The effect of insoles on symptomatic flatfoot in preschool-aged children
A prospective 1-year follow-up study

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Abstract
Flatfoot is a common reason for parents to seek help from health care professionals, and limited evidence is available regarding the effects of insoles on preschool-aged children. This study mainly investigated the effect of insoles on symptomatic flatfoot in preschool-aged children and followed up the changes in footprints after 1 year.

This study was a prospective, observational cohort study. Children aged 3 to 5 years old who exhibit the signs of flatfoot were recruited from the kindergartens in the central Taiwan between March 2010 and December 2013. The Chippaux-Smirak index (CSI) was used to determine whether the footprints of children were associated with flatfoot. The children were divided into an insole group and a no-insole group according to diagnoses by doctors. This study used the modified shoe insole as the intervention, and the CSI measured and followed up the changes in footprints after 1 year.

A total of 466 preschool-aged children aged 3 to 5 years old with flatfoot completed the 1-year follow-up study. Of these, 123 children (men 77; women 46) were in the insole group and 343 children (men 187; women 156) were in the no-insole group. After the insoles were worn for 1 year, the CSI values of the children with symptomatic flatfoot decreased by 9.7%, and the 5-year-old children had the biggest change (effect size = 1.25). In the insole group, 34.1% of the footprints were determined as normal at 1-year follow-up, and CSI values decreased by 17.5%. High prevalence of joint laxity was found in both groups (insole group: 34.5%; no-insole group: 35.1%). Of the children in the insole group, the proportion of joint laxity was significantly higher in the flatfoot group (43.1%) than in the normal group (17.7%).

This study showed that wearing insoles indeed can reduce the signs of flatfoot in preschool-aged children, and the effect is better in 5-year-old children. It is suggested that insoles can be provided as a conservative treatment for preschool-aged children with symptomatic flatfoot.

Abbreviations: ANOVA = one-way analysis of variance, BMI = body mass index, CSI = Chippaux-Smirak index.

Keywords: Chippaux-Smirak index, flatfoot, insole, preschool-aged children

1. Introduction
Flatfoot is a common reason for parents to seek help from health care professionals.\textsuperscript{[1]} It is characterized by the collapse of the foot’s medial longitudinal arch during weight bearing.\textsuperscript{[2]} The preschool stage is the main development period of foot arches,\textsuperscript{[3,4]} so it is generally accepted that foot arches will naturally develop in this stage\textsuperscript{[5,6]} and that only children exhibiting symptoms of flatfoot need to receive treatment.\textsuperscript{[7]} The common symptoms include: pain in the feet, calves, or knees; affected movements, causing the tendency to feel fatigue during walking, or unstable movements; and significant changes in foot appearance, such as a prominent medial talus, heel valgus, and tightness of the heel tendon.\textsuperscript{[8]}

Treatments for flatfoot can be divided into conservative and surgical treatments.\textsuperscript{[9]} Surgical treatments are not considered unless conservative treatments fail to correct the flatfoot. The most common conservative treatment is to wear insoles in combination with shoes.\textsuperscript{[10]} A few studies have reported correction of flatfoot with the use of insoles and indicated that wearing insoles can support the feet to improve the resting calcaneal stance position.\textsuperscript{[11,12]} and improvements of the foot arch angles can be observed in radiographic measurement.\textsuperscript{[13,14]} However, these studies have not focused on preschool-aged
children or included control groups for comparison. The correction may be due to the natural history of resolution with age.

Symptomatic flatfoot may cause disability,15 affect quality of life,16 and have an adverse effect on walking gait17,18 in adulthood if not treated. Early treatment of flatfoot can prevent the future occurrence of a prominent navicular bone or toe joint swelling.19 Moreover, studies have reported that wearing insoles can reduce the occurrence of symptoms such as pain and help better stabilize movements.20,21 Early treatment refers to early discovery, diagnosis, and appropriate intervention. Therefore, it is important to understand the effect of insoles on symptomatic flatfoot in preschool-aged children.

The aim of this study was to investigate changes in the footprints of children who wore insoles at 1-year follow-up as compared with those of children who did not wear insoles so as to identify the effect of insoles on symptomatic flatfoot in preschool-aged children.

