Study Title: RoboHear™ device: advanced haptic technology that allows the deaf to understand speech

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Background and Rationale

Of the 37.6M US adults with hearing difficulties, over 1M are profoundly deaf (i.e., unable to hear speech or participate in a normal conversation). An additional 6M to 7M of this US total have hearing loss characterized as severe[1]. Statistics from the National Institute on Deafness and other Communication Disorders (NICD) indicate that a condition called sudden deafness strikes one person per 5,000 every year - usually adults in their 40s and 50s [2]. A 2015 online report by the National Center for Health Statistics indicates that less than 2% of adults who indicated that they had any trouble hearing were deaf [3]. More than 219,000 patients globally have received cochlear implants; over 70,000 patients in the US. The average cost for one cochlear implant can range from $40,000 to $100,000 inclusive of all the treatments [4]. Many deaf patients cannot afford a cochlear implant, others (for medical reasons) are not a candidate for an implant.

Fauxsee Innovations, LLC is focused on developing new devices and assistive technology for the underserved blind and deaf communities[5]. The company designed the Roboglasses® product using advanced sensor and haptic technology for providing guidance assistance to the blind. This proposal addresses development of a RoboHear™ product to provide audible speech recognition capabilities for the deaf. RoboHear™ device will use the haptics technology in the Roboglasses® design to communicate speech information to the deaf using touch (haptic) feedback. Roboglasses® design uses a row of Linear Resonant Actuators (LRAs) located in the stems of the glasses frames to communicate distance information to the wearer. RoboHear™ design will use the same haptic devices also located in the stems of a pair of glasses. These glasses can be fitted with clear or prescription lenses as required. RoboHear™ device will convert audio speech into phonemes that are further mapped into distinct haptic effects that are felt by a deaf user in the stems of the glasses.

There is a significant body of research in sound, sound technology, hearing, speech and speech recognition, sound localization, haptics and haptic effects, and research on human ability to utilize alternate technologies and substitute one sense (e.g., touch) for either hearing or seeing in sensing the environment. New technologies such as LRAs significantly offer unique advantages. LRA outputs are not audible or vibratory. They simply touch the user in various programmable ways. The LRAs move in and out to “touch” the user and apply a slight pressure to the skin. These LRAs are commercially availables and are present in many commonly used devices such as smart phones and smart watches. The LRAs are innervating mechanoreceptors used in normal cutaneous tactile perception, not vibro-tactile input from the Pacinian receptors, which are sensitive to temporal differences but less sensitive to spatial resolution [11]. Modern speech recognition technology radically changes the speech detection, recognition and coding problem. Modern microelectronics allows sophisticated control using high-performance microprocessor technology. Weisenberger investigated the issues of communication using tactile stimuli [12, 13] as well as the role of tactile aids in speech perception [14] and the use of tactile phonemes [15]. Reed and Durlach investigated the subject of information transfer rates and differences in information transfer rates of phonemic codes using both auditory and tactual (haptic) modalities [16]. Tan, et al, have more recently investigated optimum information transfer rates for various modalities [17]. These new technologies now make it much more feasible to build devices that can recognize speech and translate that speech into haptic stimuli.

Objectives

We are testing the feasibility of using high-performance, low-cost speech recognizers for converting spoken speech into text, translating that text into a phonemic representation and then mapping the phonemes into haptic effects. We will perform a pilot study of 7-9 subjects to develop a training program for teaching users to understand haptic phonetics. We will utilize computer-aided instruction programs to facilitate learning and practice with the device. We hope to show that haptic technology can provide an alternative form of communication for the deaf population.

Investigational New Device

RoboHear uses high-performance, low-cost speech recognizers for converting spoken speech into text, and translates that text into a phonemic representation. The phonemes are mapped into haptic effects. The haptic devices (LRAs) will be housed in glasses stems that also contain microphones for receiving the audio. This ambitious research effort is feasible because we are able to reuse patented components and subsystems developed for our Roboglasses® product.

