Designing an Articulating Ultrasound Transducer Arm for Use in Clinical Trials Treating Cocaine Use Disorder

Janine T Icalla, Emerson MT Smith, Mackenzie M Zimmerman

Words: 3176

Numbers of Figures: 5

Numbers of Tables: 0

Number of Equations: 0

Number of Supplements: 0

Number of References: 5

Designing an Articulating Ultrasound Transducer Arm for Use in Clinical Trials Treating Cocaine Use Disorder

Janine T Icalla[a1], Emerson MT Smith[a2], Mackenzie M Zimmerman[a3], Tamika S Braveheart[b], Andrew F Kostelac[b]

[a] Department of Biomedical Engineering, University of Virginia, Charlottesville, VA 22903
[b] Center for Leading Edge Addiction Research, University of Virginia, Charlottesville, VA 22904
[1] Correspondence: jti6gw@virginia.edu, 415 Lane Road, Room 2010, Charlottesville, VA 22908, 804-585-8132
[2] Correspondence: ems8rw@virginia.edu, 415 Lane Road, Room 2010, Charlottesville, VA 22908, 201-704-1817
[3] Correspondence: mmz7vpc@virginia.edu, 415 Lane Road, Room 2010, Charlottesville, VA 22908, 804-972-1344

Abstract

This study focuses on the development of an articulating arm system to hold a transducer in place for low-intensity focused ultrasound (LIFU) treatment, specifically targeting Cocaine Use Disorder (CUD). CUD presents a significant challenge in contemporary society, affecting approximately 1.7% of the American population. The emergence of focused ultrasound research offers a promising intervention by stimulating the dorsal anterior insula in the brain to mitigate cocaine cravings. However, manual transducer handling during treatment poses challenges, including discomfort and potential inaccuracies due to involuntary movements. The objective of this project was to design an articulating arm system that could securely hold the transducer in place during treatment, addressing issues of range of motion, durability, and ease of use. Design specifications included articulation and stability, durability and safety, user-centric design, mobility and secure placement, and versatility and adaptability. Through iterative design processes, finite element analysis, stress analysis, and fatigue simulations, we developed a robust transducer holder attachment and gooseneck rod assembly. Results demonstrated the system's ability to withstand loads and repetitive use while maintaining stability and integrity. The articulating arm system addresses a crucial need within the medical imaging field by enhancing diagnostic accuracy and treatment precision.

Keywords: **cocaine use disorder, low-intensity focused ultrasound, articulating arm, medical imaging**

Introduction

Cocaine Use Disorder (CUD) poses a significant challenge in contemporary society, characterized by the compulsive use of cocaine despite its detrimental psychological and behavioral consequences. [1] Recent statistics indicate approximately 1.7% of the American population, encompassing roughly 4.8 million individuals, are trying to grapple with CUD. [2]The implications of CUD extend beyond individual health, manifesting long-term alterations in brain function that foster maladaptive behavior, poor decision-making capabilities, and erode self-insight which perpetuates cycles of relapse. [3] Currently, there are no pharmacological treatment options for this disorder, although some psychiatric treatments, such as cognitive behavior therapy, have shown efficacy.[1]

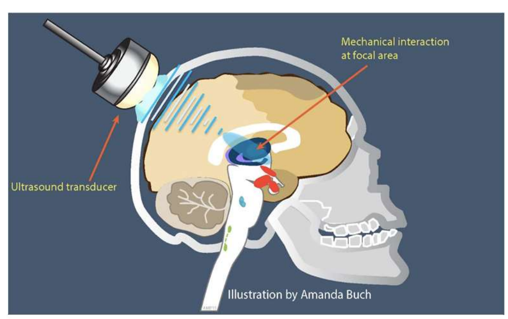

Figure 1. **Overview of Low Intensity Focused Ultrasound Procedure**

Therefore, innovative interventions are crucial to address the multifaceted dimensions of CUD and alleviate the burdens it imposes on individuals and communities.

