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Customized Athletic Shoe Midsole Development to Address Plantar Heel Pain

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Abstract

Chronic heel pain as a result of plantar fasciitis can inhibit regular activities, which can directly lead to foot, knee, and back problems as walking patterns change in an effort to alleviate pain. With one in ten adults experiencing plantar fasciitis in their lifetime and an indirect cost to the United States Healthcare system of around $390 million annually, plantar fasciitis is an important and addressable footfall impairment[1,2]. Commercially available orthotics, pain medication, and foot straps are the current standards of treatment, but the efficacy of these products vary widely across the patient population[2,3]. To provide patients afflicted with plantar heel pain a more cost-effective and accessible method of treatment, our algorithm and design process creates customizable midsoles informed by patient-specific biomechanical factors. 3D-printing infill percentage and medial post height are directly tailored to each patient based on their weight and plantar contact surface area, respectively. A number of design iterations were constructed to optimally tailor support, cushioning, and structural integrity of the midsole. Finite element analysis and digital material testing were used to evaluate the custom midsoles. It was found that the midsole design and algorithm implementation, coupled with a semiflexible model material resulted in plantar pressure distribution along the plantar surface-midsole interface, suggesting efficacy in increasing comfort during locomotion through the reduction of high-pressure regions that could irritate the plantar fascia. A full-length customizable cushioning system was used to reduce instances of highly-localized pressure between the foot and midsole. Future testing of the technology to determine clinical and therapeutic efficacy in correcting biomechanical impairments will include motion analysis to determine the midsoles' effect on patients' gait pattern, ankle angle, and stride length. This additional data will inform the implementation of future design parameters.

Keywords: plantar heel pain, motion analysis, 3D-scan, orthotic, midsole

Introduction

Plantar fasciitis is a degenerative condition that affects the plantar fascia ligament, a thick band of tissue that covers the bones on the base of the foot[4]. It is associated with acute pain between the heel and metatarsals, falls, poor quality of life, and disability[4]. Repetitive tensile overload from standing, walking, or running for long periods of time can cause acute or chronic changes in the aponeurosis[5]. There are many risk factors for plantar fasciitis including *pes planus* (flat feet), *pes cavus* (high-arched feet), overpronation, limited ankle dorsiflexion, weak intrinsic and plantar flexor muscles, poor biomechanics or alignment, repetitive foot contact with hard surfaces, and poor footwear[5].

One in ten adults will experience plantar fasciitis in their lifetime and this condition has resulted in indirect costs of $390 million per year to the United States' healthcare system[1,2]. Common forms of treatment for plantar heel pain include pain management via medication, injections, custom

orthotic insoles, foot straps, and/or surgical intervention[2,3]. However, the efficacy of these treatments vary widely across the patient population and do not offer a convenient, affordable method for pain relief. Pain medication is commonly used to treat plantar fasciitis: 6.31% of adults with plantar fasciitis treat pain with prescription medication and 70% use over the counter drugs for general pain management[4]. In order to provide patients suffering from plantar heel pain a more cost-effective and accessible method of treatment, our research team developed a customizable midsole design informed by an algorithm based on patient-specific biomechanical factors.

From toe-out angles to foot strike patterns to pressure centers of the foot, bipedal locomotion varies widely for every individual[6]. The majority of shoe manufacturers are driven by market demands to provide shoes that are comfortable and perform well, but are constrained to developing shoes that meet the needs of the average consumer. Treating locomotion impairments and gait abnormalities could be more effectively addressed using patient-specific parameters rather than prescribing a one-size-fits-most method of treatment.

There are a variety of footwear and orthotic insole options on the market to reduce undesirable loading of the joints and ligaments during the gait cycle. Most current shoe models have raised heels, or toe-drop, that cause weakening of the ankle dorsiflexor muscles and plantar fascia as well as imbalances in weight distribution, all of which can exacerbate plantar heel pain[7]. Major athletic shoe companies market footwear to a broad population, however, these shoes are not designed to address locomotion impairments, joint pain, or gait abnormalities, which has driven the market for orthotic inserts.

Foot orthoses range from 'off-the-shelf' heel pads and contoured prefabricated inner soles to custom-made foot orthoses of varying styles, construction materials, additions, and modifications. Custom-made foot orthoses are molded or milled from an impression of the foot, such as a plaster cast or three-dimensional laser scan, and fabricated according to practitioner-prescribed specifications[8]. These supplemental footwear accessories are used to counteract the shortcomings of shoes by providing additional cushioning and arch support as well as reducing plantar pressure by redistributing force over the contact area of the foot upon ground strike[9].

Addressing biomechanical abnormalities on a patient-by-patient basis is currently unavailable in the athletic shoe market without supplemental accessories such as insoles. Current footwear, casting, and orthotic insole options on the market can be expensive and unavailable to some patients. While orthotists do use patient-specific casts and other customized methods, such as collecting dynamic pressure data of the foot to create custom orthotics for patients, these methods can be cumbersome, time-consuming, and only provide a supplement for footwear[10]. Additionally, casting can take up to multiple weeks to be completed and delivered to the patient.

Midsole designs derived from a patients' specific needs may greatly reduce the loads on the knees and ankle joints, while protecting against overuse injuries, such as plantar fasciitis. By creating a method to produce bespoke footwear for individuals with plantar fasciitis, or other types of locomotion-related pain, the process of developing optimized shoes will become more customer-centric and will reduce pain associated with exercise and movement.

Midsole stiffness and damping are critical components in determining ground reaction forces (GRF) during the foot-contact phase (FCP) of the gait cycle, however methods to quantify these components are lacking in the field[11]. The aims of this project seek to expand upon this lack of methodology in the development of midsoles to target areas of the footwear most associated with plantar fasciitis-related pain. Our customization algorithm utilizes biometric data and patient-specific parameters to succinctly inform the development of a custom midsole to address plantar fasciitis beyond what is currently available on the market. For individuals struggling to find proper footwear that does not cause pain during movement, the methodologies proposed and tested by our device could create a customizable footwear-fitting experience that best addresses their unmet needs.

Results

Algorithm Criteria Selection

In order to provide patient-specific custom midsoles for users with locomotion-related