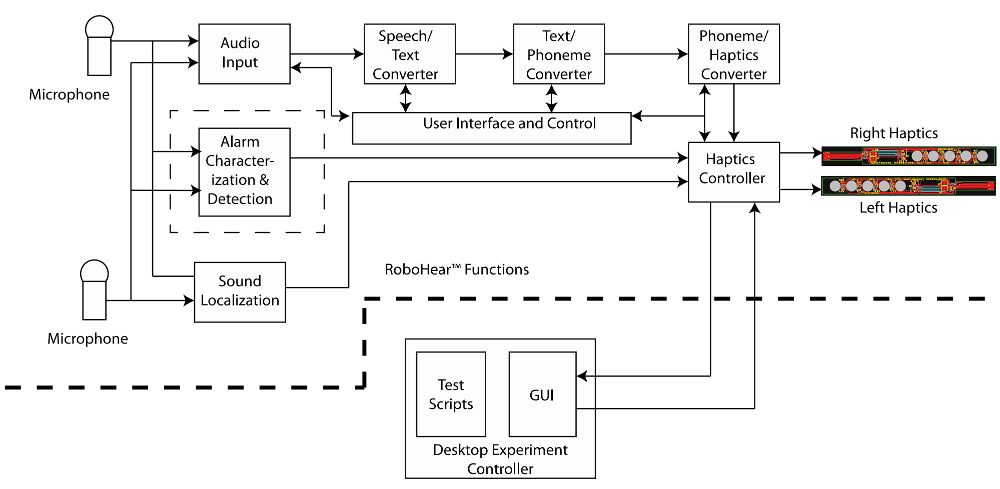

Figure 1

Our initial research indicates that it will only be necessary to fabricate one new hardware item for RoboHear™. This is the Haptic Control function. While our Roboglasses product provides a Haptic Control function, it is implemented on a small (19 x 21 mm) circuit board that is located behind the Roboglasses® lenses. Our RoboHear™ concept calls for all electronics, as well as the haptic devices, to be located in the stems of the RoboHear™ glasses (so that the lenses are unobstructed). It will be necessary to fabricate a flexible printed circuit (FPC) containing the electronics for driving the haptic devices as shown in Figure 1. Note that this is an extremely low-risk effort since the electronics design is the same as that used in Roboglasses® design. It is merely repackaged in a different form factor. This FPC is approximately 131 mm long and 12.3 mm high. The 8mm holes in the FPC surround the LRAs that play the haptic effects. The left end of the FPC is a printed connector for use in interfacing with the Haptics Controller function.

Since Fauxsee has previously developed the software for controlling and activating the proposed LRA devices, we anticipate reusing this software with only minor changes. This software consists primarily of I^2C software drivers and the code for controlling and activating LRAs. As noted earlier, we will reuse the processor and power manager hardware from our Roboglasses® product and the RoboHear™ design can utilize a large body of existing software for the haptic interface. We plan to use software from the CMU Sphinx project at Carnegie Mellon University. This is a state of the art speech recognition engine that is designed specifically for operation in computer environments with few hardware and software resources [22-24].

One primary research goal is to investigate and characterize the best mapping between phonemes and haptic effects. We are using LRAs and intelligent haptic drivers for producing haptic effects. Each LRA and haptic driver pair (DRV2605 from Texas Instruments) provides up to 123 different haptic effects. Table 1 describes a few of these haptic sensations. The haptic effects are not audible – they are touch sensations. Note that we are mapping one of 44 phonemes into 1 of 123 different haptic effects. Also note that many haptic effects can be played at different levels of intensity and this may be important in simulating loudness of the speech being processed. This means that the mapping of phoneme to haptic effect must be simple and intuitive thus minimizing cognitive effort for recognition [18]. RoboHear takes advantage of the location of the haptic effects in the row of LRAs on the stems to make it easier to learn. The spatial location allows the differentiation of effects both by the particular haptic sensation and by the location of the effect. Just as a blind person learns to read Braille by distinguishing the location of raised dots, we are using the same concept but simplifying it by taking advantage of the different haptic effects.

Table 1. Example Haptic Effects		
Effect Description	**Effect ID**	**Effect Description**
Strong Click 100%	51	Buzz 20%
Strong Click 60%	52	Pulsing Strong 1 – 100%
Strong Click 30%	53	Pulsing Strong 2 – 60%
Sharp Click 100^%	54	Pulsing Medium 1 – 100%

Figure 2 illustrates our current implementation of RoboHear™ device. This implementation uses the right and left haptics FPCs developed for use with Roboglasses® device. In this implementation, all low-level processing (managing the hardware) is accomplished in a highly integrated Bluetooth LE processor while all high-level processing (speech to text conversion, text to phoneme conversion and phoneme to haptic mapping) is accomplished in an application specific processor. This processor could be the main processor in a cellular telephone (e.g., iPhone) or an application specific processor such as that used in Roboglasses® device. This approach allows all hardware specific processing to be accomplished in the RoboHear™ processor. The embedded electronics in the RoboHear™ glasses frames communicate with the application processor over a Bluetooth LE link. In this implementation, the processor (e.g., a Texas Instruments CC2640) and one microphone are located in the right glasses stem, and a second microphone and the power manager (controlling battery

