



## Effect of foot insole and biodex balance training on balance and risk of fall in adult subjects with flexible flat foot

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### Abstract

**Background:** Flat feet or pes planus is a complex disorder with a diversity of symptoms and varying degrees of deformity that is caused by structural loading changes along the medial part of the feet and plantar arches, when the arch starts collapsing, balance is disturbed at the feet, and therefore the balance throughout the entire body is also disturbed.

**Purpose:** to investigate the effect of foot insole and biodex balance training on dynamic balance, risk of fall, and functional ankle instability in flexible flat feet.

**Methods:** Sixty subjects of both sex with ages ranging from 18-21 years and BMI ranging from 18-25 kg/m<sup>2</sup> with bilateral flexible flat feet participated in this study. They were assigned randomly and equally to two groups: group A and group B. group A received biodex balance training 3 sessions per week for 4 Weeks and short feet exercise 3 min each day for 4 weeks, each repetition was held for 5 sec and repeated for up to 3 min approximately 30 repetitions, 45-second rest period after each 10-repetition. Group B received same as group A and worn foot insole 6-8h per day. Overall stability index "OSI", anteroposterior stability index "AP-SI", and mediolateral stability index "ML-SI" were measured pre and post-treatment by Biodex Balance System at level 4. Cumberland Ankle Instability Tool was used to measure functional ankle instability "FAI".

**Results:** There was a statistically significant difference in post-study mean values of OASI (P=0.020), MLSI (P=0.012), APSI (P=0.020), and FAI (P=0.001) between the two groups in favor of group B.

**Conclusion:** Foot insole combined with biodex balance training and short foot exercise are an effective method of treatment for dynamic balance impairment, risk of fall and functional ankle instability in flexible flat feet.

**Keywords:** flat foot \_foot insole\_biodex balance training \_short feet exercise

### Introduction

Flexible FlatFoot (FFF) is characterized by deformations of the foot where the calcaneus is pronated by overweight. The weight is also concentrated on the medial side of the foot, which causes the medial longitudinal arch (MLA) to be down or disappear. Additionally, excessive movement of the foot requires more effort to maintain posture control and stability of the foot. The weakening of the soles of the plantar fascia decreases the ability to disperse impact shock, and excessive compensation of external muscles causes fatigue which leads to overuse syndrome. It may also cause functional ankle instability (FAI), affecting the entire kinetic chain, balance, and proprioception<sup>[1]</sup>.

FF subject is characterized by increased ankle stiffness during dorsiflexion without regard to demographic factors such as body weight and height. It was reported that ankle stiffness affects the mechanical behavior of the ankle muscles and reduced ankle dorsiflexion is associated with tightness of the gastrocnemius. altered movement with reduced force-generating capacity contributes to the risk of fall (ROF) and impairs the balance in daily activities in individuals with FF<sup>[2]</sup>.

The process of keeping the center of gravity inside the base of support is known as balance, and it needs continuous adjustments with joint positioning and muscular activity. Balance control can be affected by a variety of musculoskeletal and neural system diseases. There is a poorer dynamic balance (DB) in the FFF subject. It is then suggested that balance training activities be included in a traditional physical therapy program in cases of FF subjects<sup>[3]</sup>.

Nowadays, more surgical and conservative methods are used to treat or minimize symptoms of foot disorders. Foot insoles (FI) are more applied as a non-invasive treatment. Recently, FI has been found to improve arch alignment and decrease foot pronation and the amount of tibial medial rotation<sup>[4]</sup>.

It was found also that the FI with longitudinal arch support shifts the load from the forefoot and rearfoot toward the midfoot area increasing the midfoot contact area and allowing for better pressure distribution on the foot. As a result, the brain increases the effective feedback loop, alters sensory signals, and corrects hyperpronation in the feet. FI with sensory stimulation may alter sensory feedback of the plantar surface of the foot and lead to changes in plantar pressure parameters in FFF as well as improved balance and lower ROF [5].

## Methods

### Design

This was a pre-post randomized experimental design. The study adopted the regulations established by the Helsinki Declaration for human subjects. The study was approved and accepted by the research ethical committee, Faculty of Physical Therapy, Cairo University, and the clinical trials registering database under the identification number P.T.REC/012/003347.

### Randomization

Random allocation of participants into two equal groups (A, B), was done by a blinded independent researcher who opened enclosed envelopes containing computer-generated randomization serially numbered index cards using the statistical package for social science (SPSS) program (version 20 for Windows; SPSS Inc., Chicago, Illinois, USA). There were no dropouts among the participants throughout the study after randomization.

