Original Article

Effectiveness of Soft Insoles with Medial Arch Support in the Management of Pediatric Pes Planus: A Descriptive Observational Study

Muqadas Mazhar[1], Aimen Shahbaz[2], Syeda Warda Zaidi[3], Obaid-Ur-Rehman[4]
[1,2,3]Clinical Intern, Department of Orthopedics, BBH
[4]Head of Orthopedics Department, BBH

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Corresponding Author
Muqadas Mazhar,
AHS 14 Student,
Rawalpindi Medical University,
Rawalpindi
Email: aemunshahbaz@gmail.com

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Abstract

Background: Flatfoot, characterized by a diminished medial longitudinal arch, is common in children. Foot orthoses are often prescribed to alleviate symptoms and support foot development. This descriptive observational study was conducted at Benazir Bhutto Hospital from May to November 2023.
Objectives: To evaluate the effectiveness of foot orthoses in improving foot alignment, enhancing arch formation, reducing pain, discomfort, and improving functional capacity in children with flatfoot.
Materials and Methods: Fifty children (6–12 years) with flexible flatfoot were consecutively sampled and provided soft insoles with medial arch support. Data was collected at baseline, 3, and 6 months using a questionnaire, VAS for pain, and Pediatric Foot Function Index (PFFI). Statistical analysis used descriptive statistics and paired sample t-tests
Results: Among 50 participants (mean age 8.94 ± 1.69 years; 44% male, 56% female), 68% were urban. Flatfoot affected the right foot in 60% of cases. Over six months, VAS scores significantly decreased from 5.2 to 2.3 ($p < 0.01$), indicating reduced pain. PFFI scores significantly improved from 72.5 to 50.3 ($p < 0.01$), reflecting enhanced foot function.
Conclusion: The study concluded that using insoles in children with flexible pes planus effectively reduced foot discomfort and improved foot function.
Keywords: foot orthoses, pediatric, flatfoot

Introduction

Pes planus which is also known as "flat foot," is a very common foot deformity as there is loss of the medial longitudinal arch (MLA) of foot.[1] A decrease in or absence of the MLA are sometimes followed by foot and ankle abnormalities. During developmental years, flat foot is seen in as many as 14% of children[2.] Children who are obese and boys have higher prevalence of pes planus as compare to others.[3] Age, composition of body, gender, W-sitting, ligamentous laxity, genetics, age at which shoe wearing begins, and foot wear type which is used also affects MLA formation.[4] Pes planus may result in structural changes over the period of time that can lead to foot pain, ankle arthritis, hip and knee joint injury, and waist discomfort with pain.[5] The deformity typically aggravates in late childhood.[6]

To prevent complications and improve quality of life of patients some interventions are required. Treatment and prevention in early childhood is effective. In later stages, the treatment results are usually not so good, and prevention of symptoms becomes the priority rather than correction.[7]

Pes planus is either acquired or congenital.[8] Asymptomatic cases can be physiological, which improves over time or non-physiological, which aggravates with time. Symptomatic pes planus leads to altered function and treatment. Pes planus can also be flexible (non-osseous) or fixed (osseous).[9] Physiological pes planus could be a result of flexible talocalcaneal joint whereas pathological pes planus results from rigid deformities at foot like vertical talus and tarsal coalition.[10]

Pes planus diagnosis relies on clinical history, visual examination, footprint measurement and imaging such as, computed tomography (CT), magnetic resonance imaging (MRI) and bone scan.[11]

The non-surgical treatment of pes planus involves foot orthoses (shoe inserts), stretching, proper footwear, changes in activity level, pain and anti-inflammatory medications.[12] Support and stability to medial longitudinal arch is provided with the help of orthoses and also to reduce pain symptoms.[13]

The surgical treatment of pes planus includes soft tissues surgical procedures, osteotomies for realignment and techniques for motion-limiting. Surgery is only indicated if the pain continues despite using non-surgical management.[14]

For pediatric flexible flatfoot, foot orthosis is a standard first line conservative treatment.[15] The most effective are 3D printed.[16]

Foot orthoses are commonly prescribed as a first-line conservative treatment, but evidence on effectiveness of foot orthoses is limited. This study aims to evaluate the measurable outcomes of foot orthoses in children with flexible pes planus. The study evaluates impact of foot orthoses in children with flexible flat foot. Our study measured pain reduction using the Visual Analogue Scale (VAS) and also evaluated foot function index changes before and after orthotic intervention.