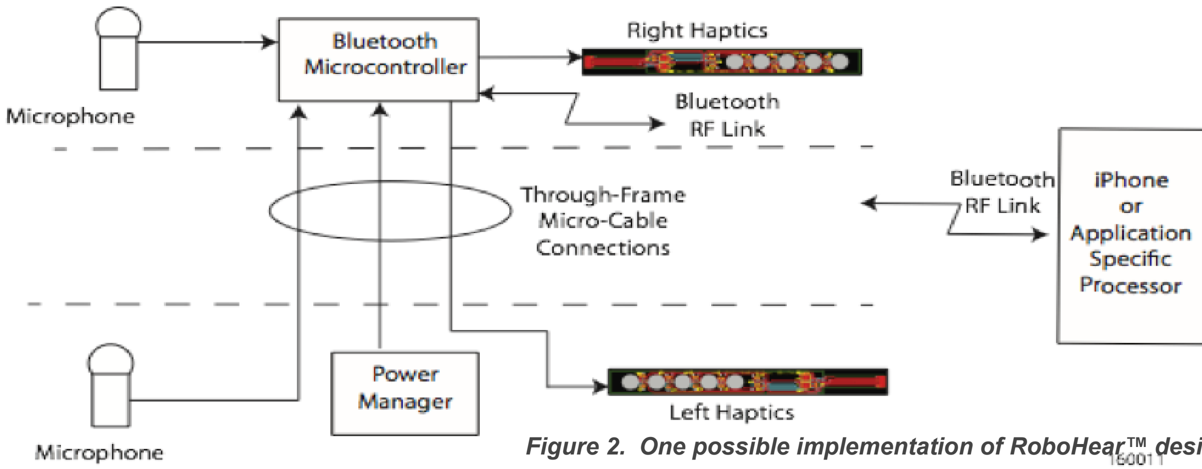

Figure 2. One possible implementation of RoboHear™ design

charging, voltage regulation, and power consumption) is located in the left glasses stem. The electronics in the stem communicate with each other over a small flat flexible circuit (FFC) routed through the RoboHear™ glasses frames.

Figure 3 shows the power manager and processor cards used in our Roboglasses® product. The 41 x 36 mm processor board (on right in photograph) provides a high-performance 32-bit processor (Texas Instruments TM4C123) that can be used to execute the RoboHear™ software. The figure also shows the Power Manager circuit card used in Roboglasses® device. This 31 x 37 mm card provides a Lithium Ion battery power source and necessary filters and regulators. These two cards provide the necessary power management and processing capabilities required in the RoboHear™ design and can be used without modification to support the proposed Phase I project.

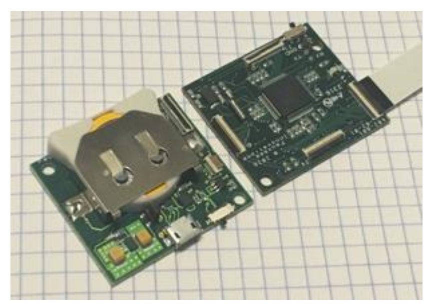

Figure 3. Processor and Power Manager

Study Design and Procedures

Participants will be asked to learn to recognize haptic sensations (touch) as phonemes and short words or phrases. The haptic sensations are generated by Linear Resonant Actuators (LRAs) situated in the stems (i.e., temple piece) of the RoboHear™ device. The actuators are made of steel but are separated from the participant's skin by a thin elastomeric covering. The covering allows the participant to feel the haptic effect without coming into skin contact with the device. Each glasses stem contains five LRAs. The haptic sensations can be described as a bump, click, purr, buzz, etc. The sensations vary in kind, duration and amplitude. The LRAs do not generate any audible sound. The haptic sensation is not strong enough to cause any pain sensation. The goal is to have the participant learn to associate a particular phenome with its paired haptic signal, much as user of a smart watch or smart phone can associate a particular function (email, text, call, alarm) with its paired haptic signal.

All trials will take place in a quiet laboratory or office space and will include the participant, a trial manager and optional observers who may include an audiology graduate student or an engineer from Fauxsee who may be present to ensure that software is functioning correctly or to make adjustments in the learning portions of the software (some participants may need a short or longer training session). The participant will be outfitted with the RoboHear™ glasses and will be seated before a computer display. The trial manager will control information presented to the participant with the RoboHear™ haptics. Trials will be conducted in two phases - a learning phase and a recognition phase:

1. In the learning phase, the trial manager will provide the participant with a particular set of haptic stimuli and a display showing the phonetic mapping of the stimuli. Phonetic mapping will be combined with word mapping. This is the same process that is used in teaching children how to read where they are learning to sound out words using phonemes. Here the participant will be learning to feel phoneme while also seeing the word and hearing the word pronounced by the computer program. Participants will be given repeated instruction over the course of a learning period.
2. In the recognition phase of testing, the participant will be presented with various haptic stimuli and will be asked to select or sound the recognize phoneme or word. Data monitoring will be done from a distance from each participant in the trial so that no participant will be affected by the collection of data. Data from our experiments will be recorded by the test coordinator and will include data about the length of time spent on various learning tasks as well as recognition time and recognition accuracy.

