Project Design Report

DeciBone

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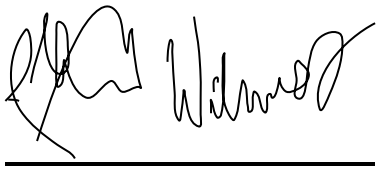
Alexis Wilmot: 

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Executive Summary

Patients undergoing brain surgery experience skull drilling and its high-intensity mechanical waves radiating from the drill contact[1]. The resulting bone-conducted and vibrational stimuli have proven to be uncomfortable for the patient, sometimes resulting in instances of post-traumatic stress disorder (PTSD) and other heightened stress signals.[7] The team designed DeciBone in collaboration with the Mayo Clinic as a noise-cancellation device that decreases the sound intensity of bone-conducted vibrations during cranial drilling by destructive interference. While the total addressable market of DeciBone is $38.4 billion calculated from the 38.4 million relevant neurosurgical, spinal, and dental procedures possibly involving awake drilling,[8-11] the serviceable addressable market of $400 million lies with neurosurgeons alone, calculated from an incidence rate of 400,000 surgeries.[8] The primary users of the device consist of neurosurgeons, neurologists, and patients directly interacting with the device, but the hospital and dental office secondary users and practicing psychologist tertiary users are also indirectly impacted by the outcomes of this device.[1]

The team conducted five methods of investigation in the design research process: 1) clinical interviews, 2) clinical observations, 3) control theory personal lectures, 4) industry professional interviews, and 5) patentability interviews. While research in the clinical setting revealed deeper nuances of the drilling problem and personal experiences from the three primary users, the control theory lessons clarified key points of confusion when developing a feedback system and the industry perspective guided the design process forward. From these research notes, DeciBone's required design inputs were updated to better reflect the current model. Certain design inputs remained from earlier in the semester, such as a 50% reduction in wave amplitude[1]; however, certain engineering characteristics were added, such as specific diameters reflecting patients' anatomies,[30] 95% accuracy of frequency measurements, and speed of adaptation to changing vibrations <50ms[1]. Others like reducing the pitch of vibration by 50% were removed; this switch reflects the team's departure from a drill-coupled solution toward an independent solution that is completely novel to the surgical intellectual property space. Human factors considerations were also expanded upon in citing a non-invasive design that boasts an integration time of <2 min including surgical monitor setup,[36,37] and the packaging requirements were further specified.[30,37-40]

The proposed design, DeciBone, accomplishes this decrease in vibration amplitude as an earpiece with an over-ear loop. An accelerometer is placed in the ear canal to sense the bone-conducted vibration from the drill, and this signal is inverted using a microcontroller within the earpiece casing. This signal is then transduced into a counter-vibration on the temporal bone that destructively interferes with the drill-produced wave as they are equal in frequency but opposite in phase. The final aspect of DeciBone is a PID, or proportional, integral derivative, feedback system that can assess the device's error in amplitude reduction and correct the counter-vibration. These components as well as additional packing considerations combine to a cost of goods sold (COGS) of $66.21[42-49] while their dimensions remain relevant to the ear area and a range of patient anatomical requirements.[32]

Engineering analysis revealed a 48% reduction in the vibration amplitude when two transducers were set equidistant from a piezoelectric sensor at 0.75 inches, but when these components were set at 2 inches apart in a separate test, the reduction was far reduced. In addition, there was not a significant percent reduction when the transducers were set 0.75 inches apart on a skull replica instead of flat plastic. These findings support the need for a control loop system to assess the error produced in varying drilling conditions, such as a different distance from the drill site and varying surface characteristics of skull bone. To tune this frequency output, a 95% accurate frequency measurement was obtained using a Fourier transform. Lastly, the PID system was validated by observing destructive interference of vibration amplitude magnitudes. Moving forward, the team hopes to achieve both prototyping advancements, such as purchasing components that are optimal for the ear area, as well as testing achievements, like performing studies in simulation software and on cadaver heads.

Project Description

Brain surgeries like craniotomies are often performed while patients are under conscious sedation,[1,2] which is when an individual experiences depressed consciousness under sedatives yet remains able to respond to prompts.[3] Surgeons aim for awake cranial procedures when operating in functional regions as they may perform live assessments before and after progressing through tissue.[4] In addition, medical professionals seek to minimize time under general anesthesia as awake patients leave the ICU hours earlier, get discharged from in-patient care days faster, and decrease rates of surgery-related mortality.[5,6]

Patients undergoing awake surgery do not feel pain due to local anesthesia and the lack of brain tissue pain receptors can still experience discomfort during the drilling portion because of intense sound waves conducted from the drilling point to the inner ear.[1,4] This sensation may be intense enough that the patient refuses further drilling until placed under general anesthesia, eliminating the opportunity for live functional testing.[1] Cranial drilling can also cause significant psychological impact such as patients developing post-traumatic stress disorder (PTSD) and showing hyperarousal from procedural recall.[7] These memories, often reported as auditory memories from the drilling process,[4] offers an opportunity for an engineering solution that improves awake patients' experiences during surgery. The overall design goal is to create a noise-cancellation device that decreases the sound intensity of bone-conducted waves during cranial drilling.

The market of interest is the USA, where there are about 400,000 neurosurgical procedures[8] as well as 500,000 spinal surgeries, [9] 17,500,000 cavity fillings,[10] and 20,000,000 tooth extractions performed annually,[11] as shown in Table 1. DeciBone's approximated unit manufacturer's suggested retail price (MSRP) is based on $1000-per-piece drill bits used with the Medtronic Midas Rex drilling system as drill bits are used once before being thrown out for sterility in the cranial operating field, and the new device will not be reusable between patients.[1] DeciBone's total addressable market (TAM) representing all awake drilling procedures that may utilize a reduction in bone-conducted sound propagation is upwards of $38.4 billion; however, the device's serviceable addressable market, or the most immediately relevant neurosurgical market to acquire, is around $400 million.

Table 1. Total addressable market (TAM) and serviceable addressable market (SAM) annual market size estimates for DeciBone in the United States.

	DeciBone Bone-Conduction Cancellation	
TAM-Incidence	*Neurosurgical Procedures*	400K
	Spinal Surgeries	500K
	Cavity Fillings	17.5M
	Tooth Extractions	20M
SAM-Incidence	400K	
DeciBone Predicted MSRP	$1000	
TAM	$38.4B	
SAM	$400M	

There is no product currently used to prevent patient discomfort from drilling noise despite local sedatives applied during awake craniotomies.[1] Some surgeons resort to placing the patient under general anesthesia instead of using local anesthesia to completely circumvent cognitive appraisal of the drilling, but this hinders neurologists from assessing brain damage and makes identifying healthy brain tissue difficult.[1] Earplugs may limit air-conducted sound but do not address vibrations conducted through the skull leading to heightened auditory stimulation.[1] While preoperative neuropsychological counseling reduces patient anxiety and increases intraoperative tolerance, there are inconsistencies between preoperative patient anticipation and perioperative perception.[12] Patient experience during drilling is currently ignored, emphasizing the need for further problem exploration.[4]

The primary users in the USA consist of operating neurosurgeons (3500),[8] neurologists interacting with the patient (2620),[13] and patients themselves (400,000 annually).[8] The secondary users, or those that would pay for the device without direct interaction, include US hospitals

offering neurosurgical procedures (5700)[14] as well as possible oral surgical offices (201,517).[15,16] The tertiary users are US psychologists (81,000)[17] and psychiatrists (56,536)[18] who treat patients' postoperative psychological trauma ranging from PTSD to depression.

