Thesis Project Portfolio

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

(Technical Report)

Analysis of the Disproportionate Rate of Lower Limb Amputations among Races

(STS Research Paper)

An Undergraduate Thesis

Presented to the Faculty of the School of Engineering and Applied Science

University of Virginia • Charlottesville, Virginia

In Fulfillment of the Requirements for the Degree

Bachelor of Science, School of Engineering

Emma Faith David Donatelli

Spring, 2023

Department of Biomedical Engineering

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Sociotechnical Synthesis

My technical work and STS research are connected as they both focus on the lower limb anatomy of humans. The technical project focuses on ankles and designing a product for the ankle to target a specific injury. The STS research focuses on lower limbs (legs) and a procedure that is associated with the limb. Both are treatment methods for underlying injuries and illnesses; however, the technical project is a common treatment method while the STS research project is used in extreme cases. Additionally, the STS research project is a life-altering and irreversible procedure while the technical work is an assistive device that can be taken off at any moment. While both projects have different aspects, the underlying theme is the same in that they both focus on improving patient health after an injury or disease.

My capstone team worked with Icarus Medical Innovations in Charlottesville, Virginia to develop a 3D-printed, customizable, and adjustable tensioning ankle brace. The design of the ankle brace went through numerous iterations starting with a cuff attached to a compression sock and ending with an orthotic and strapped support system. The goal of the brace is to target lateral Chronic Ankle Instability (CAI) which occurs when an ankle undergoes an injury to the lateral ligaments in the ankle and does not fully recover. Bracing is a common treatment method for CAI; however, our brace is unique in its customizability and tensioning system that allows the user to raise or lower tension in the brace based on their needs at the moment. One goal of our brace is to restrict movement in the inversion direction so the lateral ankle injury can heal while still allowing movement in other directions as to not hinder daily activities. The preliminary data shows that our brace does restrict movement in the inversion direction while still allowing movement in other directions.

My STS research focuses on the disparity among race seen in cases of lower limb amputations. A lower limb amputation is the removal of part or all of the leg (anywhere from the foot to hip) and can have many causes including underlying diseases including diabetes. Lower limb amputation should be one of the last options for a doctor to consider and preventative care should be attempted first. However, in the case of three teaching hospitals in Chicago, African Americans are more likely to get lower limb amputations when compared to white Americans. This is likely due to external factors such as economics and geographic location, but my paper argues that it is also due to biases that have been built into the healthcare system in America. The goal of my research is to provide a complete understanding of the disparity and expose the root issues of the problem.

Working on these two products simultaneously allowed me to ensure my technical work did not have underlying biases such as can be seen in my STS research. Seeing the unintended biases built into the healthcare system and with lower limb amputations while I was designing the ankle brace made me constantly reflect and ensure that the design was not intentionally or unintentionally excluding any groups of people. Our group saw that with our first design, it may be harder for older people to be able to put the brace on by themselves, which was an unintended bias in our design. As a result, we changed our design so that it would be easy for most people to put on. Overall, working on both the technical work and STS research at the same time made me constantly reflect on our design to ensure no biases were being built in, which ended up improving our overall design.

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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 Thesis-Related Assignments

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

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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 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.

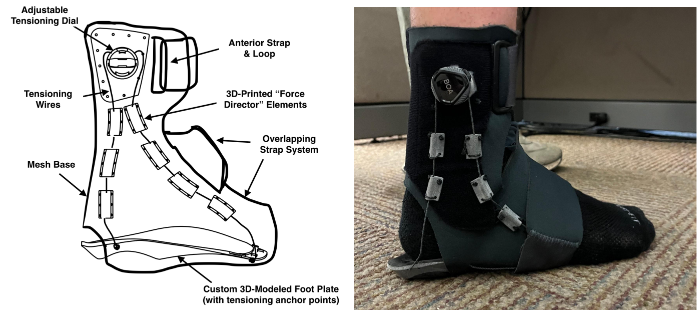

Fig. 3. Final brace design. Left image shows engineering drawing with key features and components labeled. Right image shows the final prototype.