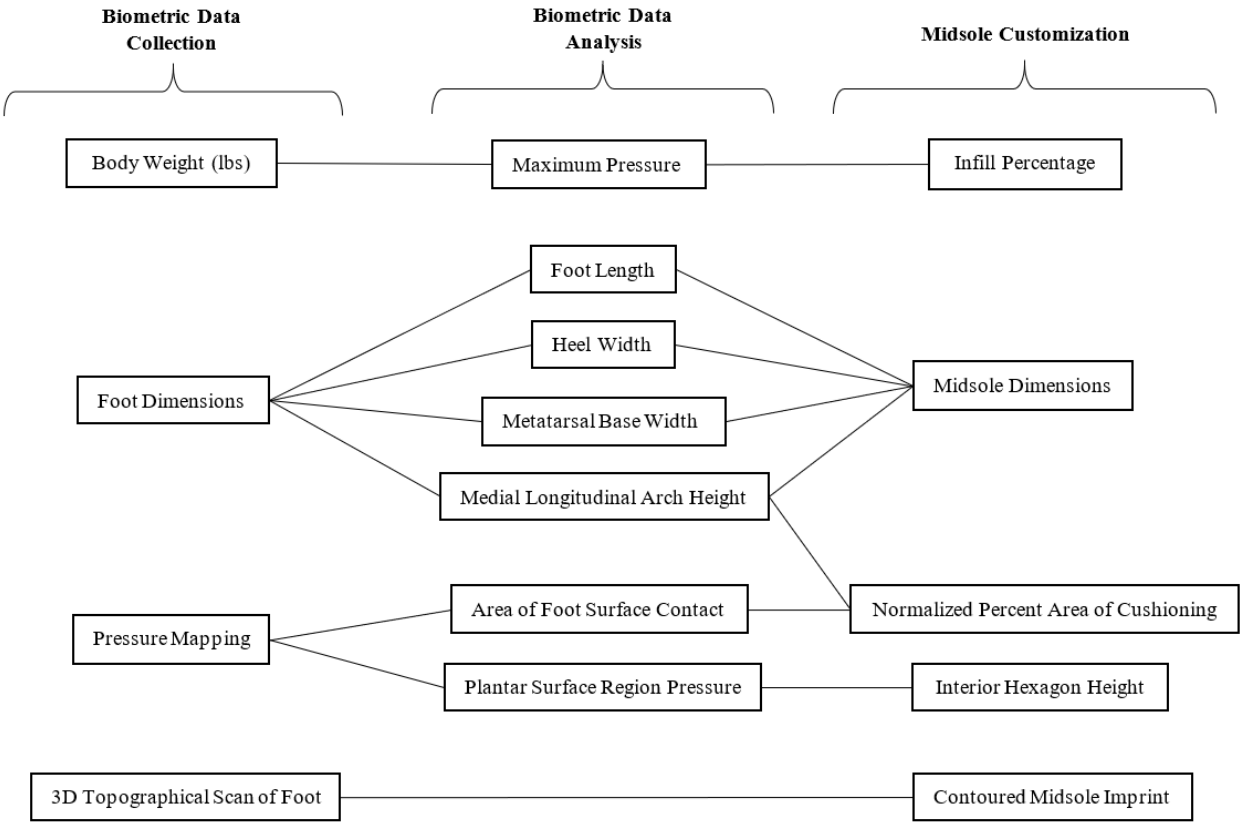

Figure 1: Algorithm Flow Chart. The midsole customization process is dependent on a number of patient-specific biometric data types that are collected and analyzed for application in our midsole design. From left to right, weight, pressure, dimensional, and topographical data is collected from the patient and then analyzed to inform midsole dimension, 3D printing infill percentage, and midsole characteristics, such as interior hexagon height and the contoured midsole imprint that provides custom orthotic support for the patient.

discomfort, a customization algorithm was formulated to guide the midsole development process. Criteria for this algorithm were selected based on relevant factors addressed by the custom midsole, namely pressure minimization and orthotic support. A series of biometric data types were identified for collection and integration into the midsole design (Figure 1).

Dimensional measurements of the foot were collected and used to guide and properly size the computer-aided design (CAD) midsole model. Another issue to address was suboptimal pressure control along the plantar surface that results in increased pain along the plantar fascia. During the FCP of the gait cycle, individuals with normal gait patterns experience double peaked vertical GRF progression[12]. These pressure peaks are directly related to the patient's body weight, therefore, the algorithm incorporated body weight as a measured data point used to vary the infill percentage of the 3D-printed midsole[12]. Decreasing the infill percentage of the 3D print with semiflexible filament results in increased compressibility, which correlates to more pliable cushioning in the midsole.

The midsole customization algorithm also accounts for the highly unique and varied plantar surfaces of patients. It was observed that individuals with higher medial longitudinal arch heights had less percent plantar surface contact area. Arch height was included in the algorithm to determine the size of the medial post region, where arch support is localized. Individuals with *pes cavus* have a larger medial post region than individuals with *pes planus*. Finally, a 3D scan of the patient's foot was incorporated into the algorithm to produce a

topographical map of the plantar surface (Figure 2). This allowed the midsole to function similarly to a custom orthotic insert.

Figure 2: Sample 3D Foot Scan. 3D scan of a team member's foot obtained via photogrammetry and imported into Autodesk Fusion 360®. The 3D scan was used to create a contour body in the CAD workspace and imprint the topographical contours of the patient's plantar surface into the midsole body to achieve orthotic support throughout the midsole.

Algorithm Linear Model Formulation

Two components of the algorithm require varying midsole design components based on biometric data input. To customize the midsole, two linear models were developed:

Weight (x) v. Infill Percentage (y)

A weight range of 91-443 lbs was used, based on the National Institute of Health standard adult Body Mass Index chart[13]. Using a series of trial-and-error sample prints, it was determined that the infill percentage range would be 20-45%.

$$y = 0.071x + 13.537 \quad [1]$$

Medial Longitudinal Arch Height (x) v. Contact Plantar Surface Area (y)

Normalized plantar surface area for an individual with *pes cavus* and one with *pes planus* were plotted against their respective arch heights.

$$y = -83.696x + 98.401 \quad [2]$$

Identification of Cushioning & Support Designs

Designing the proper cushioning to be implemented in the heel, midfoot, and forefoot plantar regions of the midsole design required experimentation with a variety of geometries and cushioning orientations within Autodesk Fusion 360®, the CAD software used in midsole model development. Initially, oval disks with varying cushion designs were modeled and printed for testing. These ovals were sized in accordance with the relative area and volume the heel and forefoot cushioning would constitute in the midsole design. Of the different extrusion geometries evaluated, hexagons were selected due to the customizability in cushioning this shape provided. Specifically, the distance between hexagons could easily be tailored to either increase or decrease stiffness by reducing or increasing separation distance between hexagons, respectively. Following several iterations, and design inspiration from Dr. Casey Kerrigan, vertical hexagon cut extrusions were the chosen geometry for implementation in the first full 3D-printed midsole prototype.

Midsole Design Iteration

The first full prototype included full-depth 3mm and 4mm vertical hexagon extrusions in the heel and forefoot, respectively, with infill constituting the midfoot (Figure 3). The use of NinjaFlex® semiflexible filament proved to be too stiff of a material in the forefoot region due to ~1.0mm separation distance between hexagons, while too forgiving in the heel with ~1.5mm separation distance between hexagons. Upon qualitative observation and physical compression of the sample print disks, it was determined that hexagon cut extrusions were more pliable and compressible along the lateral axis, rather than the axial axis. This led to the implementation of horizontal 4mm hexagons in the heel and forefoot of the second prototype (Figure 3). However, following evaluation of the second prototype, it was determined that infill within the midfoot region of the design provided more pliable and comfortable cushioning, and would also be a much more customizable cushioning method than the horizontal hexagons. Therefore, infill cushioning was added to the third prototype in the heel and forefoot regions. 4mm internal vertical hexagon cut extrusions were also included under the infill to provide additional support to the foot and to add more structure to the midsole (Figures 3 & 4). Fully penetrating 3mm vertical hexagon cut extrusions were also included in the medial arch region of the midsole design to act as medial posts.