Design Research and Investigation Methodologies

The initial exploration of the problem involved interviews with various surgeons. The first general observation made from interviews documented in Table 2 with surgeons at the Mayo Clinic was that all surgeons have different drill preferences. They may settle on a particular drill, grow comfortable with it, and are reluctant to try new versions despite possible benefits. Dr. Abode-Iyamah, a spinal surgeon at the Mayo Clinic, emphasized the importance of seamless integration as the device "should not be difficult to adapt to current practices" and that it "needs to feel 'right'" immediately upon holding in one's hand.[19] Another spinal surgeon at the Mayo Clinic, Dr. James Buchanan, states the solution must not physically obstruct the surgeon's field of view as "bulky drills block what you're looking at".[20] The team concluded that designing a universally adopted drill poses a challenge due to conflicting preferences and creating a drill that dampens vibrations without increasing bulkiness is particularly challenging.

Good Vibes also observed three awake craniotomies. The goal was to get an intuition for the workflow of the drilling process, develop an understanding of the drilling noise/vibration, and learn about the patient's perspective. Most clearly, the team noted that the drill sound was very high-pitched and excessively loud.[21] Because the surgeries were awake, team members had the opportunity to speak with the patients who said "the sound is worse than the vibration" from the drill and that the "second drill was worse than the first drill" due to the second iteration being higher pitched.[21] This report conveyed that canceling the sound coming from the drill would better address the patient comfort optimization compared to reducing the physical vibrations.

Good Vibes decided upon the final concept to be a noise cancellation system, which incorporates a control system to allow the device to react to changes in the sound produced by the drill, instead of modifying an existing drill. Due to insufficient experience with building control systems, professors conducted private lectures and provided feedback on the general concept. These sessions were less like interviews with prepared questions, but were more instructor-led regarding the theory of different control systems and the practicality of implementation. The

meeting with Professor Erik Verriest, a control systems theory professor from the Georgia Institute of Technology, proved the most significant. He suggested beginning with a Fourier transform of the signal, identifying the most important frequencies, and sending the magnitude of these frequencies to the control system.[22]

The team next interviewed Dr. Arik Hanannel who is a medical doctor and the CEO of FUSMobile, a company that uses ultrasound waves to ablate neural tissue for chronic pain relief. Due to the similarities in the physics of noise cancellation and the device his company develops, Good Vibes contacted him to help guide prototyping and testing strategies and educate the team on the physics of wave propagation.[23] Team members also interviewed Eric Miller, the lead physicist at FUSMobile. A primary goal for these meetings was to learn about building a physics simulation, and Miller suggested using k-wave, a MATLAB toolbox for acoustic simulation.[24] In addition, Dr. Hananel recommended developing a simulation before testing on animals.[23]

Lastly, patentability aspects were confirmed with Mayo Clinic advisor, Dr. Kyle Cowdrick. The team discussed how their device could differ from the most obvious related area: commercial noise cancellation headsets. One key difference from these patents, such as the filter system in Patent US 10,657,950 B2 (‘950)[25] that mitigates the overrepresentation of low-frequency vibrations by bone conduction due to blockage of the ear canal, is that the new device would need to cancel higher frequencies in a drilling context as a bone-conducted output to avoid damage to the patients’ eardrums.[26] Next, the group covered features of patents that cancel unwanted, bone-conducted feedback from hearing devices and determined that the new device should be completely non-invasive and not require coupling to another implanted device, such as in Patent US 11,212,625 B2 (‘625).[27] Lastly, the team determined how the device may differ from unpatented or expired concepts that might interfere with non-obvious claims. One such example is an unfiled senior design project from the University of Rochester that measures the drilling vibrations from the temporal region and produces a deconstructive counter wave[28]; however, team members conveyed that the new device could differ in its feedback orientation with the sensor downstream from the transducer as well as an in-ear sensor for additional blockage of the ear canal.[26]

Table 2. Comprehensive list of professional contacts in which Good Vibes conducted interviews, observed in clinical settings, and learned from during private lectures as well as topics discussed.

First Name	Last Name	Title	Topics Discussed
Sanjeet S.	GREWAL	Neurosurgeon, Mayo Clinic	*General mentor information and DBS surgery + intro to problem*
Kyle	COWDRICK	Medical Technology Development, Mayo Clinic	*Confirmation of IP differentiation*
Alfredo	QUINONES -HINOJOSA	Neurosurgeon, Chair of Neurosurgery, Mayo Clinic	*Tumor resections + patient psychology*
Stephen M.	PIRRIS	Spinal Surgeon, Mayo Clinic	*Drill specs in spinal surgery*
Kingsley O.	ABODE -IYAMAH	Spinal Surgeon, Mayo Clinic	*Anesthetics and surgeon preference*
Jeffrey	JANUS	Otolaryngologist, Mayo Clinic	*Bone conduction pathways + ENT*
Ian A.	BUCHANAN	Spinal Surgeon, Mayo Clinic	*Piezoelectric drills + drill specs*
Steven L.	GOUDY	Otolaryngologist, Children's Healthcare of Atlanta	*Pediatric perspective + surgeon preference*
Gaetano	DE BIASE	Spinal Resident, Mayo Clinic	*Neurosurgical drilling + patient experiences*
Evan J.	GOLDBERG	Director of Scientific Affairs, T3 Labs	*T3 labs introduction*
Saylan	LUKAS	Medical Device Engineer, GCMI, T3 Labs	*Craniofacial implants*
Arik	HANANNEL	CEO + Cofounder, FUSmobile	*Simulations, experimental setup*
Eric	MILLER	Lead Physicist, FUSmobile	*K-wave, simulation setup and properties of tissue*
Alper	ERTURK	Mechanical Engineering Professor, Georgia Tech	*Vibration simulations and wave propagation*
Sam	COOGAN	Electrical Engineering Associate Professor, Georgia Tech	*PID control and control theory*
Eric	VERRIEST	Electrical Engineering Professor, Georgia Tech	*Control systems and control theory*

Design Pivots and Updated Design Inputs Table

When initially receiving the problem statement and project name (GNTLdrill) from the Mayo Clinic sponsors, Good Vibes was under the impression that they had to redesign a neurosurgical drill and/or drill bit. The clinical problem presented stemmed from the drilling part of neurosurgery, so the team thought that the most effective way to solve this was by fixing the source itself; however, the group decided to pivot during ideation from the initial idea of designing a new drill or drill accessory to damping the vibrations already created by the drill. The top design as described in the Good Vibes Prior Art Report is a vibrating earpiece that contains an accelerometer in the ear canal and a transducer on the patient's temporal bone.

