

BME 3050 Final Project Documentation

Pediatric Arch Support Group 11

Prepared By: Thomas Barnett, Levi Willgruber, Hamza Al Halabi
Department: Biomedical Engineering

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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.

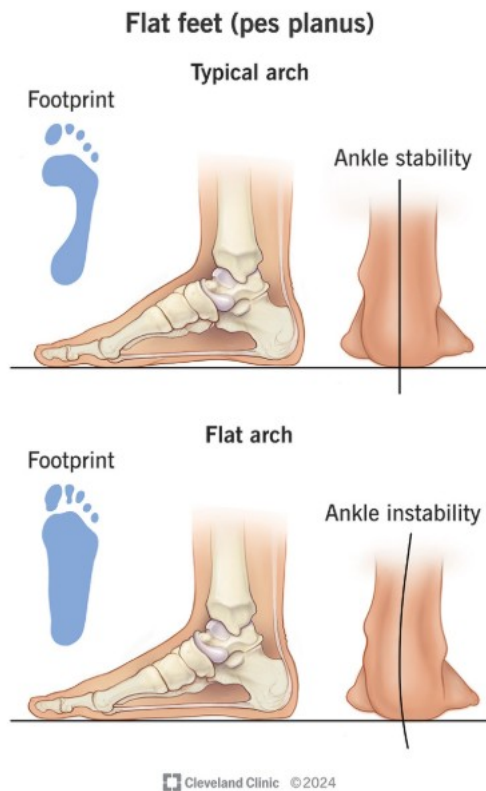


Figure 1. Typical Arch vs Flat Arch secondary Pes planus [\[3\]](#).

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.

3. Design History File (DHF)

3.1 CFR 820.30 (b) Design and Development Planning

Team Roles and Responsibilities

Team Member	Role	Responsibilities
Thomas Barnett	Team Purchaser Record Keeper	Ideation and Design of device
Hamza Al Halabi	Clinical Contact Coordinator	Research of pre-existing solutions and their shortcomings
Levi Willgruber	Team Work Coordinator	Fabrication of prototype

Key Milestones

Milestone	Target Date	Owner	Status
Design Review 1	6/18	Hamza Al Halabi	100%
Start Prototyping	7/2	Levi Willgruber	100%
Final Design Review	7/30	Thomas Barnett	100%
Final Project Delivery	8/4	Levi Willgruber	100%

Work Distribution

Deliverables	Responsible Team Member(s)	Estimated Effort (1-10)
Brainstorming Artifacts	Team	4
Downselection	Team	4
System Diagram	Hamza Al Halabi	5
Task Analysis	Levi Willgruber	5
Engineering Analysis	Hamza Al Halabi	5
Drafted Design Inputs	Thomas Barnett	4
Prototyping Plan	Levi Willgruber	7
Prototype of Device	Levi Willgruber	7
V&V Matrix Draft	Hamza Al Halabi	8
Design Outputs	Thomas Barnett	6

Key Challenges

Challenge	Potential Impact	Mitigation Strategy
Trouble with the Fabrication of device	Having an incomplete prototype	Research fabrication resources available to us (1819) and device a clear plan on how we plan on making the device.
Lack of Insight from Clinical Contacts	Having a lack of understanding of the	Setting up interviews in advance, and preparing

	patient and disease we are treating.	complex questions for them to answer.
Trouble brainstorming solutions	An incomplete or unfeasible design	Extensive research into predicate devices and many design concepts while brainstorming.

3.2 CFR 820.30 (c) Design and Development Inputs

Design User Needs & Decision Making – Group 11

Chosen Video: Best Plantar Fasciitis Arch Support Sleeves

The application of the arch support sleeve starts at 0:21 seconds in the video.

The gowning process simply includes stretching the sleeve, sliding the foot into the sleeve, and positioning it around the arch of the foot.

Once the sleeve is properly placed, the patient can put on regular socks and shoes over it and continue with their day.

Use Case Description:

This video provides instructions for the patient to apply the sleeve on themselves at their own home.

This would likely be done in the home immediately after waking up, since it is recommended for every-day, normal activity.

The gowning process for the sleeve is very simple and can fit seamlessly into a patient's routine.

Task List:

Stretch the sleeve enough for your foot to fit through

Slide foot into the sleeve

Position the gel pad under arch of the foot

Let go of sleeve and ensure the pad is adequately compressed against the arch of the foot.

