Implanted User Devices

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ABSTRACT

This paper will look at current research in the field of implantable devices, and with possible future research in mind, we examine what is in store for following generations and the possibilities of the implanted user device. To finish, we examine some concerns and issues we must take into consideration when looking forward in the field of implantable devices.

Keywords

implanted medical devices, microchips, circuitry, interfaces, inductive charging

1. INTRODUCTION

Implantable medical devices (IMDs) have been a vital innovation to the medical world in the last century. A medical device is defined as *implantable* if it is partly or totally introduced into the human body and is to remain there after the procedure [7]. As of 2013, nearly 10% of Americans have experienced an IMD, and in the United States, over 100,000 patients a year receive implantable cardioverter defibrillators (ICDs) [15]. These devices are meant to achieve one of three things; rebuilding a body function, achieving a better quality of life, or expanding longevity [7]. These devices can be electronic, such as a pacemaker, or mechanical, such as an artificial hip. Powered IMDs generally contain radios for communication with external devices, called *commercial device programmers* that can extract data from them, or reprogram them if necessary [15]. Within the accelerating world of technology and the user device, which includes cellular telephones, digital music players, and many other new forms of electronics, there are those who are looking to make the next step in innovation. Wearable technologies are becoming more and more well known, but they have been in development for years. Now, the newest stage of development has researchers looking towards the future, which may be implanted non-medical user devices.

The paper is divided into four main sections. First, we will examine some of the recent communication and security innovations that are being developed in the field of implantable devices. Next, we will discuss the future possibilities of the implanted user device, focusing some of the challenges involved and a few potential devices that may overcome those challenges. Then we will discuss considerations for the devices and the reservations that some experts have in the area of implanted devices. Finally, we will provide some conclusions and thoughts on the idea of an implanted user device.

2. COMMUNICATION AND SECURITY

Powered IMDs generally contain radios for communication with a *commercial device programmer*, which is the program designed to interact with the IMD, that can reprogram the device or extract patient data [15]. This wireless communication contains some similar risks that other wireless connections would contain, except with the ramifications of a breach being much more serious. Although IMDs use powerful security protocols, there are still several vulnerabilities such as wireless traffic sniffing (network analyzing) and wireless pacemaker exploitation [4]. With the ability for doctors to remotely or autonomously monitor patients and deliver treatments without requiring an office visit, there is also the possibility that unauthorized parties can intercept such communications or compromise the device remotely [4]. This concern has led to two recent developments; Heart-to-Heart, an authentication system for external medical device controllers to implantable devices [15], and near-field communication, communication performed through an antenna with a range of less than one meter [8].

Heart-to-Heart

Heart-to-Heart (H2H) uses heartbeat data from the patient containing the IMD, often called a *physiological value (PV)*, as an authentication mechanism, which ensures access only by a medical instrument in physical contact with an IMD-bearing patient. In the case of H2H, the inter-pulse interval is used as the PV value, which is the time between R-peaks in the heartbeat, or in simpler terms, the time between beats. The need for a more secure authentication system, as previously mentioned, is the possibility of a breach in the wireless communication that exists in current IMDs. H2H's "touch-to-access" policy is a countermeasure, and provides a practical and effective balance between access requirements and resistance to attacks. The researchers used a PV-based pairing system to avoid *man-in-the-middle* attacks. Such attack would consist of an adversary posing as a Programmer to

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an IMD, and as an IMD to a Programmer. Both the Programmer and the IMD take PV readings from the patient in whom the IMD is implanted. When the Programmer's reading of the PV was delivered, the adversary would then return the result as the IMD, and when the IMD's reading of the PV was delivered, the adversary would return the result as the Programmer, thus resulting in a successful authentication. The PV-based pairing system takes advantage of H2H's PV readings as passwords. These values are one-time values, rather than a multi-use password, allowing fresh readings to be used to authenticate every session. The protocol has two phases: first, a *secure-channel setup* phase, which uses public-key cryptography to create a secure but unauthenticated channel between the IMD and Programmer, and second, an *authentication* phase. When a Programmer seeks access to an IMD, it initiates the authentication session. The IMD takes a reading of the PV; at the same time, the Programmer takes its own reading. If the Programmer's reading is equal to the IMD reading, then the Programmer obtains access to the IMD. The synchronously sampled PV values allow for an additional security measure, which is using the time of the sample as an additional encoding.

