Development of a Dynamic Tensioning Ankle Brace for Chronic Ankle Instability

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for STS Thesis-Related Assignments

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Abstract

Chronic ankle instability (CAI) is a widely prevalent ankle condition resulting from repeated ankle sprains, foot posture abnormalities, ankle misalignment, and neurological disorders. These conditions include but are not limited to, lateral ankle sprains (LASs), medial ankle sprains, high ankle sprains, drop foot, Cavovarus deformity, posterior tibial tendon dysfunction, and Blount's disease[1]. Although there are many ankle afflictions, the leading cause of CAI is lateral ankle sprains (LASs). Approximately 40% of lateral ankle sprains will result in CAI; however, a truly user-centered design that offers sufficient ankle joint force unloading and stability does not exist[2]. Using Icarus Medical Innovation's wide array of patented technology, our team created a 3D scan-to-fit brace capable of dynamic force unloading and adjustable ankle stability in the sagittal, frontal, and transverse planes. Over the academic year, success was defined by the creation and execution of three specific aims that included an ankle-related literature review, market research, an iterative CAD design process, in-house testing, and establishing a patient testing protocol for future study of our final design's safety and efficacy.

Keywords: chronic ankle instability, dynamic tensioning, ankle brace, BOA dial, 3D scan-to-print, CAD

Introduction

Chronic Ankle Instability (CAI) is an extremely prevalent condition resulting from a variety of ankle sprains, ankle misalignments, foot posture abnormalities, and neurological disorders and characterized by persistent weakness, pain, reduced range of motion, and self-reported decreased function. CAI is most common in patients who have experienced recurrent lateral ankle sprains (LASs). In fact, 40% of individuals who experience a LAS will go on to develop CAI[2]. LASs involve supination, the outward rolling of the ankle in all three planes, that leads to the tearing of one or more ligaments[3]. Of these LAS injuries, 73% involve partial tearing of the anterior talofibular ligament. Due to the high risks of acute ankle sprains in sports, extreme CAI prevalence is seen in athletes with 23% of total athletes, 19% of college athletes, and 31% of high school athletes suffering from CAI[4].

Currently, the most effective remedy for joint pain and instability is through the use of braces. However, there is a large market gap for rapid customization of a brace to the patient anatomy that allows for rapid adjustable support. In collaboration with Icarus Medical, a biotechnology firm that has patented rapid customization knee bracing technology that performs patellofemoral compartment force unloading to address the symptoms of cartilage deterioration, through this capstone project an ankle orthotic was developed to treat and prevent CAI.

Icarus' methodology for rapidly producing custom knee braces has extreme cost-effectiveness and provides immense potential in areas other than just knee braces. Rapid customization is so important because it gives the ability to produce braces that are fully effective for all patients, regardless of the specifics or severity of their condition. By utilizing their automated scan-to-print process in the ankle brace, custom printed pieces can be easily integrated into the design based on patient ankle scans. This is a critical innovation in the product as it will allow the brace to utilize these rigid components for significant stability benefits without sacrificing the comfort level of the brace. Current ankle braces have implemented increased rigidity to provide more support at the expense of comfort, mobility, and range of motion beneficial to ligament healing, making the product less appealing.

In addition to rapid customization, this brace used an innovative BOA dial as a dynamic tensioning system on the brace. The BOA dial is a rotary dial that functions using a set of wires or cables, where a turning motion winds up and tightens the wire. The current ankle braces that utilize the BOA dial utilize it as a closure mechanism, where turning the dial encloses the brace around the user's ankle similar to shoelaces. This brace expanded on current technologies by utilizing the BOA dial to provide an adjustable stabilizing force. By guiding the cables of the BOA along specific pathways that correlate with the ankle's natural tendons, the tightening of the BOA system will provide a corrective force that can rotate the ankle into a stable position. Using these cables allows the brace to provide this force while allowing nearly full freedom of motion in the other axes. The benefit of utilizing the BOA dial to provide this force is the ability for the patient to adjust the level of stabilization from zero to max on the fly. The BOA can be disengaged at any point, effectively turning stabilization off to increase comfort in times when support is less needed. This user adjustability allows us to satisfy a wide range of patients in areas of comfort and stability, which does not exist in any product today.

The usage of this new adjustable tensioning mechanism paired with the 3D printed aspect of the brace gives the freedom to integrate the BOA into its design in a number of different ways. By printing a custom, rigid ankle cuff that can anchor the BOA in place, the brace is able to generate high levels of force while staying in position. The printed pieces that determine the position of the BOA and corresponding cable can also be designed for a patient's specific injury, providing only the needed correctional force for patients dealing with supination, pronation, or weakness in any other axes without restricting movement in all axes. The combination of the custom 3D printed components and the dynamic stabilizing system make our brace completely novel in this industry while addressing critical areas.