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

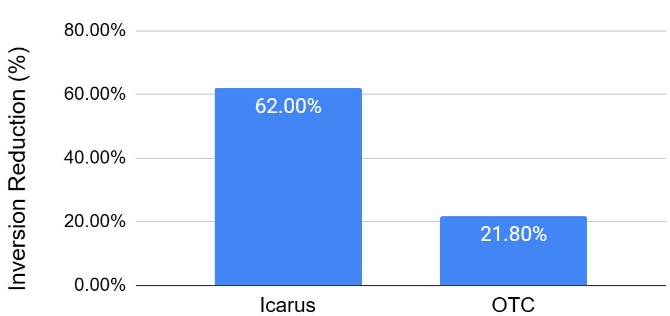

Fig. 4. The percent reduction of the inversion angle compared to the control.

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.

Acknowledgments

We would like to acknowledge our different capstone advisors Dr. Timothy Allen, Dr. Shannon Barker, and Noah Perry. We would also like to acknowledge our Icarus advisors Ben Scire, George Miroulis, Dave Johnson, and Evan Eckersley.

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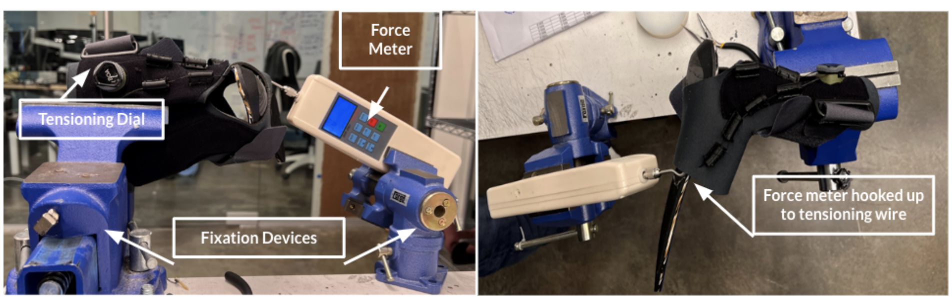
<u>Supplemental Material</u>

Supplemental Fig. 1. Three most common types of ankle braces.

Supplemental Fig. 2. Previous capstone group's final prototype.



Supplemental Fig. 3. Mechanical testing setup.

Analysis of the Disproportionate Rate of Lower Limb Amputations among Races

A Research Paper submitted to the Department of Engineering and Society

Presented to the Faculty of the School of Engineering and Applied Science
University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements for the Degree
Bachelor of Science, School of Engineering

Emma Faith David Donatelli

Spring 2023

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

Advisor

Benjamin Laugelli, Department of Engineering and Society

Introduction

Lower limb amputations are medical procedures that involve removing part of someone's lower limbs and can be necessary due to underlying diseases (Esquenazi, 2021). Treatment method of these diseases can depend on the patient's level of income, access to healthcare, race, and more. Because of this disparity in treatment, certain races are more likely to obtain a lower limb amputation over preventative measures such as medications and exercises (Swaminathan et al., 2022). Authors are currently approaching the cause of the disparity by looking at external factors such a patient's economic status and location. However, authors have yet to look internally at the healthcare system as the root of this racial difference. Failing to pay attention to both the biases within the healthcare system, and the racial and social differences will lead to an incomplete understanding of the disparity that leaves fundamental issues out. Because this treatment disparity is sociotechnical in nature, it requires attention to both the technical aspect of the structure of the healthcare system and the social aspect of race, socioeconomic status, and geographic differences in order to have a complete understanding of why there are racial differences observed in lower limb amputations.

By looking internally at the biases found within the United States healthcare system, I will develop a complete understanding of why this treatment disparity occurs. The racial differences seen with physician distrust and pain assessment are embedded into the healthcare system in America. These stigmas are the root of the issue and cause the disparity in lower limb amputations and other procedures. Technological Politics, the study of the influence technology has on society, will be used to analyze why the technology of lower limb amputations is able to advantage some groups of people while disadvantaging others. I will be reviewing a report and article written by 19th century physicians as well as a population-based survey of health care conducted in 1998, a telephone survey conducted in 1997, and a medical textbook from 1964.

