 1 for Grade 5, 21 for Grade 4, 15 for Grade 3, and 3 for Grade 2. The numbers of grades of frequency of falling after using MWI were as follows: 0 for Grades 6 and 5, 5 for Grades 4 and 1, and 15 for Grades 3 and 2 (Table 2a). The overall ratings improved and the number of incidences of reported falling decreased in 30 of 40 children. Improvement was found in 29 of 33 children in the MWT-effective group, although six of seven children did not change their ratings of pre-and post-MWI in the ineffective group. In the ineffective group, there was only one child in whom MWI reduced the risk of falling with a change in pre- and post-MWI treatment Grade from 4 to 3 (Table 2b).

Physical findings of toe-in gait group

The mean IRAB of toe-in gait and control groups was 136±17° and 117±14°, respectively. The mean ERAB was 92±22° and 84±36°, respectively. the mean TFAB was -27±21° and 13±11°, respectively. The mean FTAB was 347±4° and 348±5°, respectively, and the mean MAIB was 5.8±0.9° and 5.2±0.4°,

Table 2. Fall frequency before and after medial-wedge insole use

	(a) Toe-in gait group (n=40)		(b) Effective group (n=33)		Ineffective group (n=7)	
Redmond classification	Before MWI	After MWI	Before MWI	After MWI	Before MWI	After MWI
6	0	0	0	0	0	0
5	1	0	1	0	0	0
4	21	5	18	3	3	2
3	15	15	12	11	3	4
2	3	15	2	14	1	1
1	0	5	0	5	0	0

MWI: Medial-wedge insole.

Table 3. Comparison of physical findings between groups and subgroups

	Control group①	Toe-in gait group				
		All②	Effective group❶	Ineffective group❷		
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	*p*①/②	*p*❶/❷
IRA (°)	117±14	136±17	136±18	136±13	0.007	0.922
ERA (°)	84±36	92±22	92±23	92±22	0.394	0.943
TFA (°)	13±11	-27±21	-25±22	-35±13	<0.001	0.195
FTA (°)	348±5	347±4	347±4	346±5	0.543	0.364
MAI	5.2±0.4	5.8±0.9	5.6±0.8	6.5±0.9	0.093	0.007

❶: EG; ❷: IG; SD: Standard deviation; IRA: Internal rotation angle; ERA: External rotation angle; TFA: Thigh foot angle; FTA: Femorotibial angle; MAI: Metatarsus adductus index.

respectively. The mean IRAB of the toe-in gait group was significantly higher and the mean TFAB was significantly lower, compared to the control group (IRAB p=0.007; TFAB p<0.001) (Table 3).

Foot stabilizing effect of MWI using gait analysis

The mean maximum range of motion of the foot of the toe-in gait group in six (10 feet) children was 14.1±5.0° before MWI, which was significantly higher than that of five of the controls (10 feet) with a mean value of 6.3±2.6° (p=0.0004). The maximum range of motion of the foot in this group significantly decreased to 8.2±3.0° after using MWI (p=0.002), which did not significantly differ in the control group (p=0.162) (Table 4).

Comparison between MWI-effective and MWI-ineffective groups in toe-in gait group

The use of MWI was effective in 17 of 24 (70.8%) male and in 24 of 27 (88.9%) female children with intoeing gait, although this difference was not statistically significant (p=0.105). In addition, there was no statistically significant difference in the mean age between the MWI-effective and MWI-ineffective groups (p=0.635). However, the mean MAIB among physical findings in toe-in gait group was 5.6±0.8 in the effective and 6.5±0.9 in the ineffective groups, indicating a significant difference (MAIB p=0.007). On the other hand, no significant differences were found among the other items examined (Table 3).

DISCUSSION

The main cause of toe-in gait varies depending on age and individual, and growth. It has been reported that pes adductus is often closely associated with toe-in gate until the age of one to two years, and excessive anteversion of femur or a combination of factors related to internal tibial torsion are often closely associated with toe-in gait from age three

Table 4. Maximum range of motion of foot using gait analysis in standing posture

		Control group	Toe-in gait group	
Subject no		Without MWI/(°)	Without MWI/(°)	With MWI/(°)
1	R	7.1	12.8	6.4
	L	11.1	23.8	14.7
2	R	4.7	17	6.5
	L	4.1	-	-
3	R	10	15.8	9.7
	L	5.5	18.9	8.8
4	R	3.2	9.8	4.6
	L	4.1	-	-
5	R	7.1	11.1	8.6
	L	6.5	10.6	7.5
6	R	-	14.6	4.6
	L	-	6.8	10.6
Mean±SD		6.3±2.6	14.1±5.0	8.2±3.0