The team presented this idea to their Mayo Clinic sponsor Dr. Grewal, and he was surprised that they pivoted from developing a new drill to an independent drill vibration damping system; however, he encouraged the switch, explaining that this was elegant due to the vibrating earpiece not obstructing the surgical site while allowing him to use drilling technologies that he had become accustomed to after years of experience.[1,20] Additionally, he commended that the earpiece is easily removable and non-invasive. He recommended, however, that the device have protrusions from the over-the-ear loop that can alter where the transducer may sit on the patient's temporal bone.[29] Taking this suggestion into account, Good Vibes redesigned a version of the device with a transducer arm that extends and may be placed according to specific patient characteristics or operation locations close to the ear.

Table 3 below reflects the most recent list of specific additional or removed design inputs required by DeciBone. Because the device is located in the ear area, there are inherent dimensional requirements to both fit the right and left ear, reflected through appropriate labeling, as well as in a minimum ear canal aperture value for generalizability between patients.[30] Additional frequency considerations were added regarding cancellation such as measurement accuracy and speed of measurement to optimize the destruction of vibrations.[1, 22] Human factors such as integration speed and monitoring were further considered provided that the usage context of the device is now understood.[22] Lastly, considerations such as sterilizability, compatibility, and lifespan were removed as DeciBone is now designed to be single-use and is independent of the drill.[1]

Table 3. Updated design inputs table generated from user needs with respective metrics, citations critical or essential determinations, and respective changes. All new inputs are listed in green, removed inputs in red, and changes to existing inputs italicized in blue.

Input Description	User Need(s)	Design Input	Metric	Cite	Critical	Essential	*CHANGE*
1.) Engineering							
A. Physical							
I. Dimensional Characteristics	Compact	*Secured to the ear area alone*	*0% obstruction to the surgeon's workspace*	1, 20		X	Device is no longer at the drill site
	Able both ears on different sides of the head	Device can fit on both ears	2 mirrored orientations of the device (a right ear and a left ear) will be produced	30		X	Device is around the patient's ears, so mirrored anatomy must be considered
	Components are small enough to fit in most patients' ears	Device can comfortably fit inside the ear canal	Accelerometer <3.25 mm in diameter	31		X	Added based on the minimum ear canal aperture to adapt to all patients' anatomies
	Earpiece snuggly fits most patients' ear canal geometries	Foam insert can expand to fit a variety of ear canal apertures	Foam insert >11.94 mm in diameter when fully expanded	31		X	Added based on the maximum ear canal aperture to adapt to all patients' anatomies
II. Functional Characteristics	*Quieter drill sound*	Decrease the amplitude of the propagated wave	*Reduce amplitude of the drill propagated wave by 50%*	1	X		Device reduces the vibrations from the drill, does not alter the drill in any way
	Reduce the pitch of the vibration	Decrease the frequency of the propagated wave	Reduce the frequency of the drill propagated wave by 50%	1	X		No longer aiming to change the frequency of the wave due to variable material properties and skull thicknesses betweens patients that may cause constructive interference
	Provides accurate frequency	Measures frequency	Frequency measurement at 95% accuracy	22	X		Measures frequency, does not control frequency
III. Mechanical Characteristics	Fits each patient's ear anatomy	Device will fit for all patient anatomies	The device is adaptable for 100% of patients, regardless of	1		X	Changed from being at the drill site to the ear area alone

			skull anatomy				
IIII. Electrical Characteristics	Powering device	Device must receive enough power to operate	*Powered by a >1W power supply*	32		X	Previously was 220V
	Current supply	Power must be supplied at an adequate current value	>0.5 A of current supplied	32		X	Not specified previously
B. Usage Cases	Sterilizability	Earbud will withstand manual and automatic sterilization	Will not deform in temperatures over 194°F	32		X	Removed due to device now being single use
	Disposability	*Device, including the powering battery, is easily disposable*	Safe to throw away as per Public Law 104-142	33		X	Device is not reusable; must be disposed of properly
C. Equipment Interface	Compatible	Device must be compatible to used with a pneumatic and electric drill	Must operate around 150 psi and 220V	1		X	Removed due to the device no longer altering the drill's state
D. Reliability	Reliable despite changes in the vibrations throughout drilling process	Quick to adapt to sudden changes in amplitude and/or frequency	Detects changes in drill speed/intensity <50ms	1		X	Device is reliable during the process, not reliable for multiple and prolonged use
E. Maintainability / Repairability	Long lasting	Reliable for over 7 years	Product failure rate over time	1		X	Removed as the device is now single use
2.) Human Factors / Ergonomics	Comfort during brain-accessing phase of surgery	Increase comfort during brain-accessing phase of surgery	Patient satisfaction regarding vibrational aspects of the procedure with qualitative questionnaires	1,34, 35		X	
	Non-invasive	Must not cause any permanent changes to the patient's body	Must not break the skin or physically enter the body	36		X	Because the proposed design is independent from the drill, invasiveness must be minimized
	Fast integration	Quick application to the patient's ear	Device setup <2 min	1		X	The device is additional to current neurosurgical practices, so integration time must be considered

	Able to be monitored by surgeon	The percent of reduction is visible to the surgeon for efficacy assessment	Degree of efficacy is visible to surgeon on a 10.1” surgical monitor	37		X	
3.) Packaging and Labeling	Resistant to abrasive damage	Device will maintain sterility	Packaging will withstand the bubble leak test for 30s ISO 11607-1	38		X	
	Clearly written instructions for use (IFU)	Contains detailed instructions on handling of device	Conforms to IFU Content and Format Draft Guidance for Industry document	39			
	Device can be stored in non-extreme conditions	Device maintains function	Packaging protects device according to ISO 11607-1	40		X	
	Labeled	Device is clearly labeled according to FDA guidelines	CFR Title 21 Part 801	37		X	
	Each ear is labeled based on side of head	Device is distinguishable between left and right ear	There is 1 left and 1 right ear label per device	30		X	Technically marketing two devices that are manufactured under different specifications

Proposed Design -> 719

DeciBone is a bone-conducted noise cancellation system. This device senses vibrations produced by the cranial drill and using the concept of destructive interference, produces a counter vibration to cancel the noise from the drill. It is placed in the ear of the patient as shown in Figure 1, similar to commercial listening headsets.

