Design of a Novel Head Fixation Device for Focused Ultrasound Applications

(Technical Report)

The Use of Empathic Engineering in Medicine and Health

(STS Research 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 Your Major

By

Rithika Kormath Anand

November 1, 2021

Technical Team Members: Isha Bhatia, Jainam Modh

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

Sean Ferguson, Department of Engineering and Society

Timothy Allen, Department of Biomedical Engineering

Introduction

Engineering and technology for medicine and health is a complex process of innovation and collaboration with the mission of preserving, treating, and enhancing the health of people. Biomedical engineering and biotechnology as a discipline arose out of the need to specialize in the complex human experience of health to develop adequate solutions for problems within medicine. This led to modern biotechnology becoming highly effective and minimally-invasive, but requires further development to be widely applied. One such technology for treatment is the use of focused ultrasound for treatment of medical disorders, such as disorders of the brain. However, the machine requires the use of stabilization devices to secure the patient during treatment. We propose an engineering proposal for the design of a novel head fixation device to maximize the efficacy and application of focused ultrasound treatment. This device will improve upon current models and their limitations through the use of virtual modeling and extensive prototyping of various different alternative fixation devices until one satisfies the design aims. One of the aims of this project is to utilize empathic engineering while designing the novel head fixation device by working with an interdisciplinary team of healthcare workers and patients since it will be directly applied to the treatment of patients. Due to the practice of empathic engineering being crucial during the designing of the novel device, I propose research about empathic engineering as the future of engineering and design in medicine and health.

Design of a Novel Head Fixation Device for Focused Ultrasound Applications

Focused ultrasound (FUS) is an early-stage, non-invasive surgical technology utilized in the treatment of a multitude of medical disorders. It utilizes an acoustic lens to concentrate a multitude of intersecting beams of ultrasound with accuracy and precision in the body; at the focal point, the energy created by the convergence of the multiple beams causes biological changes that can treat certain medical disorders (White, 2021). A treatment of interest with FUS is the reversible opening of the blood-brain-barrier (BBBO), which allows for drug delivery and therapeutic access to the brain. The BBB is very impermeable, allowing approximately 5% of 7000 small-molecule drugs for neurodegenerative disease treatment to pass (Konofagou et al., 2012). The opening of the blood brain barrier opens up the possibility for many applications, including targeted drug delivery to the nervous system, tumor ablation within brain tissue, and potential treatment for neurodegenerative diseases such as Parkinson's, Alzheimer's, MS and more (Abrahao et al., 2019).

During treatment of brain disorders, the patient's head is secured to the FUS machine with a head-frame to restrict movement during procedures. These stereotactic frames used for focused ultrasound were originally designed for general radiosurgery, making the frames suboptimal for focused ultrasound techniques. The frame interferes with the treatment envelope by hindering the ability of the machine to target certain areas. It also causes patient discomfort when securing the headframe, during which four pins need to be temporarily screwed into the patient's head to attach the frame (Abrahao et al., 2019; Konofagou et al., 2012). The shortcomings of the head fixation device pose obstacles against realizing the full potential of treatment by FUS within the brain; therefore, the development of an improved fixation device remains a great need in the field.

To address this need, we propose to design a head fixation device that can be utilized for FUS treatments that minimizes interference with the system while securing and stabilizing the patient's head in a minimally-invasive way. The first aim of this proposal is to design a head fixation device for Focused Ultrasound application to increase treatment envelope by re-engineering existing devices from similar machines to minimize any interference of the frame with the ultrasound system during procedures, such as the opening of the blood-brain-barrier (BBBO). A virtual program will be used to model the positioning of the frame in the machine, and the ability of the machine to access the sites within the head that require treatment. By modeling the area of access provided by the frame, the efficacy of the headframe in securing the head while minimizing interference can be quantifiably compared to previous models. The headframe will have the capability of modulating within specified margins allowing for the use of the frame to secure the heads of patients of various sizes and shapes. This will be tested by fixing the frame to various test subjects and evaluating the fit and security of the head in the frame. The second aim is to ensure the device is mechanically and radiologically compatible with the FUS machine and can adequately secure the head by attaching to the machine. This will be accomplished by researching what materials are radiologically compatible, and by attaching prototype models to a model of the FUS machine to test its ability to stay secure and stable. The third aim of the proposal is to create a minimally-invasive device that limits patient discomfort during the placement, procedure, and removal by altering the pins used to attach the frame to the patient or creating a different attachment mechanism. Test subjects will try on the prototype head fixation device and be surveyed about the comfort of the fixation device.

The Use of Empathic Engineering in Medicine and Health

Introduction

Medicine is a constantly evolving system in its purpose to preserve, treat, and enhance the health of people. Engineering and technology for medicine and health is a fundamental part of the medical system, however, has become a potential factor of dehumanization of the stakeholders, such as patients and healthcare workers. The preservation of dignity within healthcare is a relatively modern, yet crucial, mission of medicine, and must extend to engineering and technology likewise (Hosking et al., 2015). The use of empathy, the ability to understand or share the feelings and experiences of another, within engineering and technology has been relatively inconsistent throughout history, however, should be a fundamental part of these fields to ensure that the outcomes are effective and informed while preserving the dignity of the patient (Hosking et al., 2015). I will examine empathy as an imaginary in formation in biomedical engineering and biotechnology, why engineers should care about incorporating empathy as a tool, and how the future of health will change with empathic engineering and design. The use of empathy as a tool in engineering and design will be examined through the framework of socio-technical imaginaries in formation; socio-technical imaginaries allow for the analysis of attainable futures or futures that should be attained. Imaginaries have the power to influence and shape the technological design, and therefore, offer the ability to current social, political, ethical, and cultural characteristics of society affect the trajectory, meaning, and implications of future technological developments (Hess & Sovacool, 2020). The implication of this examination is to understand who and what is contributing to a future of empathic engineering and design, and to uncover the rationale for incorporating empathy as a core part of engineering practice in the future (Hess & Sovacool, 2020).

