Development of a Custom 3D-Printed Ankle Brace for Chronic Ankle Instability

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William P. Zimmerman

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Technical Project Team Members

Emma Donatelli

Ashar Kamal

Erin McIlhinney

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 Thesis-Related Assignments

Dr. Timothy Allen, Department of Biomedical Engineering

Dr. Shannon Barker, Department of Biomedical Engineering

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Emma F. Donatelli[a], Ashar Kamal[a], Erin E. McIlhinney[a], William P. Zimmerman[a]

[a] Department of Biomedical Engineering at the University of Engineering

Abstract

This capstone project seeks to provide an engineered solution for people with chronic ankle instability (CAI). CAI is a physically debilitating condition that can stem from external joint injury or neurological disorder[1]. In the U.S. alone, over 2 million people suffer from lateral ankle sprains each year, with approximately 40% of these sprains leading to the development of CAI[2]. Despite a widespread need, there is not yet a sufficient bracing solution available. In partnership with Icarus Medical Innovations, we aimed to develop and test a custom 3D-printed ankle brace that addresses the functional limitations of current ankle braces on the market. Our brace features a dynamic tensioning system for adjustable stability, as well as multi-axial control of the ankle joint. The efficacy of this brace was then validated using an iterative computer-aided design process, patient feedback, and mechanical testing. Our brace was found to restrict users' maximum inversion angle by 62%, while a similar over-the-counter brace only restricted inversion by 21.8%, demonstrating that our brace provided substantial biomechanical support compared to other ankle braces on the market.

Keywords: *chronic ankle instability, ankle brace, computer-aided design, biomechanics*

Introduction

Acute ankle sprains are one of the most common musculoskeletal injuries with a high incidence among physically active individuals. In the United States alone, approximately two million acute ankle sprains occur annually[2]. Acute ankle sprains have a high recurrence rate, which is associated with the development of Chronic Ankle Instability (CAI)[2]. CAI is the residual damage and weakness of the ankle joint due to previous trauma or neurological disorder. Research has shown that 40% of the ankle sprains that occur will develop into CAI, leading to symptoms including discomfort or pain, swelling, and instability of the ankle leading to recurrent ankle sprains[4]. CAI encompasses a wide range of disorders such as foot drop, medial instability, and lateral instability. We chose to focus primarily on lateral instability because lateral sprains account for 85% of all ankle sprains and result in the greatest incidence of CAI[5]. As seen in Figure 1, lateral ankle sprains occur due to excessive inversion of the ankle joint and affect the anterior talofibular ligament (ATFL) and the calcaneofibular ligament[6].

Fig. 1. Diagram of ankle inversion. Highlighted ligaments are most affected in a lateral ankle sprain[3].

CAI gradually worsens over time and if left untreated can eventually lead to issues such as osteoarthritis or the degeneration of joint cartilage[1]. Some treatment options include surgery and physical therapy, but the most common practice is bracing. Although there are many bracing options as seen in Supplemental Figure 1, current ankle braces do not adequately treat CAI because they are uncomfortable, invasive, and unadjustable. The constant amount of force that traditional braces apply is a major issue when using a brace for an extended period of time because it can lead to soft tissue atrophy and a decrease in the ankle's ability to restrict excessive ranges of motion when the user is not braced[7]. Current bracing options are also limited in their treatment of CAI because they typically use the one-size-fits-all model and are tailored to the 50th percentile male[8]. This ignores the need of the atypical user and creates an underrepresentation in bracing technologies for specific demographics such as people with disabilities, people who are overweight, and women. No patient has the same needs when it comes to ankle recovery and support, making it difficult for many individuals to adequately treat their disorder with current bracing options.

