Design and Fabricate Neckwear to Improve the Elderly Patients' Medical Compliance

Xiaolong Wu(✉), Young Mi Choi, and Maysam Ghovanloo

School of Industrial Design, School of Electrical Computing Engineering, Georgia Institute of Technology, Atlanta, GA 30332—0250, USA
{xwu86,Christina.choi,mgh}@gatech.edu

Abstract. According to the estimation of the US National Council for Patient Information and Education, there is millions of prescription written each year, but only half of them are correctly followed by patients. Non-compliance with medicine prescription will result in higher medical cost, more hospitalizations, more complicated pill dosage, and even a threat to life. In order to improve elderly people's medical compliance, a new approach that utilizes microelectronics technology in wearable neckwear has been proposed. The sensors in the neckwear are able to detect whether the user has actually taken the pill and which pills the user has taken. During the design iteration, elderly participants' medication related behavioral data and their opinions towards the neckwear reminder concept were first gathered by interviews. The result has demonstrated that wearable neckwear seemed to be a potential solution to improve elderly people's medication compliance. Then a set of physical (non-functional) prototypes was created based on the initial survey input. Usability testing was conducted in order to measure elderly people's preferences in relation to shape, comfort, desirability, ease of use and other factors. This paper documented the development of this prototype and focused on the design challenges that have been encountered, and how the problems have been solved.

Keywords: Medical compliance · Wearable

1 Introduction

Medical compliance, which is commonly defined as the degree to which a patient follow the medical prescription [1]. Non-compliance with the medicine prescription is becoming a major cost of the medical care in each therapeutic area. According to the estimation of the US National Council for Patient Information and Education, even though there is millions of prescription written each year, only half of them are followed by the patients [3]. Among the patients who have difficulty in the compliance with the prescription, the elderly people with kidney transplantation gains a special concern. Because of aging, the elderly patients are commonly suffering the loss of their physical dexterity, cognitive skills, and memory. In the meantime, they must take a great amount of pills in different dosage, at different time everyday to keep their body function properly [2]. The non-compliance with medicine will result in higher medical cost, more hospitalizations, more complicated pill dosage, and even a threat to life.

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Theofilou [2] stated that the mental factors that caused the non-compliance are depression, less structured daily life, and social isolation. And for the physical side, the small label reading and understanding, child resistant container, and short-term memory also prevent the elderly people from complying with the prescription.

In order to improve elderly patients' compliance with prescription, different interventions have been provided. A simple dosage regime along with reducing the daily pill-taking frequency, and makes it easier for the patients to remember when to take pills, have been proven to be effective. Special cues have been selected to help the elderly patients memorize the time when they need to take pills. Increasing the communication between the doctor and the patients also helps in educating the elderly patients and reduce their depression. This paper mainly focuses on utilizing microelectronics technology to create a new way to reminder and monitor the pill-taking frequency of the elderly patients, and conducting usability test about it.

2 Previous Work

With the development of the electronics, they have been using to improve the medical adherence with a focus on reminding and monitoring. According to Cramer's [4] article, the development of the microelectronics has significantly affected the field of medicine compliance, especially in the area of monitoring, and the electronic monitoring has been proven to be the most sensitive method available for measuring medication non-adherence.

2.1 Category

Most of the reminding and monitoring technology above has been categorized as automated detection and reminder system. It means that the patient in the system is a passive receiver, he doesn't need to interact with the system, instead, the system automatically monitors and generates data. According to Granger's [5] article, he pointed out that there is no significant improvement by the automated detection/reminder itself. A research project has been conducted by Christensen, which utilized a Pharmaceutical database technology-a system working on filling and refilling pills, and transferring data between the doctor and the patient. The research result has shown that the patients did not react consistently to the technology, and only the automated system itself was ineffective for improving the compliance with the medicine. Besides the automated detection and reminder system, another main category is the in-person system in which the patient uses a device as an assistant [5]. Some research results have shown that it also did not improve patients' adherence to medical prescription. For instance, an in-home telemonitoring system has been used to allow the patients themselves to generate and respond to their own medical data. The biggest challenge for in-person system is the user error, which means users may report wrong data by mistake. Moreover, Christensen [13] concluded that there was no big significance between the control group and the group with the in person system in terms of medical adherence.

