Gait & Posture 109 (2024) 120–125

Contents lists available at ScienceDirect

Gait & Posture

journal homepage: www.elsevier.com/locate/gaitpost

Effectiveness of gait plate insole and lateral sole wedged shoes on foot progression angle in children with in-toeing gait: A prospective randomized control trial

Shahab Parian [a,1], Behshid Farahmand [a,*,2], Hassan Saeedi [a], Masumeh Bagherzadeh Cham [a,b]

[a] Rehabilitation Research Center, Department of Orthotics and Prosthetics, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran
[b] Neuromusculoskeletal Research Center, Department of Physical Medicine and Rehabilitation, School of Medicine, Firoozgar General Hospital, Iran University of Medical Sciences, Tehran, Iran

ARTICLE INFO

Keywords:
In-toeing
Gait plate
Lateral sole wedge
Foot progression angle

ABSTRACT

Background: In-toeing gait is defined as the internal rotation of the long axis of the foot to the line of progression. Although most of the time it is corrected spontaneously but sometimes causes torsional misalignment syndrome and maybe patellofemoral instability and arthritis of the knee.
Research question: What is the effect of gait plate insoles and lateral sole wedged shoes on foot progression angle (FPA) in children with in-toeing?
Method: In this study, a randomized control trial was conducted with 11 participants (18 feet) who were girls aged between seven and ten years old. They were randomly assigned to either the gait plate group (6 girls, 11 feet) or the lateral sole wedge group (5 girls, 11 feet). The foot progression angle was measured using the RS scanner pressure platform before and after four weeks of intervention, both with and without interventions. The interaction effects of time and group on outcomes were analyzed using Mixed ANOVA and post-hoc complementary tests with a confidence interval of 95%.
Results: It was observed that none of the interventions had an immediate impact on the FPA ($P > 0.05$). However, after four weeks, the FPA increased by 9.96 degrees with the lateral sole wedge and by 3.51 degrees with the gate plate insole. During the immediate and short-term evaluation, no significant difference was noticed between the two groups ($P > 0.05$). However, there was a large effect size (eta square = 0.269) observed in the time group interaction between the two groups ($P = 0.028$).
Significance: Conservative methods like using a gait plate insole or modifying shoes with a lateral sole wedge can improve the foot progression angle in children with in-toeing gait. However, longer studies with larger sample sizes are needed to reach a conclusion.

1. Introduction

The term "in-toeing gait pattern" refers to the inward rotation of the foot's long axis towards the line of movement [1]. This condition is often seen in preschool children and can be a cause for concern among parents, as it may lead to issues with walking, such as tripping [2]. About 30% of children aged 2 to 5 years have an in-toeing gait, and it tends to occur more frequently in both feet than in just one foot [3].

Metatarsus adductus, internal tibial torsion, and femoral anteversion are three common causes of in-toeing [4,5]. Femoral anteversion is the most common cause of in-toeing in children over 3 years old. Femoral anteversion is about 45° in newborns which slowly decreases to 10° on mature males and 15° on mature females [5–7]. Femoral anteversion usually normalizes as individuals grow into adulthood without any further treatment [8,9], but an increase in femoral anteversion may increase the risk of patellofemoral instability and knee arthritis later in life [10–12]. Torsional misalignment syndrome may be caused by the relationship between femoral anteversion and tibial torsion [13,14].

* Corresponding author.
E-mail addresses: farahmandb1@yahoo.com, farahmand.b@iums.ac.ir (B. Farahmand).
[1] ORCID: 0000-0002-4720-3521
[2] Dr. Behshid Farahmand is an academic staff (Associate professor) of Iran University of Medical Sciences which is an education and research based University affiliated to the government, located in Tehran, Iran.

https://doi.org/10.1016/j.gaitpost.2024.01.026
Received 12 January 2022; Received in revised form 8 November 2023; Accepted 22 January 2024
Available online 24 January 2024

In the treatment of in-toed gait, both surgical and conservative approaches can be utilized [4, 15–17]. One study conducted by Bowsher and Vaughan indicated that altering the foot progression angle (FPA) could potentially reduce torsional stresses on the femur [18]. The FPA is defined as the angle formed between the foot's long axis, extending from the heel to the 2nd metatarsal, and the line representing the direction of gait. A negative FPA value indicates the presence of in-toeing [19]. Correcting the FPA can be an effective method for addressing in-toed gait.