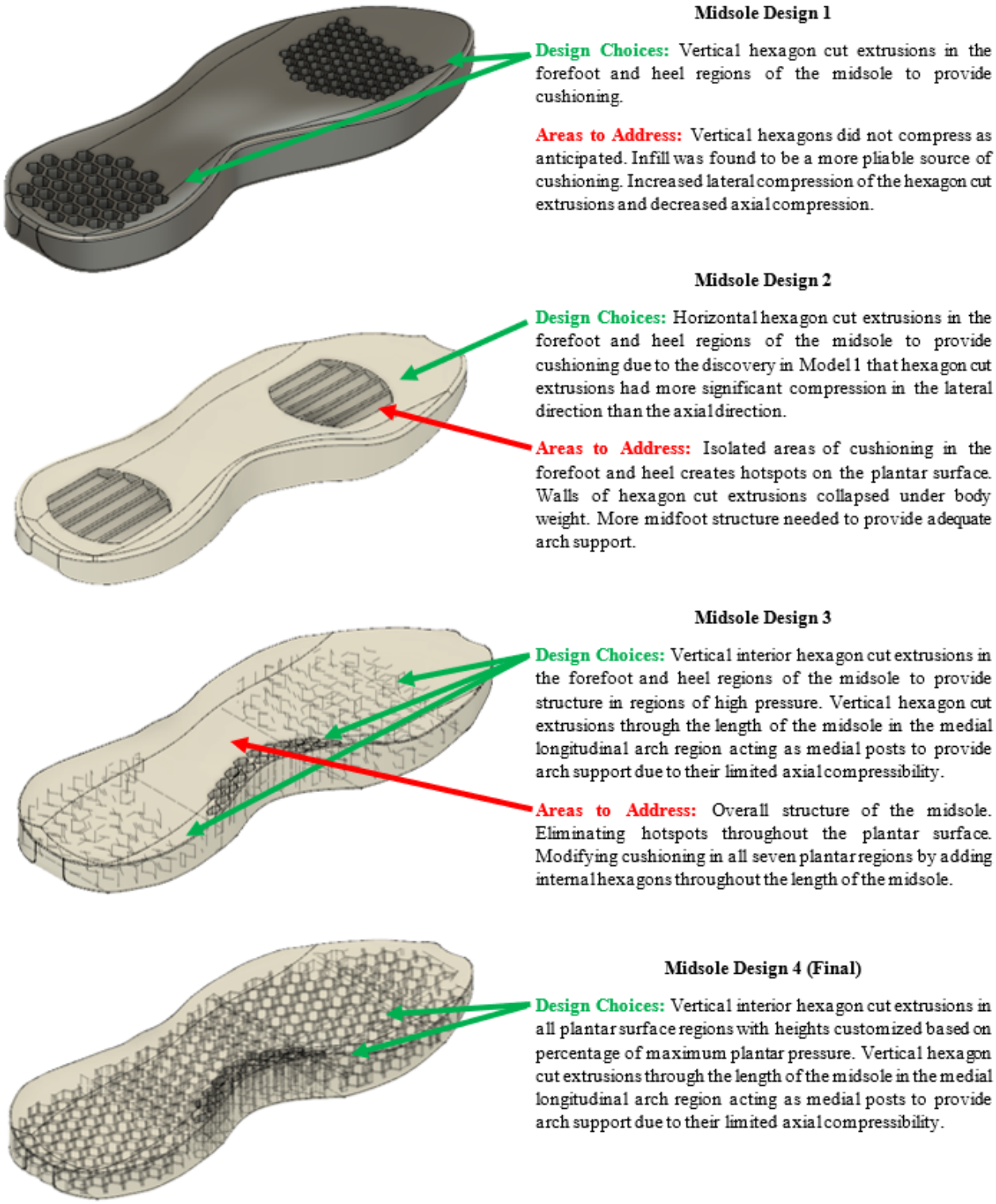

Figure 3: Midsole Design Iteration. Overview of the four midsole designs and decision-making process that resulted in the final design. All midsoles were modeled in Autodesk Fusion 360®. Midsole design 1 was modeled using one team member's 3D foot scan and midsole designs 2-4 were modeled using another team member's 3D foot scan, so there is discrepancy in the level of contouring.

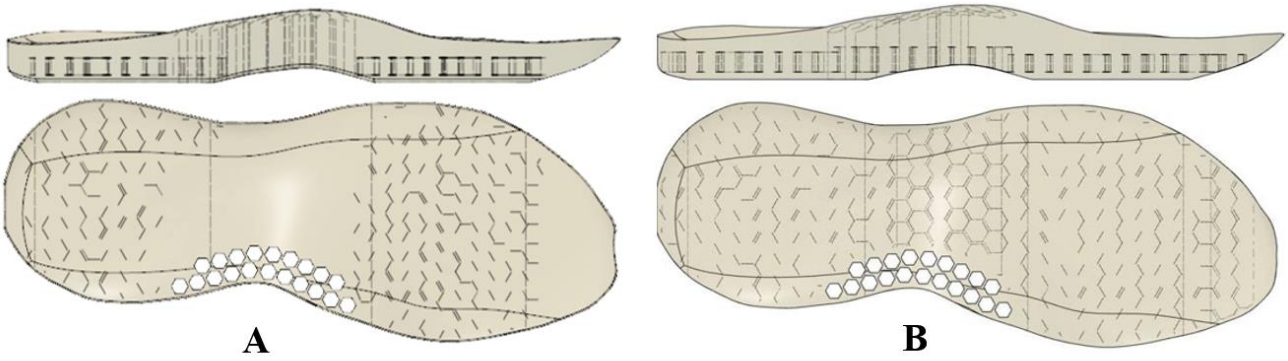

Figure 4: Midsole Designs 3 & 4 Comparison and Final Midsole Design. A) From top to bottom: right side view and top view of Midsole Design 3. B) From top to bottom: right side view and top view of Midsole Design 4. The final changes made in our team's iterative design process was to upgrade our model from utilizing three plantar regions (forefoot, midfoot, and heel) to seven plantar regions (depicted in **Figure 5**). In order to customize the interior hexagon extrusions for all seven plantar regions, we designed a model sketch with hexagons along the entire midsole length and then divided the sketch into regions based on the individual's foot shape used to create this custom model. Cut extrusions were then made based on the heights determined in **Table 1**.

Support Customization by Plantar Region

Following the first two design iterations and initial prototype fabrication, it was observed that vertical hexagon cut extrusions provided substantial structural support to the midsole. In the first three design iterations, only three plantar regions were utilized (forefoot, midfoot, heel). The final design included internal hexagon cut extrusions throughout the length of the midsole, which allowed for support and cushioning customization in all seven plantar regions (Figure 5).

<u>Plantar Pressure v. Internal Hexagon Height</u>

Each plantar region experiences unique peak pressure during the gait cycle[14]. In order to accommodate regions with higher peak plantar pressure, the internal hexagon cut extrusion height was varied indirectly with the percentage of peak plantar pressure for the entire plantar surface (Table 1). This allowed for regions with higher plantar pressure to have more infill overlay to increase cushioning. Additionally, this method was used to minimize hot spots, or regions of high plantar pressure, along the midsole surface by distributing plantar pressure without minimizing cushioning.