Literature Review

While several scholars agree that race and other factors can affect the type and quality of healthcare treatment that people receive, scholars have not yet adequately considered that these disparities are the result of built in biases in the healthcare system. Specifically with lower limb amputations, studies have shown that people of color are more likely to undergo lower limb amputations rather than to take other preventative measures than white Americans are. These studies have only considered external factors that could cause this disparity and have yet to look internally at the healthcare system and the biases that were built into it during its formation in the United States as the main cause.

A study was conducted at three Chicago teaching hospitals to observe how differences in race can affect the likelihood of lower limb amputations and lower limb repeat amputations (Feinglass et al., 2005). The study found that African American patients were 1.7 times more likely to have undergone a lower limb amputation than white or other-race patients (Feinglass et al., 2005). The study considers how different patient conditions including diabetes, infections, and other diseases are correlated to lower limb amputation levels among African Americans, Hispanics, and white Americans (Feinglass et al., 2005). Feinglass et al. (2005) argue that race is a “significant independent risk factor” for amputation and they suggest that economics might also play a role by stating that “improving access to primary and preventive care for lower-income patients could reduce amputation rates among African Americans.” The source’s central question was to determine whether the rate of primary amputation compared with secondary amputation was higher among African American amputees as compared with other-race amputees discharged from the same hospitals (Feinglass et al., 2005).

Another study analyzed data from the National VA Surgical Quality Improvement Program and the Veterans Affairs Patient Treatment File to observe if race or ethnicity is independently associated with an increased risk for amputation versus alternative solutions (Collins et al., 2002). The study found that Hispanic and African American patients were each associated with a greater risk for amputation (Collins et al., 2002). African Americans were 1.5 times more likely and Hispanics were 1.4 times more likely to get a lower limb amputation over alternative solutions compared to white American patients (Collins et al., 2002). Collins et al. (2002) argues that African American and Hispanic patients with peripheral artery disease are at an increased risk for lower limb amputation and that location may impact the likelihood of someone getting a lower limb amputation.

The two arguments relate to each other because both studies are focused on observing whether there is a statistically significant difference between the likelihood of having a lower limb amputation and the race of the patient. They differ where they discuss the possible causes of this disparity with the first source citing economics and the second source citing location as possible factors. The shortcoming of these sources is that they are exclusively looking at external factors that possibly contribute to the bias in lower limb amputation and they do not look at whether this could be a result of biases that are built into the healthcare system as a whole. My argument will address this gap in the understanding of the racial disparity in lower limb amputations by looking at the healthcare system directly as the main issue. While the external factors such as social status, economics, and location are important in discussing the issue, more emphasis needs to be put on the biases within the healthcare system itself that are causing this disparity. This paper will use Technological Politics to observe the biases in the healthcare system, specifically associated with the differences of lower limb amputations seen among races.

Conceptual Framework

My analysis of the racial and social disparities seen in lower limb amputations draws on Technological Politics, which allows me to address how the technology of lower limb amputations contains biases. In 1980, Langdon Winner proposed Technological Politics where he suggests that technology has “politics” (Winner, 1980). The use of the word politics in this framework is different than the typical meaning of the word politics. Winner (1980) is referring to politics as the aspect of power relations. Specifically, Winner (1980) suggests that technology and technological artifacts have the ability to affect relationships of power among groups of people. This relationship can end up marginalizing or excluding some while advantaging others (Winner, 1980). Intentionality is a key point of the framework that looks at whether a bias is an intended or unintended consequence of the technological design (Winner, 1980).

Intended consequences, also known as explicit biases, are biases that are purposefully built into a technology’s design in order to exclude, disadvantage, or advantage certain groups of people. Unintended consequences, also known as implicit biases, are biases that were not built into the technology’s design, but the design still ended up marginalizing some groups of people. Drawing on Technological Politics, in the analysis that follows I begin by questioning whether the technology of lower limb amputations has implicit or explicit biases. Then, I will observe the racial and social differences in lower limb amputations and look into the reasons why these differences occur.