The Neyman-Pearson lemma (which states that when performing a hypothesis test between two point hypotheses $H_0 : \theta = \theta_0$ and $H_1 : \theta = \theta_1$, then the likelihood-ratio test which rejects H_0 in favor of H_1 is the most powerful test of size α for a threshold) is used in place of the Hamming distance, which has been previously used in IMD-to-Programmer authentication. The Neyman-Pearson hypothesis testing is applied to determine whether to accept a Programmer-submitted PV value as authentic or reject it. First, the error value $\vec{u}$ is computed. Error value $\vec{u}$ captures the total number of errors u_i in each IPI bit position i, by comparison with the IMD PV. Then, the Neyman-Pearson testing of $\vec{u}$ is performed. This involves computation using this equation:

$$log(\frac{P(\vec{u})}{Q(\vec{u})}) = \sum_{i=1}^{4} log(P_i(u_i)) - \sum_{i=1}^{4} log(Q_i(u_i)).$$

The test is made efficient by precomputing a small table of u_i value probabilities and Neyman-Pearson threshold Th, both of which are stored in the IMD. [15]. The protocol itself relies primarily on symmetric-key commitment and decommitment rounds and explicit IMD testing of the condition Programmer PV $\approx$ IMD PV, rather than minimal-knowledge cryptographic comparison. The authentication protocol itself can be seen in Figure 1.

Near-field communication

Another method of communication security was examined by Kim et al., who looked at the use of near-field communication (NFC) in IMDs, to ensure minimization of security breaches. NFC refers to the communication at a distance of a few wavelengths. The current NFC standards operate in the 13.56MHz frequency band, which limits the range to about one meter. Through the experiments done by Kim et al., they were able to determine that this communication type was successful in consistent and reliable communication through tissue. This type of communication was done in their experiment via cellular telephones with NFC capabilities, and their prototype of the in-vivo (literally "within the living") NFC system of data communication was successful. This method of communication limits the range of interceptability to the distance of a few wavelengths, which would require an adversary to the system to be within that range to intercept communication [8]. One other feature that adds to privacy and security is the NXP proprietary security protocol for authentication and ciphering [8], which limits access to only devices that also use NXP NFC controller chips. Documentation on NXP protocol is limited, however, due to a previous version becoming compromised [13].

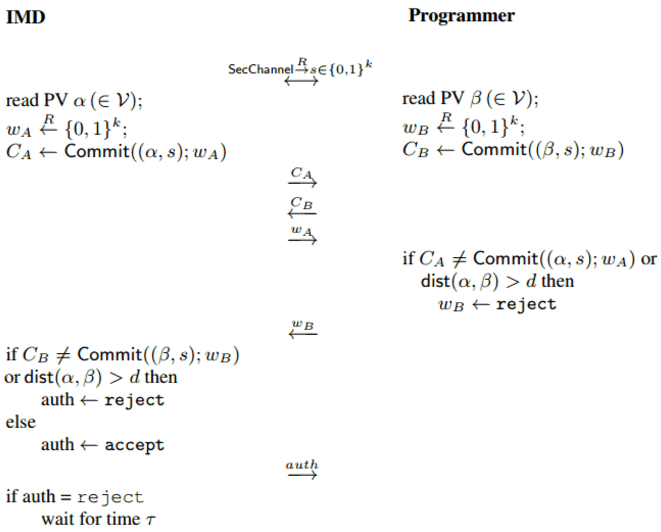

Figure 1: Heart-to-Heart's authentication protocol [15].

