The History of Cochlear Implants –
Comparing the Current Cochlear Implant Manufacturers

A Departmental Paper

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Chapter 1 –
An Introduction
Introduction

Imagine yourself, a new parent. A new little bundle of joy was handed to you for the first time only a few hours earlier and all of a sudden in walks the newborn hearing-screening technician with some devastating news. Your new daughter is deaf, possibly profoundly deaf. There are many questions that have arisen with this news. What will we do? Will she ever be able to speak? Will she ever hear me say I love you? How do I begin to communicate with my daughter? These are questions that parents of newly identified deaf children face daily. These same parents are then confronted with the decision of how to teach their child language. There are several teaching methods that are used currently including the Auditory Verbal Method, the Auditory Oral Method, Total Communication, Cued Speech, and Bilingual/Bicultural education. Today if parents choose to teach their deaf children to learn to listen and speak there is an option that allows deaf children access to language. The cochlear implant is an electronic device that allows deaf and hard of hearing children and adults access to sound. According to Wikipedia.com “A cochlear implant is a surgically implanted electronic device that can help provide a sense of sound to a person who is profoundly deaf or severely hard of hearing.” The cochlear implant does not amplify sounds like a regular hearing aid however; it bypasses the damaged part of the inner ear, replacing it with electrodes, allowing the profoundly deaf individual access to sound. (Wikipedia.com).

Currently there are three major FDA approved cochlear implants providers that are commonly used in the United States. These providers are the Nucleus Corporation, Advanced Bionics, and Med El. The Nucleus Corporation is based in Australia. They are
currently marketing the Nucleus Freedom Cochlear Implant that contains the Freedom internal transmitter and the Freedom BTE (Behind the Ear) speech processor and bodyworn speech processors (www.cochlear.com). Advanced Bionics is based in California. They are currently marketing the High Resolution Bionic Ear System including the 90K internal transmitter, HiRes Auria BTE (Behind the Ear) speech processor, and the Platinum bodyworn Processor (www.bionicear.com). Med El Corporation is based out of Austria and is currently marketing the Pulsar internal transmitter and TEMPO+ speech processor (www.medel.com).

**Justification**

“All three cochlear implant systems have similarities and differences. Although each company will boast product superiority, no implant system restores hearing to normalcy and no system can unequivocally guarantee a particular result” (Chute & Nevins, 2002). Each of the systems has their own individual accessories that are available making the systems different from each other (Chute & Nevins, 2002). Each manufacturer has a great deal of information published and available on their systems. Each of these systems has characteristics that make them different from the others and with increasing technology the companies are continuing to make improvements in their systems.

When a parent is asked to decide which cochlear implant system to select for their deaf child they are often overwhelmed with a great deal of information from each company. Even with the vast amount of information available pertaining to cochlear implants and cochlear implant systems, there are few comprehensive comparisons of
the systems that are currently available in the United States. This paper will provide a concise comparison between Advanced Bionics, Nucleus Corporation, and Med El Corporation’s cochlear implant systems, including the internal and external components.

This research will compile much of the information available to parents, teachers and adults with hearing loss and place it into a concise review of the current literature. Cochlear implants are also technological devices that are subject to failure. Included in this review of literature will be the failure rates for each company as well as reliability issues and how the companies are dealing with these issues. This allows one to be able to obtain a more complete picture of each company and their individual devices.

**Statement of Questions**

In order to provide structure and direction throughout the remainder of the paper, three questions will be proposed and discussed. The questions are as follows:

1. What is the history of cochlear implants and how have the cochlear implant companies changed over the last 20 years?
2. What is the rate of failure for each company? How do the companies address these problems?
3. What are cochlear implant companies doing to promote their product? What type of materials do the cochlear implant companies provide for parents and teachers?

**Definition of Terms**

1. **Cochlear Implants** – A cochlear implant is an electronic device that “consists of a number of basic components that function in a similar manner” including the external hardware and internal device (Moore & Teagle, 2002).
a. **Multi-channel cochlear implants** – A multi channel cochlear implant has more than one electrode. There are several manufactures that make multi channel electrodes and the number of electrodes in each differs. Nucleus Corporation currently utilizes 24 electrodes, Advanced Bionics uses 16 electrodes, and Med El uses 32 electrodes (Chute & Nevins, 2002).

b. **Single-channel cochlear implants** – A single channel cochlear implant has only one electrode (Chute & Nevins, 2002).

2. **Cochlear implant companies** – there are several different manufacturers of cochlear implants that have been approved by the FDA for use in the United States.

a. **Advanced Bionics** – This Company is located in Sylmar, California and began producing implants in 1995. They are the only American based company and have been through several generations of cochlear implants including both internal and external devices (Chutes & Nevins, 2002).

b. **3M/House CI** – This was a single channel cochlear implant and was the first approved by the FDA for use in postlingually deaf adults (Christiansen & Leigh, 2002).

c. **Med El Corporation** – This Company is based out of Innsbruck, Austria and they have been producing cochlear implants since the early 1980s. They started distributing devices in the United States in 1994 (Chute & Nevins, 2002).
d. **Cochlear Corporation** – They were the first to produce multi channel cochlear implants in the world in the early 1980s (Chute & Nevins, 2002).

