Augmentative Communication Device

BME 201 Department of Biomedical Engineering University of Wisconsin-Madison May 8, 2009

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Client

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Abstract

Neuromotor disabilities, most notably cerebral palsy, often make speaking very difficult for affected individuals. This is a cause of great frustration because many have the mental capacity but not the vocal abilities to communicate with other people. Existing technology currently on the market is not desirable for a number of reasons: it is too difficult to use, the output delay is too great, the user cannot express emotions, and it is very expensive. Our client, Dr. Lawrence Kaplan, has expressed a desire to create a device which would allow cerebral palsy patients to be actively involved in conversations and to "shape" the sounds of their voices. Our design incorporates the use of a Kaossilator pad and a talkbox to achieve these goals. Future work on this design includes miniaturization, sterilization testing, input adaptability, and complete integration.

Background Information

Neuromotor dysfunction presents itself in a number of forms, one of the most common being cerebral palsy. This occurs in approximately 1 out of every 500 people and is a result of abnormalities in the growth and functioning of the brain¹. This leads to uncontrollable reflex movements and moderate to severe muscle tightness. Cerebral palsy can be caused by head trauma after birth, but this is relatively rare. It is more common for the brain to be affected before or during birth.

Four main types of brain damage contribute to the majority of cerebral palsy cases². The first is periventricular leukomalacia, which is damage to the white matter of the brain. This is usually responsible for transmitting signals throughout the brain and body, but small holes in this white matter that form before birth do not allow this to develop properly. Another cause of cerebral palsy is cerebral dysgenesis, or abnormal development of the brain. During the first 20 weeks of development, the fetal brain is very vulnerable. Any interruption in the growth of the brain causes abnormalities that interfere with the transmission of signals. Mutations in genes, infections, fevers, or trauma could contribute to this interruption. Intracranial hemorrhage, or bleeding in the brain, is also a possibility. If blood flow is blocked by blood clots in the placenta, the baby may suffer a stroke, leading to blocked or broken vessels in the brain. The final key development malfunction is hypoxic-ischemic encephalopathy, or intrapartum asphyxia. More commonly referred to simply as asphyxia, this is a lack of oxygen in the brain. Tissue in the brain, most notably in the cerebral motor cortex, can be destroyed, and this causes cerebral palsy.

Motor functions are affected differently in everyone; some have a slight limp, while others are completely wheelchair-bound. Those with spastic hemiplegia are mostly affected in the arms and hands; those with spastic diplegia are more affected in the legs and feet³. The most severe form is spastic quadriplegia, where one has severe stiffness in the limbs, is usually completely wheelchair-bound, and has extreme difficulties speaking. Cerebral palsy is a nonprogressive disorder, meaning the disease will not worsen, but later physiological disabilities are very common.

Design Motivation

One of the common dysfunctions associated with cerebral palsy is a difficulty speaking. This is often a source of great frustration because the disorder does not always affect one's mental capacity. The affected individual may actually be very smart, but is unable to convey this to anyone because he/she cannot speak normally. In one-on-one conversations, it takes a long time to say something, and the speech is usually very difficult to understand. In large groups, the individual's voice is simply not heard. The existing technology in assisting the speech of people with cerebral palsy is not very effective. It does not speed up the process of speaking, it is difficult to use, and it does not allow one to express emotion. This does not solve the problem of actively participating in a conversation. It has long been the desire of affected individuals and clinicians to have a device which allows spontaneity of speaking; a device which allows the user to not only have instantaneous output, but also be able to "shape" the sound of his/her voice.

Client Requirements

One of the biggest complaints from patients with communicative disorders is that the devices out there to help them speak are slow and lack the ability to add emotion to what the user is trying to say. This delay, between when the user thinks a phrase and when they are able to actually communicate, can make the user feel unintelligent or feel that they are being perceived as unintelligent. It can also leave them out of a conversation since they cannot produce language within the normal pause of a conversation. In addition, they are unable to add emphasis or inflection to what they want to say. These are the issues that our client, Dr. Lawrence Kaplan, has asked us to address. Every day he encounters patients that are frustrated with the means of communication to which they are limited. Many of his patients give up trying to speak and let others do it for them. Our client is looking to break away from the conventional

communicative devices that are on the market today. He would like us to come up with something new that allows the user to have more spontaneity when they speak, as well as the ability to demonstrate emotions, like irritation or excitement, when they communicate. By doing this, we can hopefully "bridge the gap" for people with communicative disorders and help them to communicate in a way that feels more natural and comfortable.