3. IMPLANTED USER DEVICES

With our current dependence on our electronics, there are those who are studying the possibility of always-accessible user devices, whose goal is to eliminate the time it takes to retrieve and access those devices. Once a thing of science fiction, the implanted user device may theoretically be only months away. When one thinks about the future of implantable devices, look no further than the devices on hand; the cellphone, the digital music player, or the wearable computer with an optical head-mounted display are all candidates for the next implanted device. There are many challenges that arise, such as input, when one thinks of those devices, so we look to inventions that are already in prototype development, such as EarPut, a device that goes behind the ear (see Figure 2) and responds to touch events [10]. With a little imagination, one could see that device being implanted behind the ear. This is where researchers are looking for inspiration, in devices that are on the cutting edge that have adaptable properties that *may* allow them to operate when implanted subcutaneously.

The intent of researchers looking into the implanted user device is similar to the intent of those developing the latest cell phone, which is increased convenience for the consumer [6]. The procedure of receiving an implanted user device would be similar to going to buy the newest smartphone. The purpose is to provide a solution for the significant overhead on usage time required when one retrieves a mobile device, and although wearable devices are becoming available, a more permanent solution is desired [6]. An implanted device would have several main advantages over mobile or wearable devices. First, one would not have to attach an implanted device daily. Second, implanted devices have the possibility of being completely unseen. And third, the devices always travel with the user, without concern for losing or forgetting them [6].

3.1 Challenges

As with all research, the progress of implanted devices has some obvious challenges that will need to be overcome if it is to reach the potential that the researchers see. These challenges are related to all parts of the process of implanted devices; the interface, the input, the output, and the power.

3.2 Interfaces

An *interface* is the device or program that allows a user to interact with software, hardware, or other devices. Interfaces that are common are touchscreen interfaces, on user devices such as cell phones or tablets, *graphical user interfaces* (GUIs), which allow a user to interact with an electronic device through icons and visual interpretations of information, and keyboards and mice, which only send data to the electronic device. One challenge of user devices as implanted devices is the interface. The question of how one will interact with the device is key. These interactions include both delivering input and receiving output [6].

3.2.1 Input

Receiving input is what makes a device more than just a screen. Being able to interact with the device requires it to have input detection, whether it be one singular button, thirty buttons, touch sensors or light receptors [6]. Because of the nature of implanted devices, they do not have a visible interface. This causes the main challenge to providing input, but this is where one looks to devices that are currently in development.

The aforementioned EarPut device has the potential to be a contact-based input beneath the skin [10]. Lisserman, et al. make a case for using the unique affordances of the human ear for eyes-free, mobile interaction. The device uses the human ear as an interactive surface for touch-based interactions, but it is still in prototype development, as seen in Figure 2. The concept of the EarPut is that the device will track and identify touch-based interactions using capacitive sensing based on electrodes that are placed onto an arc-shaped area. EarPut's sensor is attached to 12 electrodes, allowing for 12 distinctive touch areas on the ear. These areas sense singular touches, as well as swipes between areas. Lissermann et al. provide one example of when EarPut would be most convenient: imagine you are jogging and you have your music player in your pocket, and rather than retrieving the device and finding the skip button, you are able to touch your right ear lob to skip to the next song, or swipe up the ear to turn up the volume. Initial concerns with the device were the precision of a user in touching certain parts of the ear, as well as how many areas can be targeted at all by the device. Through their experiments, Lissermann et al. were able to answer these questions, confirming that some areas of the ear were easier to touch than others. The average effectiveness of targeting areas per region-based user interface decreased monotonically over all conditions of the experiments. The average effectiveness was 80% for region-based interfaces with up to 4 areas and decreases to 64% for 5 and 58% for 6 areas, respectively. The decrease in effectiveness was in line with the qualitative findings from the semi-constructed interviews performed by the researchers. The participants stated that it was hard to precisely distinguish between more than 4 areas [10]. The current state of this device allowed it only to record the touches it sensed, but it introduces an input method that could be implanted behind the ear that would provide one possible answer to the challenge of input.