Sub-Task Breakdown:

Stretch the sleeve enough for your foot to fit through

1.1. Place fingers inside the sleeve

1.2. Pull sleeve in opposite directions to create a larger opening

1.3. Ensure that the opening is large enough to fit around your foot

Slide foot into the sleeve

2.1. Place foot through stretched sleeve

2.2. Pull sleeve towards yourself until it is fully wrapped around your foot

Position the gel pad under arch of the foot

3.1. Feel the bottom of your foot to locate your arch

3.2. Feel the bottom of the sleeve to locate the arch support

3.3. Pull the sleeve up or down your foot until the pad fits comfortably in your arch

Let go of sleeve and ensure the pad is adequately compressed against the arch of the foot.

4.1. Carefully slide your hands out of the sleeve

4.2. Feel the pad to locate the arch support and ensure that it is correctly positioned under your arch

4.3. Walk across the room to ensure the support sits comfortably, if it does not repeat step 3.

Ethical Considerations of Device:

Obese children may break the device, which not follow the beneficence or justice of the patient.

If the device breaks, it will not work which will be unfair to overweight individuals.

Unique foot anatomy (such as a protruding ankle) could prevent the device from being applied.

This will infringe on their justice, as certain disabilities may prevent use of the device.

Neurodivergent children with sensory issues (such as children with autism) may find the device severely uncomfortable and overstimulating.

This may cause discomfort, hence violating nonmaleficence, and may prevent the child from using the device, hence violating justice.

Extremely busy parents may put the device on incorrectly, especially if the device is overly complicated, and incorrect use of the device could potentially do more harm to the patient, violating nonmaleficence.

PCA Analysis

Sub-Task Step	Perception (P)	Cognition (C)	Action (A)
1.2. Pull sleeve in opposite directions to create a larger opening	Tactile feedback of elastic material tension/resistance against fingers. Visual expansion tracking of the sleeve opening.	Judging if physical resistance indicates the material limit to avoid tearing. Estimating the pulling force required based on visual sizing.	Exerting opposing muscular force with hands/fingers. Maintaining a secure, high-friction grasp on the material edges.
1.3. Ensure that the opening is large enough to fit around your foot	Visual sizing of the stretched diameter relative to the physical bulk/width of the foot.	Geometric comparison and mental mapping between the moving sleeve edge and the static foot width.	Sustaining isometric hand strength to lock the sleeve wide open at a precise dimension.
2.2. Pull sleeve towards yourself until it is fully wrapped around your foot	Tactile perception of structural friction and shear forces sliding over the dorsal/plantar foot skin. Continuous feel of progressive snugness.	Interpreting whether sensory resistance is normal fabric-on-skin friction or a critical physical snag on a toe or heel.	Performing an iterative hand-over-hand pulling movement while stabilizing the ankle/leg against movement.
3.2. Feel the bottom of the sleeve to locate the arch support	Haptic/tactile differentiation between the thin flat fabric substrate and the raised, denser edge of the enclosed gel pad.	Recalling and recognizing pad geometry; mapping its hidden three-dimensional boundary layout purely through touch.	Palpating (pressing, sweeping, and applying localized finger pressure) along the underside of the sleeve fabric.
3.3. Pull the sleeve up or down your foot until the pad fits comfortably in your arch	Tactile sensation of a pressure profile shift as the thick gel pad contour slides into the anatomical hollow of the foot's arch.	Evaluating complex physical comfort/fit feedback against a mental model of an optimal anatomical match.	Delivering tiny, incremental micro-adjustments (tugging/pushing) against strong elastic resistance.
4.2. Feel the pad to locate the arch support and ensure that it is correctly positioned under your arch	Internal deep tissue pressure sensation (plantar fascia) combined with external digital palpation feedback.	Analyzing sensory pressure symmetry to confirm that the pad is centered on the arch rather than skewed.	Manually pressing around the outer boundaries of the pad while holding the foot completely static.
4.3. Walk across the room to ensure the support sits comfortably, if it	Dynamic haptic pressure shifting under full body weight changes	Making a high-consequence binary decision: Is the	Transitioning to a standing posture, balancing, executing dynamic

does not repeat step 3	during active heel-strike, mid-stance, and toe-off gait cycles.	comfort/pressure profile safe and therapeutically adequate, or must I restart?	walking strides, and executing a device adjustment retry if rejected.
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Use Case Errors