2. Methods

2.1. Study design and setting

This prospective, observational cohort study was conducted at kindergartens in the central area of Taiwan. For the study, we recruited children aged 3 to 5 years old who exhibited the signs of flatfoot when their feet were checked between March 2010 and December 2013. The footprint data of children were collected using a footprint ink pad22 for each foot in a 100% weight-bearing position and were determined to exhibit the signs of flatfoot based on the symptoms and physical examination findings by a doctor at the baseline and 1-year follow-up.

2.2. Participants

Children with a history of musculoskeletal injury or neurological illness that affects the structure or movement of the lower limbs; previous or current correction with insoles; and inability to complete the collection of footprints were excluded. Before the measurement, informed consent forms were obtained from the parents. This study was reviewed and approved by the Institutional Review Board of a university hospital (CSMUH No. CS09114; approval date: March 17, 2010). At baseline, the footprint data of 1534 children were collected, and 656 children were determined to exhibit the signs of flatfoot. In total, 136 children with symptoms were advised to wear insoles for treatment (insole group), and the other 520 children without symptoms were assigned to the control group (the no-insole group) for comparison. At the 1-year follow-up, 13 children in the insole group dropped out and 177 children of the no-insole group were lost to follow-up because they had transferred to other schools or been admitted to elementary school early. These 190 children were excluded from this study, leaving a total of 466 children for analysis (Fig. 1). The overall follow-up completion rate was 71.0%. There was no significant difference between the...
children who completed and those who did not complete the follow-up.

At the 1-year follow-up, the children were divided into 2 different groups for investigation according to the changes at the follow-up: subjects whose footprints were originally determined as flatfoot and remained flatfoot at the 1-year follow-up (flatfoot group), and subjects whose footprints were originally determined as flatfoot but were determined as normal at the 1-year follow-up (normal group).

2.3. Data sources and measurements

Basic data of the subjects were collected, including age, sex, height, weight, body mass index (BMI), and Beighton score. BMI is calculated as weight (kg)/height (m²). In accordance with the definition of obesity for children and adolescents provided by the Health Promotion Administration of Taiwan, this study divided the weight of the subjects into 4 levels: underweight, normal, overweight, and obese. One physical therapist was responsible for assessing the generalized joint laxity measured by the Beighton score. The total Beighton score is 9 points, and a score >4 points indicates joint laxity.

The Chippaux-Smirak index (CSI) was used to determine whether the collected footprints were associated with flatfoot. The CSI is defined as the ratio of the maximum width at the middle arch of the footprint (B) to the maximum width at the forefoot metatarsus region (A) of the footprint (Fig. 2). The criteria for determining the signs of flatfoot in preschool-aged children were CSI >62.70% for flatfoot and CSI ≤62.70% for normal feet.

To reduce the differences in the use of insoles, the modified shoe insoles were unified for use as the intervention in this study (Fig. 3). Children in the insole group were provided a pair of insoles to be worn in their shoes. The insoles were designed for medical use, and the design was reviewed and approved as a Class I medical device (Ministry of Health and Welfare Approval Certificate No. 001181). The main materials of the insoles were polypropylene and ethylene vinyl acetate. The insoles could provide support and movement limitations to the subtalar joint and midfoot. The arch position and height were adjusted by an orthotist with >15 years of experience according to the wearing conditions of the children. The sizes ranged from 14 to 23.5 cm (foot length). The difference between each size was 0.5 cm, and there were 20 sizes in all. An appropriate insole size was chosen for each child according to foot length and the controlled normal position of the hindfoot relative to the midfoot.

2.4. Statistical methods

Mean and standard deviation were used to present the basic information of the participants, and independent t test was used to examine the differences between groups (insole group vs no-insole group; flatfoot group vs normal group). Paired t test and chi-square tests were used to test the differences between the initial assessment and the follow-up. The footprints of the right and left feet were regarded as independent data, and the CSI values were divided into 3 groups (3, 4, and 5 years old) according to the age at baseline. One-way analysis of variance (ANOVA) was used to test the differences among ages, and the differences were presented using effect sizes. Cohen classified effect sizes as small (0.2 < d < 0.5), medium (0.5 ≤ d < 0.8), and large (d ≥ 0.8). The statistically significant standard in this study was P < .05, and the software used was SPSS 14.0 (SPSS Inc., Chicago, IL).