Analysis

Drawing on Technological Politics, I argue that lower limb amputations perform social and political work by privileging white American patients while marginalizing African American patients. In the case of lower limb amputations, I argue that the bias is an unintended consequence that stems from the systemic racism that exists in the healthcare system in the United States. In the argument that follows, I will analyze two biases that have been embedded into the healthcare system in America, both having the ability to disadvantage African Americans while advantaging white Americans. This advantage to white Americans means they are put at less of a risk than African Americans by not having to go through a risky procedure, not necessarily that the technology directly advantages them. Overall, this disadvantage to African Americans can lead to differing treatment outcomes which has the potential to be detrimental to health and life-altering, such as in the case of lower limb amputations. As a result, these biases are allowing the technology of lower limb amputations to have politics and influence the relationship of power between races.

Physician distrust is a widespread issue in the United States that is observed to be higher among African Americans (Armstrong et al., 2011). This distrust can lead to various outcomes such as a poor relationship between the patient and physician, a lack of confidence in healthcare providers, and people avoiding going to the doctor entirely. This becomes an issue with certain diseases such as diabetes mellitus and peripheral vascular disease which can become worse without treatment (Molina & Faulk, 2022). These diseases are among the most common causes of lower limb amputations (Molina & Faulk, 2022). If African American patients are not getting preventative treatment for these common diseases because of physician distrust, they are more likely to be forced into getting a lower limb amputation. Therefore, physician distrust has the ability to perpetuate the disparity in treatment outcomes, especially with lower limb amputations.

In 1998, the Center for Health System Change conducted a community tracking study which was a population-based survey on health and health care (Armstrong et al., 2011). Some of the questions asked include whether people trust their doctor to put their needs first, whether they think their doctor runs unnecessary tests, whether they think their doctor is influenced by insurance companies, and other trust related questions (Armstrong et al., 2011). These trust related questions were only asked of people who had seen a physician in the past year and the scores were summed to create an overall score where higher levels indicated more distrust (Armstrong et al., 2011). The mean distrust score was 16.5 for African Americans compared to 15.2 for white Americans (Armstrong et al., 2011). Similarly, there was a national telephone survey conducted in 1997 by the Institute for Minority Health Research (Corbie-Smith et al., 2002). The survey consisted of eligibility questions, questions about attitudes toward medical research, and demographic questions (Corbie-Smith et al., 2002). The researchers found that 15.2% of African Americans do not believe that they can freely ask their physician questions compared to 7.6% of white Americans (Corbie-Smith et al., 2002). Additionally, 45.5% of African Americans believe their physician exposes them to unnecessary risks compared to 34.8% of white Americans (Corbie-Smith et al., 2002). Lastly, 79.2% of African Americans believe that they would be used as a guinea pig without their consent compared to 51.9% of white Americans (Corbie-Smith et al., 2002). There were four more questions that they asked and overall, every question resulted in a higher level of distrust in African Americans than white Americans (Corbie-Smith et al., 2002).

It is important to note that throughout two different studies that were conducted on a total of thousands of people, the results consistently show that African Americans have a higher level of distrust than white Americans. These studies asked a wide variety of questions related to trust that physicians would do their job and with every question, the same pattern can be seen that African Americans are less trusting of their physicians when compared to white Americans. This pattern suggests that on average, an African American person has a worse relationship with their doctor than a white American does. It is important for a patient to be able to trust their healthcare provider since they can potentially have the ability to drastically alter the patient's life such as with lower limb amputations. As it was mentioned above, if a person does not trust their doctor, they may be less likely to go as often which can result in worsening of diseases and conditions. Additionally, as was seen in the question about feeling comfortable asking a doctor questions, African Americans are less likely to ask their doctors questions because they do not feel comfortable enough with their physician to ask questions. This becomes an issue especially with complex medical procedures because if a patient does not feel comfortable enough to ask their doctor questions about what their disease means and what their treatment options are, then they are less educated and more susceptible to their doctor mistreating them.