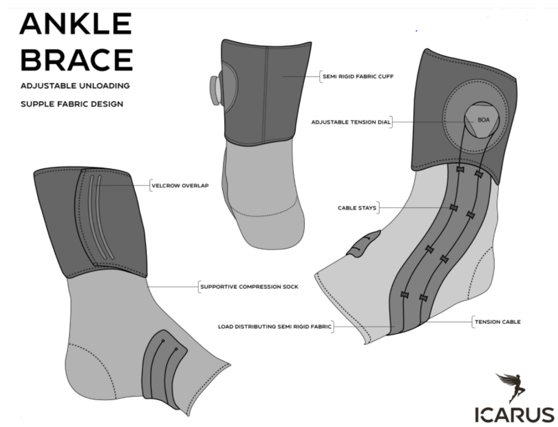

***Figure 1**. First iteration drawing of ankle brace with fixed BOA dial for dynamic tensioning.*

It was decided that the following specific aims would be pursued over the course of this project to direct the efforts of ankle brace design and development:

Aim 1: We will perform an ankle-related literature review and market research to determine the viability and purpose of our brace.
Aim 2: We will work through an iterative design process utilizing CAD software and Icarus' rapid 3D scan-to-print technology.

Aim 3: We will work towards a final design for in-house testing and establish a patient testing protocol for a future study on our final design's safety and efficacy.

As preliminary research began to determine the viability and purpose of the brace, there was initially a knowledge gap in a few specific areas that needed to be filled to facilitate the implementation of a successful design process. These specific areas include research into the specifications of CAI, health insurance code qualification research, patent/prior art research, and patient surveys. This research was necessary to establish a direction for the purpose and function of the product. Acquiring information on these topics aided the formulation of our design specifications, which aids in quantifying the efficacy of the iterative design process established in Aim 2.

CAI Research and Competitive Offerings

Establishing foundational knowledge of CAI, its causes, and its incidence rate are pivotal in determining an effective remedy for the condition and the scope of the device's benefactors. Determining the specific injuries that induce CAI aids the design specification process in not only identifying ways our brace can facilitate recovery but also in how it can help avoid reinjury. From our research, CAI typically originates from lateral, medial, or high ankle sprains, and those particular injuries require support in various planes of the ankle. Identifying the incidence rate of CAI and its derivative injuries aids with market sizing the device and determining the breadth of impact that an effective brace can reach. With approximately 2 million of these derivative ankle sprains occurring each year in the United States and an estimated ~46% of individuals with an ankle sprain history that puts them at risk of developing CAI, there is a wide target demographic that can potentially benefit from our ankle brace design and development. With it costing $5.3 billion to treat and prevent CAI in 2021 and an aging population at risk of CAI progression, there is an ample target demographic and market to pursue (Figure 2)[5].

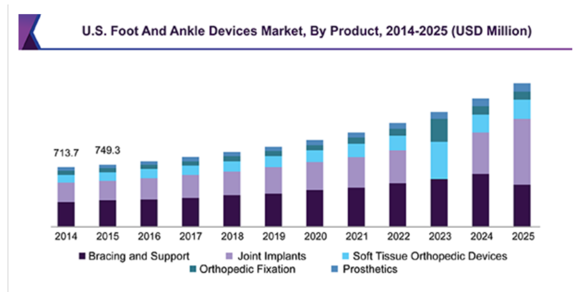

***Figure 2**. Projected U.S. Market Capitalization for Foot and Ankle Devices.*

Analyzing the competitive landscape for personalized ankle braces provides insight into which design specifications are necessary to acquire a competitive advantage over the current standard of care. Research into what remedies are currently available will dictate which bracing aspects to improve upon, which ultimately affects the brace's adoption rate and the scope of patient impact that the brace can generate. Supplemental Figure 1 and 2 detail the main competitors and patent landscape in the personalized ankle bracing market, and qualitatively describes four metrics to measure brace efficacy: stability, comfort, versatility, and pain relief.