Even though neither the automated system nor the in-person system has proven to be effective in terms of improving elderly patient's medical adherence, the combination of both the systems has shown its advantage in improving the patients' medical adherence, generating better clinical outcome, improving patients and the caregivers' satisfaction, and increasing patients' awareness of their diseases. Floerkemeier [6] has conducted a project that combined smart pill packages with mobile phones. There are sensors and microcontroller on the blister pack, when a user remove a pill from the pack, the sensors will detect the removal event, and it will send a message to the phone and the caregiver, indicating whether the user has taken the pill. Besides reminding and monitoring, he also stated that the smart package should have the function of warning the user about a dangerous dose combination, or the pill is out of date.

2.2 Devices

According to Naditz's [12] article, there are mainly three types of monitoring and remaindering devices: the large, in-home units; a smaller, battery-powered pillbox that can be put in the pocket; and the newly wearable devices. They each have their own advantages and disadvantages.

Home-based microelectronic monitoring systems have been developed to organize, distribute pills, monitor and remind the patients remotely. A mechanical device called Compu-Med [4], is able to automatically distribute pills. It provides both audio and visual reminder, and it is able to print out the data log on paper. Another device called Dosing Partner has also been developed. It tried to improve the compliance by sending the pill-taking data to the caregiver everyday. In this way, if a caregiver finds out that the patient missed one dose or being significantly late for one time, he will communicate with the patient immediately. The features of home-based microelectronic monitoring system, such as, recording the pill-taking behavior, and sending the pill-taking data to the caregivers and family members has ensured the compliance with medicine of the elderly people, and in the meantime, it significantly saved the cost of nursing-home care. However, since the sizes of those facilities are relatively bulky, the usage has been greatly limited.

In order to increase the usage of the microelectronics and to make the reminder portable, nowadays, pill containers have shifted from regular plastic boxes to containers with process chips embedded in. The smart pillbox is able to record the time and to count the open frequency by detecting the movement of the bottle cap or the inhaler. Besides the regular beeping and flashing functions, now the smart pillbox also utilized recorded voice, such as, the voice of the patient's daughter, to reminder the patients to take pills on time. In order to prevent overdosing and ensure the pill taking frequency, a pillbox named uBox [9] was developed by Massachusetts Institute of Technology. It records every opening time, when it's not reach a certain time, the opener remains close and it can't be open by others. However, even though the smart pillbox becomes smaller and portable, in terms of pill storage, it is impractical to store all the pills in a container since some kinds of pills are required to be stored in a sealed blister.

Bleser [7] also conducted a usability test about a device called the Helping Hand. It is a handheld device with a process chip, and it stores blisters inside. When the user needs to take pills, he moves the blister out of the device, take the pills and re insert the blister into the device. The Helping Hand device provides both acoustic and visual feedback to the users. It provides acoustic reminder to the user at the pill-taking time and if the device detects that the user doesn't follow the prescription, the light on the device will change color. The pill-taking frequency data can also be printed out to let both the caregivers and the patients see the pattern. Bleser's usability testing mainly focused on three aspects, user performance, user satisfaction, and acceptability. The result showed that even though generally the participants tend to like the device, there were three main obstacles. The first one was that some participants found that the acoustic reminder was too light to hear. Second one was that it requires certain level motor skill to manipulate the device, such as re inserting the blister back into the device. The third obstacle was that the device can only store one kind of pills. It's useless for the users who have to take several kinds of pills per day.

Moreover, people tend to have social stigma with the hand held or in pocket reminder devices. They don't want other people to know they are taking pills; therefore, they fear to be away from home and refuse to use the pillbox in public, which caused the noncompliance with the medicine.

In order to address the social stigma and shift from the outside the patients to the inside of the patients, along with the development of wearable computing technology, the existing sensors with the capabilities of physiological sensing, biochemical sensing, and motion sensing were utilized in health care devices. They have been widely used in the fields of medical monitoring and feedback system, monitoring social networking to reinforce healthy behavior, and to early detect the symptoms of depression and dementia [8].