As it was shown that African Americans are less comfortable with and trusting of their doctors, they would be less likely to question their doctor or ask about other treatment methods. Particularly in the case of lower limb amputations, most patients regardless of race probably do not know what other treatment options exist; however, the statistics show that white American patients would feel more comfortable asking their doctor about other options as compared to African American patients. Therefore, the disparity seen in the amount of lower limb amputations that occur per race in the three Chicago hospitals is partly due to the physician distrust that has been deeply rooted in the healthcare system in the United States. This suggests that the technology of lower limb amputations contains implicit biases as a result of downfalls in the healthcare system. These implicit biases allow the technology to advantage white Americans and disadvantage African Americans by forcing more African Americans to get lower limb amputations rather than preventative treatments. Therefore, it is not merely an issue of external factors such as geographic location and economic status that cause this disparity. Although those factors may have some impact, it is due to the biases built into the healthcare system that cause the disparities we see in the Chicago hospitals.

As I have argued that physician distrust is part of the reason for why African Americans are more likely to get a lower limb amputation than a white American, some might think that even though patients may not trust their doctor, the doctor should be able to treat patients the same regardless of their relationship with the patient. But this view fails to consider that systemic racism and biases have been built into the healthcare system since its origin in the United States. A review was conducted on textbooks that are being used to teach new doctors and nurses. These textbooks were rated on their ability to thoroughly cover topics such as the prevalence of diabetes among African Americans. The results found that “none of the textbooks mentioned prevalence of prediabetes among African Americans or Hispanics” (Ethan et. al, 2014). Additionally, the study found that the “material presented often lacked essential information” (Ethan et. al, 2014). These current medical textbooks, that are teaching the newest generation of healthcare workers, are leaving out critical information that African Americans have a greater chance of diabetes. When gone untreated and without preventative care, diabetes can lead to amputations. A doctor should only do a limb amputation on someone that has gone through all other options and where a limb amputation is the best option left; however, this is not the case we see in the Chicago hospitals. This is due to doctors not being properly taught the signs of diabetes and how to preventatively treat diabetes. So even if society hopes that a doctor would be unbiased when treating a patient, as I discuss further below, physicians have built biased views into the healthcare system itself. There is no guarantee that doctors today will not have implicit biases as a result of these biased technologies and systems.

African Americans are systemically undertreated for pain compared to white Americans and this is due to false beliefs about biological differences that occur between races (Hoffman et al., 2016). In the 19th century, when white Americans still owned slaves, many physicians conducted research to prove that African Americans were biologically different from white Americans (Hoffman et al., 2016). Current medical research, diagnosis methods, and treatment methods are built upon previous medical research, so these supposed findings are embedded into the healthcare system still to this day. This leads to a bias within the healthcare system which causes doctors to implicitly treat African Americans different than white Americans. The difference in treatment can take form as doctors not taking patient’s pain seriously or altering their typical course of action and recommendations simply because of the patient’s race. As a result, this difference could be as drastic as amputating a limb rather than using other preventative treatment methods.

A journal article from 1826 is full of supposed biological differences that different physicians and scientists have found between African Americans and white Americans. Tidyman (1826) states that African American’s kidneys secrete less compared to white American’s kidneys, African Americans secrete more saliva, and that African American women menstruate less than white women. Additionally, he states that other physicians have performed leg amputations on African Americans and have “invariably found less nervous irritability” among

African Americans than white Americans (Tidyman, 1826, pp. 314-315). Similarly, there was a report that was initially published in 1851 that claims to have found biological differences between African Americans and white Americans. One supposed finding of the book states that an African American's "bile is of a deeper color and his blood is blacker than the white man's" and that his "bones are whiter and harder" than a white man's (Cartwright, 2004, p. 29). Cartwright (2004) suggests that there are differences, based on race, in almost every part of the human body including in the muscles, tendons, and organs. Even more recently bias can be seen in a textbook released in 1964 where physicians were taught to give higher doses of radiation to African Americans compared to white Americans. The textbook *X-Ray Technology* contained a chart that recommended that standard doses of radiation that are given to white American patients should be raised "40 to 60%" for African American patients (Jacobi & Paris, 1964, p.102). There was no data or reasoning given for this increase in radiation exposure.