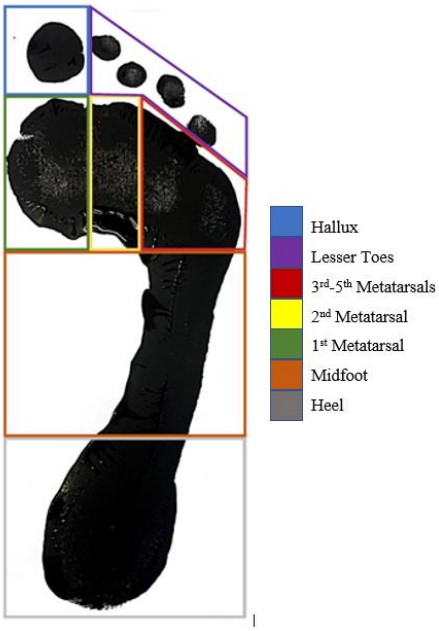

Figure 5: Plantar Regions. Seven plantar regions are identified for the human foot and each region experiences different amounts of pressure during loaded foot contact. Using a pressure map, plantar regions can be identified for the patient and maximum pressure can be identified and used to customize the interior hexagon extrusion height in the midsole for each region. This image was recreated from Stewart, Dalbeth, Vandal, and Rome (2016)[14].

Table 1. Internal Hexagon Cut Extrusion Height by Plantar Region. Minimum and maximum internal hexagon cut extrusion heights were set to 5mm and 10mm, respectively. (Plantar Region Pressure values reproduced from Stewart, Dalbeth, Vandal, and Rome (2016)[14])

Plantar Region	Region Pressure Percentage (% of Peak Pressure)[14]	Extrusion Height (mm)
Heel	100	5
Midfoot	32.4	10
First Metatarsal	71.9	7.1
Second Metatarsal	99.3	5.1
Third-Fifth Metatarsal	85.7	6.1
Hallux	79.3	6.5
Lesser Toes	36.0	9.7

Static Stress Simulation Testing

Due to testing limitations, simulations in Autodesk Fusion 360® were utilized to evaluate the efficacy of the midsole designs. Static stress simulations were conducted to mimic the FCP phase of the gait cycle and test the efficacy of the design in reducing pressure hot spots. Midsole design 1 was excluded from digital testing because design changes were made solely based on qualitative observations from the physical prototype.

A number of limitations were encountered when amending the testing procedure from physical testing with human subjects to digital simulations. First, Autodesk Fusion 360® does not contain NinjaFlex® as a material option. The strength properties of other semiflexible material options were compared in the CAD software for use in the simulation model (Table 2). Silicone rubber was determined to be the material with the closest strength properties to NinjaFlex®.

Another limitation was the issue of varied infill percentage based on weight, which is a key aspect of the customization algorithm. Models in the CAD workspace are set to 100% infill, meaning the model would be less compressive. To counterbalance this increased stiffness, applied loads were normalized and sized up using proportionality to account for the increased infill percentage:

$$\frac{Weight}{Infill\ Percentage} = \frac{Simulation\ Load}{100} \quad [3]$$

**Infill percentage* value determined using Eqn. 1

Lastly, load application in the simulations was distributed evenly across the top face of the midsole model. In practice, pressure application is localized to particular plantar regions, namely the heel and the metatarsals.

Design Comparisons: Stress & Displacement

Midsole designs 2-4 were compared using static stress simulations with a load application of 2758.645 N (simulation load calculated from Equation 3 based on a subject weight of 150lbs). It was observed that design changes resulted in a decreased and more uniform pressure distribution on the top face of the midsole, suggesting a reduction in hot spots and increased comfort along the plantar surface-midsole interface (Figure 6). However, peak pressure values significantly increased with each design iteration (Table 3). The peak pressure value observed in the final design was located on the boundary of an internal hexagon cut extrusion in the hallux plantar region. It is not anticipated that this result will be observed in practice as the hexagon cut extrusions were observed to increase structural stability through minimal axial deformation when 3D printed with NinjaFlex® and the hallux region only produces 79.3% of the peak plantar pressure (Table 1).

Table 2: Autodesk Fusion 360® Semiflexible Material Comparison to NinjaFlex® Using Strength Properties. Yield strength and ultimate tensile strength (UTS) were compared to determine which material to use in the simulation to mimic NinjaFlex®.

Strength Properties	Filament	Autodesk Fusion 360® Semiflexible Material Options					
	NinjaFlex®	Rubber, Silicone	Rubber, Nitrile	Rubber, Natural	Rubber, Butyl	Rubber, Black	Rubber
Yield Strength (MPa)	4	10.34	15	21	15	21	21
UTS (MPa)	26	6.5	15	27.6	15	27.6	27.6
Yield Strength Percent Error (%)	N/A	158.5	275	425	275	425	425
UTS Percent Error (%)	N/A	75	42.3	6.2	42.3	6.2	6.2
Average Percent Error (%)	N/A	116.8	158.7	215.6	158.7	215.6	215.6

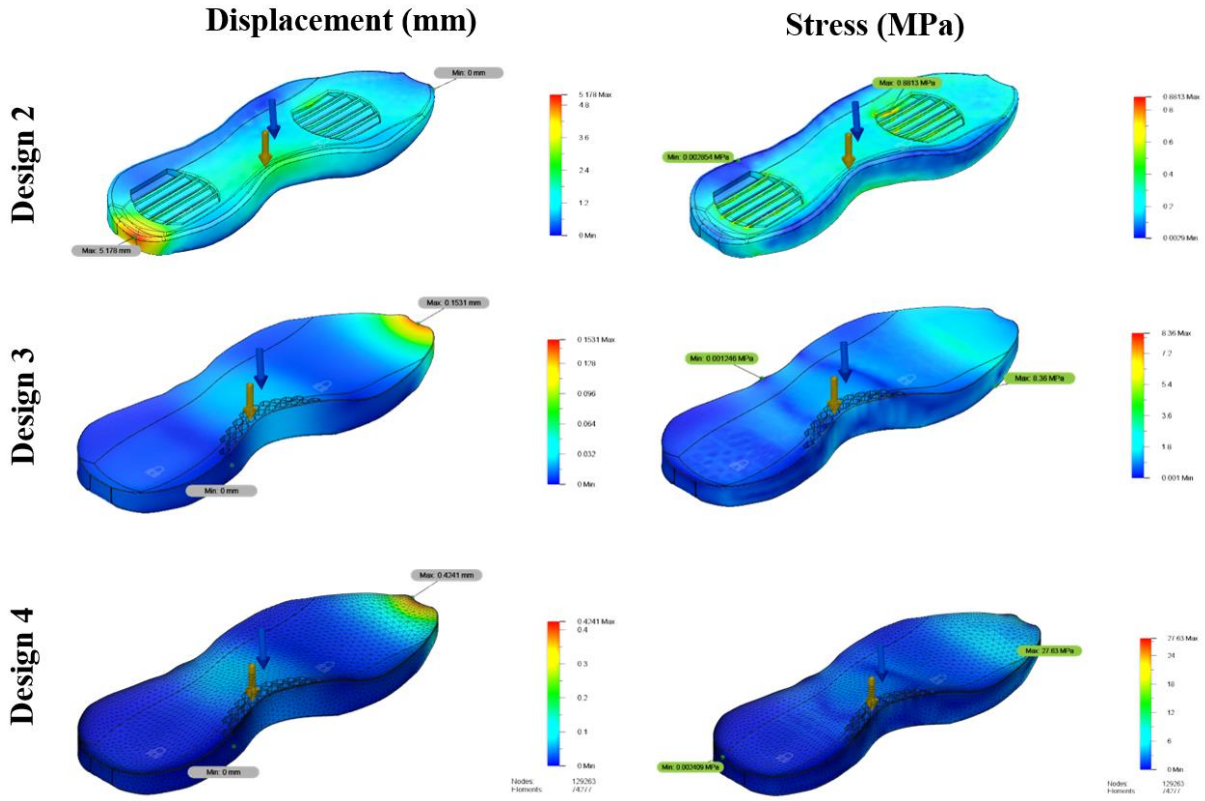

Figure 6: Static Stress Simulation Testing. Static stress simulation on Midsole Design 2 showing regions of maximum and minimum pressure. A load of 2758.645 N was applied to the top face of the midsole and the bottom plane of the midsole was constrained to be static during the simulation. Midsole Design 1 was excluded from static stress simulation testing as design changes were made based on qualitative observations from the 3D printed prototype.