Within this context, the emergence of Focused Ultrasound research being explored at the Center for Leading Edge Addiction Research (CLEAR) offers a promising avenue for intervention. By leveraging low-intensity waves to stimulate the dorsal anterior insula in the brain, this novel approach aims to mitigate cravings for cocaine, addressing a core challenge in the management of CUD. The efficacy of treatment is contingent upon precise and persistent application emitted through the ultrasound transducer. The transducer resembles the size of a hockey puck, and currently, providers must manually hold it to a patient's head for the entirety of the treatment time, approximately 15 minutes. This leads to discomfort, arm fatigue, and potentially inaccurate treatment due to involuntary hand movements. Any existing equipment for supporting the transducer is large, cumbersome, and expensive. Thus, the objective of the capstone project is to develop an articulating arm that can hold the transducer in place during LIFU treatment, with specifications including extensive range of motion, durability, and ease of use.

Design Specifications

When designing the articulating arm system, the following main design specifications were considered and prioritized: articulation and stability, durability and safety, and a user-centric design. The articulating arm must maintain precise positioning while allowing the ultrasound transducer to be maneuvered smoothly as it maintains stability in place. The arm should offer a wide range of motion to accommodate all scanning angles, as well as all head sizes and shapes. The arm must also be designed with durable materials that can withstand continuous and repetitive usage. Safety mechanisms to prevent instability and accidental movements should be incorporated to prevent inaccuracy in treatment metrics. Ergonomic considerations should contribute to the user-friendliness of the device. The arm should be intuitive and accessible to medical professionals and patients to optimize efficiency and accuracy of treatment. Lower priority design considerations included: mobility and versatility/adaptability. Mobility features should be incorporated into the device's design to relocate both the device and the ultrasound transducer across different environments, including various clinics and hospital settings. Seamless exchanging from mobile to stable will ensure accuracy of LIFU readings. Additionally, the articulating arm must cater to a wide range of medical applications and account for diverse scenarios. It should be suitable for a variety of imaging needs by accounting for patient-specific positions and placements.

Results

Choice of Gooseneck Stand

The choice of the specific stand and associated gooseneck arm was made by researching both prior art and the material properties. Given the design specifications, it was necessary for the gooseneck part of the arm to be bendable to account for 360 degrees of rotation while the stand remained sturdy. A previously designed and manufactured microphone stand was selected that was composed of various grades of stainless steel. The bottom part of the stand had tripod legs that extended out for maximized stability and was covered with a non-slip rubber material that prevented unwanted movements of the device. The rod itself was made of a stronger grade of stainless steel to contribute to better strength and weight bearing properties. The top, movable part of the device was made of a thinner, more flexible stainless steel that contributed to the articulation and adaptability. Furthermore, the stand kit contained removable attachments that exposed a threaded top, allowing for the easy attachment of the 3D-printed transducer holder via a paired, threaded hole. This threading mechanism allows the 3D-printed transducer holder to be securely positioned to the stand to complete the full design and functionality of the device.

Device Iterations for Transducer Holder

Several iterations of the transducer-holding attachment were designed throughout the development process. Figure 2A displays the first iteration. The clamping mechanism from this iteration was able to effectively hold and tighten around the transducer with no issue. Additionally, the clamping mechanism proved to be intuitive for repeatedly inserting and taking out the transducer from the device. However, the nature of this design only allowed for uniaxial rotation, which did not