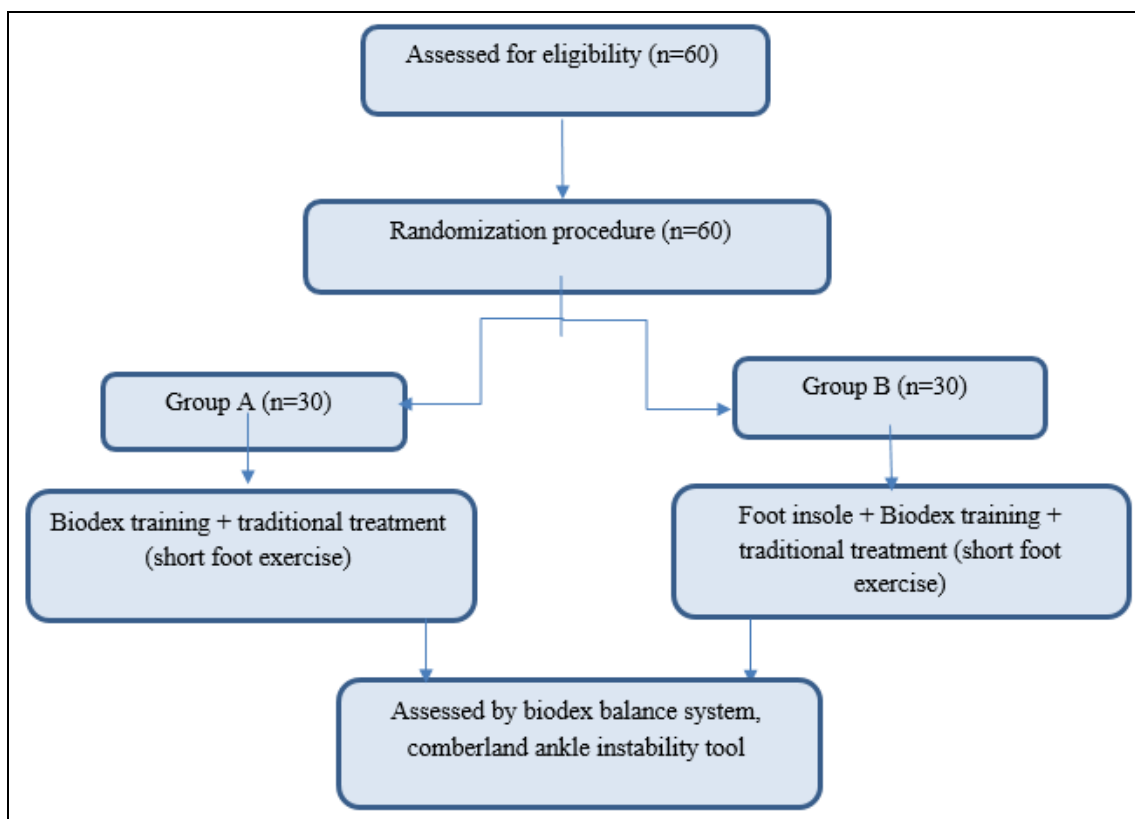


Fig 1

### Participants

Sixty subjects participated in this study and were selected from the students of the faculty of Physical Therapy, Cairo University; both genders participated in this study, with a bilateral FFF, their age was ranging from 18 to 21 years old. Body Mass Index (BMI) was ranging from 18 to 25 kg/m<sup>2</sup>.

### Outcome Measures

#### Methods measured for assessment

Assessment of flat feet using navicular drop test each subject in both groups underwent a foot postural evaluation in a weight-bearing position. Position the patient in standing so there is full weight-bearing through the lower extremity. Mark the most prominent part of the navicular tuberosity and measure its distance from the supporting surface (floor or step). Ask the subject to sit on a stool and then measure the amount of sagittal plane excursion of the navicular with tape measurement.