Health Insurance Code Research

After establishing the goal of creating a brace that can treat a wide variety of CAI patients, various insurance coverages were explored. Having the brace meet the specifications necessary to qualify for insurance coverage is necessary for maximum patient outreach and Icarus' willingness to manufacture the product. For the sale of durable medical equipment (DME), there are a set of insurance codes that correlate to different products. We isolated the codes applying to Ankle-Foot Orthotics (AFOs) and compared them based on their design qualifications, reimbursement values, and the frequency of yearly claims submitted under those codes. Using these, we identified the following target codes that had design qualifications that lined up with our initial specifications as well as ample reimbursement and claim numbers to ensure the potential for a profitable product:

L1904: Ankle orthosis, ankle gauntlet or similar, with or without joints, custom-fabricated
L1940: Ankle foot orthosis, plastic or other material, custom-fabricated

Out of all the qualifying AFO codes, these two see some of the most claims rewarded yearly with average reimbursements of around $500. On top of this, their broad design qualifications make it possible for a wide range of custom fabricated AFOs to qualify.

Materials and Methods

3D printing, a new type of manufacturing based on digital models, provides many benefits to medical device innovation such as rapid customization, greater cost-effectiveness, and enhanced design collaboration. Previously, the production of custom braces was time-consuming and expensive, encouraging the distribution of less effective ‘off-the-shelf’ braces. However, through the use of current 3D printing technology, the ability to rapidly produce effective, customized braces has become not only possible but lucrative. This has the potential to be extremely beneficial for patients across the medical industry in multiple ways. In addition to braces becoming more readily available and more effective, they will become cheaper for the consumer.

Custom Design Methodology

Icarus Medical Innovation’s design methodology was used to produce the custom components of our brace. This process begins with patient input data from a 3D scan using the Icarus iPhone application. By using 3D LIDAR technology, the app is able to take an extremely clean and detailed scan of patient anatomy in seconds, which is then immediately uploaded to an online portal. This allowed the use of several ankle scans which were imported into the Autodesk Fusion 360 Computer-Aided Design (CAD) software. Within this software, key anatomical landmarks were identified on the ankle scan and used to model a custom-fit ankle cuff. Additionally, a custom tension guide was modeled in the orientation needed to provide stabilizing force vectors on the ankle. For example, in the case of a patient with supination issues, the tension guide was modeled to mimic the pathways of the patient's calcaneofibular ligament and anterior talofibular ligament (Figure 3). After developing this methodology for modeling these custom components, Icarus Medical technology introduces the ability to automate this custom design process. Figure 3: Custom Modeled Tension Guide

Figure 3. *Custom Modeled Tension Guide.*

This means that after simply providing the patient scan and axis of correction needed, the custom pieces can be instantaneously modeled, eliminating the typical time-consuming process custom braces go through.

Component Manufacturing

The custom components of the brace were produced using an HP Multi Jet Fusion (MJF) 3D printer. Multi Jet Fusion is an industrial 3D printing process that has the ability to produce functional production parts in less than one day. This new MJF technology is adding immense value to the manufacturing field as it produces quality surface finishes, more consistent mechanical properties than other processes, and extremely fine feature resolution, all in a short period. It functions using an inkjet array to selectively apply fusing and detailing agents across a bed of material powder, typically nylon. The powder is heat fused into solid layers repeatedly until the final product is complete[6]. The custom pieces were printed out of thermoplastic polyurethane (TPU). TPU is a class of plastics that provides the strength and support of plastics while maintaining the flexibility of a more rubber-like material. This material was chosen due to its ability to ensure the structural integrity of our brace while maintaining flexibility, and its lack of rigidity was crucial to the comfortability of our product.

Product Assembly

The final product assembly required attaching the custom components to all other functional pieces into one comprehensive product. This process started with the base layer that would ultimately serve the function of hosting the attachment of all other pieces. A Crucial Compression ankle support sleeve was used for this due to its tight fit to any ankle while still providing flexibility. First, the custom printed ankle cuff was attached to this sleeve using an adhesive-backed velcro hook. This allowed for adhesive attachment to the ankle cuff which could then form a secure velcro connection to the compression sleeve. Printed into the ankle cuff was an attachment mechanism allowing for the easy integration of an L5 BOA Dial. The BOA dial was connected to the ankle cuff and the corresponding BOA cable was strung up to the dial leaving two cable strands that would serve as the source of the tension force. From here the custom printed tension guide was positioned in place according to the CAD assembly and was stitched in place onto the compression sleeve. Stitching was used for this integration instead of velcro due to the tension forces that would be pulling on this part, requiring a stronger connection method. The BOA cable strands were threaded through the internal pipes within the tension guide and were then stitched to the compression sleeve to secure it in place. Lastly, an orthotic quality padding piece was connected to the bottom of the compression sleeve using velcro. This piece ensured the Boa cables would not dig into the patient's foot.

