Developing Wearable Headband for Enhancing Slow Wave Sleep in Older Adults

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Developing Wearable Headband for Enhancing Slow Wave Sleep in Older Adults

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Abstract

Alzheimer's disease is a progressive, neurodegenerative disease that results in impaired memory and behavior of patient's over time. This disease affects more than 6 million Americans, killing 1 in 3 of those affected[1]. Current treatments focus on targeting the side effects of Alzheimer's, such as depression, agitation, and sleeplessness[2]. However, auditory stimulation through pink noise has been found to increase memory retention in patients with mild cognitive impairments (MCIs). This is because increases in slow-wave activity (SWA), which occurs during a stage of sleep called slow-wave sleep (SWS), are correlated with improved memory retention and recall. This is important as SWS decreases dramatically with age. Pink noise is constant ambient sound with a lower frequency and deeper pitch than white noise; this filters out higher frequency sounds which may disturb sleep, inducing a constant phase of sleep[3]. The overall goal that this project works towards is targeting memory retention in patients with Alzheimer's disease through the development of a wearable device that identifies the SWS stage using electroencephalogram (EEG) readings of brain waves, and delivers stimulation via pink noise to amplify SWS signals accordingly. The results of this project included designs of potential form factors and stress testing results to identify durability. Stress test results showed that Design D had the greatest deformation of 0.003 mm. Demos were created of both a potential mobile application and an audiometer to later fully integrate the headband into personal devices for maximum utility. Survey results collected regarding the designs and both demos regarded high scores of 4-5 on a scale of 1-5 as a positive indication in the categories of functionality, aesthetics, and user-intuitiveness. The mobile application received 75%, 62.6%, and 93.8% in these categories respectively, while the audiometer received 87.6%, 12.5%, and 81.3% respectively.

Keywords: Alzheimer's Disease, slow-wave sleep, pink noise, acoustic stimulation

Introduction

Alzheimer's disease (AD) is a progressive, neurodegenerative disorder that results in impaired memory and behavior of patients over time. It is the most common form of dementia, affecting more than 6 million Americans of all ages[1]. Alzheimer's typically begins with short-term memory impairment, then slowly progresses to affect all intellectual functions. In the later stages, impairment of visuospatial skills and difficulty performing learned motor tasks occurs. The prevalence of AD is found to be higher in individuals of older age, and increases from 10% after the age of 65 to 40% after the age of 85[4]. It presents a significant healthcare challenge due to the lack of effective treatments, as current treatments primarily focus on symptom management such as cholinesterase inhibition drugs and disease-modifying immunotherapy[5].

Slow-wave sleep (SWS) is a restorative phase of sleep that aids in memory strength and clearing plaques associated with Alzheimer's Disease. This is because in SWS, cerebrospinal fluid (CSF) flow, which is associated with the flushing of said plaques, synchronizes with the blood flow within the brain. Slow-wave activity (SWA) is characterized by the 0.5-4.0 Hz frequency of sleep electroencephalograms (EEG), known as delta waves, during SWS[6]. With increasing age however, there is a dramatic decrease in SWS which is concerning. The average percent makeup of the SWS decreases as age progresses. In early adulthood (16-25 years old) to midlife (age 36-50), SWS goes from constituting 18.9% of total sleep, to a meager 3.4%[7]. This is a staggering 82% decrease in SWS, which is considered the most restorative phase of sleep.

Pink noise is a type of ambient noise that can be characterized as softer, quieter, and more flat[3]. Its consistent low frequency and ability to filter out high-frequency sounds has been linked to the enhancement of SWS. In particular, acoustic stimulation using pink noise enhances cognitive functions, mitigates cognitive decline, and potentially slows the progression of the disease. By delivering acoustic stimulation with pink noise during SWS, it is expected to maximize stimulation, with the least likelihood of triggering an arousal response from the user.

Innovation in the field of sleep technology has seen several advances, particularly in the development of wearable devices designed to enhance sleep quality. Prior art in this space includes various sleep aids like white noise machines, smart mattresses, and wearable sleep trackers that monitor sleep stages and provide feedback to improve sleep patterns. Notably, some sleep technologies have integrated features such as light therapy in the form of a sunrise alarm clock from Philips, or EEG sensors to detect brain activity and auditory stimulation to enhance deep sleep[8].