The particular communicative disorder on which Dr. Kaplan would like us to concentrate is Cerebral Palsy. Most people with Cerebral Palsy are of normal intelligence and cognitive function. The disability lies in the neuromotor disorder that makes speaking difficult. Some patients have a paralyzed diaphragm, which makes it difficult to produce the air current necessary to create sound. Most patients have poor oromotor function. These patients can create sound but have difficulty with their tongue and mouth when they try to shape the sound into language. Our client has challenged us with creating a device that can help people with Cerebral Palsy create a clearer, more understandable sound quickly. Another consideration that our client has asked us to take into account is that the patient may or may not be wheelchairbound, so our device should be portable enough that someone could walk around with it, but also have the ability to be mounted to a wheelchair.

Existing Devices

The devices currently available on the market today consist mostly of touch screen tablet PCs or handheld devices. These devices have pre-programmed common phrases and keyboards to enter in custom sentences. In order to give the user the ability to speak more quickly, the devices usually prompt possibilities for the next letter or word, but typing what they want to say is still a laborious task and is frustrating because it is time consuming.

One such device is the Tango. It is geared towards children and uses images and icons to direct the child to what they want to say. This device, however, is limited only to preprogrammed phrases. While useful for kids who can't speak, this device stifles a child's creativity in that they cannot produce their own sentences. It does not allow children to expand their vocabulary and limits them to what is programmed into the device.

Another device on the market is the Dasher. This device uses some sort of pointer, whether it is a joystick, a mouse type apparatus or a slider, to point out letters to form words. The program prompts the user with possible and common letters to follow the first in order to speed up the input process. While this is a great interface for someone that cannot use a standard keyboard to type, this is still very slow and makes the user less likely to say something that would be time consuming. In our client's experience, people then tend to limit their speech and vocabulary to the minimum that is required for what they want to communicate. In this way, devices like this limit self-expression in addition to being unable to add inflection or emphasis to the words.

Another manufacturer, DynaVox, produces touch screen devices that have some preprogrammed common phrases and a keypad input system. This interface is also slow, cumbersome, and lacks the ability to add emotion. While these devices come in small handheld versions or full size tablet PC based on the preference of the user, they are still limiting because they are slow and users encounter the same frustration as they do with other devices. Users pay a lot of money for these expensive devices, and then tend to not use them because they are not an efficient means of communication.

Problems that are common to all the existing devices on the market are that they are slow, inefficient and lack emotional expression. They make users feel unintelligent because they delay the time between the thought and the speech, and they just are not efficient enough to offset their cost. In other words, people just do not use them. Our challenge this semester is to come up with an idea for a device that addresses at least one of these problems in order to help people with communicative disorders to have a more natural-feeling means of communication.

Palm Pilot Alphabet Device

Our first design is based on the single-stroke alphabet implemented by Palm Pilots. The device would be run on a tablet laptop platform off of LabVIEW or similar software. The user would use simple single strokes with a stylus on the touchscreen to create letters (See Figure 1). The screen will be arranged with a central writing pad surrounded radially by punctuation marks, a delete, and a playback button. The user would type in a sentence and then play back the sentence to be heard.

A	Λ		Ν	N		
в	B	β	0	$\dot{\bigcirc}$ $\dot{\bigcirc}$		
С	С		Ρ	ΡP		
D	b	D	Q	Ö		
E	3		R	RR		
F	ſ	Γ	s	S		
G	G	6	Т	•		
Н	h		U	U		
Ι	-		v	νv		
J	j		w	\mathbb{W}		
K	Ľ		х	$\times \times$		
L			Y	48		
Μ	M	m	Z	Z		
Sp	ace	•	Ba	ck 🛁		
Car Re	Carriage Return Period twice					
http://www.computerhope.com						

Figure 1. Palm Pilot Alphabet consisting of single strokes⁴

Advantages

This device would provide a means of communication to individuals who suffer from severe motor disabilities because the user interface is significantly larger than that of devices currently offered.

