

Design of a Novel Head Fixation Device for MR Guided Focused Ultrasound Blood-Brain-Barrier-Opening Procedures

How Hospital Interior Design Can Be Curated to Reduce Depression, Anxiety, and Stress of Cancer Patients

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
Isha Bhatia

November 1, 2021

Technical Team Members:
Rithika Kormath Anand

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

Bryn E. Seabrook, Department of Engineering and Society

Dr. Jason Sheehan, M.D., PhD, Department of Neurological Surgery
Dr. Lauren Powlovich, M.D., Associate Chief Medical Officer at the Focused Ultrasound Foundation
Dr. David Schlesinger, PhD, Department of Radiation Oncology
Dr. John Snell, PhD, Brain Program Director at the Focused Ultrasound Foundation

Introduction

Focused ultrasound (FUS) is a non-invasive, early-stage technology utilized in the treatment of a multitude of medical disorders. The technology functions by using an acoustic lens to concentrate several intersecting beams of ultrasound deep in the body with extreme accuracy and precision to exert powerful effects on target areas (White, 2021). A significant treatment of interest is the opening of the blood-brain-barrier (BBB), where a wider area of opened BBB can expand the treatment envelope. The BBB is extremely impermeable, allowing only 5% of 7,000 small molecule drugs to penetrate the barrier (Konofagou et al., 2012). Thus, BBB opening creates the possibility for many applications, including tumor ablation, or the destruction of cancerous tumors, for cancers such as Glioblastoma (Abraham et al., 2019). In the context of a FUS procedure for a patient suffering from a brain tumor, the patient's head has to be secured to the machine with a headframe to restrict movement. However, stereotactic frames currently used for FUS were originally designed for radiosurgery, making such frames suboptimal for FUS. Although headframes successfully secure and stabilize the head, one limitation is that they interfere with the treatment area by blocking ultrasound beams. Another limitation presents itself in the patient discomfort that is caused by the securing of the headframe, where four pins are temporarily screwed into the patient's skull (Bichay & Mayville, 2016). Currently, the shortcomings of fixation devices pose a significant challenge towards realizing the full potential of FUS treatment; therefore, the development of an improved fixation device remains a great need in the field. Thus, the proposed technical project deliverable will be an improved fixation device.

FUS treatments are becoming increasingly popular as a viable tumor ablation approach for brain cancer patients. To undergo a FUS treatment, cancer patients are required to go to a

hospital, as such treatments cannot be completed outside an advanced medical environment. The machines required for successful treatments are large and complex, which are intimidating for cancer patients. Intense procedures such as FUS procedures can negatively impact the mental health of cancer patients, due to the complex nature of such treatments. Hospital interior design also plays a role in patient mental stress, as hospitals are usually viewed as bleak environments associated with sickness and even death (Edvardsson, et al., 2006). It is important to change cancer patient perception of hospitals in order to maximize positivity in cancer patients. The proposed research paper will investigate how hospital designs can be altered to offset negative hospital perceptions and contribute to an improved cancer prognosis. The Social Construction of Technology (SCOT) will be used as a framework to analyze the key actors in this research question and how they contribute to societal perceptions of hospitals.

Design of a Novel Head Fixation Device

Due to the lack of fixation devices that are tailored for ultrasound applications, the development of a head fixation device for FUS will revolutionize downstream applications after BBBO procedures. Given that there is a necessity to develop an improved head fixation device for FUS, certain objectives need to be established. The first aim of developing a better stabilization device is to ensure a near-complete restriction of head movement during a Blood-Brain-Barrier-Opening (BBBO) procedure. Ensuring head restriction is done by re-engineering existing headframes or even thermoplastic masks that are currently being used for radiosurgery applications (Li et al., 2016). One of the first steps of this objective is to research about head frames and thermoplastic masks and decide which type of head fixation device is best suited for BBBO applications. In BBBO procedures, there is a larger range of allowed head movement

since the treatment area is larger than a specific target point. The chosen stabilization device, head frame or mask, will have the capability of adapting to specified margins based on device fit within the machine; correct fitting will allow for the machine to accommodate for a variety of patient head sizes and shapes while also keeping the head as stable as possible.