Sub-Task Step	Potential Use Error(s)	HF Root Cause	Potential Clinical / Physical Harm
1.2. Pull sleeve in opposite directions to create a larger opening	Pulling with inadequate force. Pulling with extreme force.	Misjudging raw elastic tensile resistance; compromised hand/grip dexterity.	Bruising or skin pinching. Broken product.
1.3. Ensure that the opening is large enough to fit around your foot	Attempting to force the foot forward before achieving an adequate diameter.	Visual sizing distortion or failure to maintain isometric hand tension.	Toes catch heavily on fabric loop, resulting in tripping or acute loss of balance.
2.2. Pull sleeve towards yourself until it is fully wrapped around your foot	Abandoning the pull motion early, leaving the sleeve bunched up near the distal foot/toes.	Misinterpreting immediate skin friction as correct placement; low patience threshold.	Bunched material creates severe local friction/shearing, causing skin abrasions or blisters.
3.2. Feel the bottom of the sleeve to locate the arch support	Failing to identify or locate the gel pad boundaries through the material layers.	Low-profile or non-contrasting pad edges; reduced tactile finger sensitivity.	Increases probability of blind misalignment, causing focal tissue pressure error.
3.3. Pull the sleeve up or down your foot until the pad fits comfortably in your arch	Displacing the pad off-center (skewed forward over the ball of foot or backward onto the calcaneus/heel).	Inability to apply fine motor adjustments against high-tension elastic material.	Plantar fascia bruising, severe structural foot strain, or severe exacerbation of existing foot issues.
4.2. Feel the pad to locate the arch support and ensure that it is correctly positioned under your arch	Blindly accepting an improper alignment.	Absence of direct visual feedback/indicators on the outer surface of the sleeve.	Prolonged wear of a misaligned device, causing gait alteration or localized nerve compression.
4.3. Walk across the room to ensure the support sits comfortably...	Continuing to walk with an obvious painful structural misalignment. Ignoring migration/slippage	Misinterpreting severe pain as standard 'therapeutic pressure'; incorrectly sized	Ischemia, severe pain, or skin tissue breakdown. Secondary fall hazard if sleeve bunches under the

	of the sleeve.	product.	heel.
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User Needs & Design Inputs (From Design Review)

User Need	Design Input (Requirement)	Verification Method
Donning: Users (Parents/Patients) need the device to be quick and easy to apply during a daily routine.	The device shall be donned in under 30 seconds without the use of secondary tools.	Human factors timed donning trials.
Intuitive Use: Users (Parents/Patients) need the correct anatomical placement of the device to be obvious to prevent harmful misalignment.	The device shall incorporate a tactile gel pocket and an elastic heel strap to passively guide proper alignment along the medial longitudinal arch.	Usability testing (evaluating the rate of incorrect placement/misalignment).
Compatibility: Users (Patients) need the device to fit seamlessly inside standard pediatric footwear without requiring oversized shoes.	The maximum thickness of the device in the midfoot region shall not exceed 8mm.	Caliper measurement of the fully assembled device.
Adjustment: Users (Patients) need the device to adapt to natural volumetric foot growth between ages 5 and 7.	The elastic sleeve material shall accommodate up to 10% volumetric expansion without exceeding safe tissue compression limits.	Tensile strain testing and compression mapping.
Durability: Users (Patients) need the device to withstand dynamic forces during normal pediatric play without failing (e.g., tearing or leaking).	The device assembly must withstand dynamic impact forces simulating up to 3600 lbs without material tearing or gel leakage.	Dynamic drop testing (e.g., 30 lbs weight dropped from 1 foot) and visual inspection.
Biomechanical Efficacy: Users (Patients) need the device to actively resist medial longitudinal arch collapse during the gait cycle.	The device must structurally sustain a minimum of 150N of ground reaction force (GRF) without bottoming out or losing elastic recovery.	Static mechanical load testing (e.g., 30 lbs static load for 1 minute).

3.3 CFR 820.30 (d) Design and Development Outputs

MATERIAL SELECTION

Bleached Muslin was selected to ensure the shape of the pattern accurately fit into place.

HYBRID SUPPORT

Gel-adhesive sandwich construction: Soft gel for immediate comfort surrounded by adhesive to encase and deform with the gel.

HUMAN FACTORS

Familiar design allows children to put on the insert themselves, as if it were a regular sock.

ASSEMBLY OVERVIEW

- Sleeve: Breathable Muslin.
- Pocket: Reinforced internal stitching.
- Insert: Gel-Adhesive Combination.
- Strap: Elastic Band

PROTOTYPE JOURNEY

V1: PROOF OF CONCEPT

Cardboard and foam inserts in standard socks.