This goal of this project works to usher in transformative changes within the field of Alzheimer's Disease and acoustic stimulation treatment. Firstly, it would diversify the spectrum of available treatment methods, going beyond the traditional pharmacological approaches such as cholinesterase inhibiting, plaque targeting, and NMDA receptor antagonist drugs. The development of a novel acoustic stimulation device could represent a breakthrough in providing a more effective and less invasive strategy for managing the symptoms of AD. Secondly, the project's success could foster a deeper understanding of the mechanisms underlying AD, specifically the role of acoustic stimulation in neurodegenerative disease therapies. This newfound understanding could open up exciting avenues for further research and innovation in the field. Thirdly, the positive impact would extend to patients, as they might experience improved cognitive functions, resulting in a better quality of life. Lastly, and most importantly, if the project demonstrates the ability to increase SWS in patients, it could be a groundbreaking development in the field of sleep study.

To meet the goals of this project, we outlined three specific aims to complete. The first aim is to design and manufacture a comfortable and wearable device, containing the required electrodes and wireless hardware for data collection, to be worn during sleep. The second aim is to develop and test an audiometer system to aid in frequency and decibel calibration of pink noise stimulation and for users to test the frequency of tones they can hear.. Lastly, the third aim is to develop a supplementary mobile application for patient use to provide feedback to our design team and display tracked sleep data.

Materials and Methods

For designing form factors of the wearable headband, design specifications and high-level needs were evaluated. It was decided that important factors include safe functionality throughout the night, comfortability, and intuitiveness for users. Design specifications were generated through analyzing basic user needs, studying existing products, and considering safety regulations. Design specifications for node placements outlined the following locations: F_7, F_8, F_z, C_z, O_1, O_2, and Ground. The F_z and C_z node electrode placements, located on the forehead and top of the head, were prioritized in terms of coverage by the headband designs as these are most important for accurate EEG readings. Sketches were created of potential designs and subsequently designed using Autodesk Fusion 360. To maximize user comfortability, the objective of these designs was to cover all of the node placements while minimizing the amount of coverage on the surface of the head. A survey was created and distributed for feedback on form factor designs of the device and had 20 participants. Stress testing through Autodesk Fusion 360 was conducted to test for durability for the potential designs. The stress applied was collected by determining the average weight of a human head, and then converting that to a pressure unit and applying it to all headband surfaces which would be in contact with the head throughout the night. For the purposes of stress testing, ABS plastics was the material used, as the device needs a rigid backbone to house required hardware in the headband. Physical prototypes of the headbands were outsourced through Sequoia Neurovitality and the material was an elastic fabric. Given that much of the design process involved in this project is aimed at providing important data to build upon in further iterations of this capstone project, the designs and stress testing results aimed to inform future work on which designs provide the greatest balance of comfort, aesthetic, and function.

Prior to beginning the development process of the audiometer, a comprehensive review of existing systems was conducted to outline design considerations and features for the intended use cases. Drawing insights from existing audiometer systems, the design leverages Python libraries such as tkinter and sounddevice to establish the codebase for the audiometer. Key features encompass the creation of a user-friendly interface facilitated by a window initialization mechanism, alongside the incorporation of interactive functionalities including a play button for tone emission and a feedback system for user response validation. The audiometer protocol entails a structured assessment with an initial tone emission at 250 Hz, progressively escalating in frequency at 250 Hz intervals until reaching 1000 Hz. Subsequently, the frequency incrementation shifts to 500 Hz intervals, enabling comprehensive frequency spectrum coverage. In instances where users fail to perceive the emitted tone, an adaptive mechanism initiates iterative adjustments in frequency increments, resulting in the user's hearing threshold. The purpose of implementing this functionality into the mobile application is so that the pink noise emission from the headband could be catered to each individual's hearing capabilities.