3. Results

A total of 466 preschool-aged children aged 3 to 5 years old with flatfoot completed the 1-year follow-up study. Of these, 123
children (men 77; women 46) were in the insole group and 343 children (men 187; women 156) were in the no-insole group. The average follow-up period was 11.3 months, and there was no statistical difference in the follow-up periods between the 2 groups (P = .08). Apart from sex, there were no significant differences in the basic data between the children in the insole and no-insole groups at baseline or at 1-year follow-up (P > .05, as shown in Table 1). At baseline, the CSI of the insole group children was greater than that of the no-insole group children, with a significant difference between the 2 groups (P < .001). At the 1-year follow-up, the mean change in the CSI of the insole group was greater. The CSI of the insole group decreased by 9.6%, and that of the no-insole group decreased by 6.1%. There was no significant difference in the CSI between the 2 groups at the 1-year follow-up (P = .35).

The footprints of the right and left feet were examined as independent data, and a total of 932 footprints were collected at the 1-year follow-up. In all, 232 footprints in the insole group and 343 footprints in the no-insole group were included in the analysis. The changes in the CSI between different age groups are shown in Table 2. In the no-insole group, the CSI fell by 2.7% at the 1-year follow-up, and the changes in the CSI at various ages were significant (P < .001). The changes in the CSI decreased with increasing age, from 8.3% in 3-year-old children to 4.7% in 5-year-old children, and the 3-year-old children had the biggest change (effect size = 0.85). In the insole group, the CSI fell by 9.7% at 1-year follow-up, and the changes in the CSI at various ages were significant (P < .001). The changes in the CSI increased with increasing age, from 7.0% in 3-year-old children to 11.7% in 5-year-old children, and the 5-year-old children had the biggest change (effect size = 1.25).

The footprints of all the children were divided into a flatfoot group (footprints remained flatfoot) and a normal group (footprints were determined as normal) at the 1-year follow-up (Table 3). In the no-insole group, 37.6% (219/582) of the footprints were assigned to the normal group. The CSI of the normal group decreased by 14.0% at the 1-year follow-up, and that of the flatfoot group decreased by 2.7%. There were statistical differences (P < .05) in the weight and BMI between the flatfoot group and the normal group; the proportion of overweight children was higher in the flatfoot group (39.7%, 144/363). This difference indicated that 35.1% of the no-insole group children experienced joint laxity, and there was no statistical difference between the flatfoot group and the normal group at 1-year follow-up. In the insole group, 34.1% (79/232) of the footprints were assigned to the normal group, and the proportion increased with increasing age, from 25.6% of 3-year-olds to 40.8% of 5-year-olds. The CSI of the normal group decreased by 17.5%, and that of the flatfoot group decreased by 5.7%. Apart from weight and BMI, there were also significant differences (P < .05) in the basic data between the flatfoot group and the normal group children. The results showed that 34.5% of the insole group children experienced joint laxity, and 43.1% (66/153) of these children were in the flatfoot group. The children were younger and the proportion of male children was higher in the flatfoot group than in the normal group.

4. Discussion
This is the first cohort study to follow up the effect of insoles in preschool-aged children with symptomatic flatfoot. The results showed that after the children wore insoles for 1 year, the

| Table 1 | Characteristics of participants at baseline and 1-year follow-up. |
|---------|---------------------------------------------------------------|
|         | Baseline Insole group (n = 123) | No-insole group (n = 343) | P  | Follow-up Insole group (n = 123) | No-insole group (n = 343) | P  |
| Gender  | 77/46                                  | 187/156                   | .03* | 77/46                                  | 187/156                   | .03* |
| Age, mo | 51.8 (11.2)                              | 52.2 (7.9)                | .50  | 63.1 (11.4)                              | 63.9 (8.1)                | .26  |
| Height, cm | 105.0 (7.6)                             | 104.5 (6.7)              | .30  | 111.2 (8.0)                              | 111.3 (6.7)              | .67  |
| Weight, kg | 18.2 (4.0)                              | 18.0 (3.4)                | .33  | 20.4 (4.5)                              | 20.4 (4.3)                | .99  |
| Body mass index, kg/cm² | 16.4 (2.1)                             | 16.4 (2.0)              | .98  | 16.3 (2.0)                              | 16.4 (2.3)                | .81  |
| Beighton score | 2.9 (1.7)                            | 2.7 (2.0)              | .41  | 2.0 (1.6)                              | 2.1 (1.7)                | .61  |
| Chippaux-Smirak index (%) | 73.3 (7.5)                        | 69.3 (8.3)          | <.001* | 63.7 (10.8)                        | 63.2 (10.1)          | .55  |