Disadvantages

Because it is computer based, this device will be inherently expensive. It will also be very difficult to prototype as very advanced computer programming skills would be required. It will also be bulky and large which will hinder its use. The device requires that the user input every single letter of a word or phrase, so the device will be comparable in speed to some of the slower devices already on the market.

Phonetic Alphabet Device

The English language has 144 phonetic sounds, all of which are used in daily language. Our second design also incorporates a touch screen interface with a button for each sound. There would also be user control of inflection and volume through a number of potential methods. The device would have immediate feedback, outputting sound as soon as the user pressed a button. For controlling inflection and volume, the user will have many options for inputs. We could use a pressure sensor that the patient holds and squeezes to affect a change in frequency. We could also use any combination of sliders or levers, either on the touch screen, or mounted to the side. This design is very adaptable in that regard and would be a great step for people who can move well. All of the phonetic sounds would be incorporated into a database that the buttons would call on.

Advantages

This device allows for complete control of language. Users would be able to control all aspects of vocal communication, most importantly volume and inflection, which is a feature missing on all existing devices.

Disadvantages

Like our first device, this would be limited by the ability of the user to move quickly between buttons. There are several syllables per word, and several sounds per syllable. This complexity requires immense dexterity on the part of the user to find the correct buttons on the screen and press them accurately. The device is also limited by the method of inflection and volume control. This design would be comparable to a keyboard with ten times the standard number of buttons, as well as additional levers, or pressure sensors that may require manual dexterity to operate. The device is also computer based so there will be significant cost limitations and limitations in our programming ability.

Kaossilator/Talkbox Device

In a radical departure from our first two designs, the third is a device based on a frequency generator and a frequency modulator. The Kaossilator Pad (See Figure 2) is a



small touch screen-driven frequency generator with many options of output sounds. One of the options, L.14, is digital talk. Originally built for the music industry, this feature produces very recognizable voice-like sounds. Users could learn the trace patterns that produce an individual



sound. The Kaossilator pad will be connected to a Rocktron Figure 3. Talk Box⁶ Talk Box (See Figure 3). The talkbox uses a midrange horn driver to produce sound that is fed through the attached tube and into the user's mouth. Inside the users mouth the sound can be modified and fed into a microphone attached to the Talk Box tube. This allows the user to modulate speech without creating any sounds, simply manipulating sound produced by the Kaossilator/Talk box combination. From the microphone sound is output to a mixer where volume can be controlled, and then out to a speaker.

Advantages

This device gives the user maximal control of speech. It also allows them to personalize their sound by allowing them to modulate frequencies. This device will give users the ability to speak spontaneously, as it is constantly on, and provides instant output. This device only requires minimal movement on the part of the user, which makes it ideal for many people with neuromotor disabilities. There is also intellectual property potential with this device, as it is a novel approach to this communicative problem.

Disadvantages

The success of this device depends on the frequency output of the Kaossilator pad. Preliminary research and demonstrations have shown that many of the necessary sounds are available, but only further testing can validate the efficacy of the device. Another disadvantage of this device is the weight. The mid range horn driver in the talkbox which produces the sound waves is magnetically driven and therefore quite heavy. Without repackaging all of the individual parts, this device would be far too cumbersome to be practical. The final disadvantage of this design is that the talkbox is powered by a standard outlet plug, so the power cord would have to be spliced to interface with a 9V battery.

Categories	Weight of Category	Computer Touch Screen/ P.P Alphabet	Computer Touch Screen/ Phonetics	Kaossilator with Talk Box
Ease of Use	25%	3	7	7
Speed	25%	4	4	10
Ease of Manufacture	20%	1	4	9
Portability	20%	4	4	6
Cost	10%	2	3	7
Total	100%	2.95	4.85	7.95

Design Matrix

Table 1: Design Matrix

We rated our three designs on a scale of 1-10 in a design matrix (Table 1). Each category was given some weight depending on the client requirements as well as existing market designs. The main problem with most existing machines today is a time delay. Due to this the user cannot speak simultaneously but can only answer questions asked. This makes him/her feel disabled. Hence, while making our design matrix, the maximum weight was given to the categories ease of use and speed.