In addition to the audiometer, a supplementary mobile application was developed for patient use to provide feedback to the design team and to display tracked sleep data. Research was conducted to determine the common sleep metrics that are displayed on current sleep tracking applications. After the research was completed, a user-interface (UI) was designed for each page of the mobile application such as the home page, audiometer test, and feedback page. Kivy, a Python framework for developing mobile applications, was used to implement the various pages that were designed. The user is first directed to the home page, where their total sleep data is displayed. The data to be displayed on this page was not intended to be fully integrated, as the data collection through the EEG technology was not attainable for this project. The usage of a Python framework, however, was utilized in order to ensure that the audiometer and EEG sleep-tracked data will be easily integrated into the preexisting framework. The audiometer page displays instructions for using the audiometer test and a pseudo-button for beginning the test. The feedback page includes a subject line form and a box form where the user can type their feedback message. The user will also have the option to upload additional images to their submitted feedback. This feedback functionality is an extension of the survey results, as the future users of the headband prototypes will be able to express their opinions and suggestions for improvements for the product directly to the capstone design teams, and the staff of Sequoia Neurovitality.

Results

Design Constraints

The four final designs are labeled as A, B, C, and D as shown in Figure 1. In creating the designs, the circumference was made to be 21 inches in an elliptical shape as this was found to be the average circumference of an adult head. Design A was made thicker in the circumferential part of the headband so that it could confidently accommodate the electrodes and hardware based on potential prototypes provided by the company outsourced for the design. In addition, this design was made to include an adjustable top piece, which would have a wire-like bendable structure in order to adjust the curvature to different head shapes. Design B was made slightly thinner in the circumferential headband and included a fully connected piece going across the C_z node in order to provide increased stability from design A. Similarly, design C was comparable in thickness to design A, but included two supports for the C_z node placement rather than one for increased stability. Design D is most unique as it does not cover the entire circumference of the head, but rather half in the back and has two prongs which cover the node placements on the forehead, connected by a piece running from the front to the back of the head to cover the C_z node. As such, it prioritizes comfortability over durability more so than the other three designs. These varying designs were chosen in order to provide a diverse set of data which will be used to

Stress Testing Results

The designs were stress tested using Autodesk 360 Fusion with an outward radial force to emulate the force of being worn on a head during sleep. The durability of each design and areas of pressure were observed. Designs A, B, C, and D had maximum displacements of 1.40×10^{-3} mm, 1.30×10^{-4} mm, 9.67×10^{-4} mm, and 3.00×10^{-3} mm respectively. The deformations in each headband appeared greatest at the locations near the C_z node, with those areas likely receiving the most stress due to the lack of support across the top of the head as seen in designs A, C, and D. Designs A and C both showed deformation in the pieces supporting the C_z node as they are only connected to the circumferential portion of the headband on either the front or back of the head, but not both. Design B also showed significant deformation around the bottom of the band wrapping around the head, which was different from the other designs. Design D had the overall greatest distortion due to the lack of support both vertically from the front to the back of the head as well as circumferentially around it. The greatest deformations reported in the designs A-D in

Figure 1 were provided as a demonstration of the greatest points of structural strain; though from the color scale provided below each form factor it is observable which areas outside of those areas also are placed under stress.

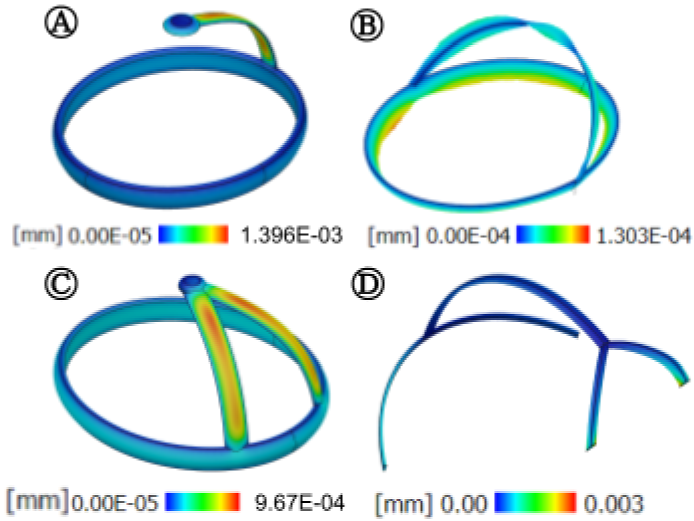

Fig. 1. Form Factor. Results of the stress testing done on the form factor designs.

Audiometer System

The first page of the audiometer system shows a “Play Tone” button and instructions prompting the user to begin the audiometer test. Once the test has begun, a tone at 250 Hz is initially played. Another pop up appears for the user to indicate whether they are able to hear the tone. If the user presses “yes,” the frequency increases. If the user presses “no, ” this indicates that the user failed to hear the emitted tone resulting in a pop up showing the user’s maximum hearing threshold.