Several studies have demonstrated the efficacy of the gait plate insole in improving foot progression angle (FPA) in children with in-toeing [15, 20–23]. This insole is constructed from rigid plastic that extends to the fifth toe on the lateral side and angles obliquely at 45 degrees behind the first metatarsal on the medial side [20,22,24]. Ganjai et al. (2016) found that immediate use of the gait plate insole resulted in increased FPA and displacement of the center of pressure in the anterior-posterior direction in children with in-toed gait caused by femoral anteversion [20]. Redmond (2000) demonstrated that after one month of using the gait plate insole, there was a noticeable but significant change in FPA, leading to a reduction in tripping incidents and increased satisfaction among parents regarding their children's walking abilities [21].

Another safe and cost-effective intervention is the implementation of a lateral sole wedge. The lateral sole wedge causes eversion of the forefoot and reduces pronation of the foot, subsequently decreasing rotation of the leg and knee [25,26]. It has been suggested that the lateral sole wedge may be beneficial for children experiencing rotational issues such as tibial torsion [25]. No published studies have examined the effect of the lateral sole wedge that was added to the outsole of the shoe on FPA in children with in-toed gait. Therefore, the objective of this study was to compare the immediate and four-week effects of a "gait plate insole" versus "shoes with a lateral sole wedge" on the FPA in children with in-toed gait.

2. Method

The present study is a prospective randomized controlled trial that took place in the department of orthotics and prosthetics at the faculty of rehabilitation science from February 2019 to April 2021. The study protocol received approval from the ethics committee of the Iran University of Medical Sciences and was registered under the name IRCT20140219016643N8 in the Iranian register of clinical trials. All participating parents provided informed consent after receiving detailed information about the study procedures and objectives.

2.1. Participants

Children aged between 7 to 10 years old with in-toeing gait caused by excessive femoral anteversion based on Orthopedist diagnosis participated in this study. The expert physician evaluated the participants with rotational profile tests to identify those with in-toeing gait caused by excessive femoral anteversion [27]. Each foot was considered separately since studies have shown that FPA, foot posture and plantar pressure differ between the dominant and non-dominant foot and only affected foot was included [3,28,29]. Participants with an angle of gait less than -3°, and parental testimonials were included in this study.

To measure the gait angle, the child's foot was dipped in finger paint and asked to walk on a two-meter path covered with white paper. The gait angle of each foot was assessed by measuring the angle between the longitudinal axis of the foot (the line that connects the middle of the heel to the second toe) and the line indicating the direction of gait (degree) [30].

Participants with a history of surgery, fracture, neuromuscular or neurological diseases were excluded. Other exclusion criteria were as follows: participants with previously worn braces or any other orthotics or a lower limb deformity leading to gait problems such as CDH, Club foot and in-toeing gait pattern caused by metatarsus adductus or internal tibial torsion [20].

2.2. Intervention

Children randomly chose the "gait plate insole" and "lateral sole wedge" from a sealed envelope.

The gait plate insole was created by molding the foot with the slipper casting method in the natural position of the subtalar joint. It was then covered with a 3 mm polypropylene sheet that extended to the lateral side to the fifth toe and to the medial side behind the first metatarsal at a 45-degree obliquity [20,22].

The shoes had a lateral sole wedge made of 3 mm rubber, covering the area between the fifth metatarsal head and the middle of the footwear.

The gait plate group used high-top shoes (All-Star Model), which it has soft (Shore A-50) and flexible Poly outran soles with 5 mm thickness. The lateral sole wedge group used leather high-top shoes that it has more rigid (Shore A-70) and non-flexible soles with 5 mm thickness.

2.3. Outcome and Instrument

The Foot Progressive Angle was evaluated barefoot, immediately and after four weeks of using the intervention.

The angle between the foot's longitudinal axis and the gait direction (FPA) was measured using the plantar pressure measurement plate from RS Scan International (Olen, Belgium). This plate has a 50 cm x 40 cm surface area and 48 cm x 32 cm Force-Sensing Resistors (FSRs) active sensor, and operates at 500 Hz. The Ganjehie et al. study used this reliable and repeatable instrument for FPA measurement [20].