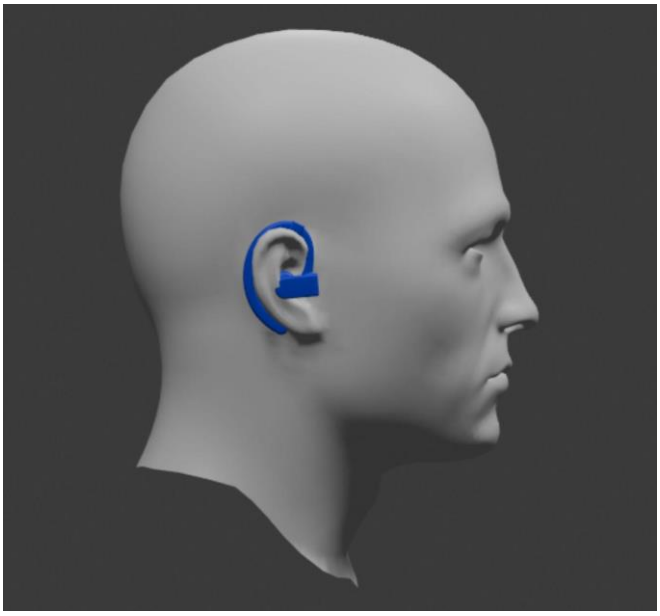

Figure 1. Intended wearability of DeciBone (only right ear device shown) on a simulated human head rendered in Blender.

As shown in Figure 2, DeciBone consists of three main components: a sensor, a transmitter, and a circuit board for processing. The sensor is an accelerometer that measures vibrations near the eardrum to correlate physiological processes with data measurements. This sensor is placed in the ear, in contact with the walls of the middle ear, to measure vibration characteristics like amplitude and frequency. The processing unit carries out necessary calculations to determine the optimal counter-vibration signal. The battery will be an alkaline battery because it is efficient and disposable,[33, 41] as required by Table 3. The counter-vibration generator, a bone-conduction speaker, then vibrates at detected frequencies with a 180-degree phase shift. These vibrations travel to the inner ear via the skull bone and decrease the amplitude of the drill-produced wave by destructive interference shown in Figure 3, resulting in diminished perceived sound intensity by the patient.

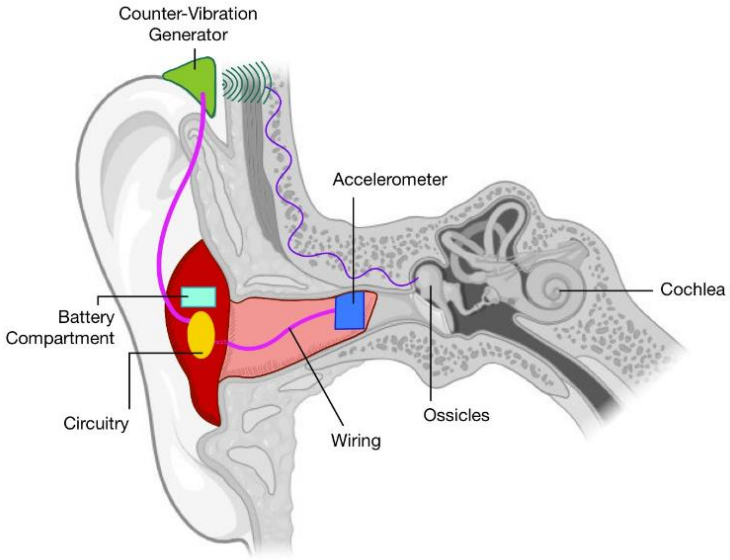

Figure 2. A diagram illustrating the functional components of the device and their incorporation relative to patients' anatomies. These components include an in-ear accelerometer to sense the drill-produced vibration, processing circuitry to invert the signal, and then a temporal-bone transducer to produce the counter-vibration.

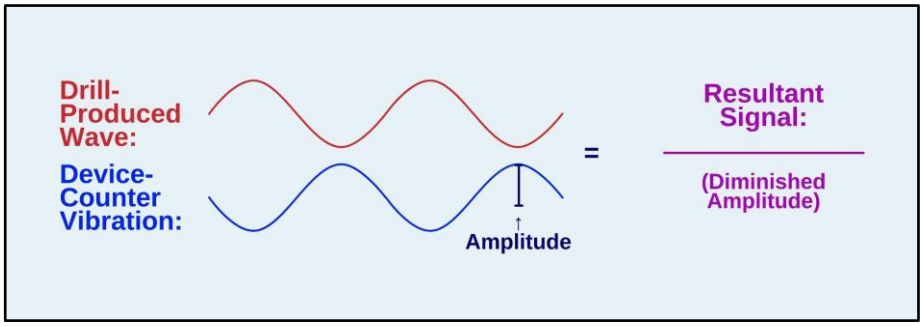

Figure 3. Destructive interference is categorized by a 180-degree phase shift between two vibrational waves of equal frequency and amplitude with a resultant wave of diminished amplitude.

The function of the processing unit and the PID control is described in Figure 4. This is a critical portion of the device because the sound emanating from the drill varies in frequency and amplitude based on the surgeon's applied pressure or location of drilling[1]. A control system ensures that the device can adapt to these variations. The processing unit calculates the two components of the counter-vibration, amplitude, and frequency, independently. The signal

measured by the sensor is separated into constituent frequencies by a Fourier transform. The most prominent frequencies are added together to determine the frequency component of the counter-vibration. The magnitude of the wave detected by the sensor is classified as an error by the system as the goal of the device is to reduce the vibration magnitude to zero. This "error" is fed into the PID control system, and the proportional, integral, and derivative terms of the error are calculated to form the control output. This output is subtracted from the counter-vibration amplitude, continually adjusting the counter-vibrations based on the error state.

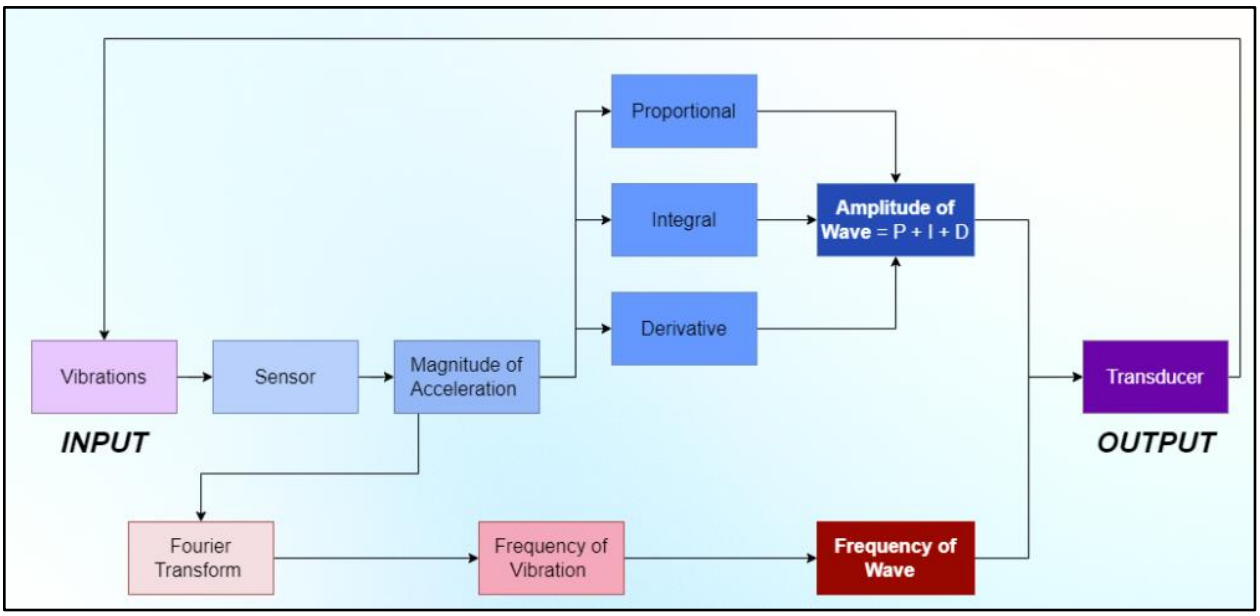

Figure 4. A flowchart indicating how the optimal counter-vibration is produced utilizing both PID control to tune the output amplitude as well as a Fourier transform to accurately measure frequency values to output.