Results

Product Iterations

The first iteration of the dynamic tensioning ankle brace was a non-custom brace designed to address ankle supination. This prototype was made up of all soft components attached through velcro mechanisms. It featured a continuous compression sleeve to ankle cuff base layer, a boa dial system glued in place, and a single tension cable traveling from the boa to the most lateral toe. This prototype proved the functionality of the boa dial tensioning system in providing a stabilizing force on the ankle to address supination.

After the proven functionality of the tension system, the next prototype was focused on integrating custom components into the design. This prototype featured a custom-modeled and 3D printed ankle cuff, made out of Nylon PA12 plastic, which houses the Boa tension system.

Other new features included a padding layer underneath the tension cables to absorb force, and the wrapping of the cables underneath the forefoot to provide more leverage during the tensioning of the cables. This prototype failed due to the rigidity of the nylon ankle cuff, which was uncomfortable and brittle to the point of snapping.

The third prototype was the first to utilize thermoplastic polyurethane for the custom printed components. On top of the custom ankle cuff from the second prototype, this design featured the custom-designed tension guide that contained internal piping to guide the Boa cables. This piece was crucial to establishing the direction of the force vectors from the tensioning system. The setback of this prototype was the thickness of the tension guard, which resulted in the overall brace being too rigid and lacking the flexibility needed for adjusted support.

Prototype four showed lots of success with an optimized tension guide that showed improved thickness and a curvature matching the anatomy of the ankle. This design had a major improvement in functionality, with adequate patient comfort levels and very high stabilizing forces. In addition, this iteration maintained an extremely low profile. The major limitations of this design were its lack of aesthetic appeal. This was due to a connection mechanism relying on zip ties to hold the tension guide in place as well as bulky under the foot padding.

Final Product

After iterating on the design of the brace a total of five times we settled on our final product design as seen in Figure 4. This includes two custom 3D printed pieces in the assembly: the ankle cuff and the tension guide. The tension guide was connected to the compression sleeve using stitching, providing a more stable connection and a more professional-looking device. The brace is extremely low profile shown by its ability to fit comfortably in a shoe and it provides the desired corrective force to treat supination of the ankle.

Figure 4. *Final brace design and demonstration.*
Patent Pending Application #: 17537476

This final brace met the required design specifications that were established at the onset of the prototyping process. Ultimately, this was accomplished through diagnosing areas that needed improvements in previous iterations and incorporating those changes into what became our final product.

Preliminary Subject Testing

Testing will be performed to assess the functionality of the brace and the ability of the user while wearing the brace as well as comfort and pain reduction levels through a clinical trial. Preliminary data was gathered to prove the ability of the brace to improve outcomes in both the Star Excursion Balance Test and the Foot and Ankle Ability Measure metrics. This improvement for one patient can be seen in Table 1.

	SEBT	FAAM
Pre Brace	0.35	61%
Post Brace	0.56	79.3%

Table 1: *Preliminary testing of the dynamic tensioning ankle brace*[7,8]

These measures will be analyzed through a 6-week clinical trial comparing the dynamic tensioning ankle brace to a standard off-the-shelf ankle brace. By doing so, we will be able to reference the data to make claims about the brace.

Discussion

Final Product Considerations

The Dynamic Tensioning Ankle Brace was tested by subjects with various degrees of ankle instability. The results of these tests were a 1.59 times increase in SEBT score and a 1.3 times increase in FAAM score. The final design of the ankle brace fulfilled the design criteria that were initially determined. By meeting these requirements, the ankle brace provides adjustable stability for supination of the ankle joint through the use of a BOA dial while yielding comfort to the wearer and maintaining a conspicuous profile. The device meets these requirements while being manufactured through additive manufacturing processes. This means that the ankle brace includes only soft goods or 3D printed parts. The use of the additive manufacturing method allows for the device to be fabricated in both a time and cost-effective manner thus providing the necessary benefits for the device to penetrate the market gap that was targeted.

Impact

Current bracing technologies are limited in their treatment of various joint conditions. This is due to the continued focus on the mass production of braces tailored to the 50th percentile male. Various challenges have prevented companies from exploring the production of individually customized braces. At the root of these challenges is manufacturing methods as almost all rigid braces rely on injection molding, an expensive method with limited scalability for custom products[9]. Production via the method of mass production can be extremely beneficial when viewed through the lens of the company producing and selling the braces. However, the tailoring of the braces to the 50th percentile male results in an underrepresentation of bracing technologies for specific demographics. These include people with disabilities, people who are overweight, and even women in general. This leaves a significant gap in the bracing technology market for a personalized brace.