The second aim is to minimize frame interference with the ultrasound system during the BBBO procedure. To achieve minimal frame interference, a virtual program will be used to model the positioning of the frame within the machine, in addition to modeling the ability of the machine to access certain points within the head that require treatment. By modeling the access areas provided by the frame and the efficacy of the headframe in securing the head while minimizing ultrasound hindrance, quantitative comparisons to previous models will be done to pinpoint where exactly the new device should be altered.

The third aim tying into building a better head fixation device is ensuring that the aforementioned device is a minimally invasive device that minimizes patient discomfort. Currently, when a patient is set up to undergo a radiosurgery procedure with a head fixation device, patient discomfort is usually maximum during the placement of the device, the procedure itself, and removal of the device. Such discomfort is usually caused by the deployment of pins into the patient's skull to ensure minimum head mobility. To combat such discomfort, the technical team proposes to develop and experiment with many designs which do not require the use of such pins, with the goal of creating a device that still keeps the head stable for the BBBO procedure. The improved headframe design will be qualitatively determined through surveys of test subjects, based on their comfort during the in-person device fitting part of the project. To test device comfort, the technical team will step foot into the clinic and test the device on a variety of subjects with different head shapes and sizes.

The proposed engineering design challenge will contribute to improving current head stabilization technology that overcomes current limitations while also increasing the potential for treatments of various brain disorders. The creation of a new headframe device will increase treatment efficacy by maximizing the treatment envelope while minimizing device interference with minimal patient discomfort. The new and improved headframe fixation model for FUS treatment can be widely applied towards the treatment of many diseases and disorders of the brain that are more challenging to treat through traditional methods or have no cure, while significantly improving patient prognosis and quality of life (QOL). The ultimate deliverable of the technical project will be the development of an improved headframe that maximizes patient comfort while increasing the treatment area for BBBO, which will be possible by working with the technical team and listed advisors.

Curating Hospital Interior Design to Reduce Depression, Anxiety, and Stress of Cancer Patients

Depression is a common medical illness that affects people diagnosed with cancer (Smith, 2015). Depression-induced stress has the potential to turn into major depressive disorder, in which psychosocial components of depression translate into physical effects in cancer patients (Smith, 2015). Cancer itself presents patients with a stressful timeline of events, including effects of initial diagnosis and shock, effects of debilitating treatments (e.g. chemotherapy), and impacts related to potential complications, whether it be the risk of cancer relapsing or knowledge that an illness is terminal. These events lead to a poorer quality of life (QOL); thus, having depression on top of a cancer prognosis can contribute to higher rates of mortality in cancer patients, as depression can exacerbate the effects of cancer. For this reason, the impact of mood and mental

well-being is a crucial factor to consider when trying to improve a cancer prognosis. The impact of mental health on cancer patients is recognized by both doctors and patients, with about greater than 70 percent of oncologists and approximately 85 percent of patients acknowledging that mental health impacts cancer progression (Smith, 2015). Additionally, the cancer experience in children presents itself as a significant childhood stressor, with most children perceiving the diagnosis, medical procedure and social impacts as the most stressful events of the disease (Sharp et al., 2017). Additionally, children tend to feel uncomfortable in “unfamiliar” hospital environments when staying overnight, indicating that pediatric oncology wards ought to be redesigned to reduce child stress (Vollmer & Koppen, 2021).

In order to contribute to a positive mental wellbeing of all cancer patients, it is important to consider the impact of the hospital environment on patient well-being. It is shown that an adverse environment, lack of green spaces and noise or air pollution contribute to depressive mood disorder (Rautio et al., 2017). As such, altering the hospital environment in specific ways alleviates and possibly even prevents depression and anxiety in cancer patients. Hospital interior design plays a significant role on how patients and family friends feel in a hospital environment; aspects of interior design such as wall color, décor, light placement, greenery addition and placement, window addition and placement, room size, and other elements can have a large impact on the perception of a healing environment (Pantalony, 2009). Factors such as sound and music also play a role towards positive patient recuperation, as it is shown that music generally has calming effects and can even lower pain perception in patients (Miller et al., 2021; Iyendo, 2016). Lastly, it is important to investigate how the creation of play areas, family bedrooms and addition of bright colors in pediatric oncology wards can reduce cancer-related stress of both children afflicted with cancer and their families (Tonetto et al., 2021).