Study Population

This pilot study will consist of seven to nine adult participants (18-year old or older). We may consent up to 15 subjects, in order to have 7-9 complete the testing. Participants will need to understand English and must be able to sit at a computer for the training and evaluation session. The session may range from one hour to up to 4 hours in length (with breaks provided as needed). Participants will be recruited from the UAMS TRI Research Participant Registry. If needed, fliers and other advertisements (newspaper, TV, etc.) may be implemented as well.

Inclusion criteria:

-18 years and older

-Able to understand and read basic words in English

Exclusion Critera

-Less than 18 years old

Unable to understand and read basic words in English

Risks and Benefits

1. Risk to participants

The potential risks to seven to nine (7 to 9) adult participants in the proposed studies are minimal. Because working with a desktop computer and wearing a pair of normal weight and size glasses with clear glass are skills and activities that are commonly performed by participants, the participants are not being asked to attempt a novel activity and will not be placed at risk of harm as a consequence of participating in this research.

Electrical Shock Risk. Participant will wear a modified version of the RoboHear™ glasses which contain the haptic devices. The glasses stems are connected to a control processor that processes speech into phonemes and then to haptic sensations. All voltages are 3.3 volts or less and there is no danger of electrical shock. No voltage in any part of the system exceeds 5.0 volts (at USB power block).

Magnetic Field Risks. Each LRA consists of a spring, moving mass, a voice coil and an extremely small NeFeB Neodymium magnet. There are no other known risks to participants in this study.

2. Adequacy of protection against risks

A Hearing person will monitor all participants in the study. Though potential risks to participants are minimal, the team will anticipate a formal risk assessment as part of the course/trial design process. Observations and data from the trial run will identify any additional potential risks to participants. In the event that additional risks are detected, the team will modify the trial procedure to mitigate that risk. Predetermined safety measures include a safety briefing for test participants, trial monitors and all participating staff.

3. Potential benefits to participants and others

There are no direct medical benefits to the participants other than the opportunity to use a new hearing device, however, test participants will benefit indirectly in that their input will be used to improve the final design of the RoboHear™ product. Honorariums ($25 gift cards) will be provided for all participants for compensation for their time.

Data Handling and Recordkeeping

The Principal Investigator will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study. All study subject material will be assigned a unique identifying code or number. This study will utilize REDCap (Research Electronic Data Capture), a software toolset and workflow methodology for electronic collection and management of clinical and research data, to collect and store data. REDCap was developed specifically around HIPAA-Security guidelines. The key to the code will be kept within REDCap. Only Dr. Dornhoffer and Dr. King will have access to database and full data set containing PHI. All information for statistical purposes and publication will be downloaded in a de-identified manner. At the conclusion of the study, the data will stored in REDCap indefinitely for use in expanding this pilot research in the future. All information shared with the company will be de-identified and will consist of learning and testing responses (such as number of words correctly identified, number of training sessions, number of attempts, etc.).

Data Analysis

We will analyze the length of time spent on various learning tasks as well as recognition time and recognition accuracy. As this is a small pilot study, most of the statistics will be descriptive. We will use paired t-test to compare recognition accuracy at the beginning and end of training session. We will look to see if any demographic data (age, gender, hearing status, etc.) has any positive or negative effect on learning capability by comparing recognition time and recognition accuracy.

Ethical Considerations

This study will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures. This protocol and any amendments will be submitted and approved by the UAMS Institutional Review Board (IRB) to conduct the study.

The formal consent of each subject, using the IRB-approved consent form, will be obtained before that subject is submitted to any study procedure. All subjects for this study will be provided a consent form describing this study and providing sufficient information in language suitable for subjects to make an informed decision about their participation in this study. The person obtaining consent will thoroughly explain each element of the document and outline the risks and benefits and requirements of the study.

The consent process will take place in a quiet and private room, and subjects may take as much time as needed to make a decision about their participation. Participation privacy will be maintained and questions regarding participation will be answered. No coercion or undue influence will be used in the consent process. This consent form must be signed by the subject or legally authorized representative, and the individual obtaining the consent. A copy of the signed consent will be given to the participant, and the informed consent process will be documented in each subject's research record.

Dissemination of Data

Results of this study may be used for presentations, posters, or publications. The publications will not contain any identifiable information that could be linked to a participant.

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