

1. Problem Statement

To design a positionally adaptable orthopedic device for growing children (ages 5-7) to accommodate up to 10% volumetric foot growth while supporting 150N of ground reaction forces.

2. Project Background Report

2.1 Disease State & Procedure Understanding

Disease Background

Pes planus, commonly referred to as flat feet, is a common foot deformity characterized by partial or complete loss of the medial longitudinal arch during weight-bearing.

Consists of several flexible and rigid subtypes.

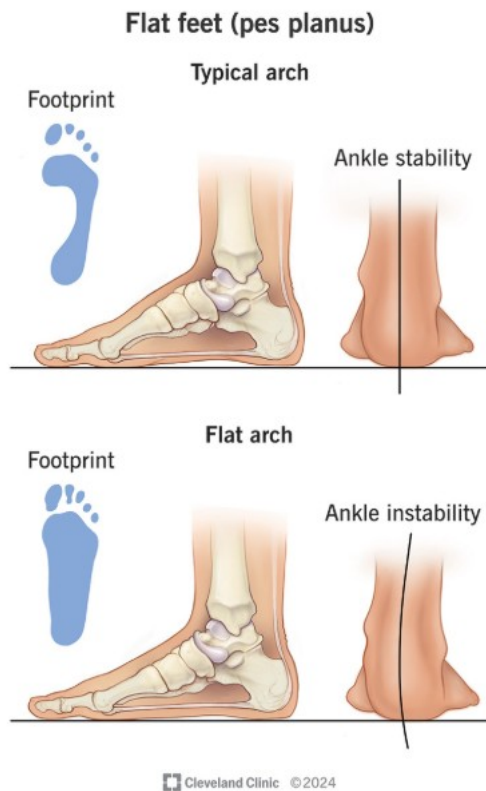


Figure 1. Typical Arch vs Flat Arch secondary Pes planus [\[3\]](#).

Causes:

Congenital:

Infants are commonly born with flat feet and do not develop a normal arch until ages 7 to 10. This is because infants have a pad of fat that lies under the medial longitudinal arch that protects the arch during early childhood but rapidly disappears as the child starts walking.

However, some children might just not develop a normal arch by the time they reach adulthood.

Acquired:

Acquired pes planus is most commonly associated with posterior tibial tendon dysfunction, which supports the arch and provides inversion and plantarflexion of the foot.

Dysfunction of this tendon can result from stretching, tears, or ruptures.

Likewise, patients with damage or trauma to the midfoot or hindfoot that results in navicular, first metatarsal, calcaneal, or Lisfranc ligament complex are at an increased risk of developing pes planus.

Other causes consist of injuries to soft tissues such as the plantar fascia or spring ligament.

Patients who exhibit congenital ligamentous laxity due to Down syndrome, Marfan syndrome, or Ehlers-Danlos syndrome can also present with pes planus.

Patients with rheumatoid arthritis or other degenerative or inflammatory conditions are likewise at higher risk of pes planus.

Symptoms:

Early symptoms might include foot pain, ankle pain, and shin splints.

Over time, patients tend to develop abnormalities in their gait, deformities like bunions or hammertoes, and even constant chronic pain.

This pain can spread upstream to the knees, hips, and lower back as well.

If left untreated, many patients develop conditions secondary to pes planus, such as arthritis, ankle instability and strains, and other repetitive strain-based injuries.

Current Treatment Methods:

Children rarely require surgical intervention for pes planus. Foot orthotics are often the primary treatment for foot pain resulting from pes planus in children.

However, surgery may be suggested for more severe cases of rigid pes planus, tarsal coalitions, and progressive, symptomatic pes planus.

Limitations of Current Treatments:

The majority of treatments for pes planus are limited because most cases are asymptomatic and developmentally normal.

Body System(s) Involved

Musculoskeletal System

Peripheral Nervous System

Structure	Function	Relevance to Project
Medial Longitudinal Arch (MLA)	Acts as a “spring” for the foot	The deformity of this structure is what leads to pes planus
Tibialis Posterior	Dynamic Stabilizer	Dysfunction of this muscle allows the foot to roll inward and flatten, causing pes planus.
Tibialis Anterior	Raises the medial border of the arch	Dysfunction of this muscle contributes to Pes planus.