Wristwatches have been programmed to remind the elderly people in a more discreet way. Different approaches have been utilized based on the watch. One is providing audio to the elderly people to remind them to take pills. However, it turns out that some elderly people are also suffering from the loss of hearing, and they may not be able to hear the reminding audio. Moreover, because of the short memory issue, under some circumstances, even people have heard the reminder, they will easily forget about it after a few seconds. In order to ensure that the elderly patients read the reminder, another approach has been developed. Instead of only producing audio reminder, it displays a short message on the watch screen, indicating the required medicine the users need to take. Also, it provides a more discreet reminder-vibration on the user's wrist, so the user can use it in public and others won't be aware of it. However, the performance of the reminder is unpredictable, since it does not implement monitoring system, so it cannot detect whether the users have followed the reminding contents or whether the elderly patients have taken the right dosage.

One project about a memory glass has also been conducted by Pentland [8] in MIT Thrill lab. The glass works as a personal memory assistant. It can store users' data and utilize sound and visual cues to remind the users under certain circumstance. He stated that the difference between the glass and the other reminders is that the glass is a context-awareness device. It means that the glass will react to different environment, and also it is personalized. He also stated that since the main obstacle of the traditional reminder is that people naturally tend to resist being reminded to perform tasks, the advantage of the glass is that it is able to provide subliminal cues directly to the users' threshold of perception-eyes. Therefore, the users may react based on the cues while they are not even aware of it. However, even though the glass has to some extent addressed the context-awareness issue, and it works effectively in terms of reminding people, there is still a social stigma about the head up device. Besides, it currently doesn't have the monitoring function, so it may be useless for the patients who require special care and attention.

2.3 Previous Study

In conclusion, with the development of technology, the medical reminder is shifting from an in-home bulky device to a smaller, portable device. The role of the patients shifts from a passive receiver to an active manipulator. Many complicated issues, such as, multiple dosage distribution, discreet reminding, require to be portable, and context awareness, have been addressed by the current healthcare products. However, there are still some issues remaining unsolved. For example, the biggest drawback of the current reminder/monitor device is that it is able to remind the patient to take pills and to detect whether the pills have been taken out of the pillbox; it is impossible to tell whether the patient has actually swallowed them. Furthermore, the current products are not able to tell whether the patients have taken the correct dosage.

- Patients tend to have social stigma with wearable products that show their diseases to the public. Therefore, the new design of the wearable product should address this problem by designing a user- friendly shape and material. In the meantime, it should look appealing to both the user and others.
- The micro electronic device should be able to detect whether the user has taken the pill, instead of the action of taking the pill out of the pillbox.
- There should be a smooth interaction between the user and the device, either passively receiving information or actively finding information has been proven to be less effective.
- The device should be portable, in order not to limit the activity of the user.
- The device should be able to identify different kinds of pills.
- There should be no special motor skill requirement for the user to manipulate the device since most of the end users are elderly people, and they are losing their motor skill as aging.
- The reminding approaches should be obvious enough for the users.
- The device should be context-awareness.

Therefore, based on the requirements, the author proposed a new combination of a smart necklace and a smartphone application concept. Since the micro controller is shifted from outside (bottles) to be on the users' body, it does not require motor skill to perform tasks any more. Moreover, compared with the head up device, the neckwear is smaller and can be hided inside the collar.

3 Data Collection

3.1 Interview

Based on the concept, interviews have been conducted among twenty elderly people. The subjects aged from 66 to 96 years old. To gain their perspective views of the new WEAMS (Wireless and Wearable Event Detection and Adherence Monitoring System) concept [10], their medication regimen, the current reminder system they are using, the usability issues they have, and their opinions towards the neckwear reminder, have been gathered during the phone interview session. And all the phone interviews have been recorded and transcribed for analyzing. The analyzed interview data demonstrated the following facts.

- People tend to have fewer adherences with their medicine as time flies.
- Very few subjects have realized the importance of taking pills on time.
- A connection between the reminder system and their daily routine is essential for elderly people to take their regimen on time. However, once the connection is broken by travels or short days visits, it's difficult for them to remember to take pills.
- Even though most of the current reminders in the market utilize both visual and audio feedback, half of the subjects reported that they only relied on their own memory, and they thought they were able to feel the difference if they missed a dosage.
- One big issue of the reminder system is that it should be integrated into the elderly people's daily life without making them look/behave different. Also the reminder system should be able to distinguish different pill sources.
- As for the neckwear concept, the subjects seemed to appreciate the benefits from wearing it, however, they did not regard their conditions as serious enough to wear it. Besides, they also worried about their privacy, which meant that they were being monitoring by their doctors all the time. Most of them also have social stigma, and some of them even worried about the waterproof issue.