Materials and Methods

A descriptive observational study was conducted in Orthopedic Department of Benazir Bhutto Hospital (BBH), Rawalpindi,

for assessing the effects of custom foot orthoses on children who have been diagnosed with flexible flat foot. The study comprised of six months, started on May 1st, 2023, and ended on November 30th, 2023**,** following formal approval of the research synopsis from departmental review board. The study was done in accordance with the Declaration of Helsinki. Informed consent was obtained from parents or the guardians of children.

A total of 50 pediatric patients aged 6 to 12 years**,** diagnosed with flexible flat foot were selected by non-probability consecutive sampling technique. Out of the 50 participants, 22 were male and 28 were female. Children were enrolled from the Orthopedics Outpatient Department of Benazir Bhutto Hospital (BBH), Rawalpindi. Inclusion criteria cover the patients with flexible flat foot, no neurological or congenital musculoskeletal disorders, those who were willing to follow prescribed treatment. Exclusion criteria included children with rigid flat foot (confirmed after tip toe test), significant neuromuscular conditions like CP (confirmed with history and reports), or those non-compliant with insole usage during the follow-up period. Bilateral cases were also excluded.

At first visit, the parents were briefed in detail about the study's objectives, methodology, and expected outcomes. Written informed consent was taken. Detailed history which includes demographic data, medical background, and family history of foot disorders was also taken. Initial evaluation involved clinical inspection, footprint analysis, and gait assessment.

A standardized questionnaire was administered at baseline, 3 months, and 6 months which involves demographic data, the Visual Analog Scale (VAS)[17] for pain intensity, and the Pediatric Foot Function Index (PFFI)[18] to assess the functional influence of flat foot. These tools were used for their reliability and significance in evaluating pediatric foot-related pain and disability.

At the first clinical interaction, footprints were taken using ink pads to visualize arch patterns. Negative molds were obtained using plaster Paris (POP) bandages while maintaining the foot in a neutral subtalar position. Then these were converted into positive molds**,** which were used as the base for creating the custom foot orthoses. On delivery of the final orthoses, patients were guided about their proper use, advised on gradual changes, and counseled for regular follow-up.

Follow-up visits were scheduled at 3 months and 6 months after the initial intervention. At each follow-up, VAS and PFFI scores were reassessed by using same validated standardized questionnaire**.** Detailed clinical observations which include changes in foot posture and gait pattern, and compliance with use of orthoses were recorded during these visits.

All data was compiled and analyzed using SPSS version 25.0. Descriptive statistics (mean, standard deviation, frequency, and percentages) were used for demographic and baseline characteristics. To assess the effectiveness of the intervention**,** paired sample t-tests were conducted comparing baseline and 6-month VAS and PFFI scores.

A p-value < 0.05 was considered statistically significant, indicating a meaningful improvement in symptoms and function due to the intervention.

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Results

Our study included a total of 50 pediatric patients aged 6 to 12 years, diagnosed with flexible flat. Out of the 50 participants, 22 were male and 28 were female. Among these patients 34% belonged to rural areas while the rest (32%) belonged to urban areas. More than half of the patients had right sided pes planus. These details are tabulated in following **Table 1**

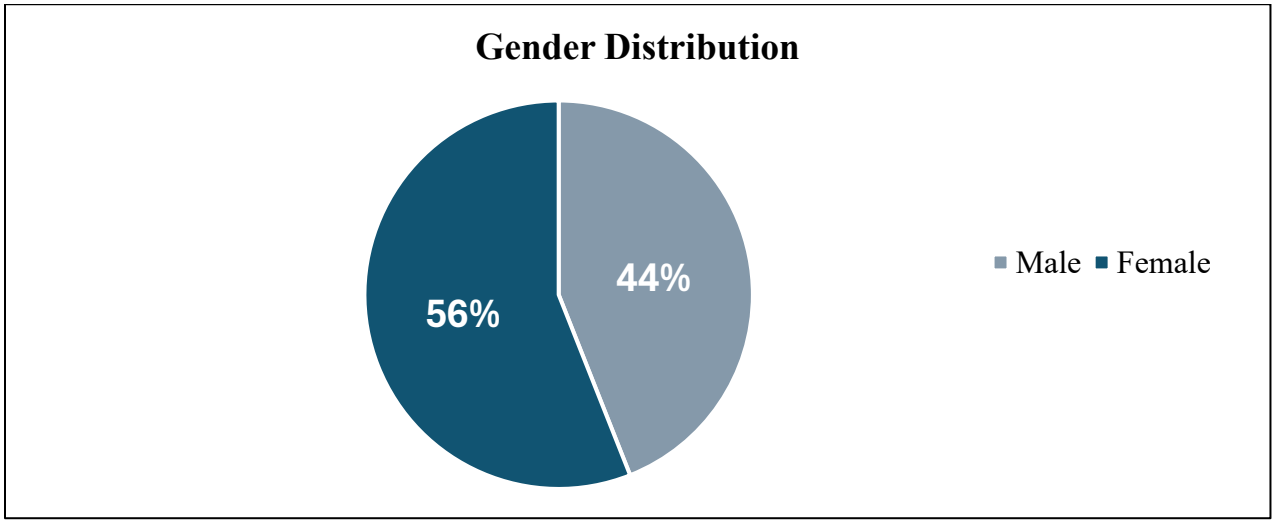
Table 1 *Demographic Details of The Participants at The Baseline Visit*