Physiological Process	Description	Impact on Design
Arch Dynamics	The foot arches are dynamic load bearing structures.	The device must not inhibit or disturb the natural dynamics of the arch.
Locomotion (The Gait Cycle)	Locomotion relies on the synchronized integration of foot joints and muscles in specific rockers or cycles.	The device must not inhibit or disturb the rocking cycles (Heel, Ankle, Forefoot) of the foot.
Shock Absorption	The foot receives forces that are several times the magnitude of the human body constantly.	The device must be flexible and soft enough to adequately disperse forces through the foot.

Research Summary:

Molina-García, C., Banwell, G., Rodríguez-Blancue, R., Sánchez-García, J. C., Reinoso-Cobo, A., Cortés-Martín, J., & Ramos-Petersen, L. (2023). Efficacy of Plantar Orthoses in Paediatric Flexible Flatfoot: A Five-Year Systematic Review. *Children*, 10(2), 371. <https://doi.org/10.3390/children10020371>

Summary: This systematic review evaluates multiple clinical trials tracking pediatric cohorts presenting with symptomatic flexible flatfoot. The article notes that orthotics treatment is the most commonly recommended treatment among pediatrics despite

lack of supporting evidence for such treatment, along with a lack of evidence supporting the effectiveness of orthotics for this matter, indicating the presence of bias in several of the reviewed studies in testing and validation methods.

Sharula, Zhao F, Wu T, Kang Q, Geng X, Qin H, Zhang Y, He J, Huang L, Xu J and Lu S (2026) Treatment of pediatric flatfoot: a systematic review-based consensus and guidelines by CPAM-LRC. *Front. Pediatr.* 14:1825355. doi: 10.3389/fped.2026.1825355

Summary: This multi-disciplinary clinical guideline synthesizes database trials to outline standard care pathways for pediatric flatfoot management. The expert panel notes that the pediatric medial longitudinal arch develops progressively during the first decade of life, meaning that conservative treatment must avoid completely rigid immobilization to prevent secondary muscle atrophy. The text concludes that successful conservative interventions require designs capable of accommodating dynamic developmental changes while simultaneously mitigating the localized pain and functional limits that trigger clinical consultations.

Dars, S., Uden, H., Banwell, H. A., & Kumar, S. (2018). The effectiveness of non-surgical intervention (Foot Orthoses) for paediatric flexible pes planus: A systematic review: Update. *PloS one*, 13(2), e0193060.
<https://doi.org/10.1371/journal.pone.0193060>

Summary: This systematic review addresses the clinical efficacy and wear compliance profiles of foot orthoses across pediatric populations. Out of 606 articles identified, 11 studies met the inclusion criteria. A diverse range of pre-fabricated and customised FOs were utilised and effectiveness measured through a plethora of outcomes. Summarised findings from the heterogeneous evidence base indicated that FOs may have a positive impact across a range of outcomes including pain, foot posture, gait, function and structural and kinetic measures. Despite these consistent positive outcomes reported in several studies, the current evidence base lacks clarity and uniformity in terms of diagnostic criteria, interventions delivered, and outcomes measured for paediatric flexible pes planus.

Procedural Flow Diagram (Generated per deliverables)

1. Diagnosis: Patient aged 5-7 presents to pediatrician or podiatrist with foot fatigue, pain, or observed gait abnormalities.
2. Assessment: Clinical evaluation of Resting Calcaneal Stance Position (RCSP) and Medial Longitudinal Arch (MLA) collapse under load.
3. Prescription/Treatment: Recommendation of non-surgical intervention (foot orthotics) to alleviate pain while preserving dynamic arch growth.
4. Application: Parent applies orthotic device to the child's foot daily.
5. Failure Modes in Pathway: Child refuses to wear rigid orthotic due to pain/stiffness; device limits natural arch muscle development; device is rapidly outgrown resulting in improper fit.

2.2 Competitive Benchmark

User Analysis:

All users of this device will fall into the three P's: Patients, Providers, and Payers.

