

Access The Ability

~2.0~

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Aim to Correcting Bunion Induced Misalignment

Bunions occur when the toes are improperly aligned, and the big toe is angled toward the others. According to the Cleveland Clinic, around **1 in 3 Americans have bunions**.

Symptoms:

- Swelling
- Pain
- Difficulty walking

Current Options

- Icing
- Cushions
- Pain medication
- Spacing inserts

For such a high prevalence, there lacks a wearable corrective solution that aims to fix the problem rather than only treating the symptoms

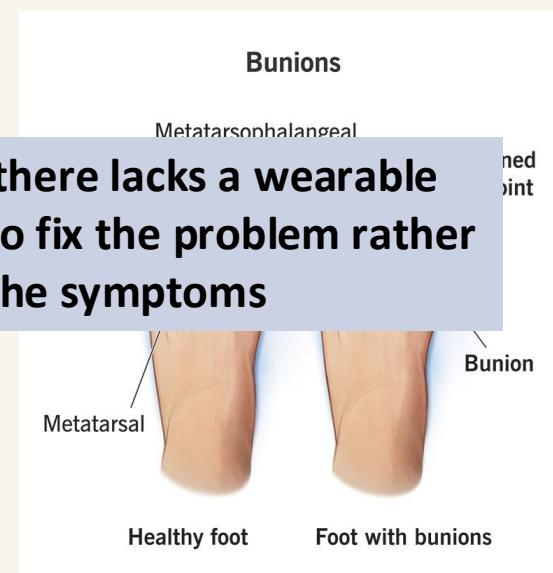


Figure 1.0, Cleveland Clinic

The goal of the product is to provide an eventual correction for the patient's misalignment

Our team seeks to specifically concentrate on the first metatarsophalangeal (MTP) joint, which is the joint primarily affected by bunions.

By targeting this specific joint, we can more effectively **address the root cause** of the gait issues that arise from bunion formation.

Customizability for our foot attachment product is key. The hope is for the product to be **adjusted over time** to match and correct the current state of misalignment. This would then allow for the patient's gait to be corrected over the course of time.



Orthopaedics360, 2024

Who are our Users & Customers?

This product is meant for anyone who has bunions and is looking for a **corrective** product. By marketing directly to the customer suffering from bunions, **we eliminate the need for a middle intervention such as a doctors' appointment**. This product will be low cost, ensuring as many people can access it as possible.

We plan to focus on **individuals with mild to moderate bunions**--These patients are more likely to respond positively to non-surgical interventions, like corrective support products, and may not yet require more invasive surgical options.

Design Process

Objective:

- Develop a wearable sleeve to support corrective alignment for users with bunions

Identify Needs:

- Primary goals included pain relief, customization, durability, and usability with daily footwear

Concept Development:

- Integrated hydrogel cushioning, 3D-printed adjustment wheel, Elastic and Velcro for cohesiveness, flexibility, and added adjustability



Prototyping & Testing:

- Iterative designs focused on alignment, material comfort, and ease of adjustment

Design Considerations

Ergonomics:

- Fit for different foot shapes and size

Adjustability:

- Wheel-based system incorporated with a radian measurer for easy adjustments

Durability:

- Reusable materials like hydrogels, flexible elastics, and stretchable fabric for long-term use