Survey Results

In addition, a survey was conducted to gauge potential user opinions about the designs themselves, which included questions about the aesthetics, durability, and comfortability of each design. This survey included feedback from 20 voluntary participants and the percentage of survey participants who voted either a score of 4 or 5 out of 5 for each criteria was calculated. The results indicated that design B had the highest scores for aesthetics, ranking at 61.1%, while design C had the highest scores for durability, at 73.3%. Both designs C and D both had the highest scores for comfortability at 33.3% each.

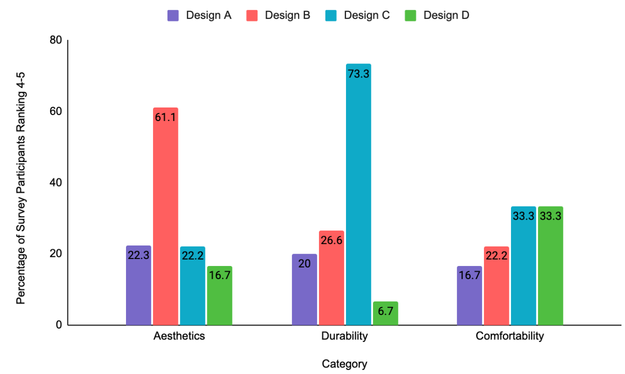

Fig. 2. Form Factor Survey. Percentage of participants who ranked 4 or 5 for four designs regarding aesthetics, durability, and comfortability.

From the same survey, participants were asked to rank the functionality, aesthetics, and intuitiveness of both the audiometer and mobile application. Using a scale of 1-5, with 1 being the lowest and 5 being the highest rank achievable. Results indicated that in regards to functionality, both the audiometer and mobile application with 87.6% and 75% of users respectively scoring between 4 or 5. Moreover, 81.3% of participants believed that the audiometer was user-intuitive and 93.8% believed that the mobile application was user-intuitive. This indicates that a high percentage of survey participants believed that the audiometer and mobile application were functional and user-intuitive. However, with regards to aesthetics, only 12.5% percent of participants voted that the user interface of the audiometer was aesthetically pleasing. Comparatively, 62.6% of participants voted that the mobile application user interface was very aesthetic. This feedback indicates that there was considerable concern over the aesthetics of the user interfaces across multiple survey participants.

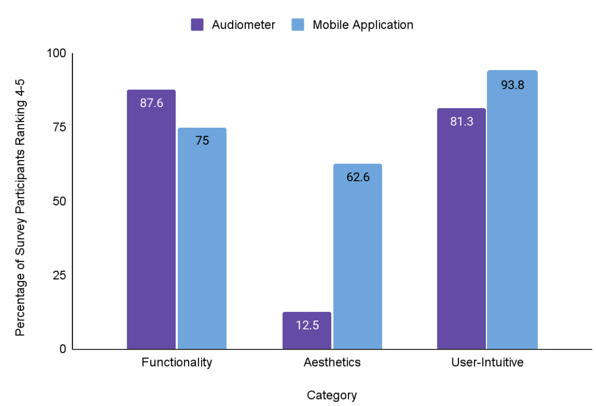

Fig. 3. Audiometer and Mobile App Survey. Percentage of participants who ranked 4 or 5 for the audiometer and mobile app regarding functionality, aesthetic, and user-intuitive

In addition to the ratings on functionality, aesthetics, and user intuitiveness, the audiometer and mobile application were ranked on a scale of 1-10 of how effective each component is at achieving the specific aims we had outlined. The audiometer received an average of 7.63 and the mobile application received an average of 8.4 of how well each meets our specific aim.

