# Electromechanical Bioreactor for Volumetric Muscle Loss Treatment (Technical Paper)

Corporate Social Responsibility in The Hair Care, Beauty, And Medical Industries: A Deontological and Virtue Ethics Analysis of Hair Care Companies (STS Paper)

> 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 **Aparna Kola**

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Technical Team Members:

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

Steven R. Caliari, Department of Chemical Engineering

Bryn E. Seabrook, Department of Engineering and Society

## **Prospectus**

#### Introduction

Volumetric Muscle Loss (VML) injuries are debilitating and affect veterans disproportionately in comparison to civilians as 92% of warfighters with muscle deformities have VML (Corona et al., 2015). These injuries result in permanent loss of muscle tissue and function and in extreme cases, the consequent loss of whole-body function. Current research in the regenerative medicine space targeted towards VML injury repair fails to reconstruct the cellular environment of the neuromuscular junction (NMJ), and there is a need for a technology that holistically mimics the chemical, electrical, and mechanical forces of the NMJ. In efforts to address this need, the Caliari Lab at the University of Virginia Department of Chemical Engineering is building a collagen-glycosaminoglycan-polypyrrole (CG-PPy) scaffolds to better mimic the three-dimensional, anisotropically aligned, and electrically conductive NMJ and research neural and muscle cell growth on this novel tissue engineering construct (Basurto et al., 2021). A component of this five-year research proposal includes electrical and mechanical conditioning of the cell-seeded-scaffold to align the particles for optimal cell growth which is achieved by the final technical deliverable of the capstone research team. The capstone team has been tasked with designing and fabricating an electromechanical bioreactor capable of electrically and mechanically stimulating the cell-seeded-scaffold in a cell-incubator environment. The final technical deliverable is a working prototype of the bioreactor with an interface to adjust the electrical and mechanical stimulation along with preliminary testing data.

As VML from NMJ injuries affects some populations disproportionately in comparison to others, the broader question follows—are some groups affected by certain phenomena more than others? This curiosity is explored in the case of a recent class-action lawsuit titled Whipple v Johnson & Johnson Consumer Inc. in which Johnson & Johnson's OGX Shampoo and 2

Conditioner line is contested to have harmful levels of a carcinogenic compound with a lack of appropriate contingency measures taken by the company (Whipple, 2021). With the recent rise of the natural hair movement, most prominent in the curly hair demographic, companies are responding by catering new products and marketing to natural, curly hair. This phenomenon begs the question whether certain minority groups have been affected by this harmful compound (Simeon, 2021). The relationship between hair care companies and their users, including the sociotechnical aspects of hair beauty and medicine, must be examined to better understand what responsibility these companies have as large influencers in the hair care space. The final sociotechnical deliverable is a virtue ethics analysis of the evolving relationship between hair care companies are affected in this relationship, and what responsibility companies hold in this equation.

### A Novel Electromechanical Bioreactor for Volumetric Muscle Loss Tissue Engineering

Volumetric muscle loss (VML) is a broad term used to describe permanent, large-scale damage to muscle tissue that results in some form of decreased function (Corona et al., 2012; Machingal et al., 2011). VML is extremely prevalent in military settings, but also affects many civilian populations (Corona et al., 2015; Grogan et al., 2011). Traditional approaches to treat VML have limited effectiveness, as muscle grafts require large volumes of tissue which, in some cases, leads to donor site morbidity (Corona et al., 2015; Sarrafian et al., 2018). Additionally, most approaches do not account for the frequent comorbidity of VML with damage to nerve and connective tissues (Gilbert-Honick et al., 2020; Yang et al., 2009). As such, functional repair of VML is difficult to achieve with traditional methods.

Biomaterials-based approaches have been attempted in recent years to address musculotendinous junction (MTJ) repair, but most approaches are only effective at treating mild

injuries (Gilbert-Honick et al., 2020; Owens et al., 2008). Since muscle function is highly dependent on innervation and a strong connection at MTJ, the goal of the CG-PPy scaffold is to encourage myogenic cells to mature and proliferate according to spatial and environmental cues to regenerate VML/MTJ injuries. Many previous studies have indicated the beneficial effects of mechanical or electrical stimulation on tissue development. In this study, the existing scaffold will be tested in a custom bioreactor while undergoing electromechanical stimulation (Maleiner et al., 2018; Goldberg et al., 1967; Goldspink, 1999). The fabrication of a multi-chamber bioreactor capable of electromechanical stimulation preferential to MDC myogenesis (see Fig. 1) will allow for the construction of a 3D multi-compartment CG-PPy scaffold capable of mimicking native skeletal muscle (Basurto et al., 2021). Establishing a computational simulation protocol capable of controlling and predicting the behavior of the bioreactor system may also provide an effective model for other electromechanically responsive such as cardiac muscle.