3. **External Components** – the microphone, speech processor, transmitter and power supply are all parts of the external devices of the cochlear implant (Moore & Teagle, 2002).
   
   a. **Batteries** – are the power supply for the cochlear implant. They can be either rechargeable or alkaline depending on the type of device that is used.
   
   b. **Cables** – deliver the sound from the microphone to the speech processor (Nevins & Chute, 1996).
   
   c. **Coils** – contain magnets that hold the implant to the head and transfer the signals from the speech processor via radio waves through the skin into the internal device.
   
   d. **Microphone** – picks up the incoming signals (Nevins & Chute, 1996).
   
   e. **Speech Processor** – “The speech processor is an electronic device that filters the input signal from the microphone and converts it into a series of electrical signals to be delivered to the internal device within the cochlea.” (Moore & Teagle, 2002).
   
   i. **Behind the Ear (BTE) Processor** – a speech processor that sits on the ear and is much smaller than the bodyworn processor (Chute & Nevins, 2002).
ii. **Bodyworn Processor** – is a speech processor that is worn on the belt or in a special harness and is pager sized (Chute & Nevins, 2002).

4. **Failure** – A failure occurs when the internal device of the cochlear implant system malfunctions for any variety of reasons ([www.nuclues.com](http://www.nuclues.com)).
   
   a. **Hard Failure** – the internal device of the cochlear implant completely stops working (European Consensus Statement on Cochlear Implant failures and Explantations, 2005).
   
   b. **Soft Failure** – the internal device of the cochlear implant malfunctions where sound cannot be heard, wearing the device is painful, sound is intermittent, or static is heard (European Consensus Statement on Cochlear Implant failures and Explantations, 2005).

5. **FM Capability** – the cochlear implant’s external device’s ability to connect to an FM system ([www.cochlear.com](http://www.cochlear.com)).

6. **Hearing Loss** – hearing loss happens when there is a part of the ear that does not function. Hearing loss can range from someone who hears well with hearing aids to someone who does not hear well even with amplification (Tye-Murray, 2004).
   
   

d. **Severe Hearing Loss** – hearing thresholds between 70 – 90dB HL (Tye-Murray, 2004).

e. **Profound Hearing Loss** – hearing thresholds greater then 90dB HL (Tye-Murray, 2004).

7. **Internal Components** – the parts of the cochlear implant that are placed under the skin behind the ear (Chute & Nevins, 2002).

   a. **Channels** – A channel is a single electrode (Christiansen & Leigh, 2002).

   b. **Electrodes** – “Actively delivers the signal to the cochlear nerve endings” (Chute & Nevins, 2002).

   c. **Electrode positioning system** – guides the electrodes into the cochlea (Advanced Bionics, 2000).

   d. **Internal electrode array** – “Electrodes placed in pairs on a carrier wire and inserted into the cochlea.” (Tye-Murray, 2004).

   e. **Internal receiver** – part of the implant that is placed under the skin behind the ear that includes that magnet and antenna (Chute & Nevins, 2002).

   f. **Shape of Array** – how the electrodes are shaped before they are placed into the cochlea (Chute & Nevins, 2002).

      i. **Straight electrode array** – electrode arrays that are not curved at all (Chute & Nevins, 2002).
ii. **Precoiled electrode array** – electrode arrays that were developed to follow the shape of the cochlea (Chute & Nevins, 2002).

8. **Programming Strategies or MAP** – The map is used to direct the sound that is coming in through the processor and change it into an electrical signal that is comfortable for the child (Chute & Nevins, 2002).

   a. **ACE** - Advanced Combination Encoder - is a fast rate and flexible programming strategy (McCormick & Archbold, 2003).
   
   b. **ADRO** – is a programming strategy that “Automatically adjusts sounds levels to deliver an ideal balance of clarity and comfort.” (Cochlear, 2005).
   
   c. **Beam** – Beam is defined as focused listening for easier listening in crowds and it is designed to make distracting sounds softer and make it easier to focus on the conversation (Cochlear, 2005).
   
   d. **CIS** – Continuous Interleaved Sampling was the first fast rate strategy developed in 1991 (McCormick & Archbold, 2003).
   
   e. **PPS** – Paired Pulsatile Strategy is a strategy that pairs pulses from two different channels (McCormick & Archbold, 2003).
   
   f. **SAS** – Simultaneous Analogue Stimulation strategy uses one reference electrode to achieve bipolar stimulation (McCormick & Archbold, 2003).
   
   g. **SPEAK** – a slow rate strategy (McCormick & Archbold, 2003).
   
   h. **Whisper** – Whisper is a programming strategy that makes softer sounds louder so that it is easier to understand them (Cochlear, 2005).
**Hypothesis**

Each cochlear implant manufacturer has a variety of different aspects of their individual systems. Because of this fact, the information that the cochlear implant companies provide to parents is often too in-depth for parents to make decisions during the time prior to implantation. The information provided in this paper will help to give parents, teachers, and clinicians an overview of all three currently used cochlear implant systems as well as discuss some of their flaws. There is no one right cochlear implant for all people, but it is important for parents and deaf adults to choose the cochlear implant system that will fit their family and their child.