In order to address these issues, our group worked with Icarus Medical Innovations to create an ankle brace with adjustable support, multi-axial control, and enhanced comfort and fit. Icarus is a medical device startup located in Charlottesville, VA that develops custom 3D-modeled knee braces. Icarus' technology uses a mobile device to take a 3D scan of a patient's knee, designs their knee brace in Autodesk Fusion360, and 3D prints the brace. We will apply this same methodology to create a custom modeled ankle brace. This project serves as a continuation of last year's team which concluded with a functional prototype and a patent on the technology used in the prototype. The patent is based on two key components of the design: adjustable stability (through the use of a tensioning dial) and multi-axial control. The tensioning dial allows users to manually increase or decrease the amount of tension in the brace and the multi-axial component essentially allows users to have full range of motion in every plane, aside from the plane of correction. Last year's group developed an early stage prototype that was functional, but has issues that limited its effectiveness (Supplemental Figure 2). One of the major issues was the migration of the ankle cuff down to the ankle when the BOA dial was tensioned, which greatly reduced the amount of support the brace could provide. Another issue was the ankle cuff being too flexible, resulting in the tensioning dial popping out of its insert in the ankle cuff.

The following specific aims were pursued over the course of this project to guide our efforts of ankle brace design and development:

Aim 1: Upon the basis of background research, develop a set of custom 3D-modeled ankle brace prototypes to combat various forms of CAI.

Aim 2: Collect qualitative and quantitative data on the brace prototypes from human subjects.

Aim 3: Synthesize data and leverage computational modeling methods to validate the product's biomechanical functionality.

Results

Brace Design

The design process was initialized by a previous BME capstone group that provided proof-of-concept and developed an early stage prototype to iterate and build upon. Although their group was focused solely on developing a brace to address lateral ankle instability, our initial goal – specified by aim 1 – was to develop a full set of ankle braces to combat multiple forms of CAI (foot drop, lateral, and medial). We designed our first prototype to address *foot drop,* a condition where an individual is unable to raise the front part of the foot due to weakness or paralysis of the muscles that lift the foot[9]. This brace featured a "hybrid" anterior cuff made up of a rigid plastic component to house the BOA dial and a more flexible thermoplastic polyurethane (TPU) shell which makes up the outer sides of the cuff (Figure 2). This design choice was made to address previous issues with the tensioning dial not being able to withstand enough force and popping out of a fully flexible TPU cuff. The tensioning dial provides force modulation in our brace and is crucial to the overall functionality of the design. Despite our new design containing some desirable features such as flexibility and increased security for the tensioning dial, it ended up being unsuccessful in practice because of difficulties connecting the two components. Therefore, we transitioned to developing a one-piece ankle cuff printed fully out of PA-12 plastic while incorporating a latticed pattern to allow the cuff to flex during use (PA-12 is a relatively rigid material). Similar to last year's group, we modeled and 3D printed a "wire guard" out of elastic TPU material. Functionally, this piece guides the two tensioning wires to anchor points on the bottom edge of the user's foot, helping to direct the force vectors applied by the tensioning system.

Fig. 2. Early-stage ankle brace prototype designed to address foot drop.

After discussing with our advisors, the decision was made to focus efforts solely on creating a brace for lateral ankle instability because the market for foot drop and medial ankle braces is not viable enough. Because of this, we translated our foot drop device into a brace that addresses lateral ankle instability. This was done by shifting the orientation of the ankle cuff and wire guard to the outside of the foot/ankle, which allowed the tensioning system to be adequately formulated to counteract ankle inversion. The lattice design in the anterior cuff was maintained, and a number of iterations and trials were used to optimize the shape and thickness of each piece. Up until this point, the 3D printed components mentioned above were stitched into a compression sock, with the idea being that it would be easier to don and more comfortable than typical ankle braces. However, in the middle stages of prototyping, we realized that the compression sock did not allow for adequate function because it was difficult to consistently anchor the tensioning system and integrate the 3D printed components into a material without much form or structure. As a result, we took our design in a different direction, while maintaining the main functional concept of the brace.