Parameters	Variables	Frequency (Percentage)
Gender	Male	22 (44%)
	Female	28 (56%)
Background	Rural	34 (68%)
	Urban	16 (32%)
Side of Pes Planus	Right	30 (60%)
	Left	20 (40%)

Note. Data presented as frequencies and percentages

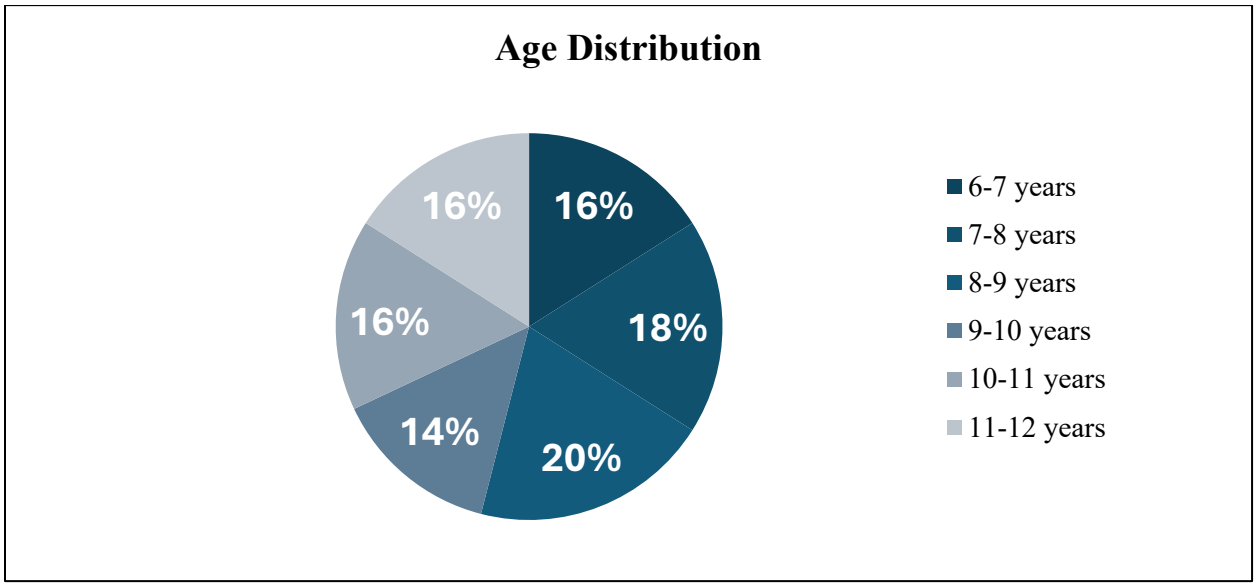
Following **figures 1** and **2** show the gender and age distribution of the patients respectively. 56% of study participants were female while 44% were males. The average age of patients diagnosed with flexible pes planus was 8.94±1.69 years.

Figure 1 *Gender Distribution of Study Population*



Note. Gender distribution of population is presented as percentages.

Figure 2 *Age Distribution of Study Population*



Note. Age distribution of population presented as percentages.

Foot pain was evaluated using the Visual Analog Scale (VAS) at three intervals: baseline, 3 months, and 6 months. This is shown in the following **Table 3**. The research indicated a notable decrease in pain levels among pediatric patients suffering from flexible pes planus, as assessed by the Visual Analog Scale (VAS). Initially, the average VAS score was 5.2 (SD = 1.1), reflecting moderate pain levels. Following three months of treatment, the mean VAS score dropped to 3.1 (SD = 0.9), signifying a 40% reduction in pain with a statistically significant p-value of < 0.01. After an additional three months of progress, the mean VAS score further declined to 2.3 (SD = 0.8) at the six-month mark, resulting in a 56% reduction from the baseline (p-value < 0.01).

