BME 4908 SENIOR DESIGN PROJECT
EXECUTIVE SUMMARY

VibroBeats

BIOMEDICAL ENGINEERING EXPO

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1. Recognition of Need/Opportunity

There is a clinical need for patients with Parkinson's disease who experience difficulty walking or standing. There are nearly one million people in the US that are affected by Parkinson's Disease with at least 540,000 people in the US that will fall each year, with a large proportion (50–86%) falling recurrently. There are no portable vibration therapy devices currently that are simple enough for users to use at home that can also produce music to aid in the release of dopamine which would improve clinical outcomes. The device would be designed to accommodate patients with tremors by using a simple design with no buckles or heavy metal pieces. The device would not need any adjustments since the material used will be stretchable so one size fits all. Therefore, it will not be any more difficult than their daily task of putting on their socks. The current treatments available for motor symptoms are whole-body vibration therapy, lifestyle changes, physical therapy, and deep brain stimulation. General Vibration Therapy or whole-body vibration apparatus, provides low-frequency stimulation that helps alleviate abnormal or involuntary motor symptoms, it does not include music synchronization which enhances relief and minimizes tremor symptoms. Lifestyle Changes use exercise and nutrition to promote increased overall health and muscle strength to slow the progression of symptoms. Physical Therapy helps treat the loss of movement and aid patients gain control over motor abilities. Deep Brain Stimulation is an invasive surgical procedure that treats advanced Parkinson's Disease and movement disorders which can only be done in a hospital setting.

The business need exists because the Parkinson's Disease Therapeutics Market is valued at around USD 5.18 billion in 2020 and is projected to grow at more than 6.5% CAGR between 2021 and 2027.This device would be oriented toward hospitals, clinics, rehabilitation centers, and mainly at-home therapy. With the increase in the population of Parkinson's patients also comes to an increase in the funding available. There are some similar modalities that currently exist that may address Parkinson's Disease motor symptoms. VibePlate offers devices that provide whole-body vibration stimulation, being able to reach proprioceptors simultaneously, however, their products are expensive and heavy which doesn't allow for patient mobility. Neurobeats was the first attempt to develop this project trying to provide electrical and vibrational stimulation synchronized to music with Bluetooth, however, the prototype was heavy and bulky without successful stimulation.

The current needs of the customer are that the device must be lightweight, water-resistant, and flexible.The device should be a lightweight device that does not interfere with the normal range of motion when walking for elderly patients.The device must operate for an adequate number of sessions in one week on a single charge without external cords or wires connecting to a stationary power source and be able to pair wirelessly to a smartphone to play music on the therapy device. The device should be able to resist moisture, such as small splashes and sweat to allow for incidental water contact and sweat. The device should be adjustable to a range of foot sizes to make it one size fits most. The device should be worn and removed by a stage 3 Parkinson's patient. and the material will not cause irritation to the skin when worn for the duration of treatment. The device should have targeted vibration stimulation to receptors on the lower leg at a beneficial frequency to treat balance and walking problems.

2. Problem Formulation

a. Project Objectives:

This will be a device. It will be a wireless device that can be placed into a lightweight sock. The sock will allow the vibration device to sit above the ankle. The device will connect to a person's device (smartphone) to play music synchronized with vibration patterns to stimulate

proprioceptors for patients with Parkinson's Disease. The project will have a budget of $300 and be completed by April of 2022. By this date, we would have been able to complete market and clinical research on the problem and assessments such as regulatory, cost, hazard, and technology. The design would have also been completed along with virtual simulations done on SolidWorks.

b. Design Specifications:

The customer needs were represented by measurable and verifiable features, also known as design specifications or design inputs. The device must be less than 1 kg and the dimensions should be equal to or under 100 mm by 60 mm. The device's electrical components should function for 1 hour on a rechargeable battery and be enclosed in a water-resistant casing to withstand a minimum of 50 liters of water sprayed at a pressure of 50-150 kPa continuously for 5 minutes at any direction. The device must have to synchronize with a smartphone and play music in the form of vibrational rhythm. The device will be made of a flexible material allowing for a stage 3 Parkinson's patient to wear and remove it without assistance in 5 minutes or less. The device must be biocompatible and can stretch between 22cm to 31cm in length. The device must have a battery capacity that depends on power consumption to allow the device to operate for at least 1 hour on a single charge. The low-frequency sound will be delivered to the patient in the form of 20-100 Hz to the lower ankle.

c. Constraints and other considerations

One constraint was for it to be washable, vibrating motors and electronics cannot be integrated into the sock which should be removable to allow for reusability. The device carrier must be able to hold the device in place securely, due to sock material being soft the device may have a lessened effect from the vibrations. A big constraint is finding the right design to fit the targeted locations due to focusing on the lower leg, there is a limited number of areas that can be targeted to create the desired effect.

