

# **Development of a Dynamic Tensioning Ankle Brace for Chronic Ankle Instability**

(Technical Report)

# **The Medical Network: An Analysis of the Factors Influencing Medical Prescriptions**

(STS Research Paper)

An Undergraduate Thesis Portfolio

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By

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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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## **Sociotechnical Synthesis**

In recent years, we have seen an unparalleled development in technology leading to new manufacturing methods, complex computer aided design processes and extremely accurate data collection. Despite this, innovation in the medical device industry has been hindered by intense regulations and established distribution networks that are resistant to change. The US Food and Drug Administration's (FDA) regulations on devices make the development of these devices costly and time consuming. On top of this, medical devices are dependent on approval from physicians and insurance companies to achieve mass-scale distribution to patients. Extremely innovative and effective devices have failed to prosper simply due to their inability to earn physician loyalty. The combination of these factors has created a lack of device innovation in the external bracing subsection of the medical device industry. The distribution of bracing devices in the US is dominated by a small number of large corporations that have established physician exclusivity to their products. The following technical thesis aims to address these issues by introducing innovative processes for the design and manufacturing of bracing devices, while the corresponding STS thesis examines the factors that are influencing physicians' prescription decisions in our healthcare system.

The technical thesis proposes an innovative ankle brace designed to treat chronic ankle instability. The production of the device uses patient data obtained from a 3D scan of the ankle to rapidly model a custom brace using computer aided design methods. The model is manufactured using 3D printing technology that provides high cost efficiency and the potential for mass scalability. Currently, the external bracing industry relies on manufacturing methods such as injection molding for the production of rigid components, making custom braces time consuming and expensive to manufacture. Due to this, bracing companies seeking mass distribution have placed a focus on standard 'off the shelf' braces that provide less functionality and comfort to patients. By establishing a methodology to produce custom braces just as efficiently as non-custom ones, this technical project introduces the potential for extreme innovation in this industry.

The STS thesis analyzes what factors contribute to the inconsistencies seen in the treatment decisions of medical professionals. Medical device companies and insurance providers are established as the major entities that have gained influence over the distribution of medical devices in our healthcare system. These private entities hold control over the device production

and the financial coverage of devices, covering both sides of the distribution process. This thesis examines the ways in which this network has affected the level of care provided to patients and why the medical industry may be more profit driven than we believe.

Ultimately, both of these projects aim to improve the healthcare industry in our country by introducing innovations in the external bracing sector, while also uncovering the factors negatively impacting the level of care provided to patients. Both of these could become crucial to establishing a healthcare industry that is truly focused on the treatment provided to those suffering.