Note that these observations from Tidyman are coming from physicians who are performing these operations and tests on African Americans at the time when they were still slaves. Therefore, I argue that any data that they might have collected or results that they found are already biased due to the imbalanced power dynamic between white American slave owners and African American slaves. With that being said, no data was even included with any of the claims that these physicians are making. Without any data to back up these claims, they cannot be validated or trusted. There should be data given alongside these claims and that data should then be replicated by other physicians to have any sort of substantial claim. If the thinking of physicians less than two hundred years ago, when the healthcare system in America was first being developed, was biased then these biases were likely built into the system. Since physicians truly believed that African Americans were biologically different than white Americans, there would be a difference in pain assessment and treatment just based on the race of the patient (Hoffman et al., 2016). These differences would have been built into the healthcare system through precedence, literature, and teaching. Particularly drawing on the section in the article that mentions leg amputations, physicians thought that African Americans could not feel as much pain as white Americans, so they were more likely to amputate an African American’s leg than a white American’s (Tidyman, 1826). Similar thinking was seen 100 years later in the textbook by Jacobi and Paris where doctors were being taught to give African Americans higher doses of radiation without being given any data or reasoning to support these higher doses. This biased thinking was less than two hundred years ago and it shows that the disparity among races of lower limb amputations occurred from the beginning of healthcare in America. We are still seeing a higher number of African Americans getting lower limb amputations than white Americans to this day in both three Chicago hospitals as well as among veterans. This suggests that this bias exists within the healthcare system itself and that physicians have passed down biases from generation to generation.

Conclusion

Using Technological Politics, I have argued that it is not simply external factors such as geographic location and economics that causes the disparity of lower limb amputations between races, rather it is due to biases that have been built into the design of the healthcare system itself that are the root cause of the disparity. These biases include physician distrust and misleading research that states African Americans are biologically different than white Americans. Both of these biases lead to African Americans being medically treated differently than white Americans, which is evident in the data collected from two different studies conducted in Chicago hospitals and among veterans. This argument gives readers a complete understanding of the racial disparity by showing that the issue goes deeper than most authors claim it does. Understanding that the healthcare system is the main issue will allow researchers to focus their effort on the root of the issue which is figuring out how to rebuild the healthcare system without biases rather than just trying to fix the surface level issues.

Word Count: 3,510

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Design of an Adjustable-Tensioning 3D-Printed Ankle Brace

Analysis of the Disproportionate Rate of Lower Limb Amputations among Races in Teaching Hospitals in Chicago, Illinois.

A Thesis Prospectus
In STS 4500
Presented to
The Faculty of
the School of Engineering and Applied Science
University of Virginia
In Partial Fulfillment of the Requirements for the Degree
Bachelor of Science in Biomedical Engineering

By
Emma Donatelli

October 27, 2022

Technical Project Team Members:
Ashar Kamal, Erin Mcilhinney, Will Zimmerman

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.

ADVISORS

Benjamin Laugelli, Department of Engineering and Society

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Introduction

Ankle sprains account for 85% of all sports related injuries (Maffulli & Ferran, 2008). Chronic Ankle Instability (CAI) is defined as the failure of rehabilitation after an acute ankle injury (Al-Mohrej & Al-Kenani, 2016). Ankle braces are a commonly used treatment for CAI. Looking at the technology of ankle braces is not sufficient on its own, it is also necessary to consider biases that occur in treatment methods. Similar to ankle injuries are lower limb amputations which can be caused by underlying diseases such as diabetes or vascular diseases. Treatment method can depend on the patient's level of income, access to healthcare, and race. Because of this disparity in treatment, certain races are more likely to obtain a lower limb amputation.