2.4. Process

Initially, children walked five meter barefoot at a normal speed on the scanner. The data were recorded five times to obtain the average FPA [2].

After ten minutes of using the intervention for adaptation, the child was asked to walk five meter at a normal speed again. The data were recorded five times to obtain the average immediate FPA.

Parents were asked to have their child walk with intervention (Gait plate insole/ Lateral sole wedge) for at least one hour a day under their supervision. After four weeks, the FPA was reevaluated both barefoot and with intervention, as in the first session.

2.5. Sample size

The sample size was calculated based on Ganjehie et al. using G*Power 3.1.9.2 [20]. An independent t-test statistical design was used for two independent groups with an effect size of 0.5, power of 95%, and alpha error of 0.05. At least 7 participants were required in each group.

2.6. Statistical analysis

Statistical analysis was conducted using SPSS software V24 (SPSS Inc, Chicago, LA, USA). Normal distribution of data was checked using the Shapiro-Wilk Test. Baseline variables between groups were compared using independent t-test. Interaction effects of time and group on outcomes were analyzed by Mixed ANOVA (2×4 which 2 groups of intervention (Gait Plate Insole and Lateral Sole Wedge) and 4 different times (1- FPA Bare Foot 2-FPA with Intervention Immediate 3- FPA with Intervention after four weeks 4-FPA Bare foot after 4 Weeks)) and post-hoc (Bonferroni) complementary tests (CI=95%). The significant threshold was set at less than 0.05.

Table 1
Demographics statistics (N = 11, NF=18).

Group (Number, Feet)		Height (cm)	Weight (kg)	Age (YR)	BMI (Kg/m^2)	FPA	
						Barefoot	Intervention
Gait Plate insole	*Mean*	134.83	29.32	8.73	16.33	-5.32	-3.86
(N = 6, NF=11)	*SD*	7.20	4.29	0.78	3.43	1.44	4.39
	Min	127.8	22.9	8	11.3	-8.12	-12.32
	Max	145.2	35.1	10	21.4	-3.57	2.86
Lateral sole wedge	*Mean*	127.7	27.94	7.43	16.92	-8.61	-3.66
(N = 5, NF=7)	*SD*	4.8	8.2	0.53	4.32	3.70	4.09
	Min	119	15.60	7	11	-13.67	-9.71
	Max	131.1	37.4	8	22.2	-4.46	2.48

Abbreviations: N, number; NF, number of feet; BMI, body mass index; FPA: Foot Progressive Angle