The proposed capstone is a year-long design project which will begin with the research and examination of the problem statement by conducting literature reviews and interviews with subject-matters experts in regenerative medicine and tissue engineering, including the Christ Lab at the University of Virginia Department of Biomedical Engineering. The research group will interface with the Christ Lab and inquire regarding their design and fabrication process of a mechanical bioreactor for a given scaffold (see Fig. 2) (Creech, 2021). Then, they will develop the design criteria specific to the CG-PPy scaffold and prototype and test the bioreactor. In the future, bioreactor preconditioning of myogenic cells within this tissue construct may guide the repair of clinically relevant VML/MTJ injuries. Overall, this novel biomaterial approach will be 4 significant to restoring muscle function and improving the lifestyle of thousands of civilians and military personnel suffering from VML.



Figure 1: Electromechanical stimulation pulses delivered to a tissue culture in a bioreactor construct (Basurto et al.,





Figure 2: Christ Lab skeletal muscle tissue bioreactor with mechanical stimulation. A. Muscle tissue construct is clamped between two screws. B. Mechanical stimulation motor control. C. Wall attached to clamps moves to stretch tissue. D. Lid allows for monitoring tissue culture. E. Filters for proper exchange of gasses (Creech, 2021).

### Corporate Social Responsibility in The Hair Care, Beauty, And Medical Industries

Before 1450, there was little separation between hair in beauty and hair in medicine— the job of a surgeon could be performed by a barber. While the hairdressers and barbers of the current day are known for their expertise in hair-styling, barbers before 1450 also performed minor surgery, administered herbs, performed bloodletting, and even pulled people's teeth (Wood, 2012). Although the medical and pharmaceutical industry may be separate from the cosmetics industry, medicine is a crucial part of advancing cometic technology and more importantly, monitoring the safety of cosmetic products. Moreover, cosmetics have developed

over time to use active pharmaceutical ingredients while pharmaceuticals have evolved to inform human wellness and beauty ideologies (Trüeb et al., 2001). This crosstalk between cosmetics and pharmaceuticals has been addressed by international regulatory bodies as well. While the Food and Drug Administration (FDA), the main regulatory body of cosmetics and pharmaceuticals in the United States, clearly delineates cosmetics and drugs, some countries such as Japan and Hong Kong have product classes which address the full spectrum of products, including 'quasidrugs' and 'cosmetic-type drugs' to address the range of cosmetics which may have physiological, drug-like effects (Trüeb et al., 2001).

One of the products commonly used at the intersection of beauty and medical treatment is shampoo. Shampoo is the most frequent type of cosmetic hair treatment and is used to cleanse the hair and scalp, enhance the beauty, aesthetic, and hygiene of hair, and even treat medical conditions like eborrheic dermatitis, or dandruff, and alopecia, or hair loss, in some cases. Companies that produce shampoo and accessory conditioners must take into account health hazards associated with the ingredients in shampoo (Zviak , 1986). For example, formaldehydes are commonly used preservatives in shampoos, but also a human carcinogen when absorbed into 6 the scalp (Trüeb et al., 2001; Whipple, 2021). Consequentially, regulatory bodies must account for the medical effects of chemicals in cosmetics (Pathak and Akhtar, 2019) and companies have a corporate social responsibility to convey their compliance with said regulations to consumers.

As a subset of this responsibility, hair care product companies must be knowledgeable regarding the users they influence, and the cultural and demographic makeup of this user population (Gavazzoni, 2015). In American history, there has existed a discourse between those that create hair-cleansing products and their users including women and men of all hair types, hair conditions, and hair cultures. More recently, the natural hair movement has gained

momentum, particularly in the Black community, and has been influencing the supply and demand for products that optimize the experience of natural, and particularly curly hair according to current beauty standards. Products such as leave-in conditioners and curl butters have gained popularity along with this movement (Camacho-Bragado et al, 2015; Simeon, 2021; Westgate et al., 2019).

Following the history of hair care, the development of cosmeceuticals, and the rise and fall of hair care movements in different communities, the discourse between hair care technology companies and hair care product users will be explored in the science, technology, and society thesis to better understand how one entity influences the other. This research stems from the recent class action lawsuit surrounding the OGX Shampoo and Conditioner product line by the large family product company, Johnson and Johnson in which Plaintiff Larissa Whipple files for false claims about the hair growth and maintenance capabilities of their products (Whipple, 2021). Multiple witnesses claimed hair loss experience, and it was found that DMDM hydantoin, a formaldehyde donor and hair loss agent, was contained in their products. From this crucial event, the research follows to explore the history of hair care and health and what role companies 7 play in influencing its evolution. Moreover, the research will explore whether particular minorities are affected by and unknowingly targeted by such influences, such as in the case of the natural hair movement and public acceptance of curly and often Black hair (Simeon, 2021).