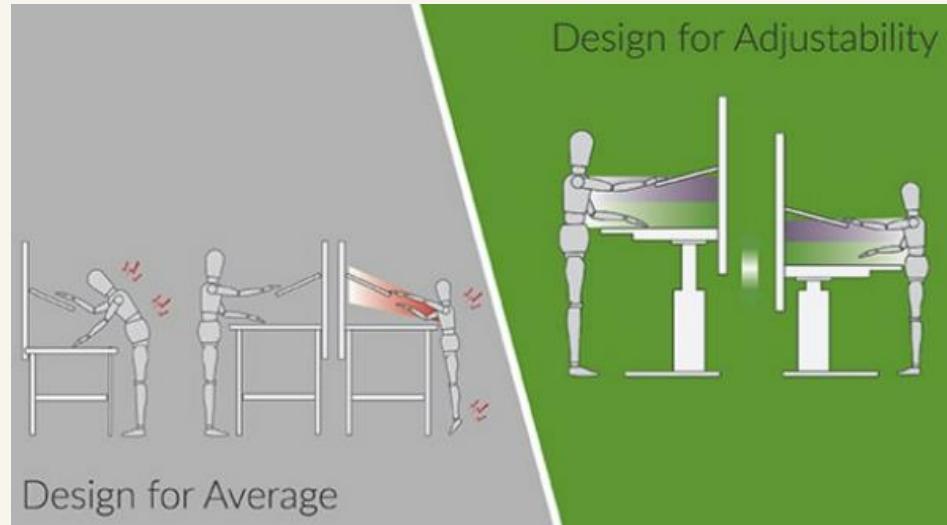
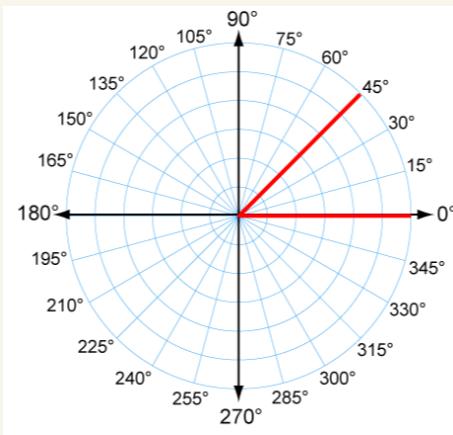
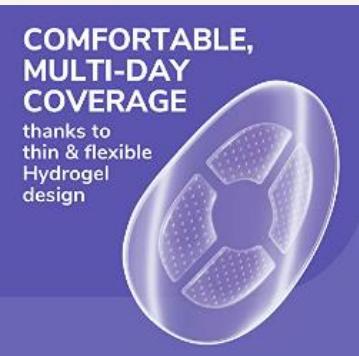
Cost Efficiency:

- 3D printing reduces production costs, allowing affordable customization



Concept Screening

- **Static vs. Adjustable Models:** Chose static sleeves for cost-efficiency but incorporated adjustable features for better alignment control.
- **Materials Selection:** Evaluated gel, hydrogel, silicone for cushioning; elastic and Velcro for adjustable band; chose hydrogel and elastic for durability and flexibility.
- **Feedback Mechanisms:** Initially, the idea of integrating sensors was proposed but instead we chose to incorporate a radian measure on the wheel for alignment as it is more straightforward and accurate



Concept Selection

Criteria	Weight (1-5) 1-least important, 5-most important	Bunion Corrector	Alternatives								Totals	Rank				
			1	2	3	4	5	Surgery	Foot Braces	Toe Spacers	Physical Therapy/ Use of exercises	Toe Splints / Correctors	Footwear modifications (e.g. wedge, splitsole, etc.)	Bunion Pads and Cushions	Orthotic Inserts	
1 Low cost	4	0	-	-	+	0	+	+	+	+	+	+	+	+	3	3
2 Reliability/ Durable	5	0	+	+	0	+	+	+	0	+	+	0	+	0	3	2
3 Safe/ Risk Free/ Breathability/ Biocompatibility	5	0	-	+	+	+	+	+	+	+	+	+	+	+	3	3
4 Comfort during correction	5	0	-	+	+	+	+	+	+	+	+	+	+	+	3	3
5 Lightweight	3	0	-	-	+	-	+	0	+	0	+	+	0	1	8	
6 Adjustability/ Ease of Use	2	0	-	-	+	-	+	+	+	+	+	+	+	+	3	3
7 Support/ Stability	5	0	+	+	+	+	+	+	+	+	+	-	0	2	7	
8 Corrective Function	5	0	+	+	-	+	0	-	-	-	-	-	-	-2	9	
9 Fashionable/ Low Profile	1	0	+	-	+	0	+	+	+	+	+	+	+	5	1	
				Totals		-3	15	20	20	30	17	15	12			
				Rank		8	5	2	2	1	4	5	7			

Splints/Correctors



Spacer



Our Concept

- Features:
 - Sock Sleeve
 - Hydrogel bunion cushion(s)
 - Adjustable Velcro strap
 - Elastic band
 - CAD designed and 3D printed wheel component with angle indication

Proof of concept: laser cut wheel



Prototyping & Proofs of Concept:



Fabrication

- Mold and cast foot model of bunion-affected individual.