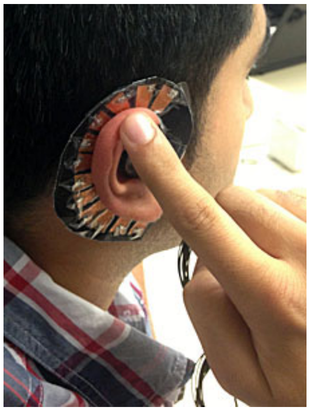

Figure 2: Prototype EarPut device [10]

SenSkin, a sensing technology and input method that uses skin deformation estimated through a thin band-type device *attached* to the human body [14], is another example of a possible input source. Although the band-type device is also not used subcutaneously, it is an intriguing solution to the issue of input. SenSkin provides tactile feedback that enables users to know which part of the skin they are touching in order to issue commands, as well as the measurement of force applied to the skin [14]. Ogata et al. proposed the device, which uses infrared (IR) reflective sensors to measure the deformation of the skin, as a wearable device that would attach to the forearm. By using the IR reflection, location of the touch, as well as the force of the touch, can be quantified. The device contains six IR reflective sensors on each band, and an elastic tape with hook-and-eye fasteners to allow easy attachment. The sensors are placed at 10 mm intervals on the band, and a cross-section of the device can be seen in Figure 3. One of the main advantages of this device, and the possibility of it becoming an implanted user device input method, is that nothing is covering the skin, thus allowing the user to have greater control of where he touches and the amount of force that he applies. There is also the possibility of using the device in other locations on the body instead of the forearm [14]. This device, yet in prototype form, also has the possibility of leading to innovations for a similar device for an implanted user interface, if researchers were able to track the same measurements read by this device subcutaneously.

Yet another possibility for receiving input is Magic Finger, a small device that is currently worn on the fingertip, which supports always-available input [21]. The Magic Finger senses touch through an optical mouse sensor, enabling any surface to act as a touch screen, and the device can sense texture through a micro RGB camera [21]. Yang et al. have many visions for the direction the device could take, such as data gloves, interactive tabletops, or even as an implanted interface. Although Yang et al. admit the

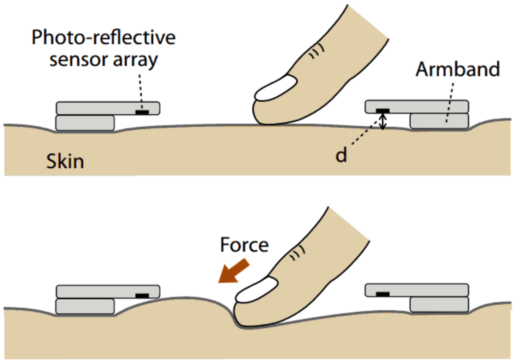

Figure 3: Section image of SenSkin armbands [14].

limitations of the device, such as needing external lighting in order to make the device work, the results of the testing of their prototype device (see Figure 4) were very promising. Those conducting the study evaluated the accuracy at which the device can recognize *environmental* textures, *artificial* textures, and Data Matrix codes. The evaluation served purely as a technical evaluation, not a user study of the device. For the *environmental* textures, the researchers collected 22 different textures from a variety of everyday objects, including public items, personal items, and parts of the user's body. To create *artificial* textures, they printed a grid of ASCII characters, of 39 characters found in a standard US English keyboard, including all 26 English capital letters and 13 other characters. For the data matrix, they randomly selected 10 out of 10,000 possible codes, and with each printed clusters of 72 x 15 identical codes. [21]