The cost of goods sold (COGS) was calculated to be $66.21 based on intended components needed for manufacturing as well as predicted packaging and shipping costs. The highest costs come from the three main electrical components shown in Figure 5: the in-ear accelerometer ($24.95)[42], processor ($17.50)[43], and temporal bone transducer ($8.95).[44] Additional costs can be found below in Table 4.

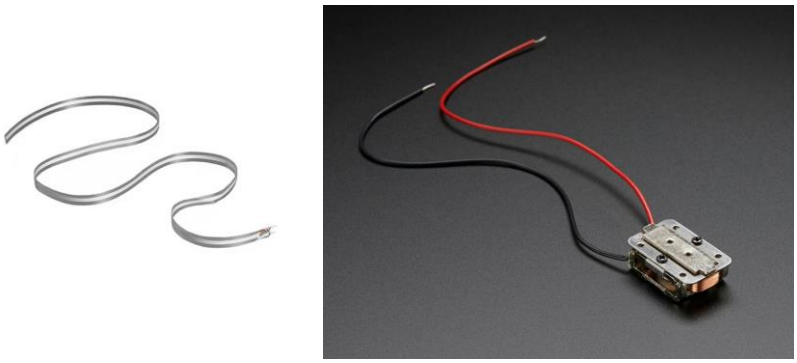

Figure 5. Left image: an accelerometer of appropriate dimension to fit within the minimum human ear canal aperture. Right image: a temporal bone transducer that will vibrate flush against the skull.

Table 4. A total cost of goods sold (COGS) assessment based on the prices of necessary components for DeciBone to be manufactured and functional.

Component	Price
In-Ear Accelerometer[42]	$24.95
Processor[43]	$17.50
Audio Amplifier[45]	$3.95
Temporal Bone Transducer[44]	$8.95
Battery[46]	$2.85
Medical-Grade Plastic Casing[47]	$0.10
Labeled Packaging and Shipping Container[48]	$7.71
Foam Earbud[49]	$0.20
	$66.21 Total COGS

The dimensions of the device are similar to that of over-the-ear-loop headphones. The foam insert containing the accelerometer can be compressed to a minimum ear canal aperture of 3.25 mm but can also expand to fit the upper diameter limit of 11.94 mm.[50] These dimensions are compatible with the average human ear canal aperture of 8.6 mm[50], as shown in Figure 6. The

transducer that lays flush on the patient's temple bone is also 7.50 x 7.00mm.[44] The compact size, as shown with a radius of 39.15 mm in Figure 6, prevents obstructions to the surgeon's operational workspace. The transducer can be connected to the earset by an adjustable protrusion that would be extended or shortened based on varying patient anatomies and surgical procedures. A mirrored version of the diagram shown will also be produced to allow for use on both the left and right ear with the right ear shown in Figure 1.

To ensure simplicity, the device features a single power button for on/pff control and an external LED indicator for power status monitoring. The output of the device, shown as a simple percent reduction value, will further be visible by the surgeon during operation on a typical 10.1" surgical monitor.[37] The device must also be insertable into the ear of the patient as shown in Figure 1 within 2 minutes including setup on the surgical monitor.[1] The memory foam tip incorporated into the device ensures comfort and a snug fit for any patient whilst remaining non-invasive.[36] This straightforward design requires minimal training, allowing surgical staff to focus on other procedural aspects.

Model of Prototype -> 95

Figure 6 represents one version of the final DeciBone prototype with the transducer located on an adjustable arm protruding from the over-ear loop, allowing for customization of where the counter vibration is produced based on individual patient characteristics and operation site.

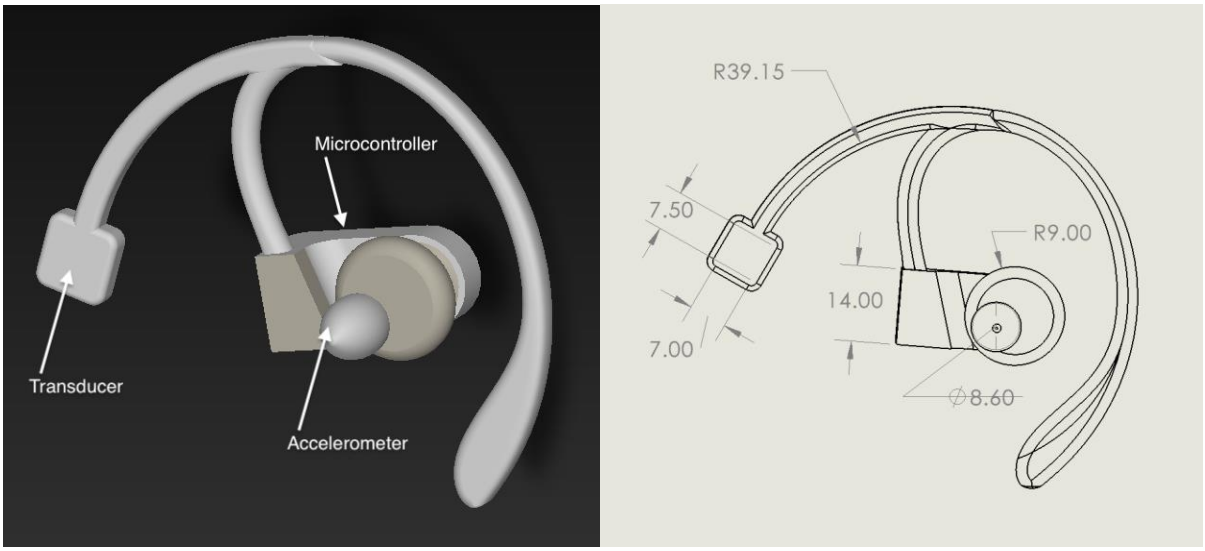

Figure 6. Left image: first model of prototype rendered in SolidWorks with labeled components and varying transducer location. The accelerometer senses the bone-conducted vibration in the ear canal, a signal is processed driven by a microcontroller, and a counter-vibration is produced from the transducer on the protruding arm. Right image: dimensions of device components.

Figure 7, however, represents an alternate version of the same prototype, except the transducer is in a fixed location on the over-ear loop to ensure maximum compactness of the device rather than adjustability.