Cushion Attachment:

- Integrate bunion cushion into sock sleeve using adhesive suited for fabric and silicone/hydrogel.



Velcro Strap Integration:

- Sew Velcro strap to elastic for secure foot placement.
- Design adjustable loop for Velcro band positioning.



Elastic Band and Wheel Assembly:

- Secure elastic band to Velcro loop, sock sleeve, and wheel attachment (exact idea for process still in works)



Quality Control and Testing:

- Test durability, especially of elasticity and Velcro adhesion.
- Confirm wheel's stability, rotation, and consistent big toe alignment with live testing and fit testing on model

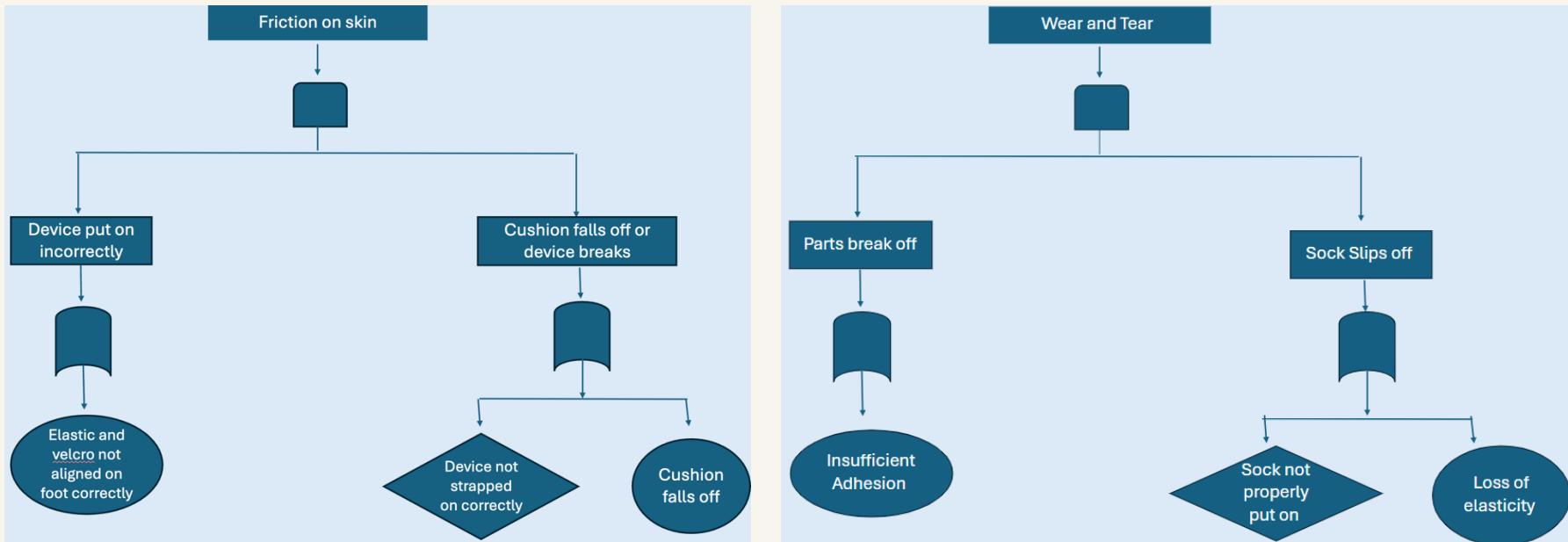


Risk Analysis

Item Number	Function	Risk Analysis							Risk Control				Risk/Benefit Analysis	Information/Comments	
		HAZARD (Potential cause of Hazard)	Hazardous Situation	HARM (Potential adverse effect)	Cause	SEVERITY	OCCURRENCE	RPN	RISK MITIGATION	SEVERITY	OCCURRENCE	RPN	Risk reduced as far as possible? (a/s/p)	Benefits Outweigh Risks? (Yes/No)	
	Functional Output														
Description		Description of why the product will not perform conform specs		Description of resulting injury, damage					The way by which the risk is reduced/eliminated				a/s/p	Yes/No	eg IFU, labeling
Example	Debris or Fragment	Small fragment from device created during use	Fragment is swallowed and in GI tract	Fragment causes blockage requiring surgery	Material strength is too low and not designed for impact	2			Material Specification of high impact polystyrene				a/s/p		
Wheel	Device creates friction	Wheel spins fast	Wheel spins fast on foot	Friction on skin, redness or bleeding	Wheel not properly attached	4	2	8	Barrier between foot and wheel	2	1	0	a/s/p	Yes	
	Device gets stuck	Device gets caught on foot	Device snags and attaches to foot	Bleeding, imprint on foot	Wheel edges too sharp or angled	3	2	6	Make wheel angles dull and rounded	3	1	3	a/s/p	Yes	
	Imprints on foot	Wheel is too tight on foot	Not enough support between wheel and foot	Imprint on foot and blood circulation cutoff	Wheel too tight on foot	2	4	8	Ensure there is barrier between wheel and support	2	1	2	a/s/p	Yes	
Hydrogel/Cushion	Tears	Friction or sharp object causes cushion to tear													
	Srips off	Humidity causes cushion to fall off													
	Sticks to foot	Glue not strong enough and cushion sticks to foot													
Elastic Strap	Snaps	Beyond elastic capabilities, fails to maintain tension													
	Detaches from wheel device and/or velcro strap	Adhesion between velcro and/or wheel breaks													