Literature Review

There exists a vast collection of literature on the tool of empathy and its ability to be incorporated into engineering and design for medicine and health. Throughout history, empathy has been studied and incorporated by a variety of disciplines, albeit with different definitions of the concept and its implementation. The concept of “empathic design” and “empathy” as a value arose during market research within the business world; this form of empathy is product-oriented and objectifies the users of the products, ignoring philosophical and psychological insight. In the discipline of engineering and design for medicine and health, empathy is actively reconstructing into a new form known as "empathic engineering," a concept that did not arise in literature until 2001. Empathic engineering seeks to advance technology taking into consideration the needs of the community, social justice, and sustainability (Tang, 2018).

Current engineering education is shifting towards teaching empathy as a commitment to communicating with and understanding different cultural, social, and personal experiences of communities. There is a lack of research about the connection between engineering and empathy, even though empathic design is a necessary tool for human-centered design and enhances the connection between the engineer and all the stakeholders (Tang, 2018). More engineers and engineering designers are shifting their discipline identity from technical problem-solvers to holistic thinkers that address complex socio-technical challenges. However, within medicine and health, there is a lack of research for how engineers can facilitate and enhance patient dignity and experience. Current approaches to foster empathy development in engineering students and engineers include involving them in focus groups, observations, and interviews with all the stakeholders that exist on the other side of design (Hosking et al., 2015). One method of evaluating the empathic ability within future engineers and designers is through a quantitative emotional evaluation that provides an "Empathizing and Systemizing Quotient" (EQ-SQ) (Jacobs et al., 2016). This evaluates the ability of students to identify the thoughts, feelings, and experiences of others and to explore, analyze, and construct systems with it. The outcome of empathic engineering is overwhelmingly positive, both for the engineers and the stakeholders; the subsequent design and usability of products, as well as the innovativeness, improved when engineers intentionally used empathic engineering practice (Jacobs et al., 2016).

This research provides an overview of the formation of empathy as a value and tool in biomedical engineering and biotechnology, how and why engineers incorporate empathy as a tool, and the potential of the future of health with the use of empathy. In addition to literature review, additional research to garner data about the EQ-SQ of engineers who actively utilize empathy, the outcome of health projects using empathic engineering, and the direction of empathic engineering in the future.

Next Steps

The completion of both the technical capstone project and STS thesis project will be around the beginning of May 2022. The table below outlines the milestones for both projects along with a relative timeline.

Timeline	Technical Capstone	STS Thesis
October 2021	• Develop the specific aims and design constraints of the device • Research current or similar models to gain insight • Become familiarized with the machine and procedure	• Conduct further literature search and data evaluation • Submit Prospectus to STS professor and capstone advisor
November-December 2021	• Design and virtually evaluate the various models of devices for the FUS machine	
January-February 2022	• Build a prototype of the device or continue further modeling	• Complete the draft of the research paper
March-April 2022	• Continue prototyping and iterating the device • Test the device on people to evaluate the comfort	
May 2022	• Submit final technical report to capstone advisor • Possibly submit device for consideration with companies or competitions	• Submit thesis portfolio

References

Abrahao, A., Meng, Y., Llinas, M., Huang, Y., Hamani, C., Mainprize, T., Aubert, I., Heyn, C., Black, S. E., Hynynen, K., Lipsman, N., & Zinman, L. (2019). First-in-human trial of blood–brain barrier opening in amyotrophic lateral sclerosis using MR-guided focused ultrasound. *Nature Communications*, *10*(1), 4373. https://doi.org/10.1038/s41467-019-12426-9

Hess, D. J., & Sovacool, B. K. (2020). Sociotechnical matters: Reviewing and integrating science and technology studies with energy social science. *Energy Research & Social Science*, *65*, 101462. https://doi.org/10.1016/j.erss.2020.101462

Hosking, I., Cornish, K., Bradley, M., & Clarkson, P. J. (2015). Empathic engineering: Helping deliver dignity through design. *Journal of Medical Engineering & Technology*, *39*(7), 388–394. https://doi.org/10.3109/03091902.2015.1088090

Jacobs, E. L., Curry, A. L. de J., Deaton, R. J., Astorne-Figari, C., & Strohmer, D. C. (2016, June 26). *Empathy and Gender Inequity in Engineering Disciplines*. 2016 ASEE Annual Conference & Exposition. https://peer.asee.org/empathy-and-gender-inequity-in-engineering-disciplines

Konofagou, E. E., Tung, Y.-S., Choi, J., Deffieux, T., Baseri, B., & Vlachos, F. (2012). Ultrasound-Induced Blood-Brain Barrier Opening. *Current Pharmaceutical Biotechnology*, *13*(7), 1332–1345.

Tang, X. (2018). From ’Empathic Design’ to ’Empathic Engineering’: Toward a Genealogy of Empathy in Engineering Education. *American Society for Engineering Education*.

White, E. (2021). *2021 State of the Field Report*. Focused Ultrasound Foundation. https://www.fusfoundation.org/images/pdf/FUSF_State_of_the_Field_2021_Final_Web.pdf