3. Solution Formulation

Our design concept is a fabric sock with an outside pocket on the ankle which fits a portable vibration device. The device is enclosed in a silicone casing with an integrated rechargeable battery. The last design concept, shown in figure 3, is where device circuitry is placed into a 100mm x 60mm plastic container coated with silicone, making it water-resistant. The device is slid into a pocket stitched onto the side of a sock. The pocket sits close to the ankle. The device is rechargeable and is made as one size fits most which fits a wide range of sizes. The device can also be placed in a variety of holders, such as a strap.

The formulation of the engineering solution is that the device will be encased in plastic to protect the circuitry from the outside environment and to keep components in place. The case will be coated in silicone for water resistance. The sock should be made from a biocompatible material so it does not cause irritation or allergic reactions. The battery will be rechargeable to increase mobility. Bluetooth connectivity from the smartphone to the device for wireless music-based vibrations allows patients to move during sessions.

This design concept is suitable for the solution to address the need. The utilization of small vibration motors will allow our system to transmit low-frequency sound vibrations (20-100 Hz) through the patient's skin reaching the proprioceptors located in tendons around articulations. This sends signals to muscles and their motor units to help improve balance when walking. The device encasing will allow the device to be water-resistant for multiple uses and protection from electric shock. The sock will allow for a wide range of foot sizes to practically use it, as well as patients being able to wash and reuse the device. The rechargeable battery will allow for the music-synced vibration to play for at least 1 hour. Bluetooth connectivity will allow the device to operate wirelessly and allow for greater mobility.

4. Engineering Analysis and Decision-Making

To make the design decisions we used the established market requirements as a basis allowing us to come up with measurable and verifiable design inputs. An extensive evaluation was done to justify the decisions behind the product's design, as well as the important characteristics for meeting the market needs of the device. Biomaterial analysis was used to determine the efficiency and safety of all possible materials (mechanical properties, elastic modulus, biocompatibility, etc) as well as extensive research on circuits analysis for all electronic components to prevent any risk of electrical injury and ensure functionality. Engineering analysis of biological systems allowed the team to identify the targeted motor receptors (proprioceptors) in the lower leg, specifically the long flexor muscle, posterior tibial tendon, and Achilles tendon. The device carrier needs to be a flexible non-allergenic material since it will be in contact with the skin of the patient. Cotton was found to cause a minimal reaction when interfacing the skin. The device will be encapsulated in a strong case using a 3D printer with PLA filaments, a strong and stiff thermoplastic material. This enclosure will be further secured by a silicone covering, which will offer low toxicity and the ability to repel water.

These receptors were tested by the sponsor and proven to increase balance in many research studies and clinical trials of whole-body vibration devices already on the market. The circuit analysis and electronic components were critical aspects that were used in the engineering analysis to choose the correct electrical components, which include the creation of a simple circuit, electronic device skeleton, and the design of the device's circuitry. The electrical components were decided based on the efficiency of using the device while being safe and being able to meet the design specifications. The three proposed design concepts were determined utilizing Solidworks to visually represent the concepts that were being considered based on the constraints found after cross-analyzing the design inputs. For this reason, the house of quality was performed to decide which design is most feasible. SolidWorks was the main engineering tool used to assist in the design concepts with the ability to create 3-dimensional models of the design concepts and perform stress analysis on the case to ensure the final version would be working. It was determined that software development and coding were required to interpret the audio file and send the signal to the vibration device to play in the form of vibration.