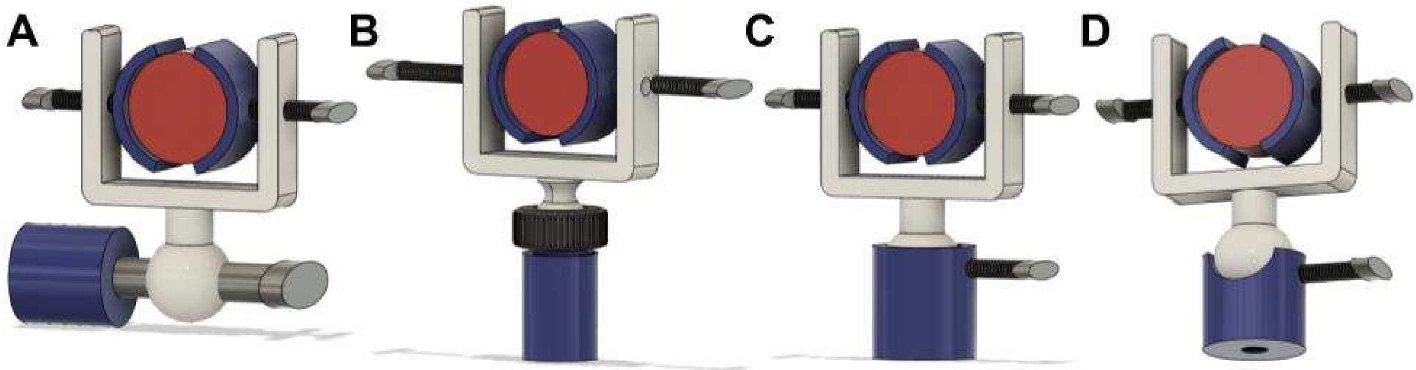

Figure 2. **Iterative Prototype Designs of Transducer Holding Attachment** (A) Iteration 1. (B) Iteration 2. (C) Iteration 3. (D) Iteration 4.

satisfy our design specification for an extensive range of motion. Additionally, it could not stay in one position about its rotating rod- the friction about the rotating rod was not great enough to withstand gravity and prevent it from defaulting into a position in which the top of the ball joint faced completely down. Figure 2B displays the second iteration. Due to the success of the clamping mechanism, this feature in the transducer-holding attachment stayed constant. This iteration pivoted to a ball-joint mechanism in an attempt to satisfy the specification for an extensive range of motion. A nut component, similar to those used in bolt, nut, and washer assemblies, was designed to be threaded upwards onto the base component, which would then secure the ball-joint in its chosen position. Unfortunately, the nut component proved to be ineffective in securing the ball component, as the required diameter needed for threading onto the base component was too large for it to tighten around the ball component. Additionally, the locking component, using the nut, proved to be unintuitive to fellow Capstone members. Figure 2C displays the third iteration. In this iteration, the clamping mechanism again stayed constant, and the ball-joint design carried over for its potential to produce a wide range of motion. The locking mechanism was switched to that of a screw to be threaded into a hole in the base component. The screw would then be used to tighten the ball joint against the walls of the base component. The screw locking mechanism proved to be very effective in securing the ball joint in place. However, the stem of the ball joint did run into the issue of hitting the tops of the base component, meaning that in one axis of rotation it could only move ~90 degrees rather than a value closer to 180 degrees. Figure 2D displays the fourth and final iteration. In this iteration, the clamping mechanism, ball joint design, and screw locking mechanism on the ball joint carried over due to their effectiveness in the previous iterations. To solve the issue of the rotation limitation in one axis, two large circular cutouts were inserted into the base component to give the ball joint stem more room to move. From this fix, the design specification for an extensive range of motion was met.

Finite Element Analysis of Transducer Holder

The durability of the transducer holder attachment against the weight of a focused ultrasound transducer was assessed. From the setup, constraints, and loads described in the Materials and Methods section, finite element analysis upon an upright transducer holder attachment produced a maximum displacement of 0.00000826 mm. This maximum displacement was concentrated directly above the stem of the main ball joint component. Additionally, the study produced a maximum reaction force of 0.094 N, more closely concentrated around the clamps securing the transducer.

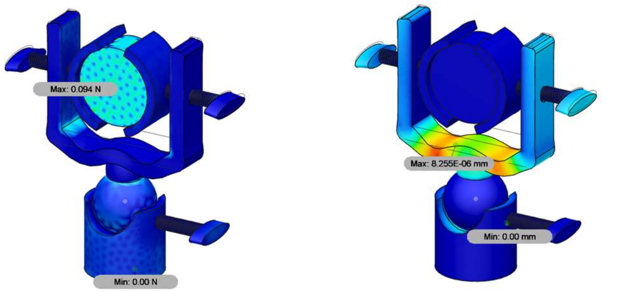

Figure 3. FEA Results. Reaction force **(A)** and displacement **(B)** of the transducer holding attachment against a top and front-facing 5 N load.