Table 3: Midsole Design Comparison of Maximum and Minimum Pressure Values and Locations. This table will show the pressure values and locations (i.e. plantar regions) of the minimum and maximum pressures experienced by all the midsole designs to justify the design changes made in our team's iterative design process. Midsole Design 1 was excluded from static stress simulation testing as design changes were made based on qualitative observations from the 3D-printed prototype.

Midsole Design	Maximum Pressure Value (MPa)	Maximum Pressure Location	Minimum Pressure Value (MPa)	Minimum Pressure Location
2	0.8813	3rd-5th Metatarsal	0.002854	Heel
3	8.36	1st Metatarsal	0.001246	Midfoot
4	27.63	Hallux	0.002409	Heel

Displacement was also found to be significantly reduced with design iteration (Figure 6). In the final midsole design, the simulation demonstrates maximum displacement in the front of the midsole near the hallux and lesser toes region. This is not anticipated to occur in practice as minimal pressure will be applied at the boundaries of the midsole. In practice, however, it is anticipated that the top surface of the midsole will deform with plantar pressure due to the varied infill levels providing cushioning and conform to the patient's foot. Structural integrity is expected to be maintained via the internal hexagon cut extrusions.

Varied Load Application: Midsole Design 4

To test the durability and efficacy of the final midsole design, static stress simulations were conducted with varying loads from 91-443lbs (load application was normalized using Equation 3). The maximum stress value increased with load increase, however, the rate of stress increase decreased with load application (Figure 7). These simulation results suggest that the midsole design is capable of accommodating the weight range used in the customization algorithm and that the structural integrity of the design will be maintained as load application increases.

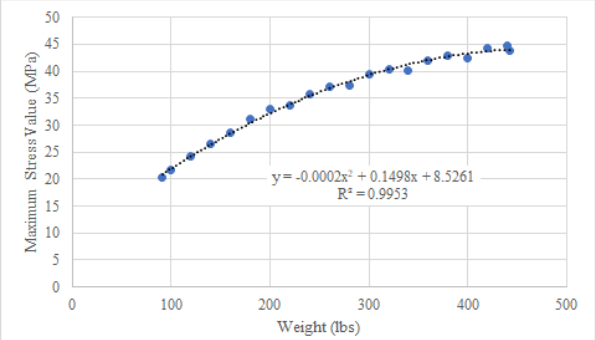

Figure 7: Maximum Pressure Values for Midsole Design 4. Maximum pressure values from static stress simulations on Midsole Design 4. All maximum pressure values occurred in the hallux region of the plantar surface. Due to material restrictions in the CAD software that prevents infill percentage from being customized, all load values were normalized based on 100% infill.

Discussion

Our final prototype, with full length hexagon cut extrusions underneath a tunable layer of 3D-printed infill lattice material, allows for customization considerations to be made when developing a midsole for patients with plantar heel pain. This full-length, easily customizable design alleviates regions of high pressure between the foot and midsole interface, and provides a more patient-specific product compared to mass-produced footwear that only include heel and forefoot cushioning considerations. Additionally, by providing patients with a therapeutic midsole option, the need to purchase both an orthotic insole and athletic footwear is eliminated. Our product provides orthotic support and comfort in a single device, which is more cost and time-effective than current treatment options.

The results of the static stress simulation tests indicate that the midsole will redistribute plantar pressure during the FCP of the gait cycle, thus reducing hot spots and increasing comfort along the plantar fascia. The simulation results are inconclusive regarding efficacy in correcting footfall impairments, such as pronation or supination, because the static stress simulations do not identically mimic locomotion. In order to confirm therapeutic functionality of the customization algorithm and resulting midsole, clinical trials involving human subjects will be necessary (see **Future Work**).

The simulation results did indicate possible areas for improvement with the final design due to high pressure levels in the internal hexagon cut extrusions in the hallux region. While this result is not expected to be replicated in practice, it is possible that further design iterations will be necessary as product development advances to improve the structural integrity of the midsole.

Due to the unique nature of our testing methods, the degree to which our device functions similarly or better than current treatment options (i.e. custom orthotic inserts, athletic footwear) is unknown. The simulation results indicate that our design distributes plantar pressure and maintains its physical shape during loading, which is the function of orthotic inserts. Therefore, we expect that our device will function similarly to current treatment options when tested on human subjects.

Our design procedure and accompanying algorithm may be used by doctors and orthotists to develop low-cost and highly-customizable patient-specific orthotics. Finite element analysis results suggest that the midsole design effectively disperses pressure throughout the midsole with applied forces, suggesting efficacy of the midsole design and algorithm as a treatment for various footfall impairments and plantar fasciitis that can be applied by clinicians as a bespoke treatment option.

3D printing proved to be an ideal manufacturing method in regards to customization, but also required a significant amount of time to produce each midsole. Although there are only a few 3D-printed athletic shoes or midsoles commercially available, as 3D printing technology continues to develop and improve, the time and costs associated with manufacturing 3D-printed midsoles will

decrease. Our findings suggest that manufacturing via 3D printing can play an important role in developing patient-specific footwear to reduce the likelihood of overuse injuries.

Materials and Methods

Biometric Data Collection & Analysis

Weight was self-reported for initial prototype fabrication, however, all successful prints utilized experimental infill percentages to determine the infill percentage range for the linear model (Equation 1). Foot dimensions, arch height, contact plantar surface area, and total plantar surface area were calculated using image analysis via ImageJ®. Contact plantar surface area was found by stamping a loaded footprint with paint and was normalized by total plantar surface area using image analysis via ImageJ®. Measurements were taken on team members and used as a representative linear model for the algorithm.

3D Scanning

The patient's bare foot was scanned using a handheld laser scanner to create a 3D mesh in VXelements® 3D software platform. The 3D mesh was then imported into Autodesk Fusion 360® and used to create a topographical map of the foot contours using the following steps:

1. Sketch an outline of the 3D foot mesh, and extrude 25mm.
2. Create a separate 'Quadball' form that is contoured to arch, toes, and heel.
3. Use the 'Combine' tool to stamp contoured form into the extruded sketch approximately 6mm (degree of imprint depends on arch height with higher arch resulting in deeper imprint).

Computer-Aid Design Modeling

3D Scans of patients' bare feet were used to inform the sketch geometry of each patient's midsole. Sketches were extruded 25mm to create 25mm thick midsoles. Stamping patient contoured 'quadball' models onto the top of the midsole designs created topographical mimics of patients' feet along the plantar-midsole contact area. Cushioning geometries were designed by sketching hexagons in an offset plane relative to the bottom of the midsoles, and subsequently extruded a particular distance based on the algorithm's output.

