Impact of Additive Manufacturing Techniques on Underrepresented Patient Demographics in the Bracing Industry

A STS 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, VA

In Partial Fulfillment of the Requirements of the Degree

Bachelor of Science, School of Engineering

Evan Wendell

Spring 2022

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

Advisor

Joshua Earle, Professor of STS, Department of Engineering and Society

Abstract

As technology develops, society's ability to solve complex health related problems and improve the overall human experience is increasing. The medical field is benefitting extraordinarily from these advancements in technology. Cures for diseases are being discovered, precise surgical techniques are producing beneficial outcomes, and tissue engineered therapies for wound healing and organ failure are being developed. However, despite rapid acceleration in the capabilities of imaging systems and production technologies, the bracing industry has remained relatively stagnant in innovation. My STS Thesis examines why the bracing device industry remains dependent on the mass production of largely ineffective, commercial-off-the-shelf (COTS) bracing solutions despite the emerging capabilities of imaging and production technologies. Using Actor-Network theory and the idea that artifacts hold inherent politics, I show how the current production technique of large scale braces results in descrimination and biases on the basis of gender, size, weight, ability and socioeconomic class. By investigating the potentials of additive manufacturing techniques and rapid prototype techniques as viable alternatives to mass production, I analyze the impacts that the adoption of these techniques could have on the current bracing solution landscape and how it could promote a more inclusive industry. Ultimately, I aim to demonstrate the possibilities and challenges that innovation would bring to the bracing device industry.

Introduction

Medical device technology has provided many beneficial outcomes for society when implemented properly. The production of various braces for virtually every aspect of the human body has made mobility attainable for a vast majority of the general population. Despite this, the bracing industry falls short of capturing true equity. Mass production produces bracing solutions tailored to the body architecture of the 50th percentile male (Bridger, 2009) (Easterby, 1982). In the study of ergonomics, Bridger states that it is important to design in order to encompass a statistical population of potential users. When applied to the mass produced landscape of bracing solutions, this population is based around the 50th percentile male. By doing this, demographics such as women, disabled populations, and the extreme weight, height, and size population are severely underrepresented in the bracing industry. The large scale production technique of current bracing solutions results in poorly fitting and ineffective braces for these demographics. As a direct consequence, patients within these demographics that are in need of an effective solution are reliant on extremely expensive braces. This results in a disparity between the availability of effective bracing solutions based on socio-economic class. However, with a shift in the production of bracing solutions to Rapid Prototyping Techniques (RPTs) such as Additive Manufacturing Techniques (AMTs), effective products can be made available to a larger patient population.

Research Methods

Analysis of the bracing industry was performed using two STS lenses. Initially, I explore the current bracing industry using Actor Network Theory (ANT). Using this lens, I am able to identify actors within the bracing industry network and analyze how they interact. I focus on the relationship between the underrepresented patient as the actor and the healthcare system as the network. By analyzing the effect that ineffective bracing solutions have on both the actor and the network that the actor is a part of, I present an explanation for why inequality exists. Expanding on this concept, I use the idea that artifacts have inherent politics to look at how the mass production manufacturing technique produces these braces that undervalue demographics not encompassed by the 50th percentile male (Bridger, 2009) (Easterby, 1982). These two STS lenses provide a framework to understand how the network that is the healthcare system uses the mass production technique of artifacts to exploit underrepresented populations for monetary value. Finally, using the lens of ANT once more, I question how RPTs would diminish the biases towards underrepresented demographics in the bracing industry. Through these lenses, I am able to identify the inherent biases that the bracing industry holds towards specific demographics and propose beneficial outcomes that the adoption of AMTs could provide for equality through accessibility to effective bracing solutions.

Landscape of the Large Scale Bracing Industry

The bracing industry addresses anatomical injuries. By providing a vast array of solutions, healthcare professionals are able to address a number of injuries such as sprains, fractures, and congenital defects for patients in need of an orthotic brace. In reality, the majority of patients require a simple COTS brace to address their injuries. The production method of these braces has been considered the status-quo for decades by the bracing industry; Mass production is an efficient, cost-effective way to produce thousands of bracing solutions. Ergonomics suggests that companies design solutions for a population of users. By doing so, they attempt to encompass that entire population. However, statistically speaking, 90% of the target population ends up being represented by the design of a solution (Bridger, 2009). In the case of the bracing industry, mass production limits the percentage of the population that a solution can encompass even further. This is because the production technique requires the solutions to be tailored to specific ergonomic dimensions. Deemed the most encompassing body type, mass production tailors bracing solutions towards the 50th percentile male body.