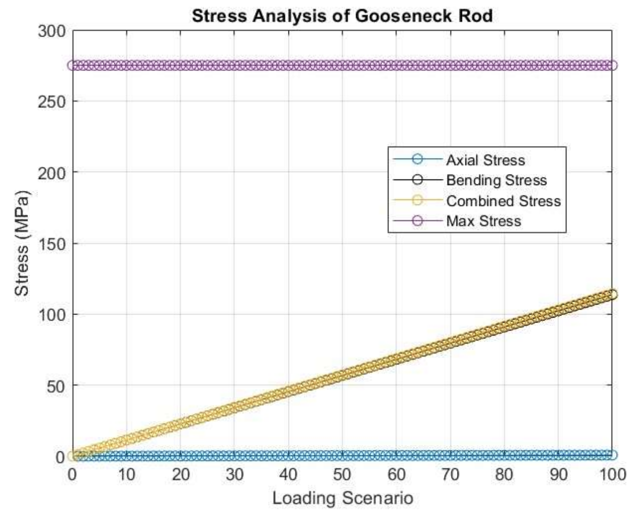

Figure 4. **Stress Analysis Results.** Max Stress (purple) found to be 275 MPa, with combined stress increasing linearly.

S*tress Analysis of Gooseneck*

Using stress analysis in MATLAB, we investigated the durability of a stainless-steel grade 304 gooseneck attachment intended for connecting to a transducer holder, crucial for repetitive use during treatment. Through simulation, we generated graphs illustrating maximum stress levels, which we found to peak at 275 MPa. Given that the gooseneck will endure a maximum load of approximately 20N from the transducer weight, this stress level comparison indicates a substantial safety margin. The stress analysis graphs reveal critical insights into the behavior of the gooseneck under load. Specifically, they demonstrate minimal axial stress, suggesting efficient load distribution along the structure. Additionally, the gradually increasing combined stress, reaching around 120 MPa over 100 loading scenarios, highlights the gooseneck's ability to withstand repeated stress without succumbing to permanent deformation. The gooseneck design, characterized by its curved and flexible nature, proves instrumental in absorbing stress and mitigating the risk of permanent deformation. By distributing the load more evenly and allowing for controlled flexing, the gooseneck ensures durability and reliability during repetitive use, crucial for its intended application in medical treatment scenarios.

Fatigue Analysis of Gooseneck

In our second round of durability testing, we conducted fatigue analysis on the gooseneck rod, plotting loading scenarios against fatigue life cycles scaled to 10^6. Interestingly, the graph exhibited a horizontal line at 1, indicating a consistent and enduring fatigue life across various loading scenarios. This result holds significant implications for the durability assessment of our gooseneck rod. Fatigue analysis is crucial as it simulates the repeated loading and unloading cycles that a component undergoes during its operational lifetime. A horizontal line at 1 signifies that regardless of the magnitude of loading, the gooseneck rod maintains a constant fatigue life, suggesting exceptional resistance to fatigue-induced failure. This consistency in fatigue life across different loading scenarios underscores the robustness and reliability of our gooseneck rod design, affirming its suitability for prolonged and repetitive use in real-world applications such as medical treatments.

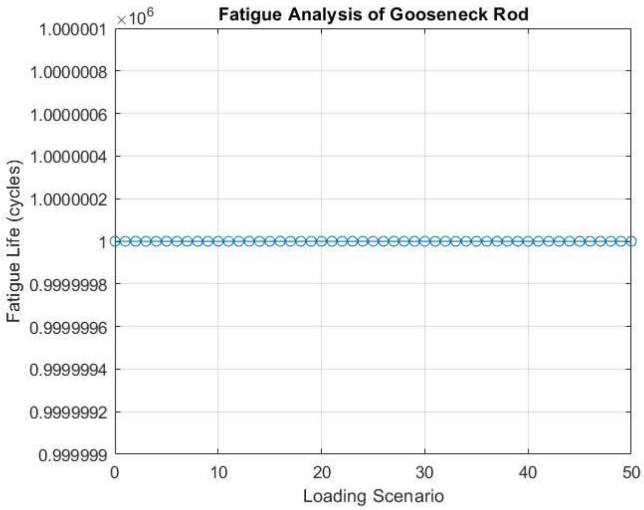

Figure 5. **Fatigue Analysis Results.** Constant scenarios found run to find that the expected life to be 1*10^6.

