StepCorrect: The Over-the-Counter Custom Molded Foot Orthotic

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Executive Summary

This report describes an innovative device to treat the common foot condition plantar fasciitis. Plantar fascia is a painful foot ailment that can limit the mobility of the person. Nearly 2 million Americans are diagnosed with plantar fasciitis every year and about 10% of all Americans will develop it sometime in their life. There are currently two methods that treat this condition. The first is over-the-counter orthotics that can be purchased at local drug and grocery stores. This option is relatively cheap and provides some temporary relief to the person. However, they are not customized to each foot therefore cannot truly treat the condition. The second option is prescription orthotics. These properly treat plantar fasciitis but the fitting and manufacturing requires the aid of professionals. In addition, they are expensive and cost up to four-hundred dollars out of pocket. The aim of the device is to bridge the gap between these two treatment options. This device is unique in that it will allow the user to custom mold the orthotic in the comfort of their home while treating plantar fascia better than over-the-counter orthotics for a fraction of the costs of prescription orthotics. This product is considered Class I (general controls) by the FDA and is exempt from premarket notification procedures and good manufacturing practices. Over-the-counter orthotics generate about $800 million in revenue a year while prescription orthotics generate about $500 million in revenue a year. Our product is expected to utilize a portion of the market share of both orthotic types.

Problem to be Solved

Plantar fasciitis is the most common biomechanical medical condition of the foot. It is documented and diagnosed in nearly 2 million Americans every year and about 10% of people develop it within their lifetimes. Additional cases of mild plantar fasciitis go largely undocumented every year. The most common treatment method is in the form of foot orthotics. Foot orthotics are currently available in two forms - soft pre-molded over-the-counter (OTC) orthotics and rigid custom molded prescription orthotics. The problem with the current orthotic options however is that simple OTC orthotics are too generalized and not rigid enough to effectively treat individuals with moderate to severe conditions, while custom prescription orthotics are extremely expensive and not covered by the vast majority of health insurance plans.

There is an extensive market for foot orthotics. For the condition of plantar fasciitis alone, there are an estimated 2 million cases per year in the United States alone. Based on manufacturer data, approximately 1.5 million prescription orthotics are produced every year, with each orthotic device on the order of $400 dollars per pair. As such, there exists a substantial market for a cheap alternative to prescription orthotics with similar treatment efficacy.

Novelty

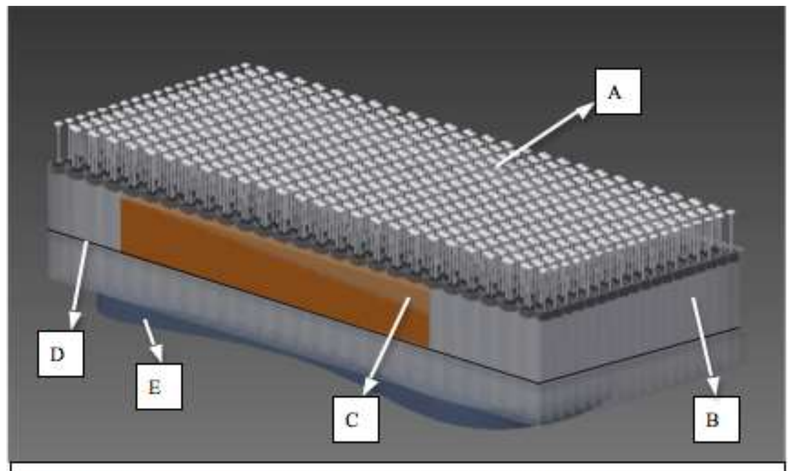
The design of our device is novel in that it uses a dynamic stepping surface to obtain the non weight-bearing mold of the patient's foot. The device also uses a two-component resin system to form the physical support structure of the orthotic. There are no existing products or patents that incorporate a dynamic stepping surface in an at home orthotic molding system. There are also no products or patents that use a resin system to replicate the non weight-bearing mold of the foot. There are no foreseeable roadblocks in terms of obtaining intellectual property for our device.

The current competition for our device is the existing over-the-counter and prescription orthotics manufacturers. Our product competes more directly with the OTC market since it is designed to be used in the convenience of the patient's home. However, there are no OTC orthotics that are truly custom moldable to the unique shape of each patient's foot. The custom nature of our device is the strongest competitive advantage over existing OTC products. Our device also maintains a competitive advantage over prescription orthotics since it is 5-10 fold cheaper.

Regulation

The FDA does not currently regulate foot orthotics. This includes both over-the-counter and prescription foot orthotics. These devices are non-invasive and pose little to no risk to the patient. Therefore, there is no expected regulatory pathway for our device, which is favorable since it significantly reduces start-up costs.