For the population of users whose anthropometric dimensions align with the 50th percentile male, there exists a cheap, accessible, and effective solution. However, for the number of demographics that do not fall under the 50th percentile male description that these solutions are designed for, this is not the case. The root of the problem resides in society's dependence on classification (Bowker & Star, 2008). In the bracing industry, normal is classified as the 50th percentile male. This classification is made in order to simplify complex body types of the human population in the eyes of the bracing industry. Having multiple body types and classifications for different demographics would increase the complexity of the required bracing solutions. Using a large-scale manufacturing method like mass production provides bracing device companies the luxury of relying on the population that the 50th percentile male description encompasses. This is due to the fact that they produce products in such a cheap and cost-effective manner that they are not forced to target the entire human population in order to turn a substantial profit (Williams, 1987). As described by Karel Williams, mass production is not practical when the user needs are so niche and specialized. Despite there being a prevalent need for these specific solutions, the bracing industry continues to heavily rely on mass production for a cheap, standard, COTS bracing solution. This conscious decision by the industry can be further analyzed through ANT.

Using the STS lens of ANT requires identification of a network as well as the actors within that network. For the purposes of this research paper, I have chosen the network of healthcare system as it relates specifically to orthotic bracing solutions and the actors that operate within the confines of this network are orthotic brace manufacturers, hospitals, medical insurers, and patients that require bracing solutions. In the current landscape, the network has used the classification of the 50th percentile male to promote the production of general, mass produced solutions. By doing so, the majority of the affected patient population is able to obtain a cheap and sufficiently effective solution and simultaneously, brace manufacturing companies make a lucrative profit. The network has been designed to satisfy both parties using this mass production technique. However, this network is not without its flaws.

Underrepresentation

Classifying patient populations into the 50th percentile male has societal consequences for demographics that are not encompassed by this description. The dependency on mass production tailored towards this classification for COTS solutions creates underrepresented patient populations when it comes to cheap, obtainable, and effective bracing solutions. These demographics include women, disabled populations, those who are very tall or short, fat or skinny, or have other bodily proportions outside this limited range. For patients in these populations, readily attainable solutions that are both affordable and able to effectively treat injuries and needs are severely limited.

Through classification, the bracing industry has deemed these groups to be imperfect (Clare, 2017). In *Brilliant Imperfections: Grappling with Cure,* Eli Clare describes the ideology of “cure” as the devaluation of human differences in the medical industry resulting in systemic eugenic treatment of non-normal human lives. While this research paper does not go so far to suggest a presence of eugenic treatment in the bracing industry, there is merit to the argument that devaluation of “imperfect” lives exists. In addition to discrimination against disabled bodies, women have been experiencing this for generations (Wajcman, 1991). In *Feminism Confront Technology,* Judy Wajcman analyzes how being a predominantly patriarchal society throughout history has led to the medical field designing instruments for the use of men. This is directly represented in the mass produced bracing market as previously described. The underrepresentation of these demographics has cornered them into pursuing alternative options to mass produced COTS bracing solutions.

Socio-economic Discrimination

Often, patients in categories outside the 50th percentile male are forced to resort to specialized bracing solutions. These products are more expensive than the standard COTS braces because they are not mass produced. Companies rely on molding and casting techniques to create these specialized braces for advanced patient needs. While insurance should cover these medical expenses, there are often cases where the patient will be left to pay a large sum of money and there are even cases when insurance will not cover the cost at all (Zifchock, 2008). When obtaining an effective bracing solution is not financially attainable, the patients become reliant on insufficient COTS braces and eventually may be forced to resort to surgical intervention for a long term solution. In other words, the actor is dependent on the network due to the network’s inherent biases (Ignacio, 2020). The network maintains this dependence through inherent politics that braces hold. Mass produced braces are not designed to adequately remedy injuries for all body types thus leaving those body types with less than ideal avenues to pursue in order to aid their injury. Therefore, by maintaining perpetual dependence, I argue that braces hold inherent politics that financially benefits the healthcare industry (Winner, 1980). The inherent politics that the braces hold over a reliant patient population emphasize how crucial it is to ensure that patients are given the necessary accessibility to effective solutions.