For each *environmental* texture, *artificial* texture, and Data Matrix, 10 samples were collected twice a day for 3 days. The accuracy of the recognition was tested using a cross validation procedure, which achieved an accuracy of 99.1% on the 22 tested *environmental* textures. For the ASCII *artificial* textures, cross validation yielded 83.8% accuracy with all of the 39 tested characters. These results indicate that Magic Finger can recognize 22 *environmental* textures *or* 10 *artificial* textures with an accuracy above 99%. The Data Matrix codes were correctly decoded for 598 of the 600 samples, which is an accuracy of 99.7%. In both failure cases, no Data Matrix was recognized. These results demonstrate the feasibility of using Magic finger for interactive tasks, as well as a possible solution to the challenge of an implanted user device form of input.

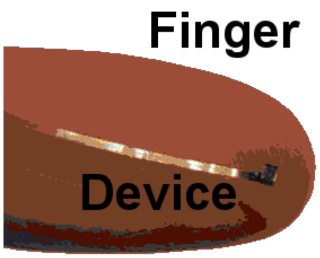

Figure 4: Prototype Magic Finger device and the field of view (outside square) [21].

Another possibility that is already in use is an audio user interface that could capture speech input for voice activation [6]. Voice activation is a technology that is already available to consumers through companies such as Apple and Google. Though the technology is far from flawless, it continues to be developed and expanded.

Whether it be buttons, tap sensors, gesture sensors, or auditory sensors, the possible solutions to the challenge of input currently exist in many forms.

A more advanced source of input or interaction that has been researched are electroencephalograms (EEGs). EEGs are currently in use for brain mapping, but have also been used for interfaces, made possible by reading the signals emitted by the cells in the brain. The target is to let the brain interact directly with an electronic device, whether it be a prosthetic or a humanoid robot [2]. The target of Brain-to-Machine Interfaces (BMI) is purely medical; they are intended to allow someone without complete use of their bodily functions to return to being fully mobile, but that does not limit the technology to that field, however, the ethical concerns with the EEGs limits the conversation to medical fields only, at this time, due to the unforeseen repercussions of extended use of EEGs. [2].

3.2.2 Output

Device output typically is dependent upon the senses of sight, hearing, and touch, possibly through vibration [6]. The reasons this is a challenge for implanted devices is that, in a typical user device, a screen is the output that one would look at. With no visible screen, an implanted device would have to have an alternative way of producing output. A few concerns with the possible choices include that, if using a visual method, the output may go unnoticed by the individual, or if using an auditory method, size of the device limits the possible intensities, pitches, and sound patterns. Tactile output may be particularly suited towards implanted user interfaces, due to the fact that it could provide output noticeable only to the host user and no one else [6].

Unlike input, research in output devices is limited due to the fact that we already have screen technologies that provide a more than adequate output source. Holz et al. examine this concern with several possible solutions. The researchers experimented with vibration, LED, and audio output, as seen in Figure 5. They discovered that their test subjects rated the LED lowest in the experiment for perception of output, with vibration motor as the most easily perceived method of output [6]. Although this does not address the concern of more advanced output, such as communication or images, the researchers concluded that the vibration was the most easily perceived method for basic output.

Figure 5: Holz et al. I/O devices used in implanted device study [6].

Although the output is currently the most limiting factor of the implanted user device in theory, there are constantly new technologies being developed.

3.2.3 Power

The average lithium battery used in a pacemaker has a lifespan of about ten years [11]. Unlike the typical consumer product, the battery of a pacemaker cannot be replaced. The pacemakers are hard wired when manufactured, and from then on, the battery is expected to power the device throughout testing, shelf life, and the duration of its implantation [11]. Compare this to the average user device, whose batteries need to be replaced or recharged as often as daily. These user devices, which could include media players, cellphones, or media capturing devices, require much more power than the pacemaker. If the theorized implanted user device were to use a hard wired battery, the device would have a life much shorter than ten years. More likely, it would need to be replaced monthly, if not more frequently. Due to the nature of implanted devices, the inconvenience it would cause would reduce its popularity immensely.