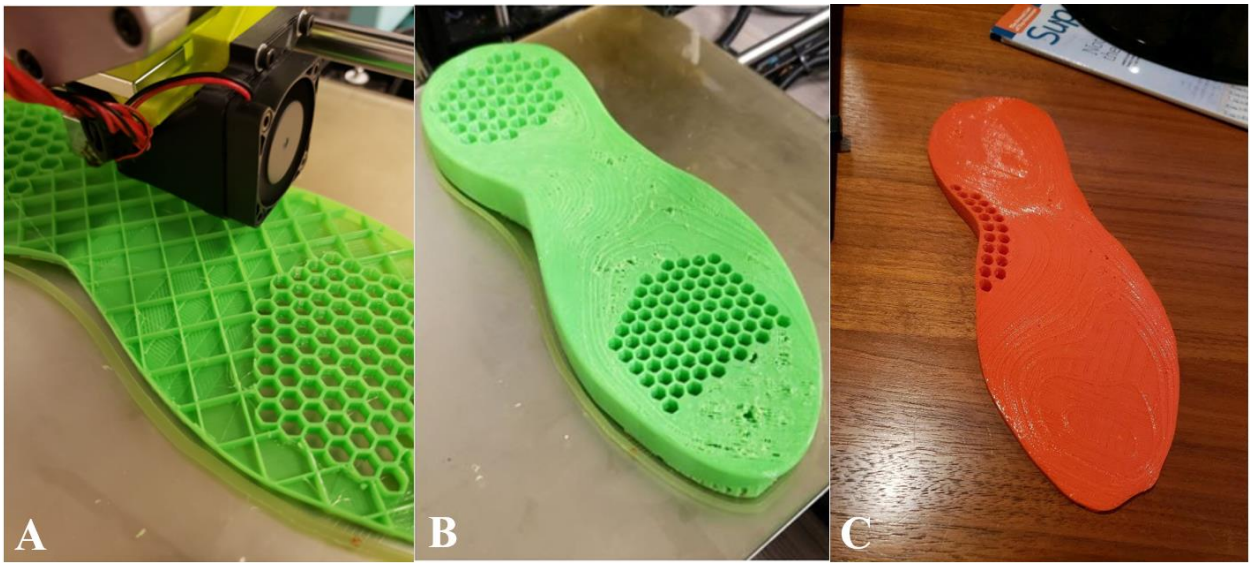

Figure 8: Prototype Fabrication. A) Grid infill design during the 3D printing process for Prototype 1 fabrication. Infill percentage was set to 10% for this print and the design included smaller, more densely packed vertical, full-depth hexagon extrusions in the forefoot and larger, less densely packed vertical, full-depth hexagon extrusions in the heel region. B) Completed 3D print of Prototype 1. C) Completed 3D print of Prototype 3.

Prototype Fabrication

Following the completion of a CAD model in Autodesk Fusion 360®, the model is transferred to the Lulzbot Cura® slicing program. The slicing program modifies the .STL file from Fusion and creates a hollow form that allows for immediate specification. The customizable characteristics utilized most in the project include infill percentage, layer height, and support structure pattern and placement. After choosing the parameters, the file is converted to a readable file for the Lulzbot® TAZ 5 3D printer. This printer is able to print NinjaFlex® filament using the Flexystruder nozzle head kit. The duration of each midsole print was observed to range from 16 to 29 hours (Figure 8). NinjaFlex® printing filament was chosen due to its compressibility and flexibility, which was deemed desirable for conformation to the human foot.

Digital Model Simulation Testing

Static stress simulations were conducted in Autodesk Fusion 360® on midsole designs 2, 3, and 4. Force loads were applied to the top face of each design and gravity was toggled 'on' for all simulations. The bottom faces of all designs were constrained to be static during the simulation. Deformation was set to 'Actual' for all simulations.

Future Work

Physical testing of our therapeutic device was limited and resulted in the use of digital simulations to verify the design choices and algorithm efficacy. However, in order to determine if the custom midsole is functional in practice to correct biomechanical impairments that cause locomotion-related discomfort and plantar heel pain, the device must be tested on human subjects. A number of tests were originally proposed for this project to test the efficacy of the customization algorithm in reducing plantar heel pain. Moving forward with product development, if these tests demonstrate clinical and therapeutic efficacy, it is anticipated that the algorithm and development process could be integrated into an application to streamline the fitting process for users.

Tensile Testing

In order to determine if the cushioning and support modalities utilized in the midsole design are optimal in practice, sample disks of varying infill percentages, internal hexagon cut extrusions, and full-depth hexagon cut extrusions will be 3D printed and compressed using an Instron® tensile testing machine. Cyclical loading will be applied to test the durability of the design and material since locomotion involves highly repetitive load application. The resulting stress-strain curves from compression testing will be analyzed to compare the modulus of resilience, the elastic modulus, and the modulus of toughness, as well as any other trends that are observed. These results can be utilized to inform future design iterations if deemed necessary.

Data Acquisition from Human Trials

In order to test the functionality of our midsole design in relieving plantar heel pain and/or locomotion-related discomfort, testing on human subjects is necessary, which will require institutional approval. Due to the novelty of our treatment method, which is a shoe midsole rather than an insole, the Institutional Review Board (IRB) at the University of Virginia informed our research team that approval from the Food and Drug Administration (FDA) would need to be acquired before clinical trials could be conducted. However, pilot study testing was approved, therefore, the midsole customization algorithm and design can be tested on team members.

The custom midsole will be compared to barefoot walking (negative control) and the subject's current athletic shoe model (positive control).

Inclusion Criteria: 1) Ages 18-65 inclusive; 2) Able to walk unassisted

Exclusion Criteria: 1) Age less than 18 or greater than 65; 2) Unable to walk unassisted; 3) Any lower extremity surgery six months prior to evaluation; 4) Any previous lower extremity surgery that is gait altering; 5) Currently pregnant

Gait Analysis & Force Plate Reading

A 12-camera Vicon Nexus® infrared motion capture system and 5 floor-mounted Bertec® force plates will be used to monitor the subject's gait pattern throughout the gait cycle. Subjects will also be filmed from the shoulders down to preserve anonymity.

A full-body modified Helen Hayes marker set of 14mm reflective markers, an Oxford foot model marker set, and a collinear set of four markers on the posterior side of the subject's foot and lower leg will be applied to the subject (Supplemental Figure 1). Subjects will walk in a straight line at their

comfortable walking speed along a level 10m walkway with five force plates mounted in the center of the walkway. Kinematic data will be collected via the motion capture cameras at 120 Hz. Kinetic data will be collected by the Bertec® force plates.

Ankle Angle

Measurements of ankle angles will be taken using motion markers on the skin placed at locations on the lower leg and foot. The base of the calcaneus (1) and the lower attachment of the Achilles tendon (2) will form the first linear segment and the center of the Achilles tendon above the medial malleoli (3) and the center of the posterior calf muscle (4) will form the second linear segment (Supplemental Figure 1). These linear segments form the rear foot angle (RFA).