Discussion

Interpretation of Results

The iterative design process for the transducer holder attachment is aimed to address key functional requirements while enhancing user experience. Through four distinct iterations, we progressively refined the design to meet specifications for both secure transducer clamping and extensive range of motion. Each iteration is built upon successful elements of the previous design, incorporating novel solutions to identified limitations. Notably, the final iteration successfully resolved rotation limitations by introducing circular cutouts in the base component, enabling a wider range of motion as per design specifications.

FEA of the transducer holder attachment provided crucial insights into its structural performance under load. The analysis revealed a maximum displacement of 0.00000826 mm, concentrated above the stem of the main ball joint component, and a maximum reaction force of 0.094 N, predominantly around the transducer clamps. These results indicate the attachment's ability to withstand the weight of a focused ultrasound transducer while maintaining stability and integrity.

Stress analysis conducted on the stainless-steel grade 304 gooseneck attachment demonstrated its durability and resilience under operational conditions. Peak stress levels of 275 MPa were observed, significantly below the material's yield strength, suggesting a substantial safety margin[4]. The analysis showcased efficient load distribution with minimal axial stress and gradually increasing combined stress over multiple loading scenarios. The gooseneck's curved and flexible design proved effective in absorbing stress and preventing permanent deformation, ensuring long-term reliability during repetitive use in medical treatment scenarios.

Fatigue analysis of the gooseneck rod further validated its durability, exhibiting a consistent and enduring fatigue life across various loading scenarios. The horizontal line at 1 on the fatigue life plot indicates exceptional resistance to fatigue-induced failure, underscoring the robustness and reliability of the gooseneck rod design. These findings affirm the suitability of the gooseneck rod for prolonged and repetitive use in real-world applications, particularly in medical treatments, where reliability and durability are paramount.

Conclusions & Significance

In conclusion, the iterative design process, structural analyses, and durability assessments have culminated in the development of a robust and reliable transducer holder attachment and gooseneck rod assembly. These components form a crucial part of the articulating arm system, which addresses a crucial need within the medical imaging field by enhancing diagnostic accuracy and treatment precision across various medical specialties. By providing secure transducer support and facilitating a wide range of motion, the articulating arm system allows the UVA CLEAR research team to perform treatment with confidence and efficiency. The successful resolution of design challenges and validation through comprehensive analysis underscores the significance of our approach in engineering solutions that can comprehensively meet demands in medicine. Moving forward, the continued refinement and optimization of these components will further enhance their utility and impact in improving patient care and outcomes.

Limitations

The main limitation of the project is the 3D printed material of the transducer holder attachment.

Ideally, the device would be manufactured completely out of metal for use in the clinic. Specifically, stainless steel would be best because it is as strong as titanium, but half the weight, contributing to the portability of the device around the clinic. The current plastic design is not as strong as either metal, making it slightly less optimal for repeated use over extended periods of time as quantitative long-term stability is unknown. Furthermore, metal is easier to keep clean between patients and has been seen to harvest less bacteria on the surface than plastic medical devices. Stainless steel can withstand higher temperatures and is resistant to common chemicals used to sanitize the device between patients. Consequently, the SLA plastic design could lead to deformation or material degradation due to temperature and chemical restrictions.

Next Steps

Our next steps include a series of significant steps to refine and validate the durability and usability of our articulating arm system. Initially, we will proceed with the manufacture of the transducer holder attachment using metal, ensuring alignment with the specifications derived from our stress and fatigue simulations. Subsequently, we will transition to conducting comprehensive testing with real users, allowing for hands-on evaluation in practical settings. With this we can gain invaluable feedback on usability, ergonomics, and overall performance, guiding us in further iterations and enhancements. By iteratively refining the design based on user insights, we aim to optimize the assembly's functionality, durability, and user experience, ultimately delivering a robust and user-friendly solution tailored to the specific needs of our intended application domain.