Figure 3 details the final brace design concept along with the key features and components of the brace. Instead of using a compression sock as in previous designs, we chose to outsource a mesh strapping brace for increased stability and support of the 3D printed components. These components remained stitched into the mesh base, but underwent further design modifications to enhance functionality and adapt to the new concept. The idea behind our final design was to have a tensioning dial housed within a smaller 3D printed piece, eliminating the full anterior cuff and replacing it with a more complex

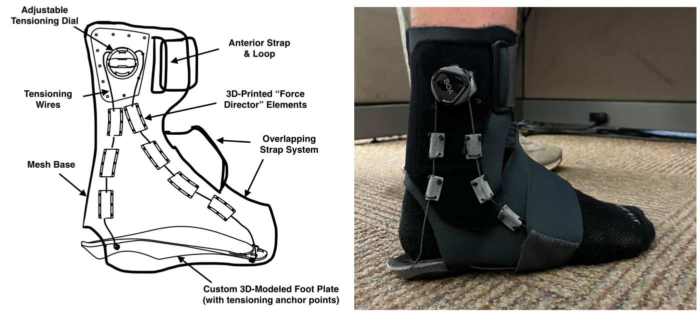

Fig. 3. Final brace design. Left image shows engineering drawing with key features and components labeled. Right image shows the final prototype.

strapping system. Two tensioning wires come out of the dial and are guided down the lateral edge of one's foot/ankle by "force director" elements, which replace the continuous wire guard seen in previous designs. This change was made in effort to obtain maximum force in the tensioning system by allowing the individual pieces to compress together as tension is engaged. The final prototype also includes a custom-modeled foot plate that anchors the tension wires, providing increased leverage and structure. The foot plate is 3D-printed using PA-12, and it has padding to ensure that it can be comfortably worn. Our design is sleek and low-profile, with the ability to be worn with shoes on. The synthesis of various features and concepts testing throughout our year-long design process ultimately led to a product with optimal function and user-friendliness.

Mechanical Testing

To gain insight on the performance of our brace, we began by testing three different mechanical metrics. In each of the three tests we made sure to fix each component in place with clamps to ensure no outside factors were influencing the results (Supplemental Figure 3). We first tested the maximum tension provided by the tensioning dial on each wire of the brace. To collect this data, we attached each wire of the brace, one at a time, to a force meter and then turned the tensioning dial to full tension. We recorded the force produced on the front wire for three trials and then repeated the process for the back wire.

The forces were recorded in Newtons and the results for the three trials from each condition were averaged. Next, we added the average forces from the front wire and the back wire to determine the average total amount of lateral support applied by the tensioning system to the foot plate. The averages for these three data points can be found below in Table 1.

Table 1. Maximum tension testing results.

	Max. Tension – Front Wire	Max. Tension – Back Wire	Total Tension
Average	12.83 N	25.5 N	38.33 N

The results showed that the front wire produced nearly 13N of force while the back wire produced 25.5N. This meant that the average total tension provided in the form of lateral support by the tensioning system to the footplate was 38.3N. In addition, as we expected, the majority of the force came from the back wire because it has a more direct path from the tensioning dial to the anchor point in the foot plate.

Next, we tested the minimum counterforce against inversion that the brace provided at full tensioning. To test this metric, we created a mechanism to test the amount of force generated by inverting the ankle. The force meter was clamped in place and hooked up to the brace, which was being worn by a participant, and then had the participant invert their ankle as much as possible. This protocol was performed on two people and the maximum force, in Newtons, for each trial was recorded. The trials were then averaged to find the average force produced when the ankle is inverted, which can be seen in Table 2. The minimum force in the inversion direction was found to be 23.23N, so we quantified this as the minimum counterforce that the brace provides as full tensioning. This metric is important because it quantifies the theoretical reduction in moment about the ankle joint due to the brace. However, this metric is based on the assumption that the brace's support system reduced inversion to 0.0 degrees, which was found to be untrue, meaning that the findings of this mechanical test are somewhat limited.

Table 2. Minimum counterforce against inversion results.

	Person 1	Person 2
Trial 1	29.0 N	22.2 N
Trial 2	29.2 N	23.0 N
Trial 3	26.2 N	24.5 N
Average	28.13 N	23.23 N

Lastly, we measured the angle of displacement for the footplate when the brace went from no tension to fully tensioned. This test was done by anchoring the brace and then using a digital goniometer to mark the beginning position of the foot plate, then fully tensioning the brace and marking the final position of the foot plate. With these two markers, the digital goniometer gave us the displacement angle of the footplate in degrees. This test was performed for three trials and the results were averaged. We found the average displacement angle of the foot plate from tensioning the brace to be 23.23°. This value was important to show that our tensioning system provided substantial displacement, because this displacement would equate to force about the joint when a person's weight is placed on the foot plate.