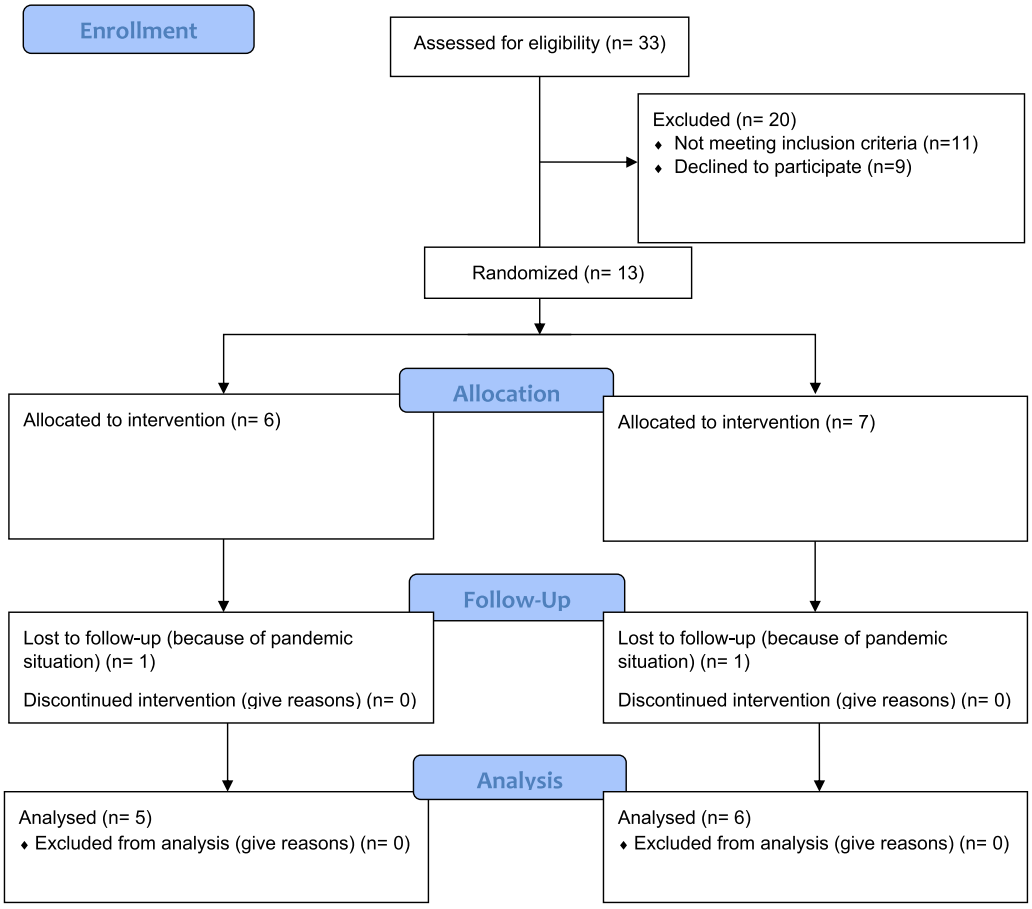

Fig. 1. Consort chart.

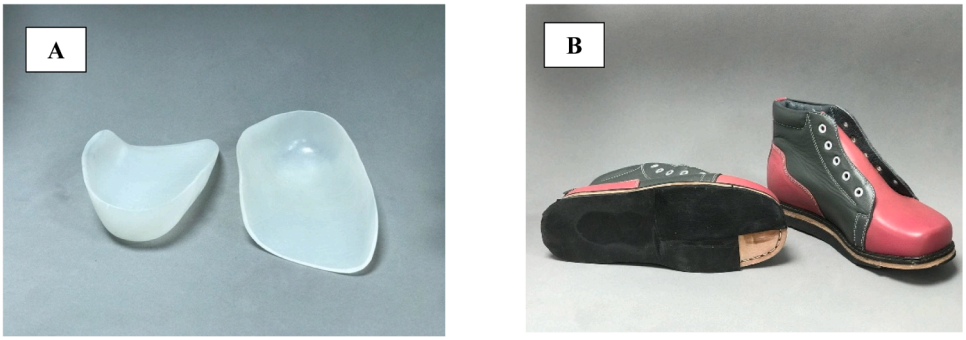

Fig. 2. Gait plate insole (A), lateral sole wedge (B).

Table 2
Comparison of foot progressive angle in two groups of gait plate insole and lateral sole wedge immediately and after four weeks.

Measurement Condition	Mean difference	Standard Error	P-value	95%CI		Measurement Condition	Mean difference	Standard Error	P-value	95%CI	
				Lower Bound	Upper Bound					Lower Bound	Upper Bound
Initial BF- Immediate GP	-1.46	1.44	1.00	-5.89	2.88	Initial BF- Immediate LW	-4.95	1.81	0.08	-10.41	0.49
Initial BF- After 4w BF	-0.80	1.16	1.00	-4.31	2.70	Initial BF- After 4w BF	-5.33	1.46	0.01	-9.73	-0.93
Initial BF- After 4w GP	-3.51	1.12	0.03	-6.89	-.13	Initial BF- After 4w LW	-9.97	1.40	.000	-14.20	-5.74
Immediate GP- After 4w BF	0.66	1.29	1.00	-3.23	4.56	Immediate LW - After 4w BF	-0.37	1.62	1.00	-5.26	4.50
Immediate GP- After 4w GP	-2.04	1.25	0.73	-5.82	1.73	Immediate LW - After 4w LW	-5.01	1.57	0.03	-9.75	-0.27