Lesson: Verified the lift required but failed on stability.

V2: FUNCTIONAL ALPHA

Gel pads in compression sleeves.

Lesson: Improved stability; identified the need for a dedicated pad pocket. Need to refine insert topography.

Note: Due to project timeline constraints, development concluded at V2. The planned V3 (Final Beta - Custom-molded hybrid inserts with reinforced pouch) remains a future milestone for subsequent validation.

3.4 CFR 820.30 (e) Design and Development Review

Regulatory Strategy:

Device Classification

Since most predicate devices listed are Class I devices (due to their low risk factor), the device we create will most likely also be a Class I device.

A simple, external orthopedic creates little to no harm on the patient since it simply forces the patient's foot to align itself properly.

However, since we are focusing on children for the design of this device, we will need to put a larger emphasis on molding the proper arch into the patient's foot.

This is because they are at an extremely formative time of development, and any discrepancy in the device may cause more harm than good.

FDA Submission Pathway

Since this device is Class I, we will need to consider several general controls for the device.

These include manufacturing devices in accordance with cGMP regulations, labeling devices in accordance with applicable regulations, and submitting a premarket notification 510(k).

The main action item from the FDA submission pathway will be the 510k.

To tackle this, we must have an in-depth understanding of predicate devices, so we can argue that it is substantially equivalent to other devices on the market.

Furthermore, we will need to know the specifications of our device inside and out and be able to justify any design decisions we made along the way.

Reimbursement Strategy and Relevant Codes

Q66.51: Congenital pes planus, right foot (Centers for Medicare & Medicaid Services [CMS], 2026).

Q66.52: Congenital pes planus, left foot (CMS, 2026).

Clinical Interpretation: Applied when the pediatric flatfoot represents a failure to develop a normal structural arch from birth, without an outside trauma history.

M21.41: Acquired flat foot, right foot (CMS, 2026).

M21.42: Acquired flat foot, left foot (CMS, 2026).

Clinical Interpretation: Applied if the arch collapse is secondary to an outside condition, such as pediatric posterior tibial tendon dysfunction, physical trauma, or underlying ligamentous laxity.

HCPCS Code L3040: Foot, arch support, removable, premolded, longitudinal, each (CMS, 2026).

Application: Direct fit for off-the-shelf, prefabricated pediatric devices that offer fixed or minor modular modification configurations.

HCPCS Code L3000: Foot, insert, removable, molded to patient model, "UCB" type, Berkeley Shell, each (CMS, 2026).

Application: Reserved for custom-fabricated devices built from a unique physical cast or 3D digital scan of an individual patient's foot.

Payer Policies and Coverage Landscape

Traditional commercial insurance and Medicare frequently classify prefabricated orthopedic inserts as "non-covered over-the-counter personal care items".

However, because this device targets young children with symptomatic deformities, the primary billing pathway shifts to state-managed Medicaid programs under the federally mandated Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit.

If a pediatric podiatrist or general practitioner explicitly documents a diagnosis of symptomatic Q66.5- or M21.4- accompanied by structural pain or gait abnormalities, state Medicaid protocols will reimburse for prefabricated or adjustable orthotics to avoid long-term skeletal degradation and future liability.

FDA Guidance Documentation & Standards:

Voluntary Consensus Standards

ISO 10993-1:2018: Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.

Relevance: Mandatory for skin-surface contact devices with prolonged wear cycles. Materials must undergo screening for cytotoxicity, sensitization, and intracutaneous irritation to protect sensitive pediatric skin.

ISO 14971:2019: Medical devices — Application of risk management to medical devices.

Relevance: Governs the required Failure Mode and Effects Analysis (FMEA), forcing specific tracking of physical failure points, structural wear, or user-mediated assembly errors.

Relevant FDA Guidance Documents

FDA Guidance: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (Issued September 2020).

FDA Guidance: Premarket Notification 510(k) Submissions for Orthopedic Devices (General administrative guidelines mapping performance data profiles required to establish baseline substantial equivalence).

Initial Patent Search:

Patent Name: Orthosis for the treatment of tibial torsion in children

Patent Number: US 4,981,132 A

Granting Entity: United States Patent and Trademark Office (USPTO)

Current Status: Expired / Public Domain

Patent Owner / Assignee: Individual

First Inventor Listed: Andrew Chong

Relevant Claims & Features: Details structural lower-limb housing constructed from overlapping, nested thermoplastic segments designed to slide relative to one another along a longitudinal plane. This configuration allows for rapid structural length adjustments to accommodate a child's skeletal growth directly during long-term active clinical treatment protocols.