5. Detailed Design

All the electrical components will be connected and assembled to be contained within the assembled case. The case with the electrical components will be assembled and covered in a thin layer of silicone to further close off and protect the circuitry inside. The device will sit on the ankle and produce low-frequency signals by transmitting these stimulations produced from the vibration motors inside the case. The device will be placed in a device carrier sock with a side pocket located exactly where the targeted area is to hold in place the vibrations and be able to efficiently stimulate proprioceptors in the tendons and muscles. The case assembly is divided into two components which are the main body and the cover of the case. The main body includes the area where all the electrical components are housed and it includes all the entry points to the assembled circuit for the device to work. Two openings in the device were placed to allow for openings of one switch and the USB charging port. The cover of the case includes a slit so that it is possible to put a strap through it that makes the device independently functional without the need for a sock. There will also be 4 screws to connect the cover to the main body of the case.
This device incorporate all the functions required in the construction of a pulse-width-modulation (PWM) control circuit on a single chip. Designed primarily for power-supply control, this device offers the flexibility to tailor the power-supply control

circuitry to a specific application. The TL494 chip contains two error amplifiers, an on-chip adjustable oscillator, a dead-time control (DTC) comparator, a pulse-steering control flip-flop, a 5V, 5% precision regulator, and output-control. The oscillation provides provides a positive sawtooth waveform to the dead-time and PWM comparators for comparison to the various control signals. The frequency of the oscillator is programmed by selecting timing components RT and CT (resistor and capacitor). This chip sends out two out-of-phase signals creating DC from the AC music signal, acting as a comparator or operational amplifier. While this design worked fine, the filtering of the peaks needed to be more precise. The executive decision of interveting the order of the chips used (TL494 and LM358) was made with the intention of using the latter mentioned as a peak detector, low-pass filter, and amplifier. The former chip mentioned was kept simply as the wave comparator. This fixed the precision of the filter and allowed the song “Eye of the Tiger” to vibrate accurately throughout the motor.

6. Testing

Verification tests were selected and designed to ensure the project was completed within the boundaries of our expected market requirements and design inputs. The first Design Input (DI) was that the “dimensions should be equal to or under 100mm x 60 mm and it should be made of low-density material less than 1 kg per cubic meter”, thus a simple and accurate test protocol was created where the scope is to measure the length, height and width of the vibration device, sock, and the sock pocket, as well as to measure the weight of the vibration device. This will be accomplished by using a ruler with a centimeters measurement and a scale in kilograms and grams. The second DI required the battery capacity to operate for at least 1 hour on a single charge and the way the team found most efficient was to utilize a Battery Life Cycle Test to accelerate the cycle life of batteries by conducting an extended session where the device is on and vibrating with music until the battery dies. This test assesses whether a battery will meet the requirement to operate for 5 days with 2 sessions per day and last the entire duration of the treatment session. The third DI demands the device’s circuitry to be enclosed inside a case able to withstand a minimum of 50 liters of water sprayed at a pressure of 50-150 kPa continuously for 5 minutes in any direction. It is critical to test the moisture resistance of the device and ensure that it is properly protected against small splashes and sweat that may occur with normal use. This will be tested by utilizing a water pressure system and a visual moisture detection test while exposing the device to the standard specifications of IPX4 for water resistance. The last DI states that low-frequency vibration will be delivered to the patient using a range of 20 - 100 Hz, and to confirm these are the outputs of the device we will implement an Oscilloscope machine to acquired the average frequencies being outputed by the waveforms.

7. Evaluation of Verification Testing

For our first verification, the dimensions and weight of the device case that contains the electrical components is within the boundary limits of 100 mm x 60. The device was measured to be 90 mm x 60 mm x 30 mm. Just reaching the border of our constraints therefore satisfying our market requirement of the device dimensions and weight. The average calculated length of the device is about 89 mm. The average calculated width of the device is about 58mm. The average calculated height of the device is 29mm. The average weight is about 87 grams. The average height range of the device carrier is 246mm to 312mm. Our acceptance criteria is the device should have dimensions of 90 mm x 60 mm x 30.15 mm and weight of less than 1 kg. The height of the stretched sock should be no less than 310 mm. Therefore, this verification test is met successfully as all the results fall within these constraints. For our second verification, the stopwatch protocol average calculated time lag time is 0.66 seconds or 66 milliseconds. Our acceptance criteria is the device