	Srips off	Elastic strap slides off or shifts position													
Sock Sleeve	Sock is damaged	Material failure	Sock tears during use	Skin abrasion or injury	Inadequate material strength	3	3	9	Use high-strength, tear-resistant materials	2	2	4	a/s/p	Yes	
	Sock no longer taught	Slippage, loose components	Sock slips out of position	Misalignment and ineffectiveness	Poor design fit	3	4	12	Design sock with a gel grip inserter for stability	2	2	4	a/s/p	Yes	
	Overheating of the Sock	Heat retention	Sock retains heat	Discomfort	Insufficient breathability	3	3	9	Ensure breathable materials and design for airflow	2	2	4	a/s/p	Yes	
Velcro Strap	Elastic device fails to give bunion relief	Velcro strap loosening over time	Device shifts or loses tension, no longer applying corrective force	Decreased efficacy, potential worsening of bunion due to improper alignment	Insufficient strap adhesion, worn-out Velcro	2	2	4	Use high-quality, durable Velcro rated for long-term wear.	1	2	2	a/s/p	Yes	
	Accidentally detaches/removes	Velcro snags or catches on fabric	Device catches on other materials, causing discomfort/misalignment	Pain, interruption of function, frustration	Velcro edges not covered, misalignment during wearing	2	1	2	Enclose the Velcro edges to prevent snagging.	2	2	4	a/s/p	Yes	
	Allow unable to adjust tension as needed	Improper adjustment by user	Device is too tight or too loose	Pain, discomfort, ineffective correction	User error in adjustment, unclear instructions	1	1	1	Put markers on the velcro to indicate the distance that should be placed between the strap and foot	2	1	2	a/s/p	Yes	
FINAL															
Overall Residual Risk is Acceptable (Yes/No):															

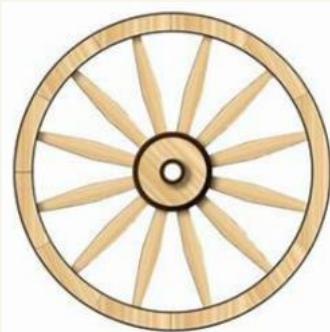
We considered in our risk analysis wheels, hydrogel cushions, elastic straps, sock sleeves, and Velcro straps. Overall, we found that the calculated risks were acceptable, when considering the risk mitigations

Risk Tree Analysis



Challenges Going Forward

1. Mechanical Adjustability and Durability of Wheel Mechanism
2. Retention of Corrective Positioning with Elastic band and Velcro Mechanism
3. Implementing adequate Variability and Customization



Next Steps



- Optimize CAD design with ease of rotation with
- Figure out best material to print wheel
- Test elastic band elasticity
- Test adhesion
- Test stability of wheel rotation and durability in maintaining corrective force
- Find best method to attach elastic to wheel mechanism to ensure secure but adjustable fit
- Tape measure type mechanism
- Locking mechanism



Thank You and Stay Tuned!