3.2 Initial Prototypes Testing

Since the interview results have indicated that elderly people tend to accept the WE-AMS concept, several appearance conceptual models have been made to further gain users' perspectives. The appearance models of the neckwear are based on the analysis of the phone interview data. Generally there is a locking mechanism on the neckwear, which enables the user to put it on and take it off easily. It is intentionally made tiny, which is used to reduce the social stigma the users may have. Also it is designed lightweight to make the users feel comfortable.

Six devices have been tested in a controlled environment, half of the devices are appearance models and the rest of them exist monitoring devices. The first appearance prototype is called Adjustable. It utilized a clasp mechanism to fit for different sizes of the neck. The shape of it is also designed to avoid resting on users' collarbone, so it can reduce the discomfort when the user is wearing it. The Snap one utilized a slipcover that there is a locking mechanism inside. The third one is called Magnetic, which used small magnets for locking. The three exist devices are Jawbone Up wristband, MIO alpha watch, and BodyMeida FIT armband.

Twelve subjects whose average age is 77.7 were involved in the test. The test procedure consisted of two parts. The first part included the users' current medication evaluation, medication adherence, medication management, using wearable systems, consumer preferences, and their physical strength. The second part included the device evaluation and ranking. The three prototypes were evaluated first, and then the three exist devices. All the devices have been evaluated in terms of ease of use, comfort, and physical characteristics. Subjects were asked to wear it to perform several tasks, and then evaluate each device via Likert Scale. In the ranking session, the subjects were asked to rank the three prototypes and three exist devices based on their appearance, comfort, and overall preferences.

The test result showed that Magnetic was significantly better than the other two in terms of ease of usability field. There was no significant difference among the three prototypes in terms of comfort and desirability. However, Magnetic was a slightly better. As for the ranking, in terms of appearance, there was significant difference among the three prototypes. Both Magnetic and Adjustable were preferred. In terms of comfort, Magnetic was preferred over Snap. As for the overall preference, there was no significant difference between Adjustable and Magnetic, but they both are preferred over Snap. Magnetic clasping mechanism tends to be more intuitive to the user, and it's easy to use since it require less motor skill and strength. Even though in the comfort and desirability fields, there was no significant difference among the three prototypes, Magnetic concept is always ranking high. As for the appearance, the result has demonstrated that the users preferred simply design features.

3.3 Limitations

Since the prototypes in the test were only appearance model, there were several limitations of the data. First of all, the prototypes did not simulate the actual weight of the final product. Since the final concept requires the neckwear to work for at least one week continuously, the battery of the neckwear is relatively large and heavy. Besides, the appearance model did not include the size and shape of the sensors. Therefore, based on the initial testing data, a functional prototype was created.

4 Design

The design and fabrication of the working prototype was undertaken by a graduate industrial design student. According to Jayaraman's book [11], there were eight principles for wearable product design; comfortable, no skin irritation, lightweight, breathable, moisture absorption, easy to wear and take off, easy to access body, and maintain range of motion. The design challenge for the necklace was how to arrange those electronics in the necklace to make it work effectively and efficiently, in the meantime, appealing and comfortable.

4.1 Material

In order to make the necklace user friendly, several kinds of materials were considered in the very beginning of project. Besides lightweight, since the necklace should fit different users' neck diameters, the material must not be too rigid. Also, since there are sensors and batteries fixed in it, the necklace should not be too soft in case the electronics would vibrate inside or the users would break it by accident. Moreover, it should not hurt the skin since the users will wear it all day long. Finally silicone material was chosen in this project since it is relatively light, rigid and skin-friendly. Then different types of silicone have been tested. The number of silicone represents its rigidness. Silicone with the rigidness of 30 was the first one to test and it turned out to be too soft, it was difficult to maintain its shape after it became solid. Then silicone with the rigidness of 60 was tested and the rigidness of it perfectly fulfilled the requirement (shown in Fig. 1). Therefore, the silicone with the rigidness of 60 was used for the necklace body.

Fig. 1. It shows the difference between the silicone 30 and silicone 60. Silicone 30 is too soft to stay on users' neck.

In order to create a necklace that fits different users, the diameter of the neckwear should be flexible. Therefore, a pair of connector that allowed the users to adjust the size of the necklace has been made. Since the RFID sensor should go around the neck with a closed loop, and all the other sensors in the front necklace body should connect back to the power source and the main process chip, there are eight wires in total for each side. Therefore, a pair of connector that works both as a clasping mechanism, and connecting the wires inside, was created. To ensure the connector attach the silicone body tightly, several "T" shape hooks were created on the connector. Therefore, all these hooks were embedded in the silicone body before the silicone became dry.