Discussion

Stress testing results showed that greatest possible displacement occurred in design D, however the physical demonstrations of stress in the designs showed maximum distortion in designs A and B due to the fact that there was the least amount of supporting pieces in the Cz node placement. Additionally, the stress testing results only demonstrate the stress placed upon the rigid "backbones" of each of the designs, as the elastic or foam material used to cover the plastic or other structural materials had not yet been decided. Future work will aim to integrate the decided-upon materials to evaluate more accurate locations of stress. Survey results indicated that the most comfortable designs were C and D, however, these results are based upon only visual perception and not physical trial, indicating that they are subject to change once physical prototypes are tested on potential patients. Moreover, feedback from the survey indicated that a headband not fully wrapped around the head is most ideal as the head is not perfectly circular. This feedback from the survey will be considered when developing more designs and prototypes of the final headband device, however may not be integrated fully as the necessary node placements for accurate EEG readings surround the entirety of the head circumference. In terms of future work for this project, this will involve finalizing the design and further developing the physical headband prototypes, while integrating necessary hardware. Particularly, implementing the rechargeable battery, primary controller, and all of the electrodes and the required wiring would be essential, as these are necessary design features that must be accounted for when optimizing the comfort and durability. Broader surveys on design feedback will also be required during this iterative portion of the prototyping process. Additionally, the project will involve integrating EEG sleep-tracking technology and acoustic stimulation to the headband, which will require additional hardware which can also be stress-tested to examine durability once fully assembled into the headband.

The audiometer is crucial for the development and effectiveness of the wearable headband device. To successfully enhance the user's SWA using AS, it is essential that the user can hear the pink noise during sleep. Determining the limitations of the user's hearing ability is pertinent to the success of this product, and for this purpose, the audiometer needs to perform its function. As indicated in Figure 3, the functionality and user intuitiveness of the audiometer both received scores above 80%, demonstrating strong performance in these areas. However, while the audiometer is in a promising stage for future development, it is not yet ready for deployment. It currently scores low in aesthetics, with only 12.5% of participants rating it a 4 or 5. This suggests a significant need for improvements in the design and visual appeal of the audiometer to enhance its overall user acceptance.

The mobile application is another aspect of our project that aims to connect the user with the design team. It allows the user to keep track of their sleep track data, while also being able to submit feedback to the design team in order for them to make necessary changes and improvements to either the headband device, audiometer test, or the mobile application itself. Furthermore, the mobile application ideally hosting the audiometer test within the application streamlines the project and reduces the amount of devices and additional services the user needs to utilize. Similarly to the audiometer, at least 80% of the users rated the functionality and user intuitiveness a 4 or 5, indicating that users deemed the application to be functional and easy to understand for use. Additionally, 62.6% of the users from the survey rated the aesthetics to be a 4 or 5, also indicating that it looked visually appealing. Despite these ratings, the mobile application can further be improved upon by first successfully integrating the audiometer into the mobile application, instead of having a pseudo-test in place. This would aim to create a fully functioning mobile application. Future work for the mobile application can also include adding more sleep metrics onto the homepage, that can be received from the wearable headband device. Examples of sleep metrics can include quality of sleep, stages of sleep, and time of pink noise delivery/stimulation. Another component that can be added is profile login so that different users can login to their personalized account from any device, as well as enter user information such as an email address. This email address can be used to send updates to the email if that option is selected. All of these can work together to greatly improve the overall functionality of the application. By increasing personalized profiles in the app, certain functionalities such as seeing sleep data trends over time, and saving previous individualized-data that the headband could access would increase its ability to cater each patient. Considering this application would communicate wirelessly with the headband, the future machine-learning aspect of the project – the adaptable tracking of the sleep cycles to output pink noise AS only during SWS – would benefit from being able to access the individual profiles of data. This would also allow for the audiometer test to not be administered every use, rather every few months to ensure a similar result.

Some limitations are that we initially sought to design and manufacture the headband device and produce a finalized product. After discussion with our advisors from Sequoia Neurovitality through meetings throughout the year, it was determined that it is best to focus on the design specifications of the headband device. Due to conversations with the manufacturer, it was decided that it would be more advantageous and productive to focus on the specifications, given that the manufacturer had access to higher quality materials for the headband to be made from a comfortable material to wear during sleep. Additionally, as the project relied on funding, there was delay in determining the specific deliverables. The prototypes are also being worked on by an outside manufacturing group, to whom the materials for the mockups were more accessible. This is one of the reasons why we focused more on trying to identify design specifications and narrow down the priorities for the design.

End Matter

Author Contributions and Notes

All authors contributed to survey preparation. Radadiya and Calhoun contributed to form factor designs of headband. Tran and Vijayaragavan contributed to the audiometer. Park contributed to the supplementary mobile application.

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