By applying the framework of the Social Construction of Technology, or SCOT, this paper will explore widely held perceptions of hospital environments and delve deeper into why many view hospitals in a rather negative light. Before explaining SCOT however, it is important to understand what social construction in itself signifies. Social construction is a concept or perception that is contingent upon the collective views that are developed, maintained, or changed within a social group or society. In other words, social construction represents how social groups attach meaning to certain aspects of life. For example, social constructs have been developed to justify appropriate colors for boys and girls; pink is viewed as “feminine” and girly, while blue is usually thought of as a color for boys (Lobue & Deloache, 2011). The concept of social construction is used to explore how collective societal views shape and influence the development of technologies, which has been investigated thoroughly by many scholars. SCOT was first introduced in the 1980s by British sociologist Trevor Pinch and Dutch philosopher Wiebe Bijker and further explored and improved upon by Hans K. Klein and Daniel Lee Kleinman. Initial concepts that arose from SCOT emphasized that the development of technology is heavily influenced by the interactive process between technologists and engineers, along with relevant social groups. In other words, SCOT highlights that instead of technology shaping human action, it is rather human action that shapes the creation and unique characteristics of technologies. Klein and Kleinman note that a central critique of SCOT is “SCOT’s view of society as composed as groups,” implying that SCOT fails to consider power asymmetry between groups, where certain groups may not influence the technological process at all (Klein & Kleinman, 2002). The insights gained from both concepts derived from SCOT and its critiques will ultimately shed light into which groups heavily influence hospital design, and how current societal perceptions of hospitals can catalyze changes in hospital technologies

related to interior design and ambience. Ultimately, research and sociotechnical analysis into hospital design is important so that the healing environment can be improved for patients 8 suffering from debilitating disease. Positivity during times of illness can pave the path towards a better outlook towards life and stronger relationships with loved ones, especially if cancer prognoses can be improved.

Research Question and Methods

The conducted background research and STS framework analysis ultimately leads to the research question at hand: How can hospital designs be curated to reduce depression, anxiety and stress of cancer patients to ultimately improve cancer progression and patient QOL?

To answer this question, documentary research methods will primarily be used. The first aspect of this research question involves significant context and background into the reason why a positive mental state is crucial for cancer patients. Subsequent research will involve questions into how hospitals negatively impact patients, and how negative mental states can translate into physical co-morbidities. Furthermore, information about what aspects of interior design currently exist in hospitals is necessary so that an argument can be made as to how to improve those aspects of interior design. Building off of those aspects, more background research will need to be done separately to determine how aspects of interior design (e.g. light) impact human psyche. The sources that contain the aforementioned information will most likely come in the form of formal studies summarized in National Institute of Health (NIH) articles, due to the experimental nature of the research question at hand. Additionally, more research will be done to explore current technologies related to interior design (e.g. sound systems) and patient comfort in hospitals, and how such technologies have the potential to improve.

Discourse analysis will also be a valuable research method to answer the proposed question. Resources in the form of interviews on the web (e.g. YouTube), blog posts, and forums will be used to gauge patient experiences in hospitals. Such resources will provide more of a personal insight as to why cancer patients feel uncomfortable in hospitals and underline the desperate need for improved hospital design.

Conclusion

This paper emphasizes that there is a dire need for improved head fixation device design in the context of FUS applications. The development of a new and improved head fixation device is crucial to increasing access to tumors within the brain by reducing any hindrances to ultrasound beams. To achieve this goal, the technical team will need to consider how certain parameters of the head fixation device will be altered, while ensuring that the device is comfortable for patients. The successful creation of an improved head fixation device will revolutionize cancer treatment, since increased access to tumors can be accomplished by opening the BBB by at least 1-2 cm. An increased access to tumors in turn will allow for more tumor mass to be destroyed, ultimately reducing the risk of cancer relapses and other cancer-related complications. It is anticipated that at the end of this project timeline, iterative improvements on different designs can be made by testing them on patients in the clinic, with the overarching goal of finding the best design to be used for FUS applications.