4.2 Connecting Mechanism

To allow wires to connect each other, small conductors were used inside the connectors. (Shown in Fig. 2) To make a stable connection, besides the conductor, extra magnets have been used on the connectors, and a tilt connecting surface was used instead of flat one. When the user attaches the male part to the female part, the magnet on each part automatically attach to each other. And the tilt surface increased the connecting interface. However, even though the attaching and detaching was easy, it still required some motor skills to perform that action. Therefore, reducing the time that users need to take it on/off is very important, which required a power source that was able to last for one week. After testing, two AAA batteries were selected for the neckwear.

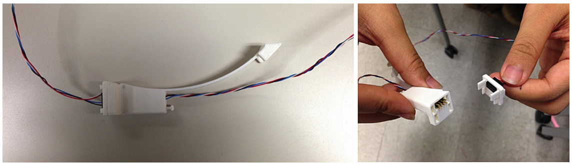

Fig. 2. It shows the connector with wires coming through and conductors inside

4.3 Sensors

In order to collect the user's throat movement and the sound of chewing, two bio microphones and a flex sensor were used. Since the neckwear touches directly to the user's skin, it was able to provide vibration reminder besides audio and visual reminders. The neckwear with radio frequency identification (RFID) and other sensors aims at solving the dose personalization problem. Harmless RFID tags which are pre programmed to contain several data, such as its type, dose, manufacturer and expire date, were embedded in the pill capsule. An inert polymer based coating material is used to protect the tag from decomposing in the process of falling in the user's body [10]. The RFID reader in the neckwear is used to detect the RFID tag to see whether the pills go through the throat. Moreover, combining with a flex senor and a biotical microphone that are used to detect the chewing sound and the movement of the throat, the RFID reader is able to accurately detect whether the user has taken pills. The neckwear also addressed the portable issue since users can wear it to wherever they go, it read the pills directly and it didn't need an extra carrier. A smart phone connected to the neckwear can receive data. Therefore, both the patients and the caregivers will be able to know whether the patients have taken pills on time.

4.4 Social Stigma

In order to address the social stigma issue, the necklace was designed light-weighed and small. Both the batteries and the process chips were located in the back part of the body, which was hidden behind the neck. (Shown in Fig. 3) To make the user feel comfortable, the back part of the neckwear follows the contour of the user's neck, and the batteries are located in both side of the neckwear separately.

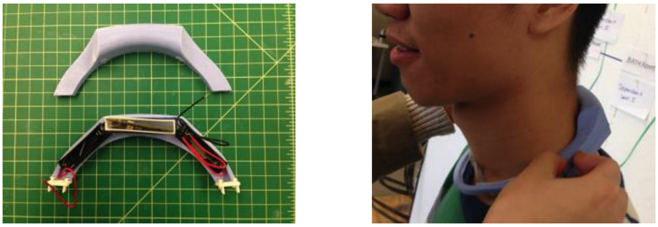

Fig. 3. It shows the connector with wires coming through and conductors inside

4.5 Final Design

The final design of the neckwear is shown in Fig. 4. The front part of the neckwear was used to hold the shape; the flex sensor and microphones were located directly to users' necks. The connectors on either side ware used as both connecting mechanism and conductor points. Two AAA batteries and a board sit in the back part of the neckwear, which can be hidden by users' necks.

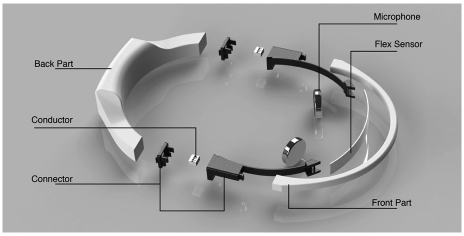

Fig. 4. It shows how the neckwear is assembled, and the location of each item

5 Fabrication

5.1 Connector

Since the connector is still in the prototype phase, and it only required low volume production, 3D printing technique was used. Therefore, the connector model was all made of ABS plastic (shown in Fig. 5).