Neutral foot strike patterns will result in the angle between these linear segments staying within the range of 4° valgus (eversion) to 4° varus (inversion)[15]. An RFA of 5° or greater in the valgus and varus directions results in pronation and supination respectively[15]. Deviation from the neutral axis can result in injury or discomfort during locomotion. Increased support in the midsole, particularly in the arch region can counteract ankle rotation and keep the alignment of the RFA. It is expected that the custom midsole will produce an ankle angle correction of 4°±3.5° in the means during the gait cycle for the experimental group when compared to the controls (range accounting for mild to severe pronation).

Stride Length

The motion capture markers and force plates will track motion of the lower extremities and the contact points on the floor to determine stride length. Athletic footwear has been found to increase stride length by 11.1cm and significantly impact gait ($p<0.0001$)[16]. Stride length is expected to increase by approximately 10±8cm from the barefoot trial to the prototype trial, as the prototype is expected to provide a similar effect to wearing athletic footwear.

Center of Pressure Progression Angle

Force plate readings during the gait cycle will collect force and moment values in all three directions, which will be used to calculate the center of pressure (COP) during the initial contact of the foot onto the force plate and the last point of contact during the foot contact phase of the gait cycle. A Cartesian coordinate system will be established using the initial point of contact as the origin, the direction of movement as the axial axis, and the direction normal to the direction of motion in the plane of the foot contact as the lateral axis. The location of the COP at the end of the FCP of the gait cycle will create an angle with the origin, the COP progression angle. The COP displacement for adults is approximately 95% of the foot length and 31% of the forefoot width[17]. normal COP progression angle is 4.1°±1.6° and an inward curve, however, age and gait impairments cause the trajectory to stay along the midline of the foot and produce a larger progression angle[17,18]. COP progression angle is expected to trend toward normal displacement percentages with the midsole when compared with barefoot trials and reduce the COP progression angle towards a value of 4.1°[17].

Pre-Test & Post-Test Surveys

Subjects involved in the pilot study will be asked to complete a voluntary survey before and after gait analysis testing to determine the comfort level of the custom midsole. Comfort will be ranked on a 5-point Likert scale. The pre-test survey asks about the subject's level of locomotion-related discomfort (if any), the treatment options they have pursued for locomotion-related discomfort (if any), and their ranking of the level of comfort of their current midsole model (Supplement 2). The post-test survey asks the subject to rank the comfort of the custom midsole and to identify any areas on the lower extremities or foot where discomfort was felt during the gait analysis (if any) (Supplement 3). It is expected that the mean value of Likert ratings will increase for the midsole in comparison to barefoot walking and be similar or higher when compared to the subject's current athletic shoe model.

Statistical Analysis of Human Trial Data

To determine the statistical significance of the collected data from the pilot study using human subjects, a paired, two-tailed Student's t test will be used on each of the gait analysis data sets. All statistical analysis tests will be conducted using an α value of 0.05, and a power value of 0.80. Subjects will walk a total of 12 steps during the gait analysis portion of testing.

End Matter

Author Contributions and Notes

O.J.D., B.O., and B.M.P. designed research, O.J.D., B.O., and B.M.P. performed research, B.O. created the CAD models, O.J.D. performed simulations, O.J.D., B.O., and B.M.P. analyzed data; and O.J.D., B.O., and B.M.P. wrote the paper.
The authors declare no conflict of interest.

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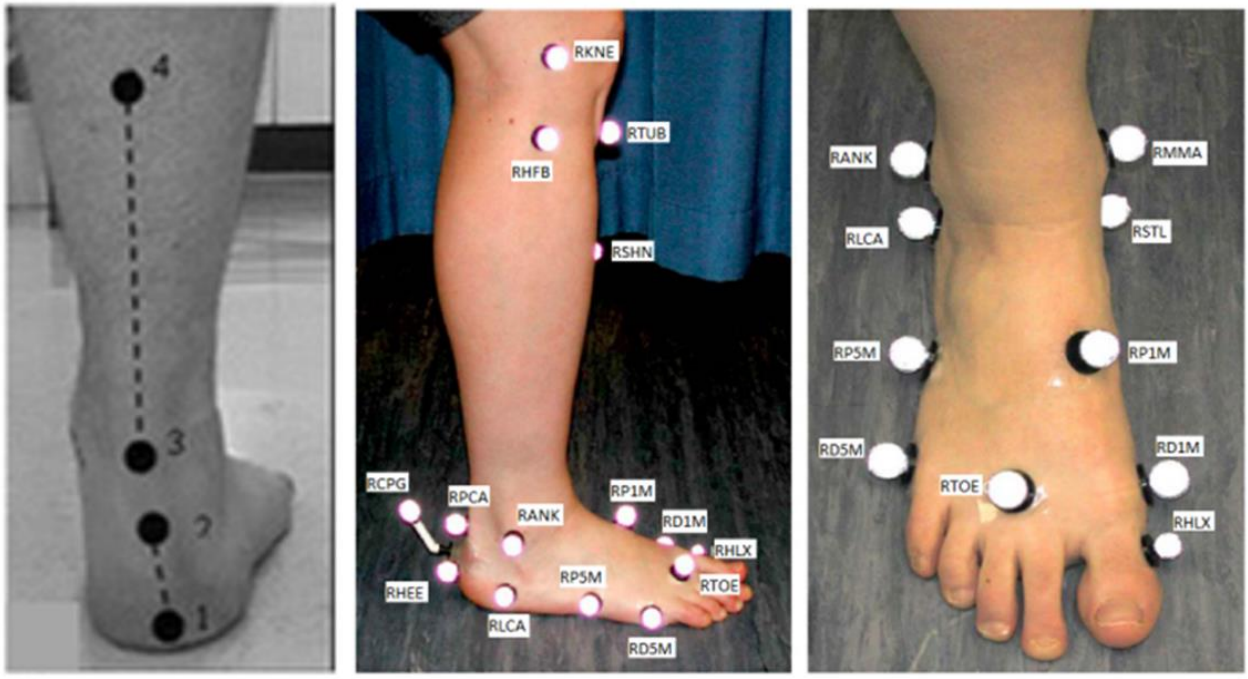
Supplementary Material



Supplemental Figure 1: Motion Capture Marker Locations. From left to right: motion capture marker locations for ankle angle measurement (image reproduced from Kothekar, 2019[15]), side view of Oxford foot model marker set (photo courtesy of Dr. Shawn Russell), top view of Oxford foot model marker set (photo courtesy of Dr. Shawn Russell). Motion capture markers are a Helen Hayes marker set of 14 mm reflective balls and a full body set will be used. Placement of reflective markers is key to spatial recognition of joints and movement during the gait cycle. Kinematic data from the motion capture markers will be collected with a 12-camera VICON Nexus® 3D Motion Analysis System at 120 Hz. This data will be used to measure the rear foot angle to determine degree of pronation or supination during the foot contact phase of the gait cycle. Participants will be monitored by a 12-camera Vicon Nexus motion capture system that tracks the motion markers attached at all major joints, lower limb shanks, and the feet. These motion markers will also provide data on stride length to determine if stride length is significantly altered by the midsole prototype or comparable shoe model when compared to the barefoot trial.

Pre-Test Survey

Below are preliminary questions about your history of locomotion-related discomfort and the treatment methods you have pursued or are currently pursuing to alleviate this discomfort. This data will help investigators conducting this study to determine if the customization algorithm used to construct your custom midsole is an effective treatment method for reducing locomotion-related discomfort.