IRB

At the onset of this project, an IRB of this device had not been started. Therefore, to prepare for clinical testing, we created a protocol and submitted an IRB application with the intention of testing our ankle brace on patients with CAI. However, after six months of attempts through prereview, we have still not been able to get our application approved because of issues and questions related to our affiliation to Icarus Medical Innovations as well as FDA device classification. Still, we are looking to pass along our application so that clinical data can be collected next year. After prereview, our study will undergo a full board review by the IRB, and testing can begin as soon as it is approved by the board.

User Testing

While we were not able to get the IRB application approved, we did set up a testing protocol for our study. The goal was to get roughly 30 people into the lab in order to test three conditions: the study team's Icarus brace, a competitor over-the-counter (OTC) brace, and a control (no brace) condition. Our inclusion and exclusion criteria were developed in order to ensure we were testing the brace on potential users. Therefore, the criteria for participating in the study was for the participant to be between the age of 18-40, have CAI based on published standards, and have no other injuries to the lower limbs. These criteria would have ensured that we had a generally healthy participant which would have reduced confounding factors while collecting data. We were able to complete our protocol on each of the study team members as well as some friends. The following will discuss our proposed study protocol, which was completed on six people in an unofficial study. With each of the conditions, we tested balance, ankle range of motion (ROM), and the time to don (put on) and doff (take off) the two braces. Balance is affected by vision, ankle stability, and the nervous system. Therefore, our balance testing was completed with the participant's eyes closed to take vision out of the equation. The nervous system can come into play if there is a neurological issue that affects neural signaling. Therefore, we were curious to see if our ankle brace had any affect on ankle stability which is the third factor of balance. In order to test balance, our team used a pressure mat that allows you to observe the pressure the foot exerts on the force plate mat as well as how that pressure changes over the course of 10 seconds. The test took place with the participant's eyes closed, hands on their hips, and standing on one leg. The pressure mat observes how much the foot moves throughout the 10 second trial which is summarized in a statistic that represents the area of an ellipse around the foot. The balance protocol was completed for three trials for each condition. In order to test ROM in the inversion, eversion, plantar flexion, and dorsiflexion directions, we used a goniometer. The goal of our brace is to reduce movement in the inversion direction since that would cause pain and potential reinjury to our target patient. However, we still want to allow freedom in the other directions. The ROM protocol was completed for three trials per direction for each condition. Lastly, for the time to don and doff the brace, this was measured with a stopwatch. The goal of collecting this data was to make sure our brace did not drastically differ in times from the OTC brace.

As mentioned above, the data that we collected is not a part of any official study and was collected on the study team members and friends for a total of six people. With that being said, the data was consistent among the six participants. For ROM testing, our data can be seen in Table 3, which shows the average ROM in each of the four test directions.

Table 3. Ankle range of motion testing results.

	Plantar Flexion (°)	Dorsiflexion (°)	Eversion (°)	Inversion (°)
Icarus	36.056	15.556	12.611	12.444
OTC	41.806	14.972	13.722	25.611
Control	43.722	17.500	16.694	32.750

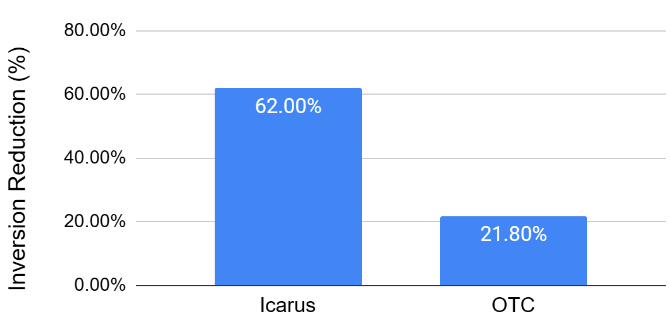

Fig. 4. The percent reduction of the inversion angle compared to the control.