Abbreviation: BF: Barefoot; GP: Gait plate insole; LW: Lateral sole wedge

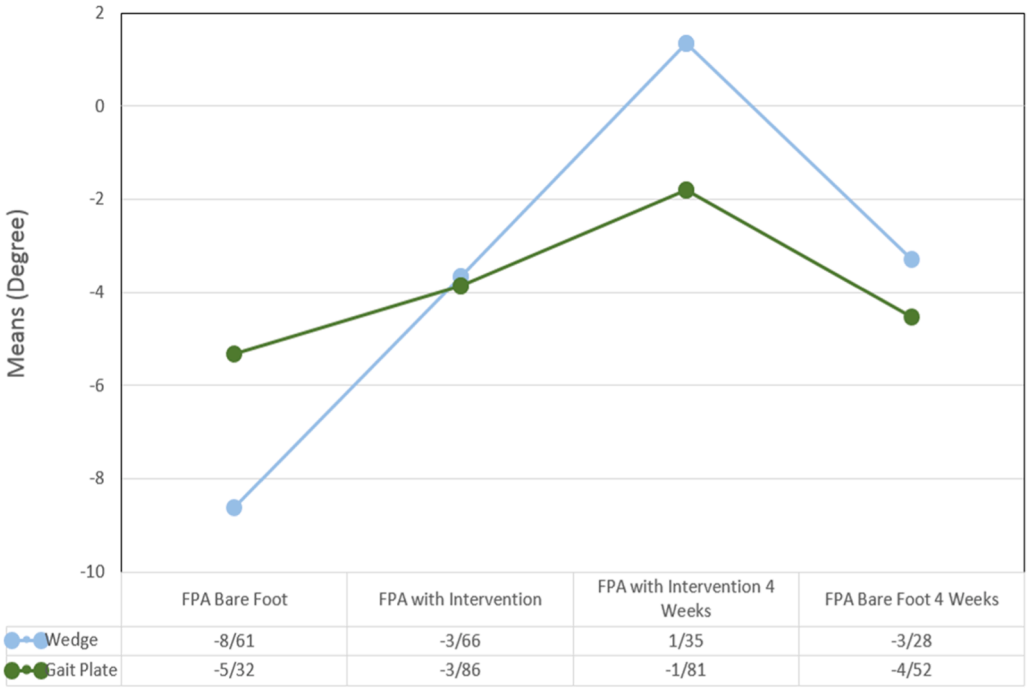

Fig. 3. Time- group interaction between gait plate insole and Lateral sole wedge group (negative values indicate more in-toeing and positive values indicate more out-toeing).

3. Results

Eleven girls (18 feet) participated in the study, with seven cases exhibiting bilateral in-toed gait (14 feet) and four with unilateral. The gait plate insole group consisted of six girls (11 feet), while the lateral sole wedge group consisted of five girls (7 feet). Demographic parameters are detailed in Table 1.

The Shapiro-Wilk test indicates that all variables are normally distributed ($p > 0.05$) except for age in the lateral sole wedge group ($P < 0.05$). No significant difference was found in the demographic variable or FPA ($P = 0.059$) between the two groups (Figs. 1 and 2).

Based on the results of post hoc tests, the FPA did not change immediately with the use of the gait plate insole ($P = 1.00$). However, after four weeks there was a significant increase in the FPA compared to the initial barefoot ($P = 0.039$) (Table 2).

Post hoc tests also demonstrate that the FPA did not change immediately with the use of the lateral sole wedge ($P = 0.08$). The FPA significantly increased in the lateral sole wedge condition after four weeks compared to the initial barefoot ($P = 0.013$), and also increased in the barefoot condition compared to the initial barefoot ($P < 0.0001$) (Table 2).

There was no significant difference in the effectiveness of the two interventions on FPA during immediate ($P = 0.924$) with effect size (partial eta squared = 0.001) and 4-week follow-ups ($P = 0.493$) with effect size (partial eta squared = 0.03). Fig. 3 shows the mean FPA in different states of each group. Time-group interaction between two group was significant ($P = 0.028$) with large effect size (partial eta squared = 0.269).