Patent Name: Weight adjustable calibrated orthotics

Patent Number: US 20170318898A1

Granting Entity: United States Patent and Trademark Office (USPTO)

Current Status: Abandoned

Patent Owner / Assignee: Sole Supports inc.

First Inventor Listed: Ty Totty

Relevant Claims & Features: Protects an adjustable inner core profile featuring a lower baseline pocket configured to receive a series of variable-stiffness plastic leaf components or internal tension keys. The structure allows changes to the physical spring rate and mechanical resistance profile over time without requiring modification or destruction of the outer structural shell.

Patent Name: Individually formed footwear and a related method

Patent Number: US 7793433B2

Granting Entity: United States Patent and Trademark Office (USPTO)

Current Status: Active

Patent Owner / Assignee: Foot Balance System Oy.

First Inventor Listed: Erkki Hakkala

Relevant Claims & Features: Claims a personalized footbed structure containing a variable-profile lower channel that locks with geometric modular blocks to directly raise, lower, or modify local structural height properties across the midfoot zone.

Patent Name: Foot orthosis support device method and apparatus (Buethorn, 2009).

Patent Number: US 2009/0139113 A1 (Granted as US 7,758,528 B2)

Granting Entity & Status: USPTO; Granted / Active

Patent Owner & First Inventor: Cascade DAFO, Inc.; Donald R. Buethorn

Relevant Claims & Features: Claims a flexible support device adapted to provide overall structural biomechanics support and contouring of a human foot (Buethorn, 2009). The structural framework incorporates specific configuration lines and variable flexibility zones to maximize precise alignment holding properties without causing secondary localized skin pressures or shifting during loading cycles (Buethorn, 2009).

3.5 CFR 820.30 (f) Design and Development Verification

Risk Analysis (FMEA)

Failure Mode	Effect	Severity	Mitigation
Pad Slippage	Loss of arch support	Medium	Non-slip pocket lining
Material Tearing	Device failure	High	Industrial Sewing
Circulatory Constriction	Pain / Numbness	Extreme	Limited compression gradient
Hygiene (Sweat)	Skin irritation	Low	Antimicrobial mesh choice
Pad Burst	Loss of support, Device Failure	High	Reinforcing gel casing

Verification Testing

PROCEDURE

Place the insert and Sleeve on a flat, supported surface

Place a 30lbs dumbbell on the insert for 1 minute

Drop the 30lbs dumbbell on the insert from a distance of 1 foot

Success Criteria:

Rationale:

The purpose of this test is to see if the insert is able to withstand the forces it will be exposed to during normal use.

A 1 minute static hold is used to simulate the insert being used at rest.

The drop test simulated how the insert reacts in high-impact situations, such as sports.