The palm pilot method received the lowest score because the user has to learn the symbolic representation of each letter in the alphabet, therefore making it difficult. For speed, we gave a score of 10 to the Kaossilator with talk box because there is no time delay. One gives an input and receives a simultaneous output. This is really important for our design as we want a device that will help people build conversations, not just reply to the questions being asked. This device earned a score of 9 in its ease of manufacture. This is because we already have the Kaossilator and talk box existing in the market. All we need to do is connect them together. Not much variability exists in the scores for portability because we cannot determine much without actually building these devices and testing them. The general cost range for these devices ranges from \$800 - \$2000. If we make our prototype design and package it in a plastic box, it will amount to around \$1000, which is inexpensive as compared to other models.

We made calculations on the basis of the weight assigned to each category and the score awarded for each design. Table 1 clearly shows that the Kaossilator with Talk box is the clear winner with a final score of 7.95.

Final Design

Our final design consists of a Kaossilator, the Talkbox, microphone, mixers and speakers. The figure below explains the basic functioning of our device. The Kaossilator acts like a sound frequency generator. The user touches the pad of this device to produce sound signals. These are then fed into the Talkbox. The function of the talkbox is to reproduce sound from an amplifier after allowing the user to modulate the signal. The user then harmonizes the frequency by changing the shape of his lip, and then this signal enters a microphone via a mixer. In the process the **user is not producing any sound**. This signal will enter the mid range horn driver, which is a transducer for the horn. The electrical signal is converted into mechanical vibrations which thus reproduce sound in the speaker located either inside or outside the talk box (See Figures 4 and 5).



Figure 4. Block diagram of device process.

This device comes with various advantages. Since the user is just modulating the sound signal and not producing it, almost everyone can use this device. Only those, who have

complete muscle function failure in the mouth cannot use this device. Secondly, since the machine is highly modulation sensitive, there is no time delay at all. Also, the sound frequency generator has a different range of frequencies which allows the user to create inflexion. Therefore, one can use any sort of emotion while talking. Since our device is phonetics based, any language can be spoken with the help of it. This gives our device the ability to be universally used.



Figure 5. Preliminary device set-up.

Testing

After obtaining the parts required for the device and integrating them together, it was important to test various aspects of the system to determine the best method of producing speech. The first test was determining the most human-like sound from among the 100 frequency-generating channels on the Kaossilator. Each channel was tested with the same phrase, and team members recorded the channels that produced recognizable human sounds. After this was completed, the list of acceptable channels was compiled, and these were then re-tested. After discussion, channel L.14 was determined to produce the most realistic sounds to send to the talkbox.

Next, the proper placement of tubing in the mouth was tested. When the tube was outside of the mouth, no words were distinguishable because the user was unable to modulate the frequencies

from the talkbox. However, when the tube was fully inside the mouth, speech was difficult to understand because the tube was partially blocked by the inside of the cheek. This occluded the flow of air from the tube, which prevented the sound from leaving the mouth. It was determined that the best speech was produced when the tube was approximately 1 cm inside the mouth, as seen in Figure 5. This provided the most understandable statements, and it allowed for greater user control. The user can simply place the tube between his/her front teeth. By using the tongue and teeth to purposefully occlude the air flow in certain manners, various consonant sounds are created.



Figure 5. Quality and control of sound was greatest when the tube was placed 1 cm into the mouth, with the user holding the end of the tube between his/her teeth.

Another important test was determining the proper tubing diameter. The tubing provided with the talkbox was 3/8", and this seemed to work very well. Other tubing widths were also tested, however, such as 1/4". None of the tubes seemed to sound better than the others, so it was decided that tube diameter does not affect the sound quality. However, the 1/4" tube was the most comfortable to hold in the user's mouth. For this reason, it will likely be the best option for the future of the design. The thinner tube will also allow for attachment to some type of head gear with a small microphone.

One of the main purposes of this device is to allow the user the ability to introduce inflection into his/her speech. This led to a test of inflection comprehension. Fifteen phrases were produced using the device: five statements, five questions, and five exclamations. Each phrase was said twice, and observers recorded whether they believed each phrase to be a statement, question, or exclamation. The results were tallied, and a percentage of correct speculations was calculated. As seen in Figure 6, inflection was correctly understood an average of 91.11% of the time on the second attempt at speech. This surpasses the 75% requirement that was stated in the PDS.