The n values are the number of the participants. The values are given as mean (standard deviation). P < .05 was considered statistically significant.

| Table 2 | Changes of Chippaux-Smirak index (CSI) between different age groups of flatfoot footprints. |
|---------|---------------------------------------------------------------|
| Insole group | Baseline | Follow-up | Effect size (d) | P  | No-insole group | Baseline | Follow-up | Effect size (d) | P  |
| 3 years (n = 90) | 73.2 (5.6) | 66.2 (8.4) | 1.08 | <.001* | 3 years (n = 187) | 72.6 (7.7) | 64.3 (10.1) | 0.85 | <.001* |
| 4 years (n = 71) | 75.8 (6.6) | 64.7 (8.7) | 1.10 | <.001* | 4 years (n = 296) | 71.5 (5.7) | 64.6 (9.6) | 0.81 | <.001* |
| 5 years (n = 71) | 74.2 (6.3) | 62.5 (12.2) | 1.25 | <.001* | 5 years (n = 99) | 70.1 (4.9) | 65.4 (8.5) | 0.61 | <.001* |
| Total (n = 232) | 74.3 (6.2) | 64.6 (10.2) | 1.10 | <.001* | Total (n = 582) | 71.6 (6.4) | 64.6 (9.6) | 0.78 | <.001* |

The n values are the number of the participants. The values are given as mean (standard deviation). Effect size was calculated as Cohen d. P < .05 was considered statistically significant.
The n values are counted by foot.

The values are given as mean (standard deviation).

* P < .05 was considered statistically significant.

values decreased by 9.7%, and 34.1% of the footprints initially determined as flatfoot were determined as normal. This study further demonstrated that the changes in the CSI values increased with increasing age and that the 3-year-old children had the biggest change (effect size = 1.25). This finding verified that wearing insoles can improve the signs of flatfoot in preschool-aged children and that the effect is better in 3-year-old children.

It is believed that most pediatric flatfoot resolves spontaneously, so treatment is indicated only for those who have symptoms. Based on that practice, this study focused on flatfoot children and divided the changes in footprints into a flatfoot group and a normal group at the 1-year follow-up for subsequent investigation. It has previously been reported that the prevalence of flatfoot decreases with increasing age in preschool-aged children,[6,27,28] and that CSI values decrease with increasing age.[4,9] This study found similar tendencies in both groups, but the proportion of change was significantly greater in the insole group than in the no-insole group. The CSI of the insole group was only 2.7% lower. This indicates that being overweight could be a factor that leads to flatfoot in preschool-aged children. Weight control may be beneficial to the improvement of flatfoot symptoms.

The prevalence of joint laxity in preschool-aged children is approximately 30%,[31] and children with joint laxity are more likely to experience flatfoot symptoms.[31,33] This study showed a high prevalence of joint laxity in both groups (insole group: 34.5%; no-insole group: 35.1%). In the no-insole group children, there was no statistical difference between the flatfoot group and normal group at 1-year follow-up. However, in the insole group, the proportion of joint laxity of the flatfoot group (43.1%) was significantly higher than that of the normal group (17.7%). These findings suggest that a higher proportion of preschool-aged children with flatfoot symptoms experience joint laxity, which may reduce the effect of wearing insoles. Joint laxity may easily lead to instability of the lower limb joints and thereby to the tendency of the foot arches to collapse. Wearing insoles helps stabilize and change support positions, but it has a minor effect on the structure of the joints themselves. Children with flatfoot in combination with joint laxity should receive muscular strength training to achieve a better effect.[39]

Due to the limitations of manpower and funds, this follow-up study only enrolled children aged 3 to 5 years old. Moreover, the follow-up time was not sufficient to reflect changes in flatfoot in all the preschool-aged children. According to the clinical observations of the researchers, most of the children treated with insoles experienced symptoms such as pain or poor posture. However, subsequent longer-term follow-up studies should be performed to investigate the changes in various symptoms in children with flatfoot and include investigation of the effects of different factors on flatfoot.
5. Conclusion

Although flatfoot in preschool-aged children may resolve spontaneously with increasing age, wearing insoles can reduce the signs of flatfoot in preschool-aged children with symptomatic flatfoot, especially in children whose footprints remain flatfoot after 1 year. The findings of this study can be provided as a reference for clinical workers to treat flatfoot in preschool-aged children.

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