The ineffective solutions ensure that dependent patients will continue to need new solutions. This will inevitably result in them purchasing additional bracing solutions through their doctors and healthcare providers. The network itself is set up in a way to exploit the actors. By creating solutions that are easily accessible, effective, and personalized to specific patients' needs, there would be less dependence upon expensive bracing solutions and there would be less need for surgical intervention. These are two aspects of the healthcare industry that have been deemed crucial for capital (Best, 2020). However, just because the current network operates this way does not mean that it is correct or permanent. Currently, it can be widely attributed to the production techniques of bracing companies. Because of the current day's lack of cost efficiency outside of mass production, prices for specialized bracing solutions need to be expensive. With the introduction of additive manufacturing and cheap customizable solutions, the network could be changed for the better.

The Capabilities of Additive Manufacturing Techniques

Innovation in technological capabilities has given rise to a number of different manufacturing techniques. Despite the current large scale bracing industry’s devotion to mass production, there are cutting edge technologies in today’s society that can be utilized to combat the discrimination in the bracing industry. Currently, the most prevalent in the bracing device landscape are Rapid Prototyping Techniques (RPTs). Rapid prototyping in the bracing device industry is the fabrication of a fully functional orthotic from a three dimensional model without the use of machining (Barrios-Muriell, 2020). This production technique has given rise to Additive Manufacturing Techniques. Additive Manufacturing is a specific form of rapid prototyping that involves the use of 3D printing, a technique that has proven to be effective in producing strong, lightweight parts out of polymers and thermoplastics. Additionally, with additive manufacturing, it is possible to produce complex geometric designs that allow for customization and personalization of parts. These features are ideal for applications within the bracing device industry.

Despite the clear benefits of additive manufacturing, it is currently responsible for only 0.4% of the production within the medical industry (Thomas & Gilbert, 2014). There is significant opportunity for the growth of AMTs in the orthotic bracing industry. Pursuit of this opportunity for growth would have significantly beneficial impacts on society. In *Care Works: Dreaming Disability Justice,* Leah Lakshmi Piepzna-Samarasinha explores what she calls care webs (Piepzna-Samarasinha, 2021). This is the idea that society has an obligation to care for disabled people outside of the medical-industrial complex. While I believe this to be valid, I also see potential for the medical industry itself to create more effective care webs when it comes to bracing solutions. Using the idea of care webs, Piepzna-Samarasinha argues that society should view it as a pleasure rather than a burden to support disabled populations. In the current bracing industry, a burden is exactly how it is presented through a necessary increase in time, cost, and man power in order to produce effective orthotic solutions for people with disabilities. With the implementation of additive manufacturing, the process of caring for these demographics would become comparable to caring for a simple ankle sprain thus increasing the reach of the care web produced by the bracing industry.

Expanding care webs for all demographics should be at the forefront of medical innovation strategies. Additive manufacturing has proven it has the capability to do just that in multiple medical disciplines. The development of hearing aids and dental models for dentures shows the viability of additive manufacturing within the medical field (Dodziuk, 2016). Sophisticated printers such as the Connex500™ and Multi Jet Fusion (MJF) 3D printers are able to print parts out of new materials such as Polyamide 11 (PA11) and Thermoplastic Polyurethane (TPU) (Tey, 2021). The novelty of these materials is their flexibility. With flexion moduli ranging from 66.1-77.87 MPa based on the orientation of the applied stress, TPU exhibits very high flexibility under small stress (**Figure 1**).

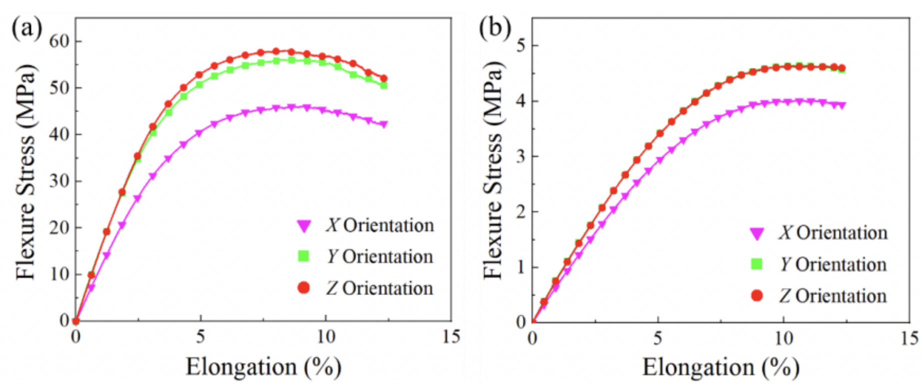

Figure 1: Stress-strain curves of flexural specimens: (a) PA11 and (b) TPU from "A comprehensive investigation on 3D printing of Polyamide 11 and thermoplastic polyurethane via multi jet fusion" by Tey, W. S., Cai, C., & Zhou, K. (2021)