MWI: Medial-wedge insole; SD: Standard deviation.

years among many causes of the alignment of lower limb.[1,2] Comparison of the control and toe-in gait groups, the IRAB was significantly higher and TFAB significantly lower in our study, although there was no significant difference in the MAIB, which is used to evaluate metatarsus adductus and valgus. In the present study, the IRA also showed a correlation with femoral anteversion and TFA showed a negative correlation with the internal tibial torsion, suggesting that the etiology of toe-in gait of children aged over three years was a combination of internal torsion of both tibia and femur mainly.

The age that gait of children evolves into that of adults varies among different reports. Sutherland et al.[16] reported it as three years old, Noguchi[17] as ranging from five to nine years, Beck et al.[18] as five years, and Tsurumi[19] as ranging from five to seven years. In this study, children showed toe-in gait at ages ranging from three to eight years and nine months, which is the transition period of the gait pattern from child to normal adult values.

Since the 1960s, various types of insoles have been used in the treatment of pediatric toe-in gait,[10,20] including a device with a flexible leather counter splint in 142 children,[21] an out-toeing wedge in 48 children,[22] a torque heel in 10 children,[23] a gait plate in 18 children,[9] and a sensomotor insole in 10 children,[24] although none of these treatments have been well-established. In the present study, the MWIs were made-to-order to fit each foot of 51 children of whom 80.8% of children and their parents reported the treatment as effective. Good therapeutic effects were obtained in this study, even compared with the efficacy of 73% (103/142)[20] to 78% (14/18)[9] in previously reports. In the objective evaluation of frequency of falling before and after using MWI using the method of Redmond, an improvement was seen in each grade (ranging from 5 to 1), and none of the children had a worse score after MWI use. These results indicate that MWI is effective in reducing the risk of falling in children with toe-in gait. In our study, all assessments were made after a mean period of only 1.8 month of using MWI to reduce the possibility that the symptom of being prone to easily fall resolved spontaneously with growth, thus, it was suggested that this improvement was associated with the MWI use.

It has been reported that excessive rearfoot valgus causes various impairments in runners.[25-27] Although there is one report available showing that MWI enhanced the lateral thrust of medial knee osteoarthritis,[28] it has been also reported that MWI is effective in preventing impairments likely to develop in runners by limiting the rearfoot valgus when landing, thereby reducing excessive internal tibial rotation which occurs subsequent to the valgus.[27-29] In the present study, gait analysis showed that the maximum range of motion of the foot significantly decreased in six children using MWI and improved to a value equivalent to controls. Based on this result, we suggest that there is a possibility of MWI in reducing the excessive internal tibial rotation and limiting forefoot turning inwards, in the same mechanism as the effect of MWI on the runner and thereby stabilizing gait in toe-in gait children.

However, we found that MWI was ineffective in 20% of children. Based on the comparison of age, gender, and the physical findings between the MWI-effective and ineffective groups, the only significant difference was in the MAIB, indicating that MWI may be less effective for children with severe metatarsus adductus.

Nonetheless, there are limitations to this study. First, we were unable to evaluate the torsion of the thigh and the lower leg from CT images, since we were unable to perform computed tomography imaging to ensure less-invasive treatment modality. Second, gait analysis was not performed in all cases. Third, the sample size was relatively small and gait analysis was not performed in the MWI-ineffective group. In addition, the evaluation of the likelihood of falling is not an objective measure, despite the fact that we adopted a method of quantifying the number of falls by questionnaire which was previously described.[9] Finally, this study has a retrospective design and, therefore, we recommend further large-scale, randomized-controlled studies to compare children treated with and without MWI.

In conclusion, the MWI use is effective in reducing the risk of falling in children with toe-in gait, mainly due to the internal torsion of the tibia or femur. In addition, MWIs are effective in reducing the maximum range of motion of the foot in toe-in gait children without any expected adverse effects. Based on these findings, we suggest that the use of MWI is an effective and simple method in the treatment of children with the symptom of being prone to falling due to intoeing gait.

Declaration of conflicting interests

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