Each of these groups all have different needs that will have to be factored into our design, and we should keep all stakeholders in mind when making design decisions.

First, there are multiple people to consider when thinking about the patient's needs.

Since this device is targeted at children aged 5-7 with Pes Planus, it must be not only comfortable for the child, but easy for the child's parent to use and put on them.

Furthermore, the device must be very durable to survive daily use from a toddler.

Overall, the patients using this will be children aged 5-7 years at risk of developing Pes Planus, and to accommodate them best we must make an easy to use yet durable device that will improve the child's arch.

Next, there are a wide range of providers that may recommend this device.

A pediatric podiatrist may prescribe this device to the patient at a doctor's office, a physical therapist may suggest it during a recovery session, and a general practitioner may refer a family to one of these professionals if the problem is presented to them.

Ideally, the doctor will only need to demonstrate how to use the device to the family and initially set it up for the child.

This once again means the device must be easy to use, since many different professionals may be using it, and it must work so that the doctor continues to recommend them to families.

Overall, the needs of the provider of the device are very similar to the needs of the patient's device: to prevent flat feet from forming and to be simple to operate.

Lastly, the payers of the device will be insurance companies and hospitals, which want the device to make profit and be safe enough to avoid any liability.

If the device poses a significant risk to the patient, such as inducing Pes Planus instead of preventing it, the payers will be liable for the damages that are caused.

The main priority of the payers is to get a return on their investment, meaning the device must work well enough to sell to patients, and it must prioritize safety while doing so.

Overall, the users may have different motives for their needs, however a safe, durable device that successfully prevents Pes Planus will make everyone happy.

Application Predicate Devices

Device	Manufacturer	Approx.	Key	Advantages	Limitations
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		Cost	Features		
FootChair Kids Medical Grade Adjustable Orthotic	FootChair	\$35 - \$45	Pocketed arch design under the cover containing removable, pocketed elastomer arch pads.	Allows manual adjustments to arch height and comfort without needing a brand-new insole.	The base chassis length is fixed; as the child's foot grows lengthwise, the entire insert must still be replaced.
Little Steps Pediatric Foot Orthotics	Northwest Podiatric Laboratory	\$45 - \$60 per pair	Prefabricated, deep heel cup, static medial longitudinal arch support.	Standard over-the-counter clinical choice; simple to use.	Zero adjustability. Requires buying a new size every 6 months to match a child's rapid growth.

Technology Predicate Devices

Device	Original Application	Technology of Interest	Adaptation Potential
Foot Orthosis Support Device (US 2009/0139113 A1)	Biomechanical stabilization and custom contouring of lower limb structures.	A flexible support device utilizing specific structural indentations and contour lines to control alignment across the foot bed (Buethorn, 2009).	Highlights established methodologies for deploying variable flexibility zones to contour to human feet without introducing localized high-pressure areas
Weight Adjustable Calibrated Orthotic (US 2017/0318898 A1)	Adult Arch Support and stiffness tuning	Interchangeable structural "leaf springs" or base snap-on tension keys.	Allows the device to scale its mechanical stiffness up as the child gains body weight from ages 5 to 7.

Competitive Benchmarking (From Design Review)

Criteria	Rigid Orthotics	OTC Insoles	Group 11 Solution
Adaptability	None (Fixed)	Minimal	High (Sleeve)
Comfort	Low (Rigid Plastic)	Moderate	High (Gel/Fabric)

Cost	\$200+ (Custom)	\$15 - \$30	\$18-\$24
Growth Scaling	Requires Replacement	Disposable	Modular Inserts

2.3 Conclusion (So What?)

As synthesized from the above research and competitive benchmarking, standard rigid orthotics present substantial limitations for pediatric patients due to the rapid volumetric foot growth between ages 5 to 7. Traditional interventions frequently fail due to low compliance caused by physical discomfort and the high cost of constant replacement. Group 11's solution presents a strong commercial and clinical opportunity by offering a positionally adaptable, comfortable sleeve-based design that scales with the child's growth. This reduces pain efficiently while lowering the financial burden on parents and payers, fulfilling a critical unmet need in pediatric podiatry.