Having the ability to print extremely flexible materials alongside the standard Acrylonitrile butadiene styrene (ABS) and polylactic acid (PLA) materials that possess much stiffer material properties gives engineers the option for variability in their designs of orthotic solutions thus allowing for geometries such as breasts and birth defects or abnormalities to be compensated for accurately and with ease (Barrios-Muriel, 2020). While it seems like additive manufacturing should be catching the attention of orthotic bracing companies, many continue to focus on mass production of their braces while smaller, niche companies use machining intensive and costly methods to manufacture braces specific towards the underrepresented populations.

Economic Challenges

At the core of the hesitance of the bracing industry to fully invest in additive manufacturing is the numerous economic challenges for creating a business that utilizes AMTs. Of these challenges, the most prevalent are production efficiency, profitability, and scalability. These are aspects of industry that can't be overlooked for the obvious reason that if you are unable to produce enough products at a price that allows you to make a profit, the business will fail. Fabricating products using AMTs is costly when compared to methods such as plaster molds as it stands. To overcome this, companies who adopt additive manufacturing would need to produce vast quantities of products in order to stay competitive in the orthotic brace market. However, because 3D printing is a relatively new technology, it is constantly evolving. Therefore, companies are wary of investing in large quantities of 3D printers under the assumption that a more advanced version will soon be available. This has been the roadblock that additive manufacturing is on the cusp of overcoming (Mardis, 2018). As the capacity of technology increases, the challenges that AMTs face will become surpassable.

Opportunities for additive manufacturing to become more cost effective than traditional manufacturing techniques exist through changes to the supply chain. As Douglas Thomas and Stanley Gilbert describe in *Costs and Cost Effectiveness of Additive Manufacturing,* opportunities lie in the ill-structured costs and challenges lie in the structured costs (Thomas &

Gilbert, 2014). Because 3D printers have the ability to fabricate a number of different parts simultaneously, the production of an entire assembly is centralized. This reduces the steps in the supply chain and in production. Furthermore, this could lead to faster production times allowing for companies to produce assemblies and parts alike on demand thus essentially eliminating the need for inventory of unordered parts (Trauner, 2018). This presents a clear benefit to AMTs over traditional manufacturing techniques. However, equipment and material costs remain an issue. Currently, the cost of an aluminum alloy part is roughly 1000% more for AMT than for traditional manufacturing (Atzeni, 2010). Furthermore, the machine cost is responsible for approximately 62.9% of the entire production cost for additive manufacturing as calculated by Lindemann in his attempt to understand the cost drivers of additive manufacturing (Lindemann, 2012). Industry's answer to these expensive costs lies in the economic principle, economies of scale. Simply stated, the scale of enterprises is directly responsible for cost advantages.