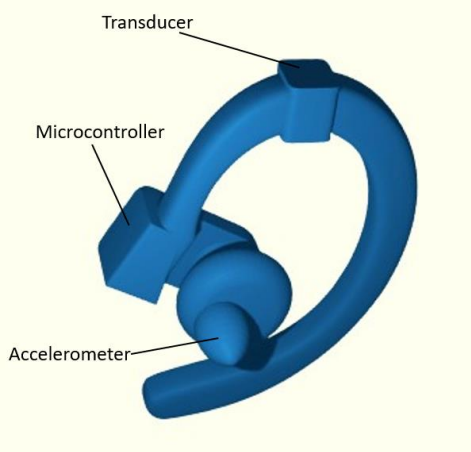

Figure 7. Second model of prototype rendered in SolidWorks with labeled components and fixed transducer location. The accelerometer senses the bone-conducted vibration in the ear canal, a signal is processed by a microcontroller, and a counter vibration is produced from the transducer on the temporal over-ear loop.

Lastly, Figure 8 displays an expanded circuit model for these components used during testing with results shown in the Engineering Analysis section.

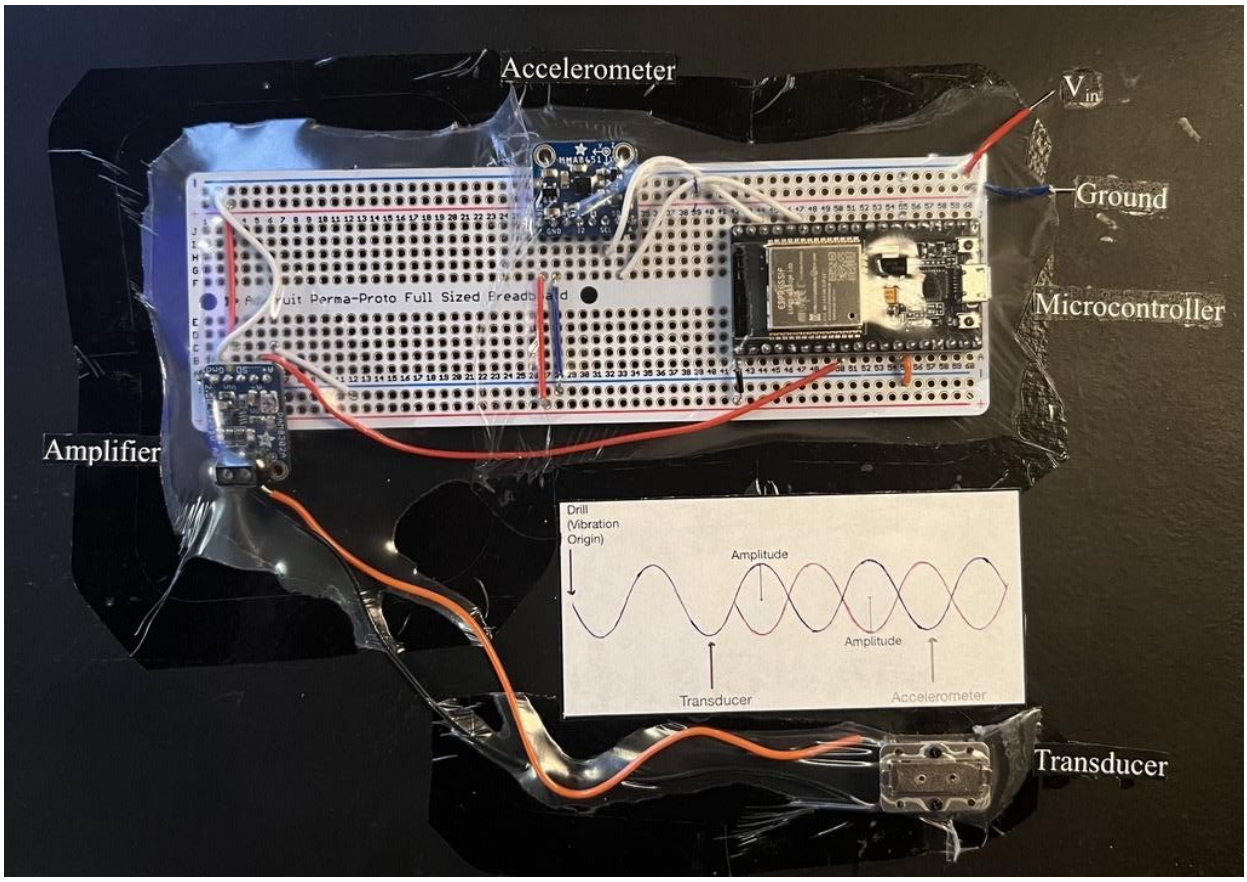

Figure 8. Functional, physical prototype containing a microcontroller for calculations and processing, an accelerometer to measure vibrations, an amplifier to send a louder signal to the transducer, and a transducer to generate a vibration.

Engineering Analysis

DeciBone's goal is to reduce drill-produced wave amplitude, as shown in Table 3. This is achieved through a noise-cancellation system that measures skull vibration and outputs an anti-vibration waveform for a net vibration reduction. This requires two complex sub-systems. The first is accurately estimating skull vibration frequency using an accelerometer or piezoelectric sensor. The second is to use this frequency information to construct an output signal of the correct pitch and then dynamically adjust the waveform's magnitude for a net reduction in vibration amplitude.

Proof-of-Concept: Destructive Interference

Testing began with a proof-of-concept of destructive interference occurring in an elastic medium. This would provide confidence that the underlying fundamental principles of DeciBone behave as expected. To test this, a thin piece of plastic and two transducers were used. One transducer acted as a "drill" producing a vibration of constant amplitude and frequency. The other acted as DeciBone. The transducers were placed 0.75 inches from the piezoelectric sensor, with a general setup shown in Figure 9.

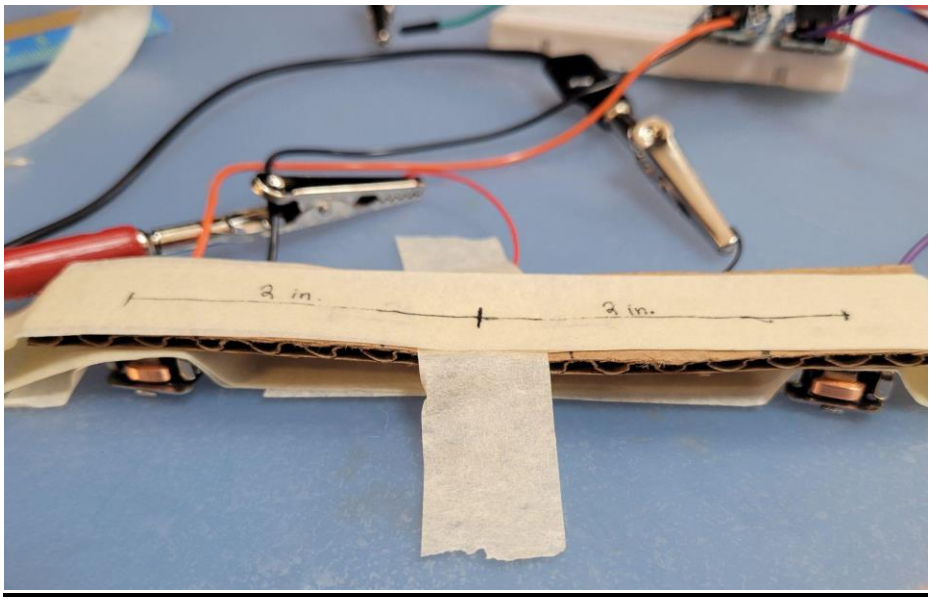

Figure 9. Proof of concept testing setup with two transducers a set equidistant from a piezoelectric sensor on a thin piece of plastic. This distance was altered between 0.75 in and 2 in.