It is well-known that cancer patients need to experience many hospital visits as they undergo intensive procedures in hopes to eliminate the cancer. This prospectus also discusses the importance of making a hospital environment better suited to increase cancer patient positivity, as improved mental states ultimately translate into positive physical effects. Altering interior

design components of hospitals has the potential to improve cancer patient prognosis in ways such as increasing patient lifespan and QOL. In answering this research question, it is hoped that different technologies and interior design components can be combined and optimized in oncology wards to yield positive hospital experiences for cancer patients.

References

Technical Paper 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>
- Bichay, T. J., & Mayville, A. (2016). The Continuous Assessment of Cranial Motion in Thermoplastic Masks During CyberKnife Radiosurgery for Trigeminal Neuralgia. *Cureus*, 8(5). <https://doi.org/10.7759/cureus.607>
- 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. <https://doi.org/10.2174/138920112800624364>
- Li, W., Bootsma, G., Von Schultz, O., Carlsson, P., Laperriere, N., Millar, B.-A., Jaffray, D., & Chung, C. (2016). Preliminary Evaluation of a Novel Thermoplastic Mask System with Intra-fraction Motion Monitoring for Future Use with Image-Guided Gamma Knife. *Cureus*, 8(3), e531. <https://doi.org/10.7759/cureus.531>
- 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

STS Paper References

- Edvardsson, D., Sandman, P. O., & Rasmussen, B. (2006). Caring or uncaring--meanings of being in an oncology environment. *Journal of advanced nursing*, 55(2), 188–197.
<https://doi.org/10.1111/j.1365-2648.2006.03900.x>
- Iyendo T. O. (2016). Exploring the effect of sound and music on health in hospital settings: A narrative review. *International journal of nursing studies*, 63, 82–100.
<https://doi.org/10.1016/j.ijnurstu.2016.08.008>
- Klein, H. K., & Kleinman, D. L. (2002). The Social Construction of Technology: Structural Considerations. *Science, Technology, & Human Values*, 27(1), 28-52.
<https://doi.org/10.1177/016224390202700102>
- Lobue, V., & Deloache, J. S. (2011). Pretty in pink: The early development of genderstereotyped colour preferences. *The British journal of developmental psychology*, 29(Pt 3), 656–667.
<https://doi.org/10.1111/j.2044-835X.2011.02027.x>
- Miller, C. R., Patmon, F. L., & Knapp, H. (2021). Music to reduce stress in hospitalized patients. *Nursing*, 51(8), 62–66. <https://doi.org/10.1097/01.NURSE.0000757168.77552.58>
- Pantalony D. (2009). The colour of medicine. *CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne*, 181(6-7), 402–403.
<https://doi.org/10.1503/cmaj.091058>
- Rautio, N., Filatova, S., Lehtiniemi, H., & Miettunen, J. (2018). Living environment and its relationship to depressive mood: A systematic review. *The International journal of social psychiatry*, 64(1), 92–103. <https://doi.org/10.1177/0020764017744582>

- Sharp, K., Lindwall, J. J., Willard, V. W., Long, A. M., Martin-Elbahesh, K. M., & Phipps, S. (2017). Cancer as a stressful life event: Perceptions of children with cancer and their peers. *Cancer*, 123(17), 3385–3393. <https://doi.org/10.1002/cncr.30741>
- Smith H. R. (2015). Depression in cancer patients: Pathogenesis, implications and treatment (Review). *Oncology letters*, 9(4), 1509–1514. <https://doi.org/10.3892/ol.2015.2944>
- Tonetto, L. M., da Rosa, V. M., Brust-Renck, P., Denham, M., da Rosa, P. M., Zimring, C., Albanti, I., & Lehmann, L. (2021). Playful strategies to foster the well-being of pediatric cancer patients in the Brazilian Unified Health System: a design thinking approach. *BMC health services research*, 21(1), 985. <https://doi.org/10.1186/s12913-021-07018-7>
- Vollmer, T. C., & Koppen, G. (2021). The Parent–Child Patient Unit (PCPU): Evidence-Based Patient Room Design and Parental Distress in Pediatric Cancer Centers. *International Journal of Environmental Research and Public Health*, 18(19), 9993. [doi:10.3390/ijerph18199993](https://doi.org/10.3390/ijerph18199993)