4. Discussion

This study aimed to investigate and compare two different types of treatments for managing in-toeing gait patterns due to femoral anteversion. Four weeks of use of gait plate insoles and lateral sole wedge both were significantly effective as they respectively changed mean FPA by 3.51° and 9.96 ° compared to initial barefoot. Gait plate insoles and lateral sole wedge were not significantly effective immediately after their application as the mean FPA respectively changed by 1.46° and 4.95°. Mean barefoot FPA changed and increased after four weeks of use of gait plate insoles and lateral sole wedges at 0.8 and 5.33, respectively

which was significantly effective in the lateral sole wedge group.

The current study found that none of the interventions had an immediate impact on the FPA. This result is not in line with previous studies. The Ganjehie et al. [20] study involved 17 children between the ages of four and ten, while the Munuera et al. [30] study involved 18 children between 18 months and five years old. In this study, only seven children participated in the gait plate insole group and four in the lateral sole wedge group. Knittel and Staheli's [31] study, conducted with a small sample size of only ten children, showed that the gate plate does not have an immediate effect. In this study and the Ganjehie et al. [20] study, scanning was used to measure FPA, while other studies [30,31] utilized the less accurate footprint method.

The exact mechanism by which gait plate insoles works is not fully understood, but it appears that using gait plate insole during push-off in the front part of the foot helps produce external rotation in the normal sequence of load distribution. The elongation of the gait plate insole on the lateral surface of the forefoot may cause instability during push-off. However, this can be corrected by providing support from the medial surface and externally rotating the lower limb. Continued use of the gait plate insole in the lower limb may help acquire new, more physiologic walking patterns and resolve internal torsional alterations [24,30].

Lateral sole wedges are commonly prescribed to alleviate the pain caused by knee osteoarthritis [32]. These wedges work by shifting the foot into pronation and moving the center of pressure to the center of the knee, which reduces the knee adductor moment and lessens the pain [33,34]. However, increasing the anteversion of the foot and promoting an in-toeing gait can actually increase the knee adductor moment [35,36]. Nonetheless, no published study has investigated the specific effects of lateral sole wedges.

There have been limited studies examining the short-term effects of gate plate insoles, but all of them have shown that using these insoles leads to a small yet noticeable increase in FPA [21,22] and a decrease in tripping [21], and in-toeing symptoms [21]. The results indicate that using gate plate insoles increases FPA by 3.51 degrees and using lateral sole wedges increases it by 9.97 degrees. The change in FPA is more significant in the lateral sole wedge group, and both groups showed a significant increase after four weeks compared to initial barefoot conditions. Additionally, studies have shown a significant correlation between FPA changes and initial FPA [22], with the lateral sole wedge group starting at − 8.61 degrees compared to the gate plate insole group at − 5.32 degrees.

Even though using the gate plate resulted in only a 3.5-degree increase in angle, this change was still statistically significant. Other studies have reported an average increase in walking angle of 6.5 degrees [22]. The goal of implementing interventions is to prevent tripping [22], enhance the quality of walking, and bring the walking angle closer to the acceptable appearance angle of − 5 degrees or better [21].

The main limitation of the study is its small sample size, which was impacted by the COVID-19 pandemic. To ensure statistical power, we recalculated based on having at least 5 people in each group, resulting in a reduction from 95% to 79%. While gait speed may be a useful parameter for measuring FPA, it would be more accurate if controlled by a digital device. Additionally, longer follow-up periods have a significant impact on FPA. Therefore, future studies should have longer follow-up periods and evaluate changes in FPA after abandoning the intervention.

5. Conclusions

For children with in-toeing gait, using conservative methods like a gate plate insole or modifying shoes with a lateral sole wedge can enhance their foot progression angle. While there was no significant difference between the immediate and short-term use of both methods, the lateral sole wedge showed greater improvement in FPA both barefoot and with the wedge after four weeks. However, due to a limited sample size and short follow-up period, further studies are required to confirm the efficacy of these interventions.

Declaration of Competing Interest

In the current study there was no financial or personal interests or belief that can affected the author's objectivity.

Acknowledgment

The authors would like to thank the Orthotics and Prosthetics Department of Iran University staff and Shafa Yahyaian Hospital manager and staff for the support of this study. This research was supported by grant number 24150 from Neuromusculoskeletal Research Center, Iran University of Medical Sciences, Tehran, Iran.

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