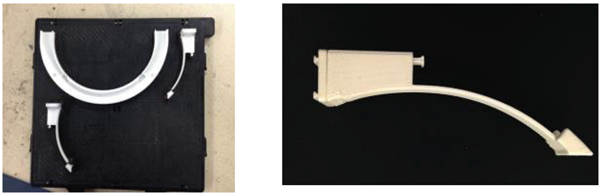

Fig. 5. It shows a 3D printed, plastic connector. The gears on the connector will be embedded in the silicone model.

5.2 Neckwear Body

In order to save time and the cost, instead of traditional way of silicone model making, in design iteration phase, 3D printing method was used in this project. The 3D printed plastic molds were used to replace the urethane molds, because a urethane mold requires sixteen hours to become solid, and the material itself is too costly. The whole silicone model has been divided into several parts to build. And since the inside of the silicone model is hollow, each model part requires two mold pieces (one female and one male) to create. And there were two holes of each mold pieces to let the air go in and out (Fig. 6).

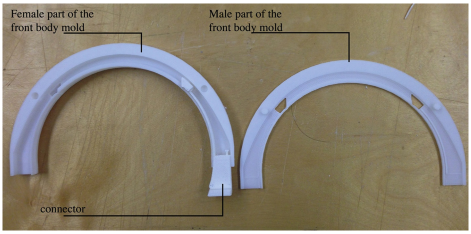

Fig. 6. The picture shows the two pieces of the 3D printed mold and one connector

A small scale and a plastic beaker were used in the fabricating process. At first, 10 portion of the silicone rubber and 1 portion of the catalyst were poured into the beaker, after they totally mixed up; the beaker was put into a vacuum chamber for degasing. During the time when the air bubbles went out from the liquid, the universal release was spray painted on the molds to avoid silicone rubber and plastic mold sticking to each other. As soon as most of the air bubbles vanished, the silicone liquid was poured into the mold slowly (Shown in Fig. 7).

Fig. 7. The picture on the left demonstrates how the silicone was measured on the scale. The picture on the right shows the process of filling the 3D printed mold.

After a piece of the female part mold was full of silicone liquid, the mold was covered by its male part. Two clamps were used to tighten the two parts. Then after 16 h' drying time, the silicone liquid became solid, and a piece of the model has been created. This process was repeated again to create the other part of the necklace model.

In order to keep the wires in position inside the model and make the connecting part strong, the wires and the hook of the connector were seated in the mold before silicone liquid was poured into.

After each body has been created, a silicone proxy was used to attach the two pieces of the back part together. The finished silicone model is shown in Fig. 8.

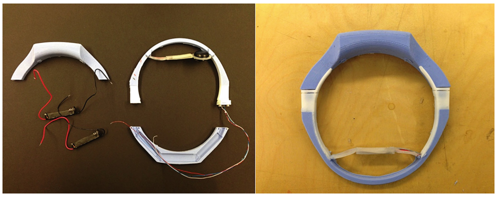

Fig. 8. The picture on the left shows a dissembled view of the fabricated model. The picture on the right shows an assembled one.

5.3 Microphone Shell

Since the neckwear is in charge of telling whether the patient has swallowed the pills, a bio-microphone and a piece of flex sensor are used. In order to better hold the electronic devices, a piece of silicone shell is specifically designed (Shown in Fig. 9).

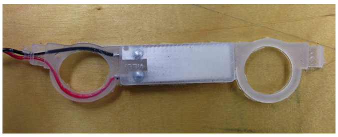

Fig. 9. The picture shows a finished silicone part with flex sensor in it. The two holes on both sides are for microphones.

In order to make the flex sensor embedded in the shell, the flex sensor with all the wires connected was pre positioned in the mold before the silicone gets dry. When the silicone shell gets dry, two microphones are placed inside the two circles. To make the silicone shell strongly attach to the front part, a "T" shape is made on both end of the shell. Before the front part is made, the shell has been seated inside the mold, with the "T" shapes stuck inside the mold. Besides, all the wires (microphone, RFID wires, and the flex sensors) have been connected to the conductors.

6 Future Work

Limited by the electronic technology, the battery currently used in the prototype is relatively big and heavy; this issue can be solved by the advancement of technology. The connector in the neckwear is an existing product; it did not fit the neckwear well.

A customized connector may need to be developed. Moreover, the neckwear was only fabricated, and was tested within real environment. Users' perspectives about the functional prototype need to be collected for further design iteration.

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