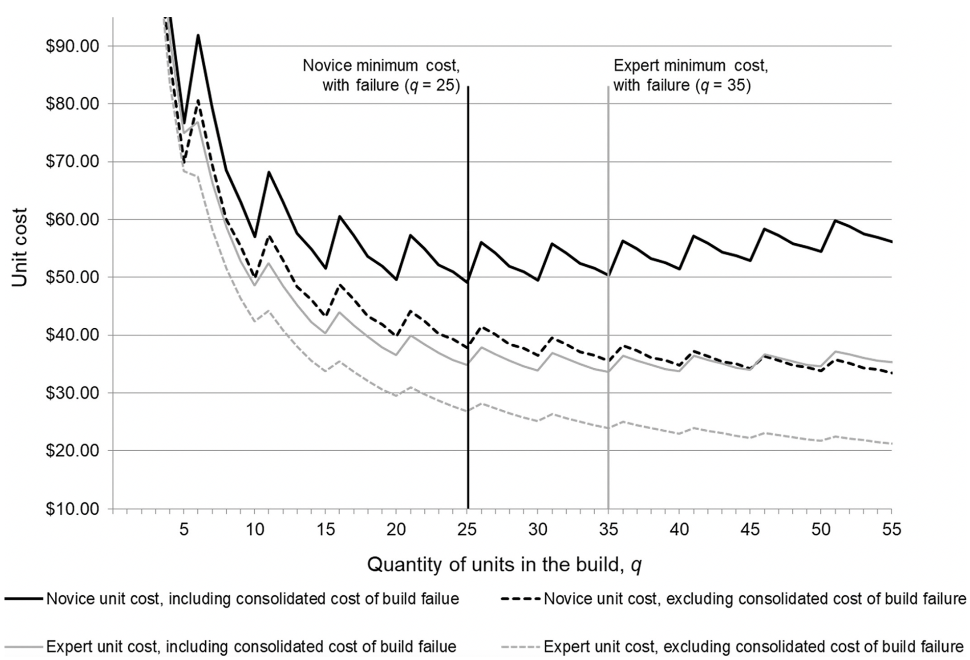

Figure 2: Cost and Quantity Relationship for Additive Manufacturing: Illustration of quantities of scale from 'On the economics of Additive Manufacturing: Experimental Findings' by Baumers, M., & Holweg, M. (2019)

Under this idea, if industry adopting AMTs upscaled their infrastructure in order to increase output, the cost of materials and machines would decrease (**Figure 2**). A significant initial investment would be required but the potentials that AMTs possess to decrease supply chain costs coupled with the inevitable decrease in material and machine costs would give way to an extremely profitable business model.

Social Impact

With the economic challenges addressed, it is important to acknowledge the probable social implications of a shift towards additive manufacturing. The production process itself differs from that of mass production and standard casting techniques including, but not limited to, the allocation of the workforce. With the decrease in machining and the simplification of the supply chain, the introduction of AMTs would cause workforce displacement. An industry reliant upon 3D printers would change the machine shop floor similar to how current day mass production and the assembly line altered the course of history (Marx, 1887). Karl Marx explored how the assembly line and mass production would displace human labor in the late nineteenth century. In a similar manner, AMT would affect machine workers and production floor management because of the simplification of the process. Since the only machine required for 3D printing is the printer itself, a skilled workforce that is able to program and maintain the previous generation of machines will be extraneous. Emphasis will be placed on the engineer using CAD software and the skilled worker who programs the machines will slowly become obsolete. This will see many skilled laborers displaced by warehouses filled with vertically arranged 3D printers. While 3D printers still need to be maintained and managed, this will require a completely different set of skills and require fewer laborers. Therefore, workforce displacement will be prevalent following the adoption of additive manufacturing.

Furthermore, an inevitable outcome is the further integration of the human race with technology. Donna Haraway argues in *Cyborg Manifesto* that even in today's technological age we should consider ourselves cyborgs (Haraway, 2018). The successful, large-scale implementation of AMTs into not just the bracing industry but the medical device industry as a whole would increase human dependence on technology. While some argue that this could be bordering on transhumanism, I argue that this simply approaches a reality in which disabled individuals are cared for through technology that is designed to value their unique experience (Earle, 2019). By recognizing these individual experiences, categories such as gender and ability may become obsolete in the bracing industry leading to less strict classification and a larger acceptance of body types outside of the 50th percentile male. The overwhelming benefit that society would see from this becoming a reality is reason enough for the adoption of AMTs to be viewed as a necessary step in the advancement of health sciences. Socially, improvement in the lives of people who have been negatively impacted by the inherent biases of the bracing industry is a much desired outcome.

Conclusion

Advancements in technology continue to advance both our understanding of medical problems and how to effectively solve those problems. The bracing device industry has a responsibility to utilize these technologies to provide solutions for all patients. Mass production has resulted in an industry that represents individual patients as a general classification: the 50th percentile male. Populations that aren’t encompassed by this classification, are forced to resort to expensive and complex solutions that can be unattainable thus leaving these populations with poor quality solutions, or without solutions at all. After decades of dependence on mass production, the bracing industry needs to embrace technological advancements in imaging and production techniques. Rapid Prototyping Techniques such as Additive Manufacturing have the capacity to shift the industry towards mass customization. By doing so, the bracing industry would be able to provide attainable and effective solutions to a wider percentage of the patient population. This is necessary in order to foster a healthcare environment that fosters equality for all demographics.

Based on the analysis presented in this research paper, a clear alternative to mass production is possible for producing commercial-off-the-shelf braces in the orthotic bracing industry. As Actor Network Theory suggests, if the network were to shift towards Rapid Production Techniques as its preferred method of production, the actors would exist within this network and evolve their relationship. The ability to customize solutions for specific needs suggests that the patients and companies would benefit from this shift in production technique. That being said, the possibility of worker displacement is present under this shift in production technique. This is something that may not be avoidable but has the potential to be mitigated. Despite these challenges that would need to be addressed, this would represent a shift away from mass production and towards a focus on mass customization thus resulting in a more inclusive and equitable bracing environment.

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