Figure 6. Inflection was understood 91.11% of the time on the second attempt at speech.

Ethical Concerns

As with any project, ethical concerns have been raised in the design of this communicative device. One of our biggest ethical concerns involves testing the device. We need patients with communicative disorders to test the device so that we can be sure the device works for those whom we are designing it for. In our testing we need to make sure that we use IRB patients and follow all procedures regarding our subjects. It is of utmost importance that we show absolute respect towards those who we ask to test our product. In addition to following the IRB regulations, we want to be sure that we are not exclusive in the groups that we test this product on. We would like to test our device on subjects with a wide range of disabilities so that we can get an idea of the adaptability of our product and how we could adapt it for certain conditions to make everyone's experience with our product a good one. One example is mobility. We want to make the product portable for people who are not wheelchair bound, but we also want to make it wheelchair adaptable so that neither group of people is excluded from use of our product. We would also like to test it across many languages so that we do not exclude non-English speaking subjects. Our design is a phonetics-based device so it has the potential to be used by people who speak other languages, and we would like to include these groups of people in our testing.

In addition to our ethical testing concerns, we are also concerned about safety. One factor is sterilization of the piece inserted into the mouth. If the device is used many times throughout the day, the opportunity for bacteria to grow on the mouthpiece is great. We plan to add a sterilizing mechanism to our device to keep people from getting sick. General safety of the product should also be considered. The material that we encase the components in should be durable, and if it does break it should not shatter into sharp pieces. Another concern is the weight. If the patients were to drop it on themselves, it should not be so heavy that it would injure them to do so.

Another ethical concern is that we do not infringe on the patents of others. We will do this by creating our own circuit for the device to make sure that all of our work is original. We

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will keep current with patents on the technologies that we are using so that we can be sure that we do not infringe on others' intellectual property rights. We will also make sure that we follow all University procedures when it comes to finding funding for continuing research on our product design.

Management Planning

When designing this product, there were many aspects of this project to manage. One of the first things we had to take into account was our budget: what it would be, where it would come from, how we acquired the funds. Our client, Dr. Lawrence Kaplan, received the funding through his work at the Waisman center and went and purchased the parts we needed for your device. We were aiming to stay below \$1,000 and we came in at \$799 so we succeeded in that aspect of our plan.

The design process was another aspect of our design that took great planning. We split up a lot of the research into areas such as common communicative disorders, human factors, existing devices, and existing phonetic technologies. These areas came together when we created our final design since we drew from every area. From our information on communicative disorders and human factors we learned what kind of problems people face when communicating and what their physical limitations are. From existing devices we learned what is out there and why it is not effective. From existing phonetic technologies, we learned what technologies exist that might help us generate speech in a more intuitive, effective and expressive manner. Our research also included an introduction to existing devices and a speech primer about how people produce and process language from a speech pathologist, Julie Gamhardt, at the Waisman Center. In addition to research, we also held a formal brainstorming session to organize our ideas and possible designs for our product. After comparing them based on a scale we determined, we chose the direction we would go for our final design.

Testing was another aspect to our project that we planned for. We met at least once a week for the last four weeks of the semester to test different aspects of the design. These aspects included clarity, tube length and diameter and input settings of the frequency generator. By managing our budget, the design process and the testing process we were able to effectively chose and pursue a design, and we are now moving further into testing.

Future Work

Although this project has come a long way from the conceptual level, much work remains to be done. We plan to make two miniaturized prototypes; one from connecting circuitry we already have, and one consisting of an integrated circuit that we build from scratch. By removing the packaging of the parts we already have we hope to be able to create an integrated device with no dependence on power plug-ins. The device will be made by adapting power supplies to 9V batteries, and creating a polycarbonate housing to hold all of the compiled circuitry. We would like to integrate the sound tubing onto an invisible performance microphone so it will be much less invasive and visible than it currently is. Our second prototype will be made entirely from scratch. We hope to create a touchpad similar to the Kaossilator pad which only contains one channel in a human frequency range. This will give the device a more human sound, rather than the mechanical garbles it has currently. Hopefully by synthesizing the Kaossilator, and Talkbox circuitry and purchasing a small microphone mixer we can integrate the entire device into a portable, light, functional, and aesthetically pleasing product that will impress both users and passersby.