Materials and Methods

Creation of Prototype Designs and Physical Model

Design iterations of the transducer holder attachment, as well as the final prototype, were created using the computer-aided design software, Autodesk Fusion. Each iteration was 3D printed using stereolithography (SLA) filament by a Bambu Lab X1 Carbon Printer at Stacey Hall's BME Fabrication Space. All major components of the final physical prototype were printed separately (i.e. base, ball joint, clamps, screws) and then assembled. First, one screw was threaded into the right threaded hole in the main ball joint. Super glue was applied to the circular indent of the right clamp, immediately followed by the end of the screw being press fitted into the circular indent of the right clamp. These two steps were repeated for another screw, the left threaded hole on the main ball joint, and left clamp. Next, the main ball joint was seated into the base component. The third screw was threaded into the side base hole until flush with the ball joint to ensure it did not move. The entire transducer holder attachment was then attached to the gooseneck arm by threading the base onto the top of the gooseneck stand. Finally, the ultrasound transducer was added to the attachment by loosening the ball joint screws, placing the transducer between the clamps, and re-tightening the ball joint screws until the transducer was completely secure between the clamps.

Finite Element Analysis

The durability of the transducer holder attachment was computationally evaluated using finite element analysis. Finite element analysis on the transducer holder attachment was performed using the static stress analysis feature in Autodesk Fusion. Each component was modeled using ABS Plastic, as PLA was not an available option. Along with PLA, ABS is one of the most common materials used for 3D printing. ABS is also known to have a much lower tensile strength and flexural modulus compared to PLA, thus introducing a worst-case scenario that makes it appropriate for use in finite element analysis. 5 newtons of load were applied both to the top of the transducer and the front face of the transducer, representing a load double that of the actual transducer to introduce another worst-case scenario that tests the strength of our 3D-printed attachment. The resulting study produced results for the anticipated displacement and reaction force of the transducer holder attachment, creating visuals for identifying points of potential failure.

Stress & Fatigue Simulations

Material properties utilized include a yield strength of 275 MPa and Young's modulus of 193 GPa. Geometric properties of the rod, such as its length (0.4572 meters) and diameter (0.0127 meters), are specified[4].

Loading scenarios ranging from 0 to 100 Newtons are considered. Stress analysis is conducted, incorporating axial and bending stresses, with combined stress calculated using linear superposition. Maximum stress is compared against the yield strength to evaluate structural integrity. Results are visualized through line plots depicting stress analysis outcomes. Fatigue analysis is then performed to assess the rod's endurance under cyclic loading conditions. S-N curve parameters, including a stress amplitude limit of 200 MPa and an endurance limit of 1 million cycles, are utilized. Fatigue life estimation is conducted using Basquin's equation, considering the stress amplitude for each loading scenario. The resulting fatigue life values are plotted against loading scenarios to visualize the rod's fatigue behavior. Additionally, tensile strength simulation is carried out, with the maximum stress from stress analysis representing the simulated tensile strength, providing further insight into the structural performance of the gooseneck rod.

End Matter

Author Contributions and Notes

J.T.I. created CAD designs; J.T.I., E.M.S., and M.M.Z. constructed prototypes, performed computational testing, and wrote the final report. T.S.B. and A.F.K. advised on device specifications. The authors declare no conflict of interest.

Acknowledgments

The capstone team would like to thank Tamika Braveheart, Andrew Kostelac, and the team at UVA CLEAR for providing us with this project opportunity and advising us throughout the device's development. We would also like to thank Dr. Timothy Allen and the rest of the BME 4063/4064 teaching team for their advising throughout the project.

References

1. Schwartz, E. K. C., Wolkowicz, N. R., De Aquino, J. P., MacLean, R. R. & Sofuoglu, M. Cocaine Use Disorder (CUD): Current Clinical Perspectives. *Subst. Abuse Rehabil.* **13**, 25–46 (2022).

2. Key Substance Use and Mental Health Indicators in the United States: Results from the 2020 National Survey on Drug Use and Health. (2020).

3. Koob, G. F. & Volkow, N. D. Neurocircuitry of addiction. *Neuropsychopharmacol. Off. Publ. Am. Coll. Neuropsychopharmacol.* **35**, 217–238 (2010).

4. Grade 304 Stainless Steel: Properties, Fabrication and Applications. AZoM https://www.azom.com/article.aspx?ArticleID=2867 (2005).

5. Buch, A. Ultrassom Focalizado no Parkinson. NeuroSharing https://en.neurosharing.com.br/post/ultrassom-focalizado-no-parkinson-estudo-nejm (2013).