The distance between the original height of the navicular in weight-bearing position and its final relaxed position will be recorded as the subject's navicular-drop score. Repeated measures were taken, using the average measurement to classify the subject's foot into a pronated foot; with more than 9 mm of navicular drop, or a

normal foot; with five and nine mm of navicular drop <sup>[6]</sup> Navicular Drop (ND)  $\geq 10$  mm was regarded as a flexible flat foot <sup>[7]</sup>



**Fig 2:** ND measurement (WB)



**Fig 3:** ND measurement (non-WB)

Assessment of dynamic Balance and risk of fall using biodex balance system was used for all participants in the two tested groups. The system utilizes dynamic multi axial platform. This platform allows approximately degrees inclination in 360 degrees range and is interfaced with computer software. It measures the participant's ability to control the platform's angle of tilt, which is quantified as a variance from the center, as well as the degree of deflection over time at various stability levels. Stability levels allowed by the system ranged from one to eight. Stability level eight, allows the highest level of stability as it makes the platform to be the least tilted and is easier for the subject to maintain stability on. On the other hand, stability level one represents the least level of stability as it makes the platform to be the highest tilted and is more difficult for the subject to maintain stability. The participant's ability to control the platform's angle of tilt was measured by the system. The participant's performance was noted as a stability index. The stability index represents the variance of platform displacement in degrees from level. A high number is an indicative of a lot of motion, which indicates balance problem. The data regarding the balance of the tested participant were supplied from the system. These data include overall stability index (OSI), anteroposterior stability index (APSI), and mediolateral stability index (MLSI). Overall stability index (OSI) represents the participant's ability to control the balance in all directions, anteroposterior stability index (APSI) represents the participant's ability to control the balance in sagittal plane, and mediolateral stability index (MLSI) represents the participant's ability to control the balance in frontal plane. Before the testing procedures, the participant's weight, height and age were introduced into the system. All participants were tested on stability level four for 20 seconds. Firstly, each participant has been received verbal explanation about the testing steps. The participant was asked to assume the test position (standing on both feet without feet wear) with arms were held at both sides. Then each participant was asked to center himself on the feet platform before starting the test. They asked to try to control his/her balance as much as possible during the testing procedures. Each participant was asked to perform two test trials before the actual testing procedures for the purpose of instrument familiarity prior to data collection. The participant was instructed that the platform was unstable just after the alarm. Each participant was instructed to maintain a level platform for the period of the test. Instructions were given for the participants to focus on a visual feedback screen directly in front of them and

attempt to maintain the cursor, which represents the center of the platform, at the center of the bulls'-eye on the screen equated to a level platform. Finally, after conducting the test, a printout report was obtained. This report included the information regarding the OSI, APSI, and MLSI [8] The risk of falls would only be presented by the actual score in the overall stability index [9]



**Fig 4:** Test position on biodex balance assessment

Assessment of functional ankle instability using Cumberland Ankle Instability Tool was used for all participants in the two tested groups. is a nine-item questionnaire intended to identify and grade ankle instability. The authors designed the CAIT specifically to not require comparison between limbs. Each answer is assigned a point value ranging from 0 to 5, and participants separately score left and right limbs. If individual scores 27 or less on a limb, they are likely to have functional ankle instability. Founding authors reported excellent test-retest reliability (ICC = 0.96). Subsequent articles have suggested lowering the FAI threshold to scores less than 24, which was the score used for this study [10]

#### **Methods measured for treatment**

##### **Group A: Biodex Balance Training (BBT) and traditional treatment (short foot exercise)**

Biodex balance system is a unique system with a movable balance platform at variable degrees of instability. They were used to improve sensory-motor control skills, postural sway control, and postural stability [11]

which consists of a movable balance platform that provides up to 20 degrees of surface tilt in a 360-degree range of motion. The platform is free to move about the AP and ML axes simultaneously [12]

After familiarization, each subject was instructed to stand on the "locked" platform with both legs. The researcher advanced the platform to an unstable state while instructing the subject to focus on the visual feedback screen. Arms were free at the side of the body and not grasping handrails [13]

After selecting the stability training program (dynamic balance training), Stability levels were changed depending on subjects' ability to maintain balance, and subjects were instructed to maintain their COP in the smallest concentric rings (balance zones) of the BSS monitor, named A zone [12]

The stability level of the platform was set at level plate stability 8 (the most stable) for the first two sessions. After that, the plate stability was decreased one level every two sessions to increase the difficulty in training [11] 4-week Biodex stability program (12 min per session, three times a week) [12].