Figure 4 provides a better visualization of the inversion restriction data, demonstrating that the Icarus brace restricted inversion movement by 62% while the OTC brace restricted inversion movement by 21.8% when compared to the baseline of the control condition. Additionally, the other directions were constrained more by the Icarus brace, but not by much.

As for the balance data, the software gave an output with the area of the ellipse for each of the three conditions. A larger area in the ellipse means there was less stability in the ankle while testing. Table 4 shows the elliptical area that was observed during testing. We did not find a significant difference in balance between the three conditions. For the time to don and doff the brace, we found that the Icarus brace took slightly longer to don and doff.

Table 4. Elliptical area from balance testing.

	Icarus	OTC	Control
Area (cm^2)	33.47	33.62	31.89

Discussion

Interpretation of Results

Although data was only collected on six participants,, the ROM findings were consistent with the goals of our brace design, which were to restrict motion in the inversion direction while allowing motion in the other directions. There was a significant difference in how much our ankle brace restricted inversion compared to the OTC brace. With eversion and plantar flexion, the Icarus brace restricted motion more than the OTC, but not by a large percentage. Additionally, for the dorsiflexion motion, the OTC brace restricted motion more than the Icarus brace. Our main concern, since the brace is designed for patients with lateral CAI, was to restrict the motion of inversion while also allowing freedom of motion in the other directions. Therefore, based on preliminary data collection, our group was successful in developing a functional ankle brace. The balance data did not show that either brace significantly improved balance, rather we saw similar stability levels throughout all conditions. With this being said, none of the people we collected data on have CAI, so if we were to test the braces on someone with CAI, we would likely see different results. People with CAI would likely have a worse baseline control condition and we would anticipate some improvements in balance associated with both braces. The time to don and doff the brace showed that the Icarus brace took longer on average to don and doff; however, the difference was a matter of no more than a couple seconds. Therefore, our group is satisfied given the complex nature of the brace that it is comparable in times to don and doff with the OTC brace.

Significance

Our brace has the potential to revolutionize the ankle bracing industry because of how it leverages additive manufacturing techniques (eg. 3D-printing brace components) while enhancing functionality, comfort, and ease of use. The aforementioned limitations within the current bracing market presents a massive opportunity to create a product that can be used by a wide range of CAI patients, from those with lingering weakness and discomfort, to those with severe instability and even pain due to recent ankle trauma. The dynamic tensioning system in our brace allows users to adjust the level of support provided externally, serving as a catered solution to their particular pathology. In addition, the fact that preliminary data demonstrates efficacy is a huge step towards achieving a final product that is marketable, cost-effective, and that can be scaled up in manufacturing.

Limitations

The biggest limitation of our project was the inability to get the IRB application approved due to time constraints. This led to only six participants in data collection, which is not enough to make any substantial claims about the efficacy of the brace. Despite this limitation, the preliminary data was very promising and the IRB application is awaiting approval.

Future Work

In order to bring this device closer to the market, future steps must be taken including improving the aesthetics of the brace, conducting patient testing, validating the results, and iterating the design based on patient feedback. Although the aesthetics of the brace are improved from our initial prototype, additional manufacturing and fabrication changes are needed to make the device into a marketable product. One necessary change is improving the method for integrating the force directors into the strapping system. Currently the 3D printed force directors are sewn into the strapping system which exposes knots and looks unprofessional.

Our group this year put a significant amount of effort into submitting the IRB. We hope this progress will allow a future group to start testing the brace early into their semester. This would allow the group to collect a sufficient amount of data and run statistical analysis on their results. From these quantitative results, as well as from patient feedback, we would like to iterate upon our brace design. Another future goal is to create a biomechanical model using OpenSim to validate mechanical and patient testing results. These future steps will bring us closer to our ultimate goal, which is to create a marketable product for Icarus Medical Innovations.

End Matter

Author Contributions and Notes

All authors completed background research and preliminary design ideation. A.K and W.P.Z designed the brace. E.F.D and E.E.M completed forms and submitted IRB application. All authors designed the study protocol and participated in testing procedures. E.F.D and E.E.M performed data analysis.

The authors declare no conflict of interest.

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