This is a voluntary study and a voluntary survey. You may stop the survey at any time. You may skip any questions you are not comfortable answering or ask investigators questions at any point during the survey. If you do not understand the questions, please ask the investigators to provide clarification. If you would like to have the survey administered verbally, please ask the investigators to accommodate this request. There is no time limit on this survey and you may take this survey in the presence of the investigating team or alone if you wish (investigators will still be available to answer any questions you may have).

Please mark answers clearly and legibly. If you need more space to answer the questions, please ask an investigator and spare paper will be provided and attached to your survey

1. Please describe your history with locomotion-related discomfort (if any):

_____
_____
_____
_____

2. How often do you experience pain or instability when walking or running?

Always Often Sometimes Rarely Never

3. Please rank the pain on a scale of 1-5:

No pain	Mild	Moderate	Severe	Unbearable
1	2	3	4	5

4. Do you take any prescription medications to alleviate the pain associated with the footfall impairments? Yes/No

5. Do you take any over-the-counter (OTC) medications to alleviate the pain associated with the footfall impairments? Yes/No

6. What model of athletic footwear do you currently wear when walking, running, or performing physical activity?

_____
_____
_____
_____

7. Please rank the comfort level of these shoes on a scale of 1-5:

Very Uncomfortable	Somewhat Uncomfortable	Neutral	Somewhat Comfortable	Very Comfortable
1	2	3	4	5

8. Do you currently wear orthotic inserts? Yes/No

9. If yes, are the orthotic inserts custom-made? Yes/No

10. If yes, please rank the comfort level of the orthotic inserts on a scale of 1-5:

Very Uncomfortable	Somewhat Uncomfortable	Neutral	Somewhat Comfortable	Very Comfortable
1	2	3	4	5

Post-Test Survey

Below are follow-up questions about the comfort level of the custom midsoles. You will be asked to compare the comfort level of the custom midsole to the two control trials: your current footwear and barefoot walking. This data will help investigators conducting this study to determine if the customization algorithm used to construct your custom midsole is an effective treatment method for reducing locomotion-related discomfort.

This is a voluntary study and a voluntary survey. You may stop the survey at any time. You may skip any questions you are not comfortable answering or ask investigators questions at any point during the survey. If you do not understand the questions, please ask the investigators to provide clarification. If you would like to have the survey administered verbally, please ask the investigators to accommodate this request. There is no time limit on this survey and you may take this survey in the presence of the investigating team or alone if you wish (investigators will still be available to answer any questions you may have).

Please mark answers clearly and legibly. If you need more space to answer the questions, please ask an investigator and spare paper will be provided and attached to your survey

1. Please rank the comfort level of the customized midsoles on a scale of 1-5:

Very Uncomfortable	Somewhat Uncomfortable	Neutral	Somewhat Comfortable	Very Comfortable
1	2	3	4	5

2. Was the customized midsole more or less comfortable than your current athletic footwear model? Please circle:

More Comfortable

Less Comfortable

No Difference

Please explain: _____
_____
_____

3. Was the customized midsole more or less comfortable than barefoot walking? Please circle:

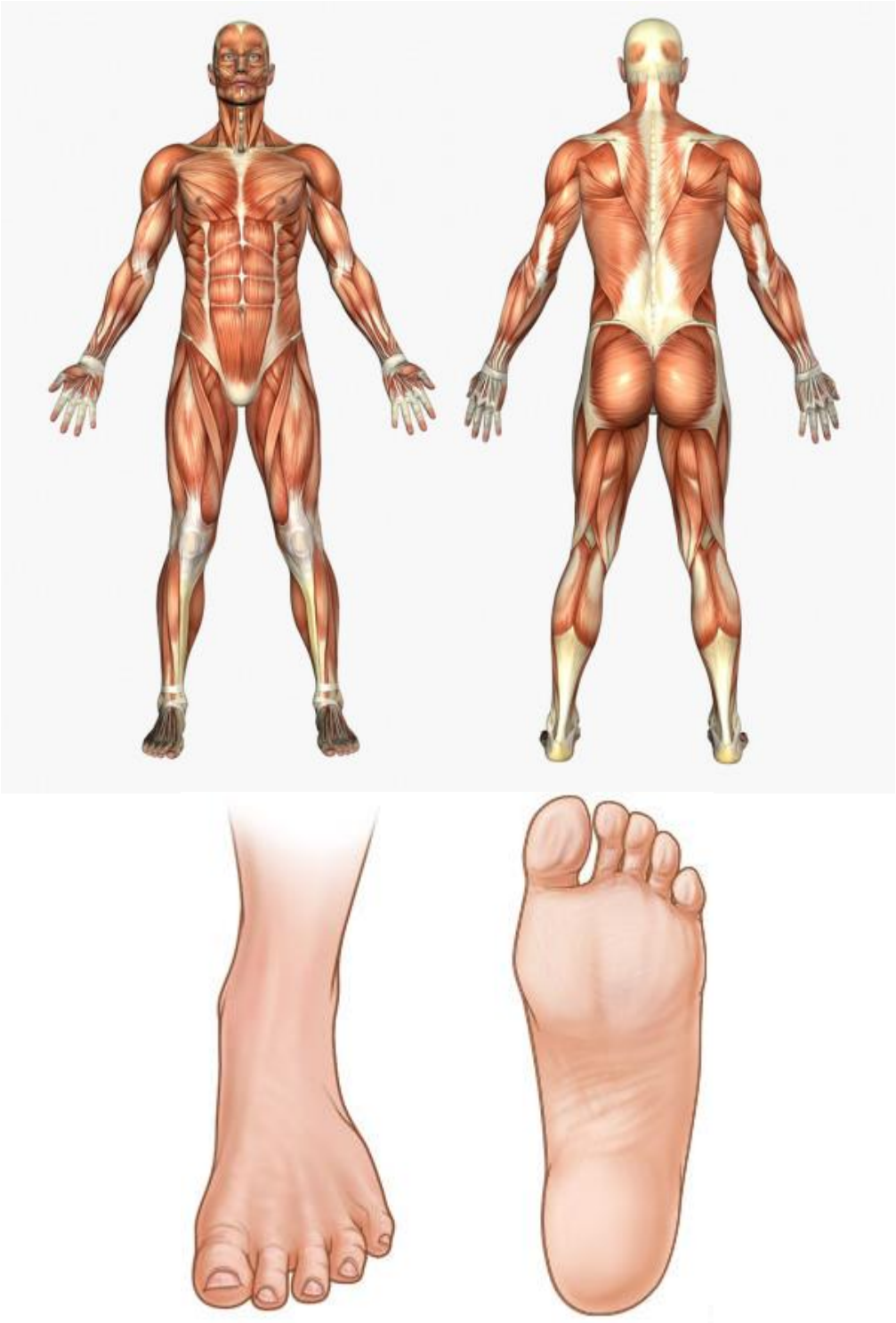
More Comfortable

Less Comfortable

No Difference

Please explain: _____
_____
_____

4. If you indicated that the custom midsoles were less comfortable than either of the control trials, please indicate what area(s) of your foot or leg experienced heightened discomfort. (Circle on images below)



(Images reproduced from: Depositphotos, n.d.[19]; Healthwise Staff, 2019[20])