RESULTS

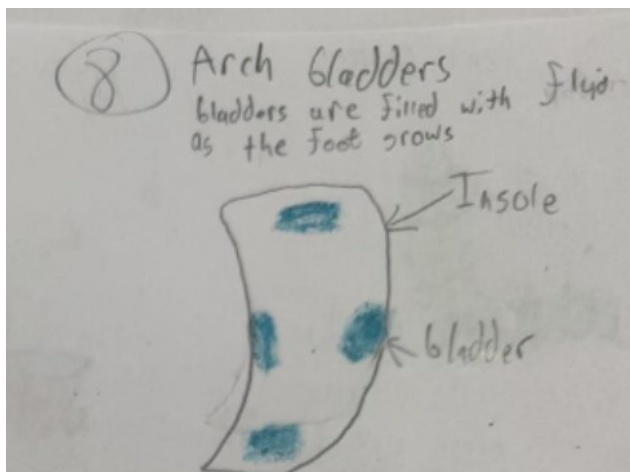
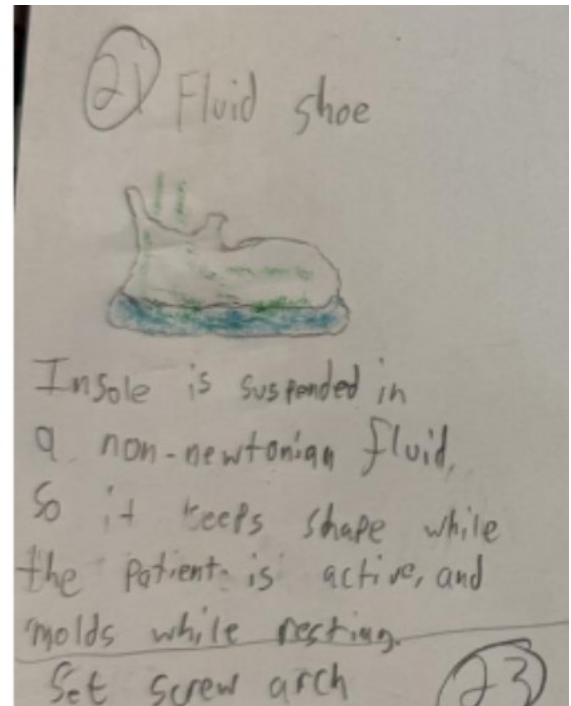
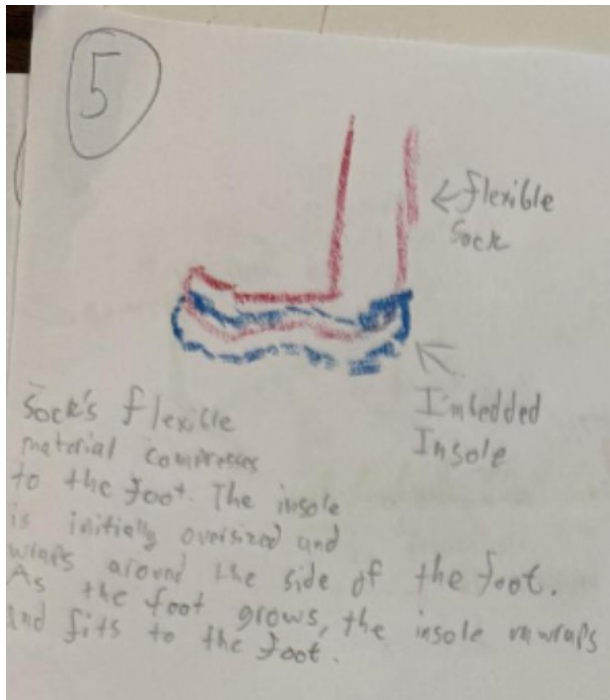
In both the static loading and impact testing the insert must remain fully intact.

This means no gel should seam outside the pouch, no stitching should come undone, and none of the fabric should tear.

Test	Pass	Fail	Comments
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Static #1	X		Insert Unaffected
Static #2	X		Insert Unaffected
Static #3	X		Insert Unaffected
Impact #1	X		Insert Unaffected
Impact #2	X		Insert Unaffected
Impact #3	X		Insert slightly damaged, but contained, slight leakage

Brainstorming Artifacts:



4. Technical Memo: Suggestions for Future Project Team

To the future BME capstone/design team taking over the Pediatric Arch Support project:

We have successfully developed this device up through our V2 functional alpha iteration. By utilizing gel pads within compression sleeves, we significantly improved structural stability over our V1 cardboard proof-of-concept and successfully identified the need for a dedicated pad pocket.

Because of the constraints of our timeline this semester, we unfortunately never made it to V3 (the final beta stage, which would have consisted of custom-molded hybrid inserts with a reinforced pouch). Therefore, V3 remains ready for your team to fabricate and put through rigorous biomechanical validation.

As you pick up where we left off, please direct your attention to the following key learnings and areas for future improvement:

1. **Material Containment:** During our impact testing (specifically Impact #3), we observed that the adhesive may struggle to contain the gel under high, dynamic loading. You will need to address this limitation, potentially by exploring a TPU printed encasement to fully reinforce the gel casing.
2. **The "Growing Child" Constraint:** Balancing the need to scale with child growth against maintaining support is fundamentally a material science problem. Our breathable muslin was a great start for donning human factors, but sleeve tension and elasticity must be perfectly balanced against tissue compression limits to avoid circulatory constriction. We recommend looking into flexible elastic fabric integration.
3. **Manufacturing Feasibility:** To make this highly tailored yet scalable, we strongly suggest exploring a 3D Scan-to-Print workflow for the custom inserts.
4. **Clinical Validation:** A necessary next step for the V3 prototype will be a longitudinal gait analysis using actual pediatric subjects. You will need to prove the device actively corrects the Resting Calcaneal Stance Position (RCSP) while mitigating muscle fatigue.

Best of luck moving this design into the beta phase.

Sincerely,

Thomas Barnett, Levi Willgruber, and Hamza Al Halabi (Group 11)