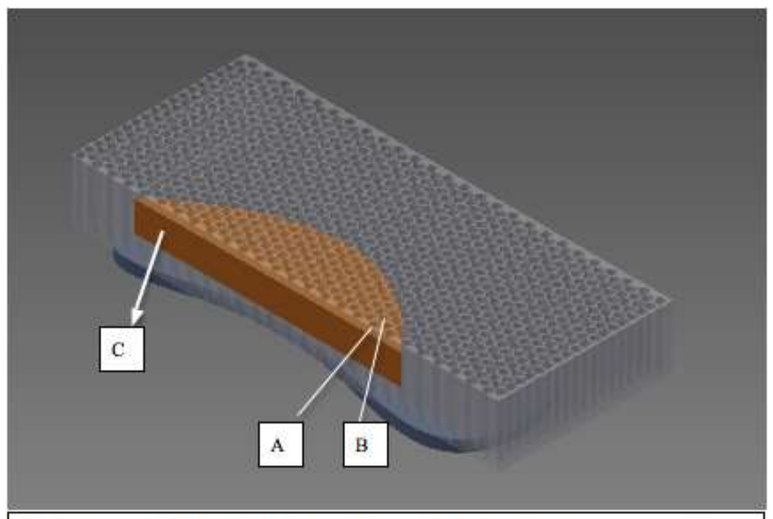
Design Description



StepCorrect device overview. A. Stepping surface B. Vertical channels C. Polyurethane resin system D. Interface between stepping block and well plate E. Orthotic base

The StepCorrect orthotic device is composed of an ABS plastic stepping block with vertical channels throughout. The stepping surface is made up of an array of soft plastic pins that extend outward from the vertical channels contained inside of the stepping block. The pins are initially positioned at the top of the channels so they can be depressed into the block during the non-weight bearing mold. The vertical channels in the target area (orange) are preloaded with resin, while the rest of the channels are left empty. The resin is a two-component polyurethane rubber system and polymerizes into a solid material upon mixing of the components. Since the resin is a two-component system, each neighboring channel is filled by alternating between the two components (See image below for resin layout) .

At the bottom of the channels is an orifice plate, which acts as a syringe nozzle for each channel. This also prevents the resin from being dispensed prematurely. The stepping block and orifice plate sit on top of an acrylic well plate, which acts as a reservoir for the resin components to fall into after the non-weight bearing mold. The well plate is designed such that the resin from each pair of neighboring channels is dispensed into a single reservoir. Therefore, when the resin components are dispensed into the well plate they mix with the complement component, initiating the curing process. The resulting support structure of the cured resin matches the unique shape of the patient's non weight-bearing mold.



StepCorrect resin layout: A. Vertical channel containing resin component "A" B. Neighboring vertical channel containing resin component "B" C. Target area for resin

Estimation of Product Costs

The main components of our device including the stepping block with hollow vertical channels, plunger heads, and well plate will be produced by outsourcing to a manufacturer. This will save overhead costs associated with the equipment needed to manufacture each of the parts. The raw material costs can be seen in the table below. Prices account for bulk scale discounts. Additional tests will be required for quality assurance purposes. This will include testing our product on patients currently using foot orthotics for an extended period of time (> 1 year).

Part Description	Units Required	Quantity Unit	Unit Cost	Total Cost
ABS plastic block	180 cubic inches	768 cubic inches	$53	$12.19
Syringes (pins)	250	1000	$40	$10
Resin	5 oz	2 gallon	$98	$3.87
Foam layer	1	100	$50	$0.50
				$26.56

Market Potential

The target customer for our device are patients with moderate to severe cases of plantar fasciitis, as well as patients with mild cases who have tried over-the-counter orthotics and are not satisfied. Both the existing premolded over-the-counter and prescription orthotic markets possess substantial customer bases. It is estimated that in the United States alone about 2 million cases of plantar fasciitis are observed in doctors' offices every year (2).

The market size of the prescription foot orthotic industry can be evaluated using annual production data from orthotics manufacturers. Approximately 1.5 million pairs of prescription foot orthotics are manufactured in laboratories across the country every year. Assuming an average cost to the consumer of $400 (on the conservative end) per pair of prescription orthotics it is calculated that the industry does about $600 million in revenue every year (4). The vast majority of the orthotics manufactured are plantar fasciitis related, as it is the most common medical condition requiring foot orthotic treatment.

The over-the-counter orthotic foot orthotic market has a much larger customer base than the prescription market, as it represents all consumers with less severe medical conditions. The over-the-counter market is aimed at consumers who may be in need of an economically feasible treatment solution since prescription orthotics are not covered under the vast majority of health insurance plans in the United States. In a marketing plan prepared by Dr. Scholl's the current over-the-counter foot orthotics market was valued at about $900 million in sales per year (5).
An over-the-counter custom molded orthotic would possess market value in both of these industries since its customizability will outperform the premolded market while its low cost will offer a more affordable alternative to the prescription orthotic market. In the over-the-counter foot orthotic market, top of the line plantar fasciitis treatment products such as Dr. Scholl's custom fit inserts range from $50-$60. Given the manufacturing costs of our device we have a target price of $60, which would be competitive with current OTC orthotic prices.

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