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Fully implantable middle ear hearing implant

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Introduction

Hearing Aids (abbreviated as HA) are "external listening devices that provide amplification and are traditionally used to treat hearing loss" (Pulcherio, et al., 2014). Two companies make a type of hearing aid called a hearing implant, one is Otologics, they created Carina (not approved in the United States). The other is Envoy Medical, they created Esteem, which is available for use in the United States.

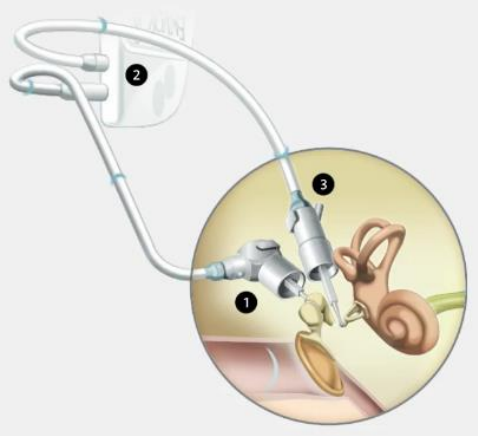

Figure 1. How Esteem Works. Number two on this figure is the where esteem converts vibrations into electrical signals which are sent to the implanted sensor. Number 2 is the sound processor which recieves, adjusts and intensifies these signals. Number 3 is the driver, which transfers these adjusted and intensified vibrations to the stapes. Adapted from How IT Works – Esteem Hearing by Envoy Medical, 2016, Esteem http://esteemhearing.com/how-it-works/. Copyright 2016 by Envoy Medical.

Esteem depends on piezoelectric technology (Pulcherio, et al., 2014). Piezoelectricity is "electricity or electric polarity due to pressure especially in a crystalline substance (as quartz)" (Merriam-Webster, 2016), meaning an electronic charge gathers in a specific material as a response to mechanical stress, Esteem uses a piezoelectric crystal (Pulcherio, et al., 2014). The battery life of this device depends on frequency of use. The median battery life for the sound processor is 5 years, and there is no need to recharge daily (Envoy Medical, (2016b)).

The Esteem device contains three parts; a sensor, a sound processor and a driver (Envoy Medical, 2016a), the sound sensor and the driver are both attached to the ossicular chain, and the

sensor is implanted behind the ear (Envoy Medical, (2016b)). The sensor senses the vibrations of the incus that are created by sound, and it converts these vibrations into an electrical signal which is then sent to the sound processor, which adjusts and intensifies the sound signals to pre-determined levels, and then these newly customized signals are translated back into vibrations in the driver which is attached to the stapes bone.

Carina is a hearing implant that uses a rechargeable battery to power it. (Bruschini, Forli, Santoro, & Bruschini, 2009) One charge takes 40 minutes, allowing for 16 hours of use (Cochlear Ltd., 2016). The internal battery has a life of 10 years (Sockalingam, 2015). Carina is made up of a microphone, a transducer, an electronic module, a battery and a magnet. The microphone is implanted under the skin against the mastoid bone, the implant itself is placed under the skin behind the ear (Pulcherio, et al., 2014). It converts sound into an electrical signal, and it is adjusted to the wearers desired levels before being sent to the transducer in the middle ear. The transducer changes the signal into a mechanical motion which is transferred to the incus, the stapes, the round window or the oval window, all of these locations are possible (Pulcherio, et al., 2014).

Biology Background

There are three parts of the ear, the outer ear, the middle ear, and the inner ear (Watson, 2012). The outer ear has two parts, one is the pinna, which captures, focuses and filters sounds, and the second part of the outer ear is the ear canal. The middle ear consists of the tympanic membrane (the eardrum), the ossicles, and the oval window. The ossicles, (the malleus, the incus, and the stapes) is made up of three small bones that transmit vibration to the to the oval window. The inner ear contains the snail shaped structure known as the cochlea, which contains

the primary cells for hearing and cochlear fluid. The movement of this fluid that triggers a response from the auditory nerve (Watson, 2012).