Holz et al. examined the use of inductive charging, commonly called *wireless charging*, in implanted devices [6, 19]. Inductive charging provides a convenient means to charging electronic devices. The process is based upon the principle of *inductive power transfer* (IPT), or magnetic resonance, which is the process of transferring energy between objects through coils. A time-varying magnetic field is induced in the transmitter coil by an alternating current (AC), which sends energy from the transmitter to a coil in the receiver, or target device, via a process called *magnetic coupling*. Circuitry in the receiver then converts the energy received through the magnetic coupling into a direct current (DC), which can then be used to charge the battery. The AC signal can be transferred through solid objects, such as walls, furniture, or human tissues [19]. The ability to wirelessly charge a device gives the advent of implanted user devices a much greater possibility.

Holz et al. used an inductive charging mat combined with an implanted inductive charger to test the possibility of using wireless charging for implanted devices. During their study, Holz et al. placed the powering mat on the surface of the skin directly above the implanted device. By comparing the voltage between a baseline condition of a device directly on a charging mat, which was 5.12V, and the implanted device, they found that the voltage provided was insubstantially smaller, about .01V less. The study shows that inductive charging would be a viable option for powering implanted devices that required higher energy levels to operate [6].

4. CONSIDERATIONS

When the subject of implanted devices arises, one has to consider the physical and ethical ramifications of the issue.

4.1 Physical

Due to the theoretical nature of implanted user devices, the physical repercussions of the implantation of the devices are unknown. There are already theories on the damage caused by excessive cellular telephone usage, so one would assume that those who believe that cell phones are harmful in *traditional* usage, would believe that they would be much more harmful when implanted in the body.

There are other physical concerns besides the cellular communication anxieties, such as malfunctions, infections, and rejection by the body. The implanted device would be a foreign object to the body's immune system, and if allergens were present, the body would react in a negative, defensive way.

Concerns about malfunctions include battery combustion, component detachment, and similar issues. This could cause considerable internal injuries, depending on where the device was implanted.

As with infections, all medical procedures are at risk of infection, but if the popularity of the theoretical implanted user devices rises, so will the number of infections. This will be caused by a need to have in-and-out surgeries to accommodate the volume of consumers.

4.2 Ethical

One of the main questions surrounding the ethical concerns of the implanted device is that if functions can be restored for those in need, is it right to use these technologies to enhance the abilities of healthy individuals as well [2]? Although the advances in implantable user devices are mostly theoretical, they are not an unthinkable next step, and so the questions must be faced.

Initial costs of implanted user devices will be very high, available to only the wealthy and interested. This is already the case with traditional hand-held devices, but where consumer technology becomes affordable, the cost of the implantation might keep the cost of this technology out of reach from the low-income individuals. This will create a greater divide between the high- and low-income individuals in society, especially when the implanted user device will give those who own them a range of benefits. So another question that must be faced before the widespread use of the devices is their availability; will they be made affordable for any and all? Is it a reasonable concern?

And the final main ethical question is that of human rights. As these devices get more advanced and powerful, there are those who fear that implanted devices will become mandatory [16]. This is a question leads past implanted user devices, but the medical field in general, as well as our rights as humans. As the technology advances to preserve brain function, when do we decide to to end the sustained life? As more and more devices get implanted into humans sustaining life in general, where is the line drawn? [20]

5. CONCLUSIONS

One could say that ever since the invention of the first printed circuit board, technology was headed in the direction of implanted devices. Since 1958, those in the medical field have been implanting critical medical devices in patients. We have looked at the components of the pacemaker as the building blocks that have gotten the technology to where it is now, as well as the recent innovations that will lead to the future of implanted devices. After discussing the physical and ethical considerations surrounding the topic, one should now know that we are on the precipice of a decision, and that decision *will* change the way we interact with technology. Does the field continue research and development towards the implanted user device and tackle the ethical concerns, or does it leave the devices in our hands?

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