Testing started with only turning on the "drill" transducer to act as a control. The average peak-to-peak voltage of the piezoelectric sensor was recorded for 5 trials. This experiment was repeated two more times. One with the "drill" and DeciBone producing the same waveform, resulting in constructive interference to act as a "worst-case scenario", and the other with the "drill" and DeciBone opposite in phase to serve as an ideal application of the device. A Kruskal-Wallis and Dunnett test was used to test for significance between groups. There was a significant 48% reduction in vibration amplitude with the device on and in-phase compared to the device on and out of phase, as shown in Figure 10.

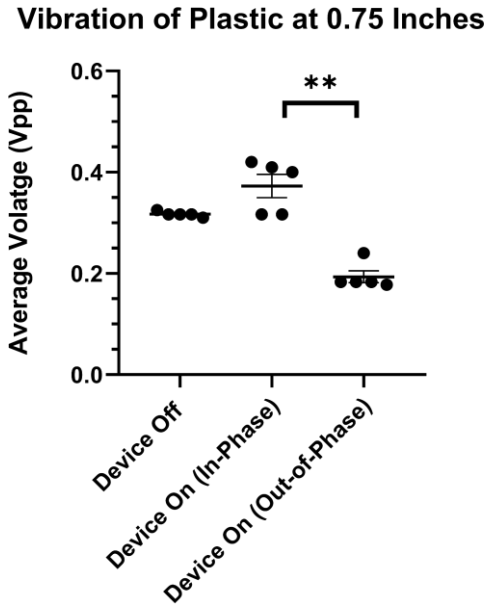

Figure 10. Average peak-to-peak voltage of piezoelectric sensor measuring vibration of a thin piece of plastic with the device off, worst-case (in-phase), and best-case scenario (out-of-phase) at 0.75 inches apart.

This experiment was repeated but with the two transducers 2.0 inches away from the piezoelectric sensor. The purpose of this experiment was to investigate the effect of distance on destructive interference. The results are shown in Figure 11 and the significant decrease in vibration between the different groups is not present. This may be due to some sort of phase shift occurring as the vibration conducts through the bone, but is not significant at close distances. The results of this experiment heavily motivated the need for a control loop to account for these transfer functions.

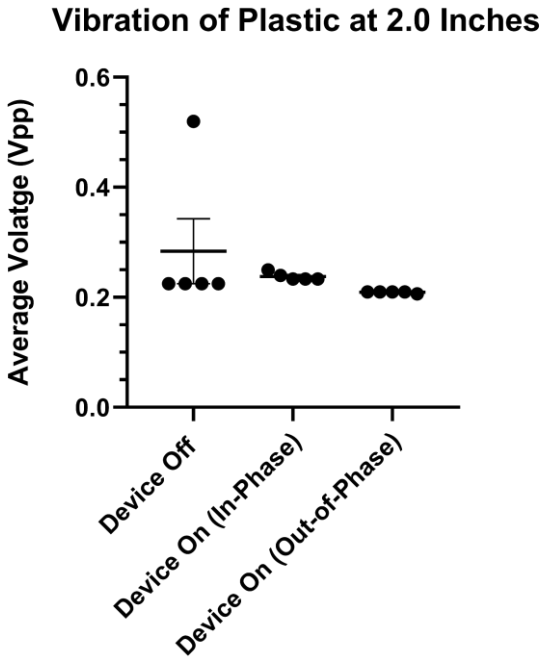

Figure 11. Average peak-to-peak voltage of piezoelectric sensor measuring vibration of a thin piece of plastic with the device off, worst-case (in-phase), and best-case scenario (out-of-phase) at 2.00 inches apart.

The thin piece of plastic served as a convenient and ideal medium for the previous experiments. By using a skull replica made of a bone surrogate material, more accurate experiments could be conducted. The previous experiments were repeated with the setup shown in Figure 12 and the results in Figure 13. The same trends observed with the plastic were present with the skull replica, giving confidence that the physics underlying the project are effective in decreasing the amplitude of bone-conducted vibrations.

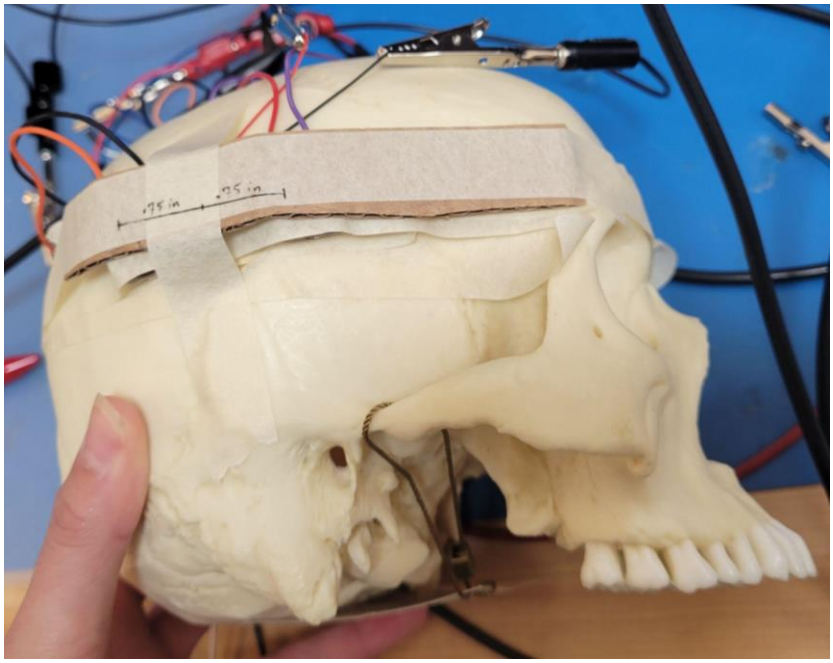

Figure 12. Testing setup for measuring device performance on a skull replica setup with two transducers a set equidistant from a piezoelectric sensor.