The Centers for Disease Control and Prevention (CDC) states that there are different types of hearing loss. Sensorineural hearing loss (a problem with how the inner ear or hearing nerve works), sensorineural hearing loss (a problem with the inner ear), conductive hearing loss (sound waves cannot get to the cochlea), and mixed hearing loss (a combination of the above types) (Centers for Disease Control and Prevention, 2015)

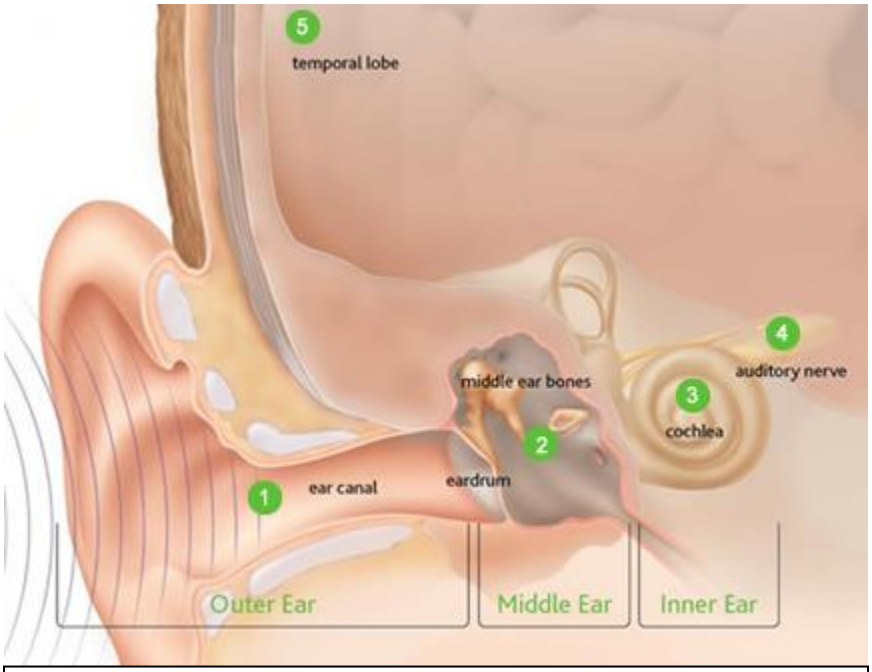

Figure 2. The different parts of the ear. Number 1 is sound, which is vibrations in the air. These vibrations move through the ear canal to the eardrum. Number 2 is the middle ear, where the ear drum vibrates, and causes the ossicles to vibrate. Number 3 is the inner ear, the cochlea. The cochlea is fluid filled, and has tiny hair cells in it that convert the vibrations into electric signals. Number 4 is where the electrical signals are sent to the brain (Number 5) through the auditory nerve. Adapted from Iowa ENT Center » Hearing Loss Explained by Iowa ENT Center, PLCC, 2016, http://www.iowaentcenter.com/specialties/hearing/hearing-loss-explained/. Copyright 2016 by Iowa ENT Center, PLLC.

The CDC (2015) lists four different levels of hearing loss, ranging from mild to profound; Mild means able to hear speech sounds, can't hear soft sounds. Moderate hearing loss means hearing no normal level speech, only loud sounds. Sever hearing loss means no speech when at a normal level, and only some loud sounds. Profound hearing loss means only being able to hear very loud sounds (Centers for Disease Control and Prevention, 2015).

Hybrid System

The HA, currently, is a therapy used to help people who have suffered hearing damage/loss or were born hard of hearing. Once someone is given a HA the technology combines with the biological auditory system. Most HAs are conventional, meaning they are not fully implanted. Conventional HAs can work wonders, but there are also a lot of problems; such as the insufficient high-frequency gain for those who have "ski-slope" hearing loss, feedback, the inability to wear in water, the large amount of daily maintenance, skin conditions, and the blocking of the external auditory canal (which can sometimes cause occlusion effect and also affects how sound travels in the ear) (Bittencourt, et al., 2014). The Occlusion effect is when the wearer of the HA hears their own voice, but it is distorted, and often it is described as "hollow" or "boomy" (Ross, 2004). Another problem with conventional HAs involves cosmetic issues, and the negative stigma of inferiority or disability that accompanies the use of HAs (Bittencourt, et al., 2014).