**Fig 5:** Biodes Balance training

SFE was implemented as sensory-motor training for balance improvement in the flatfeet. Before the intervention, the researcher demonstrated the short feet exercises while giving verbal instructions. Thereafter, each subject was instructed to sit on a height-adjustable chair and bend the hip joint, knee joints, and ankle joints to  $90^\circ$ . Thereafter, the subject was instructed to pull the head of the first metatarsal bone toward the heel without bending the toes the exercise was performed 3 min each day for 4 weeks, three sets of 10 repetitions were performed each repetition held for 5 sec, and repeated for up to 3 min approximately 30 repetitions<sup>[14]</sup>, the 45-second rest period between sets<sup>[15]</sup>



**Fig 6:** Short foot exercise



**Fig 7:** Short foot exercise

**Group B: Using Foot insole with Biodes Balance Training (BBT) and traditional treatment (short foot exercise)**

The insoles were prefabricated, rigid, and formed from ethylene-vinyl acetate (EVA) plastic. They covered about  $2/3$  of the foot length, from the heel to the base of the first metatarsal head. Its thickness was nearly 2 mm beneath the heel and ranged from 10 to 15 mm in the arch center, depending on the orthotic length. The shoes should comfortably support the insole. A velcro strap was used to fix the insole in place inside the shoes. Sandals and moccasin styles of shoes should be forbidden because they don't allow patient foot support. participants were instructed to wear the insoles each day (6 to 8 hours per day)<sup>[4]</sup> for 4 weeks<sup>[16]</sup>.



**Fig 8:** Foot insole



**Fig 9:** Foot insole

### Statistical analysis

Data were expressed as mean  $\pm$  SD. Unpaired t-test was used to compare between subjects' demographic data of the two groups. MANOVA was performed to compare within and between groups' effects for all measured variables. A statistical package for the social sciences computer program (version 20 for Windows; SPSS Inc., Chicago, Illinois, USA) was used for data analysis. *P* less than or equal to 0.05 was considered significant.

### Results

There was no significant difference between both groups of mean age, weight, height, and BMI ( $p > 0.05$ ). (Table 1) (Table 2) show this there was a statistically significant difference in post-study mean values of OASI between the two groups ( $P=0.020$ ) in favor of group B, there was a statistically significant difference in post-study mean values of the anteroposterior stability index between the two groups ( $P=0.002$ ) in favor of group B, There was a statistically significant difference in post-study mean values of the mediolateral stability index between the two groups ( $P=0.012$ ) in favor of group B.

(Table 3) show this There was a statistically significant difference in post-study mean values of functional ankle instability between the two groups ( $P=0.001$ ) in favor of group B, so group A is better than group B.

**Table 1:** Demographic data of subjects in both groups

Measured variable	Group A Mean $\pm$ SD	Group B Mean $\pm$ SD	t-value	p-value
Age (years)	19.5 $\pm$ 0.5	19.7 $\pm$ 0.6	-0.924	0.360
Weight (kg)	61.4 $\pm$ 9.3	60 $\pm$ 8.5	0.550	0.584
Height (cm)	163.6 $\pm$ 8	163.8 $\pm$ 8.1	-0.064	0.949
BMI (kg/m <sup>2</sup> )	22.7 $\pm$ 1.7	22.2 $\pm$ 2.1	0.966	0.338

**Table 2:** Comparison between pre-and post-study mean values of dynamic balance within groups.

Balance	Pre-study Mean $\pm$ SD	Post-study Mean $\pm$ SD	% of change	P-value
Overall stability index (Risk of fall)				
Group A	4.3 $\pm$ 1.5	2.2 $\pm$ 0.5	49%	0.001*
Group B	4.8 $\pm$ 1.4	1.5 $\pm$ 0.3	69%	0.001*
(P-value)	0.076	0.020*		
A/P stability				
Group A	3.3 $\pm$ 0.9	1.7 $\pm$ 0.4	48.5%	0.001*

Group B	3.6 ± 0.9	1.2 ± 0.3	67%	0.001*
(P-value)	0.074	0.002*		
M/L stability				
Group A	2.7 ± 1	1.6 ± 0.4	41%	0.001*
Group B	3 ± 0.8	1.1 ± 0.2	63%	0.001*
(P-value)	0.090	0.012*		

**SD:** standard deviation p-value: probability value \*: significant

**Table 3:** Comparison between pre-and post-study mean values of functional ankle instability within groups.

Functional ankle instability	Pre-study Mean ±SD	Post-study Mean ±SD	% of change	P-value
Group A	18.4 ± 3.4	21.4 ± 3.3	16%	0.001*
Group B	18.8 ± 3.1	25.2 ± 3	34%	0.001*
(P-value)	0.691	0.001*		