Two key frameworks will be used to develop the research process. Paradigm Shift Theory is a concept developed by Thomas Kuhn which is defined as a fundamental change in the principal concepts of a scientific discipline. For the purposes of this discussion on the history and evolution of hair, Paradigm Shift is defined as a profound change in a population's perception of events (Kuhn, 2012). Paradigm Shift will be used as the primary framework to analyze how the

public perception of hair care and hair beauty standards have evolved over time. The history of hair the United States will be analyzed over the timeline of immigration and fashion trends. Paradigm Shift Theory will help uncover the evolution of curly hair standards and the more recently developed natural hair movement (Sadick et al., 2017). Paradigm Shift theory has been criticized by philosopher Martin Cohen and philosopher of science Paul Feyerabend for suggesting that science is more subjective to change rather than objective, and less factual than humanity allows itself to believe (Cohen, 2015). This criticism is countered, however, by the definition of science itself and what is considered follow the scientific methods including testable predictions, controlled experiments, and measurable results. Biology, one of the core, natural sciences, and the social sciences have been criticized for being more subjective and less quantitative than physics and chemistry (Smith et al., 2000). Still, they are considered scientific disciplines. Paradigm Shift is grounded in the idea that even the commonly held notions about the core sciences are challenged with the development of human knowledge over time. An example of this is seen in wicked problem framing, where even the simple definition of a molecule can fundamentally differ between a physicist and a chemist (Seager, Selinger, & Wiek, 8 2012). Furthermore, epistemology presents a perspective against this criticism questioning what knowledge is truly held by humanity, and addressing that this knowledge is always subject to be discovered in new ways.

As a supporting framework, Deontology will be used in the evaluative component of the research. Deontology is one of the three major approaches to normative ethics which highlights that people and entities must act ethically by a clear set of rules as dictated by their duty (Britannica, 2020). Through the lens of Deontology, it will be evaluated whether large personal care product and beauty companies are responsible for the health of their consumers' hair and to

what extent. Moreover, this framework will help to evaluate what role these companies play as influencers in the hair technology space, and suggest corporate social responsibility as a profitable approach for these companies to reposition their perception in the consumer eye. Overall, it is important to study the sociotechnical discourse that occurs in the health and beauty industry between large corporations and the consumer population to monitor constructive and destructive feedback between the two entities, especially when that discourse leads to implications as significant as health, safety, and even racial discrimination.

### **Research Question & Methodologies**

Research Question: How has the feedback loop between hair care companies and hair care product consumers evolved through history and how have minority populations been affected by the stated phenomena?

To collect background and evidence for this research question, the discourse analysis research methodology will be utilized. Hair care, cosmetics, hair loss, history of hair, and the biology of hair are examples of keywords used to collect background knowledge for the thesis 9 (Gavazzoni, 2015; Trüeb, 2001; Wood, 2012, Zviak, 1986). Keywords describing the natural hair movement such as 'curly hair,' 'Black hair,' and 'curl butter' will be used specifically to gather insights regarding historically marginalized and minority groups in hair care (Camacho-Bragado et al., 2015; Simeon, 2021; Westgate et al., 2017). The documentary analysis methodology will be used to identify primary sources as the key evidence for the research. The Whipple v. Johnson & Johnson Consumer Inc. case will be used as the primary source of evidence while surrounding lawsuits, case studies, and regulations from the Food and Drug Administration (FDA) will be examined as supportive evidence (Cornell et al., 2019; Pathak and Akhtar, 2019; Whipple, 2021). Keywords including regulation, corporate social responsibility,

and class action lawsuit will be used to collect data on the stance of hair care companies in this system.

#### Conclusion

The technical capstone addresses a major need in treating VML in both military and civilian populations who experience this debilitating injury. The research will deliver on a design and prototype for an electromechanical bioreactor to stimulate CG-PPy scaffolds and investigate muscle and neural cell proliferation as a result of this stimulation. Out of a curiosity for representation in the beauty and medical industry, similar to the representation of military and civilian populations in VML injuries, the sociotechnical component of the research thesis explores the relationship between hair care companies and users. This component will address the history of hair care and perception in the United States and examine regulations placed on hair care products in addition to lawsuits as an implication of these regulations, or the lack thereof. More importantly, the sociotechnical component will consider the phenomena of changing hair trends from a diversity lens, and the outcome will be a view on the responsibility 10 of hair care companies and regulatory bodies to have awareness regarding the populations they influence. Ultimately, the two research projects will explore ethics in the fields of medicine, pharmaceuticals, and cosmetics.

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