should have latency no greater than 1 second so the delay is not noticeable. Therefore, this verification test is met successfully as all the results of lag time fall under 1 seconds.
For our third verification, the oscilloscope test protocol will be used to measure the vibrational frequency output from the vibration device. The frequencies that were recorded are about: 130 Hz, 73 Hz, 54 Hz, 130 Hz, and 43 Hz. Our acceptance criteria is the device should have an output frequency in the range of ± 10% of 20-300Hz. Therefore, this verification test is met successfully as all the results of the frequency output were within a range of 20-300 Hz. For our fourth verification, the ingress protection test protocol will be used to test if the device is resistant to moisture that it may come in contact with, such as small splashes, spills, or sweat. A total of 6 tests were performed and the result for each was that there was no moisture detected on the paper towel. Our acceptance criteria is the device should be able to not allow any moisture inside the device. Therefore, this verification test is met successfully as there was no water detected anywhere on the paper towel during any of the tests.
For our fifth verification, the battery discharge and consumption test protocol will be to test if the battery is rechargeable and able to operate for an adequate number of sessions in one week on a single charge without any external attachments. The average current the circuitry was pulling was 89.306 mA. There are 2 batteries being used with each having a capacity of 982 mAh each obtained by the battery discharge test, giving a total of 1964 mAh. By dividing the total mAh by the current readings we obtain the hours the circuitry can operate. The total average time of operation with the batteries being used for this circuitry is 21.97 hours. Our acceptance criteria is the battery should have a discharge time of no less than 1 hour and a calculated time of operation of at least 1hr. Therefore, this verification test is met successfully as the results of the battery consumption will take about 22 hours which highly exceed our 1 hour functionality requirement. The sixth verification test was used to determine biocompatibility of the material of the device carrier to ensure there is no irritation to the patient's skin during the duration of the therapy session. Through this research and consideration we concluded that the three main materials that we will use for the device case and carrier are polylactic acid (PLA), cottom fabric and spandex. This verification test passes since the two fabrics and the synthetic fabric are all classified as biocompatible materials and would not cause irritation over an extended amount of time.

8. Relevance to the BME Curriculum.

While completing this senior design project, we were able to apply knowledge of physiology and the symptoms of Parkinson’s Disease to develop an Engineering design suitable for Parkinson's patients. We were able to apply the knowledge from Engineering Analysis of Biological Systems, Data Evaluation Principles, Biomaterials, Circuit Analysis, Medical Instrumentation, Signals and Systems, and Mechatronics. The results from the verification tests were analyzed and interpreted using the knowledge gained from data evaluation principles. We were able to meet the BSBME learning outcomes by using statistics, experimental design, and testing to complete the device verification tests. We worked as a team and combined our different knowledge to work together as a multidisciplinary team to create our device design or prototype. We were able to communicate effectively as a team and with our sponsor to identify a clinical requirement from our sponsor, create success measures, build a system to address these needs while keeping in mind crucial functional and user restrictions, and measure the metrics to ensure that the design outputs to create a device that will be used as a treatment for Parkinson’s Patients.

BSBME Program Learning Outcomes

1. Ability to apply knowledge of mathematics (including differential equations and statistics), physical and life sciences, and engineering to carry out analysis and design to solve problems at the interface of engineering and biology;
2. Ability to design and conduct experiments, as well as to measure, analyze and interpret data from living systems;
3. Ability to design a system, component, or process to meet desired needs, including systems that involve the interaction between living and non-living materials, within realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability, and sustainability;
4. Ability to identify, formulate, and adapt engineering solutions to unmet biological needs,
5. Ability to use the techniques, skills, and modern engineering tools necessary for engineering practice, including the ability to model and analyze biological systems as engineering systems;
6. Ability to function on multi-disciplinary teams;
7. Ability to communicate effectively;

Courses **Outcomes**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
BME 1008C Intro to Biomedical Engineering						X	X	X
BME 2740 BME Modeling & Simulation	X				X		X	
EEL 3110 Circuit Analysis	X	X	X		X	X	X	X
EGM 3503 Applied Mechanics	X			X	X			
BME 3632 BME Transport	X			X	X	X	X	
BME 3403 EABS I	X			X	X		X	
BME 3404 EABS II	X			X	X		X	
BME 3721 BME Data Evaluation Principles	X	X			X			X
BME 4011 Clinical Rotations		X						X
BME 4050L Lab I	X	X	X	X	X	X	X	X
BME 4051L Lab II	X	X	X	X	X	X	X	X
EEL 3135 Signals & Systems	X			X	X		X	X
BME 4100 Biomaterials	X	X	X	X	X		X	X
EGN 3365 Materials in Engineering	X		X	X	X		X	X
EML 4804 Introduction to Mechatronics	X	X	X	X	X		X	X
BME 4908 Senior Design Project	X	X	X	X	X	X	X	X
BME 4800C Design Biomedical Systems Dev	X	X	X	X	X	X	X	X

8. Awareness of the characteristics of responsible professional engineering practice, including ethical conduct, consideration of the impact of engineering solutions on society in a global and contemporary context, and the value of life-long learning.

Relationship between the BSBME Courses and Program Learning Outcomes