Another issue that needs to be addressed in the future of the device is sterility. As it stands, there is no simple, safe, and fast method for ensuring that the device is sterile in between uses, or after it has been removed from the mouth, so a patient can eat for example. To fix this problem we will develop a small UV sterilization box where the user can insert the tip of the speech tube to sterilize. This will be a better method than ethanol of other liquid sterilization techniques because there is no potential for spilling. We will also be following up with the patent that our client Dr. Kaplan filed earlier this year. With all of these issues addressed and a working professional prototype we would like to present our device and ideas to corporations like Medtronic and GE Healthcare to get corporate support and get the device out to market where the public can have access to it. Of course this requires much more research. Mr. Tong has suggested that we focus the majority of our research now on markets and learning about how the current market would respond to the introduction of the device. This will give us an idea of how many devices would be needed on the world stage and help us pitch production to interested corporations concerned about their bottom line.

At this point in time we are hoping to continue the project over the summer but are waiting to hear back from a finding source and to check that we are following university protocol. Should that fail we look forward to continuing this project next fall.

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Works Cited

[1]EMedicine. "Cerebral Palsy." http://emedicine.medscape.com/article/1179555-overview

[2]National Institute of Neurological Disorders and Stroke. "Cerebral Palsy: Hope Through Resarch." http://www.ninds.nih.gov/disorders/cerebral_palsy/detail_cerebral_ palsy.htm#88033104

[3] Gait Analysis Laboratory. "Cerebral Palsy Program/Guide."

http://gait.aidi.udel.edu/gaitlab/cpGuide.html

[4] Image: <http://www.computerhope.com/help/pp1.gif>

[5] Image: <http://www.chipcollection.com/wp-

content/uploads/2008/12/_dbase_pics_products_0_1_5_539015.jpg>

[6] Image: <http://i203.photobucket.com/albums/aa47/raf_fiol/kompoz/banshee.jpg>

Communication Device

5/5/2009

Brian Mogen, leader Erin Devine, communicator Steve Wyche, BSAC Prachi Agarwal, BWIG

Product Design Specifications

Function: To design a device that allows people with communicative disabilities but who maintain motor function to speak and express emotion with their voice. The device must provide immediate output, and it must be intuitive and accurate.

Client Requirements: The device should meet the following requirements:

Must be able to speak 30 words per minute

Must be understandable 75% of the time

Must be intuitive

Must be phonetics-based

Must not have any time delay

Must be adaptable to may forms of disabilities in terms of inputs

Design Requirements

1. Physical and Operational Characteristics

a. *Performance Requirements*: The device will be used daily and must be able to withstand the force equivalent of a laptop computer including loading patterns and a drop height of 1m.

b. *Safety*: The device must not provide any risk hazards. It should not have any sharp, poisonous, or shocking parts.

c. *Accuracy and Reliability:* The device must enunciate, be audible and be able to produce functional statements

d. Life in Service: The device must be useable for three years

e. *Shelf Life*: the device must work after a 6 months of inactivity

f. Operating Environment: The device will be used in standard temperatures and pressures. It must withstand a small amount of water (equivalent to rain) and temperatures ranging from 0 – 37 C. It must resist the build up of body oils from daily use.

g. *Ergonomics*: the device must be adaptable to patients with a range of motor control and literacy

- h. Size: the device should be easily transported
- i. Weight: the device should weigh less that 5 pounds

j. Materials: the device should be nontoxic and be able to be sterilized

k. *Aesthetics, Appearance, and Finish*: the device must be aesthetically pleasing and have a professional finish and appearance.

2. Production Characteristics

a. Quantity: for class purposes only one prototype

b. *Target Production Cost*: under \$1000 (budget undecided as of 2/11/2009)

3. Miscellaneous

a. *Standards and Specifications*: There are not regulatory standards that this device must conform to.

b. *Customer*: The customer may have a wide range of physical disabilities which must be taken into account when designing adaptive interfaces and inputs for the device.

c. Patient-related Concerns: There are no patient related concerns

d. *Competition:* There are several devices on the market currently. They are all expensive, cumbersome, and ineffective.