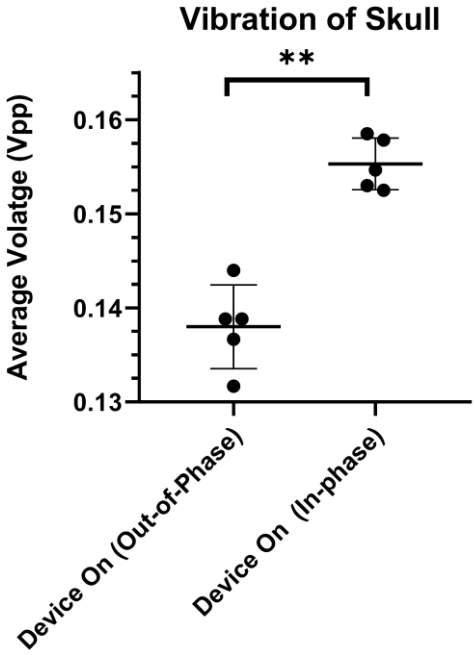

Figure 13. Average peak-to-peak voltage of piezoelectric sensor measuring vibration of skull replica with the worst-case (in-phase) and best-case scenario (out-of-phase).

Sub-System 1: Frequency Estimation

After rigorously proving the fundamentals of DeciBone, testing the frequency estimation component of the critical design input began. The Fourier transform is a powerful mathematical tool used to estimate the frequency components of a time-series signal. For this application, the input is a time series of scalar vibration amplitudes measured from an accelerometer that is then sent to a microcontroller. The arduinoFFT library calculates the most prominent frequency component of the input signal in real-time on the device.[51] This was validated by using a waveform generator to send a signal of known frequency to the transducer and measuring the vibration from an accelerometer placed close to the transducer. ArduinoFFT was 95% accurate in estimating the frequency of vibration and an example of data collection is shown in Figure 14.

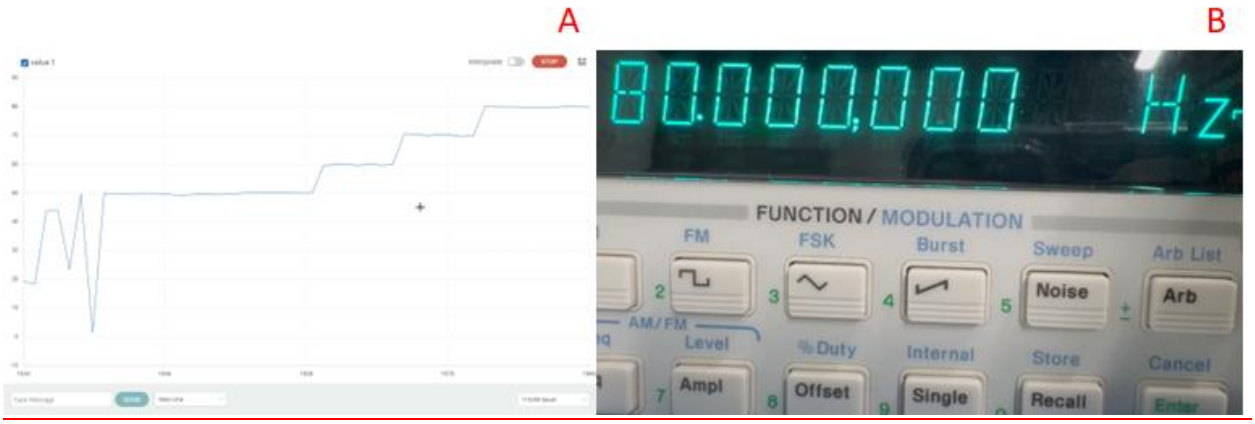

Figure 14. (A) Frequency measurement and (B) frequency input from a waveform generator.

Sub-System 2: Dynamic Amplitude Control

Now that the frequency of the input is known, the loudness or amplitude of the output must be estimated. Utilizing proportional integral derivative (PID) control will make this possible. As explained in the "Proposed Design" section, the PID controller calculates the current level of vibration and suggests an output amplitude of DeciBone, to reduce the overall amplitude of vibration. This was tested by placing a "drill" transducer on a plastic breadboard next to an

accelerometer. The “drill” created vibrations of a known amplitude and frequency, and the output of the PID controller is shown in Figure 15.

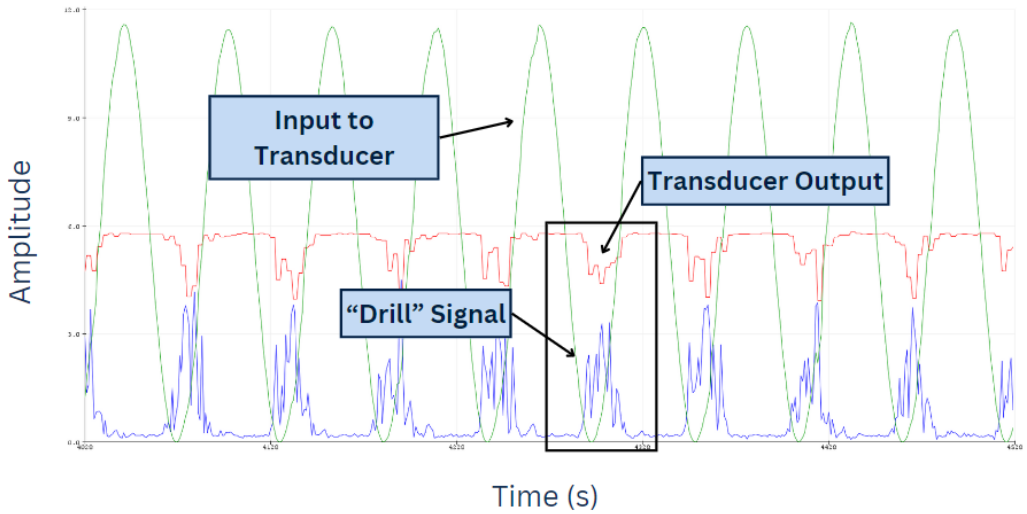

Figure 15. Plot of the vibration of the drill signal (blue), the magnitude of output to transducer (red), and output waveform to transducer (green).

The PID controller is successfully increasing the magnitude of the signal being sent to the transducer out of phase from the vibration input, ideally resulting in a decrease in net vibrations with further testing.

Future Work

To increase the precision of the DeciBone, focusing on perfecting the PID control loop will cause a greater reduction in the intensity of the waves and an increase in the speed of the control system. Iterative prototyping will be used to optimize the control algorithm. Additional funding is crucial to the development of a more accurate physical prototype. With the funds, Good Vibes would acquire a smaller yet more powerful accelerometer, downsizing the microcontroller, and utilizing a Printed Circuit Board (PCB) design, allowing for testing on higher frequencies and making more realistic prototypes.

Further testing on the skull under controlled conditions will allow further validation of the device's efficacy. A simulation in COMSOL would serve as a comprehensive computational model that represents the behavior of wave interaction with bone and its propagation characteristics. Utilizing advanced simulation tools will also provide insight to understand how the device influences the structure of the skull. After, the device would be tested on skull replicas because they provide more of a real-world application regarding how the device will affect the skull. Testing with cadavers will be conducted to simulate real-world scenarios and will be used to evaluate the application of the device as the heads include the real anatomical components with material nuances. Collaborating with medical professionals and institutions to receive more insight will further reveal this device's possible impacts.

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