**SD:** standard deviation p-value: probability value \*: significant

## Discussion

As the pronated state of the heel is maintained in the subjects with flatfeet, the talus bone is moved to the inside of the sole leading to the disappearance of the medial longitudinal arch so that the ability to accommodate and distribute the weight is reduced compared to normal persons. minor biomechanical alterations in the support surface may influence postural-control strategies. When the arch starts collapsing, balance is disturbed at the feet, and therefore the balance throughout the entire body is also disturbed [17]

The results of this study revealed that there was a statistically significant difference between pre and post-study mean values of OASI between the two groups (P=0.020), there was a statistically significant difference between pre and post-study mean values of the anteroposterior stability index between the two groups (P=0.002), there was a statistically significant difference between pre and post-study mean values of the mediolateral stability index between the two groups (P=0.012) and there was a statistically significant difference between pre and post-study mean values of functional ankle instability between the two groups (P=0.001).

Our current study demonstrated that wearing FI (6-8h) each day combined with biodex balance training (12 min per session- 3days per weak) and SFE 3 min each day for 4 weeks has shown statistically significant improvement in the dynamic balance, functional ankle instability, and decrease the risk of fall. Our explanation is referred to wearing FI associated with correction of the flat foot, redistribution of weight and stimulate exteroceptors, controls body positions during movements by neuromuscular conditioning and neural adaptation of the Proprioceptors, and improve DB, FAI, and decrease ROF among subjects with flat feet. This explanation is agreed with the explanation done by Radwan, *et al.*, (2020) [4]

The results of the current study were concurrent with the result done by Radwan, *et al.*, (2020) which revealed that in normal human movement, postural reflexes are organized well ahead in anticipation of movement or perturbation to balance. Effective postural control by FI involves maintaining balance and controlling the body. Also, the perturbation in FI is self-initiated, it is expected that the central nervous system can predict the changes and pre-program itself to the dynamic challenges posed by FI. And he revealed that the FI when used as a rehabilitation tool, may help in the improvement of strength and proprioception in patients with chronic low back pain. [4]

The results of a study conducted by Su, *et al.* (2017) revealed that an orthopedic insole could improve the patient's foot arch, thereby relieving foot pain, preventing inflammation of soft tissue and tendon sheath, and other pathological features, this is in agreement with the results of the current study that the influence of design parameters, including material hardness and support arch height of personalized orthopedic insole on the correction of the foot arch and plantar pressure distribution, and the biomechanical effects on the foot tissues, including stress distribution on joint cartilage and ligaments, were quantitatively analyzed by *in vivo* experiment and finite element modeling. [18]

Another study done by Rome and Brown (2004) showed a significant difference in the mediolateral direction 4 weeks after orthosis use. The result revealed that orthoses decrease the over-pronation of foot structures and calcaneus-valgus and finally improve the alignment of the foot structure, the improved stability may be the result of improved foot structural alignment, as it reduces the stress on the ligaments and tendons and finally improves proprioception and kinesthetic awareness. The differences between the results of the various studies are a result of the variation in methods (dynamic or static balance analysis) and material of the selected insole used. The rigidity of orthoses might affect postural stability in those with flatfoot. So, thin and hard insoles provide better stability than thick and soft insoles. [16] The results of the current study were in disagreement with Rothermel *et al.*, (2004) that in a static stability test conducted on normal healthy adults, the COP excursion velocity decreased substantially more in a traditional balance training group than in an SFE balance training group and control group after 4 weeks. They stated that the traditional balance training group concentrated on maintaining balance only, whereas the SFE balance training group concentrated too much on maintaining the SFE positions, which interfered with their involuntary neurological activity, the lesser improvement in dynamic balance among the subject in the SFE group may be due to less sensory input by dynamic loading on the limb while performing the SFE exercises, or the absence of perturbations during exercise performing [20].

### Conclusion

It can be concluded that the FI is an effective correction to the foot, dynamic balance and FAI improvement through using Cumberland ankle instability tool and decreasing ROF in the participants with flat feet at stability level four using the Biodex Balance System compared with those in the control group. Furthermore, this improvement through FI can be effective in demanding the physiological and neuromuscular system among subjects with flexible flat feet, in improving dynamic balance, FAI and decreasing ROF. Therefore, Adding FI can be recommended for flexible flat feet to improve their dynamic balance, FAI and decreasing ROF.

### Conflict of interest

No conflict of interest to be disclosed by the authors

### Acknowledgments

We would like to express our thanks and gratitude to all individuals who contributed to the completion of this work, especially study participants.

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