The broader goal that is advanced by the design of my technical project is to develop a brace as a treatment method that depends solely on the patient's anatomy and form of CAI and not on race, ethnicity, or socioeconomic status. This will be done by improving on existing ankle brace designs by making braces more specialized for each form of CAI, keeping the cost of the brace as low as possible, and making sure our validation testing is done on a diverse group of people. All of these improvements will help create a more effective ankle brace that better serves patients with CAI. Technological Politics, the study of the influence technology has on society, will be used to analyze the social factors in a case of disparity seen in the prevalence of lower limb amputations among races in Chicago, Illinois.

Failing to pay attention to both the amputation procedure, and the racial and socioeconomic differences will leave this challenge unresolved. Because this treatment disparity is sociotechnical in nature, it requires attention to both the technical aspects of ankle braces and limb amputation and the social aspects of race and socioeconomic status. In what follows, I elaborate a technical project that functions to develop a custom and adjustable ankle brace and an STS project that examines the disparate rate of lower limb amputation among races.

Technical Project Proposal

It is estimated that around 20% of all acute ankle sprains will develop into CAI (Al-Mohrej & Al-Kenani, 2016). Treatment methods for CAI include rehabilitation, strength training, taping, bracing, and as a last resort, surgery (Rodriguez-Merchan, 2011). There are many ankle braces on the market, but there are few that are custom-made based on the patient's form of CAI. Icarus Medical Innovations is a medical device startup located in Charlottesville Virginia that develops custom 3D modeled orthopedic braces. Icarus technology uses a mobile device to take a 3D scan of a patient's knee, designs their knee brace in Autodesk Fusion, and 3D prints the brace. My team's technical project serves to take this technology for developing knee braces and apply it to developing an ankle brace.

Studies have shown that bracing is effective in reducing the incidence of ankle sprains (Sharpe et al., 1997). Current ankle braces can be rigid, semi-rigid, or non-rigid, and the rigid braces contain hinges that restrict movement in certain directions (Alfuth et al., 2014). Current designs usually include padding on the bottom of the foot, some form of plastic or elastic shell to hold the ankle in place, and can contain Velcro or another material to hold together the brace and adjust tightness. Limitations of current ankle braces include higher costs, restricted movement, and generalized patient care. Current ankle braces serve as a one-stop-shop no matter the form of CAI and are not modeled to fit the patient's specific needs and anatomy. The anatomy of a lateral ankle sprain is different from a medial ankle sprain, yet patients are wearing the same brace to treat all forms of CAI. If patients continue to use generic ankle braces, then their recovery time will last longer and they will be more prone to recurrent injuries. By investing in a custom-fit ankle brace that addresses their specific needs, the patients will have more freedom in their movement and a better quality of life.

My team will design a 3D printed, custom made ankle brace that specifically targets the patient's form of CAI and is modeled based on their anatomy. Our design will include a BOA dial which allows for adjustable tension in the brace. Patients who suffer from CAI should use this ankle brace because it will help increase recovery times and decrease the number of recurrent injuries. These benefits will arise by adjusting the wire vectors in the BOA dial to fit the anatomy of the patient's foot and constraining the vectors to support a specific form of CAI. Our group has developed three specific aims to aid in the completion of the project. First, we will develop a set of custom 3D modeled ankle brace prototypes to combat various forms of CAI. Second, we will collect qualitative and quantitative data on the brace prototypes from human subjects. Lastly, we will synthesize data and use computational modeling methods to validate the brace's biomechanical functionality. To achieve these three aims, we will develop prototypes using Autodesk Fusion and print the prototypes using a HP Multijet Fusion 4200 3D printer. To test the prototype design, we will conduct stress and biomechanical testing to obtain quantitative and qualitative data from a patient study. Additionally, we will use OpenSim, a biomechanical modeling software system, to create a model of the ankle and validate the ankle brace's functionality.