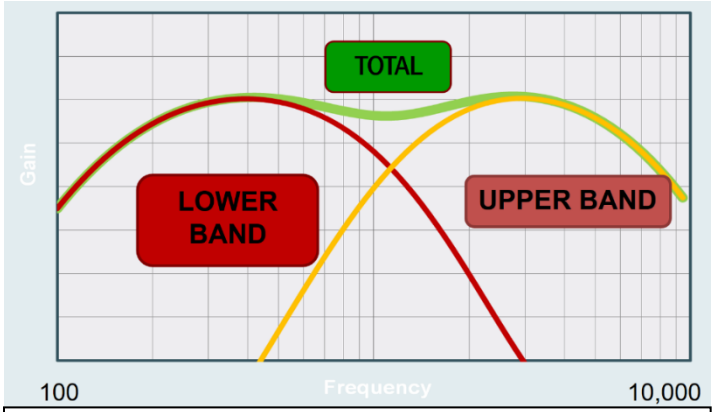

Figure 3. The Esteems Gain Settings. Esteem uses two bands to adjust gain levels (the Upper and Lower Bands), dividing the audio frequency range into low and high frequency regions. This allows the Esteem to help a wide range of hearing loss profiles to separately compress the high and low frequencies resulting in the gain curve for the whole audio range. Adapted from *The Esteem Hearing Implant* [PowerPoint slides] by Envoy Medical. Copyright 2016 by Envoy Medical.

Hearing implants help the individual hear much better (*Table 1*) while also addressing many of the issues above. There is no need for daily maintenance, which means they are far easier to maintain and much less intrusive in the individual's life. They do not block the individuals ear canal, meaning there is no risk of blocking the external auditory canal or

changing how sound is heard. Implants help with "Ski-Slope" hearing loss because they are able to divide the audio frequency range between high and low frequencies to address both. The whistling that is most associated with feedback in a conventional HA is not present in implants. (Hearing Link, 2013). Implants are also able be worn in water because the electronics are protected under the skin, and in the middle ear. Because they are implanted beneath the skin, there is no irritation of the HA rubbing against the outer skin, and the implant is invisible meaning that the negative stigma and judgement many associate with having a HA doesn't exist.

Table 1.
Auditory gains obtained with the conventional HA and the implant, in free-field conditions.

	Pure-tone audiometry								Speech testing	
	250 Hz	500 Hz	1 KHz	1.5 KHz	2 KHz	3 KHz	4 KHz	6 KHz	50% WRS	% WRS at 65dB
Hearing aid	10	25	20	10	5	0	10	5	5	40%
Implant	25	30	25	25	40	25	40	45	20	80%

Note: Reprinted from A middle ear implant with a titanium canal wall prosthesis for a case of an open mastoid cavity by Arnaud Deveze, Charbel Rameh, Mélanie Sanjuan, Jean-Pierre Lavieille, Jacques Magnan. A Pure-tone audiometry is the typical test used to test for hearing loss. WRS stands for word recognition score. 65Db is the average volume of human speech. Free-field conditions mean the location in which this data was gathered had no reflective surfaces within the frequency region of interest.

There are negatives with implants, the Esteem works by disconnecting the stapes and the incus bones in the middle ear, and this is done to eliminate feedback (Shohet, 2016). Disconnecting these two bones helps to eliminate feedback, it also means if the implant is damaged or the batteries die the patient will be unable to hear, no matter what their hearing levels were preimplantation (Shohet, 2016). The Carina implant works without disconnecting these bones (Pulcherio, et al., 2014).

Future Directions

As technology gets smaller and more focused on wireless connections HAs have also made this evolution. Modern conventional HAs include Bluetooth abilities through secondary devices (Sivantos, Inc., 2016). Brent Edwards, PhD believes that in the future when one person is wearing two HAs, the HAs will be able to communicate to each other; meaning that the person wearing them will have their binaural perception restored. The reason that this is currently impossible is due to the fact that a HA requires less than 1 mw of power, and a Bluetooth chip needs over 30 Mw of power. (Edwards, 2007). Adding in a Bluetooth chip would drastically reduce the battery life of a HA. As technology advances, and digital wireless chips continue to become smaller it will become possible to add Bluetooth connectivity directly into both HAs and implants.

In the future implants will be the new "conventional HA". They will also be able to be used as an enhancement. People will be able to use their implants to hear an expanded range of sounds. Implants will become inseparable from phones, like an internal Bluetooth. As connected as people are with their phones and technology today, we will only become more connected, to the point of having our phones implanted beneath our skin.

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