Table 2 *Visual Analog Scale (VAS) Scores of Study Population*

Time Interval	Average VAS Score	Standard Deviation (SD)	p-value
Baseline	5.2	1.1	-
3 Months	3.1	0.9	< 0.01
6 Months	2.3	0.8	< 0.01

Note. Data presented as Average and Standard Deviation

The Pediatric Foot Function Index (PFFI) was developed to assess foot function. The Pediatric Foot Function Index (PFFI) results depicted in **Table 3** indicated significant improvement in foot function among pediatric patients with flexible pes planus during the study period. At baseline, the PFFI score was 72.5 (SD = 10.3), indicating a significant decrease in foot function. After 6 months of care, the mean PFFI score reduced to 50.3 (SD = 8.7), indicating a 31% improvement in foot function compared to baseline. The statistically significant improvement (p-value < 0.01) suggests that the observed improvements are unlikely to be chance.

The paired sample t test was conducted to compare variables. The results were significant. The reductions in VAS scores from baseline till 3 months, $t(49) = 14.79$, $p < 0.001$ and then from 3 months to 6 months, $t(49) = 6.67$, $p < 0.001$. When compared from Baseline to 6 months, $t(49) = 21.32$, $p < 0.001$. The PFFI scores also improved from baseline to 6 months (mean difference = 22.2, $p < 0.01$), which indicated enhancement in foot function.

No significant side effects were recorded during the research. Only 15% of participants reported slight discomfort at first, which went away after a few weeks of wearing the insoles.

Table 3 *Pediatric Foot Function Index (PFFI) Scores of Study Population*

Time point	Mean PFFI Score	Standard Deviation	p-value
Baseline	72.5	10.3	-
6 months	50.3	8.7	<0.01

Note. Data presented as Mean and Standard Deviation

Discussion

This study aimed to evaluate effectiveness of soft insoles with medial arch support in the management of pediatric pes planus by introducing VAS and PFFI. It showed how orthoses help in reducing pain and improving foot function in patients with flexible flat foot over a six-month period. The statistical analysis of this study showed improvement in both VAS and PFFI scores in all intervals indicates clinical importance of orthotic intervention in management of pes planus

Previous work on orthoses in flat foot showed that it can alleviate pain and symptoms but very few studies showed with long term follow up of patients using foot orthoses. This study adds to the evidence by using validated tools like VAS and PFFI over a proper follow up period. The results showed consistent and significant improvements. The most improvements in scores were noted from baseline till 6 months, which suggests that prolonged use increase the functional outcome of orthoses.

A randomized controlled trial by (Narastiti, Setyawan, & Ningsih, 2023) was conducted on children with flatfoot in an Elementary School that supports the effectiveness of orthotic intervention in pediatric population. In this study, the soft arch-support insoles were given to children with gross motor training, and they observed significant improvement in balance within 30 days. $P = 0.002$ was measured by using Pediatric Balance Scale. In this study the basic outcome was balance rather than pain or foot function as that of ours, but their findings complement and reinforces our results of the role of insoles or foot orthoses in improving lower limb biomechanics and overall quality of life in children with flexible flatfoot. Their study also focused on stability and short-term

clinical outcomes. Our results add to their evidence that orthotic use improves balance-related outcomes, reduces pain and enhances functional foot performance over a longer follow-up period of six months.

Findings from systemic review by (Oliveira, et al.) also support the clinical importance of orthotic intervention in the management of pediatric flatfoot. This systemic review analyzed data from 213 patients under 18 years of age and give the conclusion that medial arch support insoles is an effective solution in improving alignment of lower limb, specifically ankle and knee rotational mechanics, better gait and coordination. The results from this systemic review are consistent with ours, where there are significant reductions in pain (VAS) and improvements in foot function (PFFI) This review emphasized biomechanical alignment and coordination over a longer follow-up period (12 months). Our findings add to the evidence by working on symptom relief and functional outcomes. Both studies together reinforce that foot insoles are a reliable and non-invasive intervention for pediatric population who have flexible flat foot.

Our study concluded that orthotic insoles are useful in treating the flexible pes planus, with considerable reduction of the pain levels at three and six months ($p < 0.01$). Based on the findings of this research, children with flatfoot may be treated by using orthotic insoles as has been reported in previous research and studies.

The treatment was found to have a safe profile as no major adverse effects were found in the study. In the beginning, 15% of participants experienced moderate discomfort that decreased within a few weeks of using the insoles. This research emphasizes patient education and gradual changes in orthotic device to reduce patient discomfort and attain good patient compliance in treatment.

The findings of the study are encouraging but further randomized controlled trials are needed to validate these outcomes and to find out long term effects and changes.

Conclusion

The use of orthotic insoles in this population may result in significant pain and foot function improvement in pediatric patients with flexible pes planus, as this study suggests. According to the study, non-invasive therapies can enhance the health and quality of life of children with flatfoot. More research is needed to improve treatment procedures and investigate the long-term benefits of these therapies.

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