Factors we plan on studying include how the brace affects balance, stability, gait (walking) patterns, and more. We will collect quantitative data using tools such as the Tekscan pressure mat which will allow us to monitor balance before, during, and after brace usage. We will collect qualitative data through google forms and surveys to gather feedback on comfort and aesthetics. Based on this data, we will iterate through the engineering design process and make improvements to the prototype.

STS Project Proposal

Lower limb amputations affect approximately 150,000 patients in the United States every year (Molina & Faulk, 2022). Common causes leading to lower limb amputations are diabetes, vascular diseases, and trauma (Molina & Faulk, 2022). Before turning to amputation, other medical options are sought out (Molina & Faulk, 2022). For example, with a diabetic patient, efforts are focused on achieving adequate glycemic control before turning to amputation (Molina & Faulk, 2022). Lower limb amputations are utilized for severely ill or debilitated patients in which amputation will improve their ability to perform daily activities, reduce pain, and improve their quality of life (Gil et al., 2019). In reality, lower limb amputations do significant social and political work; for example, a study conducted at three Chicago teaching hospitals found that African American patients were found to be 1.7 times more likely to have undergone a lower limb amputation than white or other-race patients (Feinglass et al., 2005). While the intention of a lower limb amputation surgery is to remove an impaired limb, the surgery tends to target African Americans, while Whites receive more preventative care before amputation is sought out.

Previous writers have used Actor Network Theory to consider the social factors associated with vascular diseases, a common cause of lower limb amputations, in healthcare (Greene, 2005). Writers have not yet used Technological Politics, the study of the influence technology has on society, to consider the affects lower limb amputations have on societal standings. In the book *Network theory in vascular laboratories*, Kathleen Greene (2005) suggests that “the technology is a factor that advances the power, influence and leverage of the technologist and the physician over the patient and his/her disease" (p. 15). I will be considering the technical and social impacts of lower limb amputations to argue that the technology is marginalizing people who have lower income and do not have adequate access to healthcare, which tends to be African Americans. If we continue to think that lower limb amputations only perform the functional work of surgically removing part of a limb, we will miss how it also works to express the power relations among different races. We will become more educated and could potentially reduce the disparity by understanding the disproportionate power relationship among races that limb amputations perpetuate.

Drawing on Technological Politics, I argue that lower limb amputations perform social and political work by privileging higher income patients while marginalizing lower income patients. These higher income patients tend to have better access to healthcare and are able to take preventative measures before turning to amputation. Typically, those with better healthcare access tend to be White while those with less access to healthcare are African American and Latinos (Waidmann & Rajan, 2000) . Langdon Winner (1980) proposed Technological Politics which suggests that technological designs can affect the relationships of power and privilege among groups of people. This relationship can end up marginalizing or excluding some while advantaging others (Winner, 1980). Intentionality is a key point of the framework which looks at whether a bias is an intended or unintended consequence of the technological design (Winner 1980).

In the case of lower limb amputations, I argue that the bias is an unintended consequence that stems from the systemic racism that exists in the healthcare system in the United States. To support my argument, I will analyze evidence from a multihospital study conducted in teaching hospitals in Chicago, which provides information about the racial differences observed in lower limb amputations (Feinglass et al., 2005). This study considers how different patient conditions including diabetes, infections, and other diseases are correlated to lower limb amputation levels among African Americans, Hispanics, and Whites. Using this evidence, I will look further into the racial differences in limb amputations and why these differences occur.

Conclusion

At the conclusion of the technical project, our team will have a fully functioning ankle brace that targets each patients' form of CAI, allows for dynamic, adjustable tensioning, and improves ankle injury recovery. Additionally, Icarus will be able to present the brace to investors and to manufacture the brace. The STS research portion will use Technological Politics and the case of disparity found in the Chicago teaching hospitals to determine how the technology of lower limb amputations has built in bias against certain races. I will apply the insights found in this case to the design of our technical project by being consciously aware of the biases that could occur and actively working to ensure no biases are built into the design. The combined results of the technical and STS reports will address the broader sociotechnical challenge of disparity in treatment methods based on race and socioeconomic factors.

Word Count: 1,762

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