The utilization of the additive manufacturing process by Icarus Medical Innovations has provided an avenue to address this market gap. This is currently being done with the Ascender Knee Brace and the opportunity to expand into other areas of the body is present. The ankle brace described in this report has the potential to provide customized support and dynamic stability to all demographics at an affordable price. By doing so, this product will be able to help a wide range of people who suffer from CAI during both the recovery process and in daily life.

Limitations

Throughout the development of this product there were limitations that the developers faced. These include the turnaround time of 3D printed parts and a lack of information and knowledge regarding the IRB application process. Due to the iterative nature of the design process, heavy reliance was placed on the ability to quickly design and print custom parts fitted to our model ankle anatomy to test aspects such as strength, comfort, and donning and doffing. For this reason, the principal limitation was the extensive time between ordering the 3D printed parts and the delivery of the parts. Occasion backups in the processing, production, and delivery of these parts from the printing company located in California caused unaccounted for delays in the prototyping process. This led to rushed engineering and design of certain parts resulting in the mechanical failure of these pieces during the donning process before testing could be performed. Additionally, the IRB application process was an unforeseen hindrance that, thanks to the aforementioned challenge, ended up being resolved. While waiting for the delivery of the custom parts, the IRB application was the main focus. Limited knowledge of the process of applying for IRB approval as well as the required aspects of a health-science clinical trial caused the IRB application process to be slower and more arduous than expected. Despite these limitations, both the device and the application were completed in the time allotted.

Future Work

There are steps that will eventually be taken to further develop this product. These include improving the aesthetics of the brace, reducing assembly time, performing the previously mentioned clinical trial, and applying for FDA approval of the brace. Primarily, while the final design of the brace is functional and meets the design matrix criteria, it will need to be aesthetically refined to make it attractive for patients on the open market. Due to the time restrictions and a lack of expertise, the final product has rough stitching and noticeable glue patches. To create a desirable product, the assembly of this brace will need to be perfected to make it appealing and cost-effective. Reduction of the assembly time will be necessary for the ability to upscale production and distribution of the brace to customers. This can include simplification of the attachment mechanisms used to bond the custom parts to the padding as well as automation of the patient matching process to make it instantaneous. Furthermore, completing the clinical trial is necessary to apply for FDA approval of the brace as a class I device. Though FDA approval is not necessary for selling the device, it is needed to make marketing claims about both the clinical relevance and the overall performance of the brace. These are all desirable aspects of the bracing solution and therefore, are goals that will be targeted in the future.

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Supplemental Material

Need #	Design Constraint/Metric	Unit of Measure	Marginal (Acceptable)	Ideal Value
1	Lightweight	Ounces	4.5-6.5	4.5
2	Stability	Torque (Nm)	11-23	23
3	Ease of donning and doffing	Time (seconds)	20-30	20
4	Pain Reduction	ΔFAOS Value	0.43-17.7	17.7
5	Provided Inversion and Eversion Range of Motion	Degrees	0° - 24° Inversion 0° - 15° Eversion	0° - 30° Inversion 0° - 18° Eversion
6	Provided Dorsiflexion and Plantarflexion Range of Motion	Degrees	0° - 13.2° Dorsiflexion 0° - 40° Plantarflexion	0° - 16.5° Dorsiflexion 0° - 50° Plantarflexion
7	Provided Abduction-to-Adduction Range of Motion	Degrees	0°-17.7°	0° - 22°
8	Comfort	1-10 sliding scale	7-10	10
9	Includes BOA Dial for Adjustable Tensioning	Y/N	Yes	Yes
10	Water-resistant	Y/N	Yes	Yes

Supplemental Table 1. *Design specifications matrix.*

Supplemental Figure 1. *Qualitative review of the patent landscape.*[10–14]

	Stability	Comfort	Versatility	Pain Relief
Arizona	Full fixation	Considered hot and heavy	None	Lack of movement and custom sole
Richie	Allows plantar and dorsiflexion	Lighter and more comfortable	None	Custom orthotic footplate
Fabtech	Full fixation	Bulky and puts stress on knees	Different strengths and foot orientations	Complete unloading with orthotic footplate
Exosym	Full fixation	Bulky and puts stress on knees	None	Complete unloading with orthotic footplate
Ultra-ankle	Allows plantar and dorsiflexion	Light but not custom	Two different style braces	Not unloading or shock absorbing
Airloc	Allows plantar and dorsiflexion	Light but not custom	Air pockets change compression	Not unloading or shock absorbing
Icarus	Adjustable tension for stability	Custom made with comfortable sole	Adjustable tension for stability	Custom orthotic footplate

Supplemental Figure 2. *Qualitative review of competitor offerings.*