**Conclusion**

This chapter includes the following parts: the introduction which allows readers to acquire general background knowledge relating to the topic of cochlear implants and the justification stating why this information needs to be compiled into one easily accessible place for parents, teachers, and adults with hearing loss. To provide the reader with some insight into what will be included in the remainder of the paper, the three questions that will be addressed throughout the paper were also introduced. To give the reader a clear understanding of the research a list of definitions that will be used throughout the paper was also provided. Lastly, the hypothesis is included showing why this information is so pertinent and how it can benefit people who interact with deaf children and adults who currently use or are considering using a cochlear implant.
The next chapter will address hearing loss in general. It will discuss the types and degrees of hearing loss. The educational placement and communication options available for deaf and hard of hearing children will also be addressed. A brief overview of cochlear implants, their history, how they work, and the three companies that are currently manufacturing cochlear implants in the United States will also be looked at. Finally, a brief introduction to my three questions that were mentioned in this chapter will be given so that the reader is able to understand the remainder of the paper.
Chapter 2 –

Review of the Literature
**Introduction**

The National Institute on Deafness and Other Communication Disorders (NICDC) website states that every deaf child is unique and that it is important to understand the full nature and extent of the child’s hearing loss to provide the best possible outcomes for that child (NICDC, 2006). This chapter will discuss briefly the many options available for teaching deaf children to learn how to communicate. The remainder of this paper will focus on the option of teaching deaf children to listen and speak. With the advancements in hearing technology, learning to listen and speak is greatly aided with enhancements in hearing aids and cochlear implants. According the Oberkotter Foundation (2006) even children with profound hearing loss can learn how to listen and speak by combining enhanced hearing technologies and intense early intervention. This chapter will address the anatomy and physiology of the ear, types and degrees of hearing loss, and types of amplification systems. How cochlear implants work and an overview of the history of the various cochlear implant companies and their products will be examined in order to provide a basis of understanding for the remainder of the paper.

**Anatomy and Physiology**

The ear is one of the smallest parts of the body, but it provides a great deal of information to the brain by converting sound waves into electrical energy that then travels to the brain. Although this process is complicated, it occurs very quickly. The ear has three main parts: the outer ear, the middle ear, the inner ear (MedEl, 2006).
The outer ear consists of the pinna (visible part of the ear) and the external auditory meatus (ear canal) (MedEl, 2006). The pinna funnels the sound waves into the external auditory meatus, which allows sound to travel to the tympanic membrane (ear drum) (MedEl, 2006).
The middle ear contains the tiniest bones in the human body. These bones are called the Malleus (Hammer), Incus (Anvil), and Stapes (Stirrup). The sound that is captured by the ear canal vibrates the tympanic membrane. The tympanic membrane then converts the sound waves into vibrations, which travel through the bones of the middle ear. As the bones vibrate the oval window begins to push in and out of the cochlea transferring the sound into the inner ear.

http://hope4hearing.org/anatomy.htm

In the inner ear, sound is converted from the vibrations into hydraulic energy. Inside the cochlea there are tiny little hair cells that are stimulated by a fluid in the inner ear. When these nerve cells are stimulated they send an electrical signal to the auditory nerve. The auditory nerve then sends the signals to the brain where it is interpreted as sound.

The inner ear also includes the semicircular canals, which are part of the balance system. “The inner ear monitors the direction of motions such as turning, stopping, and starting” (http://www.earspecialtygroup.com/dis_bal_frm.html). Although this paper
does not focus on the semicircular canals it is important to note that they are located in the inner ear and hearing loss can affect balance.

http://www.brainconnection.com/med/medart/l/anat/990702.jpg

Types and Degrees of Hearing Loss

There are three main types of hearing loss. The first type is conductive hearing loss. This type of hearing loss occurs when there is an abnormality of the outer or middle ear (Boothroyd, 1993). This can be caused by otitis media (middle ear infection), a perforated eardrum, otosclerosis, or a missing outer or middle ear. The next type of hearing loss is sensorineural hearing loss, which is damage to the sensory or neural structures of the inner ear (Advanced Bionics, 2003). Cochlear Corporation (2004) also describes this type of hearing loss as,

One in which the bones, eardrum, and membranes of the ear are intact but the tiny hair cells have been damaged. The damaged hair cells do not allow the
electrical impulses to reach the remaining nerve fibers. The nerve fibers do not have information to call to the brain. (pg. 5)

This can be caused by a variety of factors including, but not limited to, genetic causes (connexin 26), injury, illness, the natural aging process, or ototoxic drugs (Cochlear Corporation, 2004).

The third type of hearing loss is a mixed hearing loss, which can occur when a person has a sensorineural hearing loss as well as a conductive hearing loss. This can happen if a child with a moderate sensorineural hearing loss contracts a middle ear infection or is missing part of their outer ear.

Hearing loss is also classified by the degree of hearing loss. Degree means how much hearing a person does or does not have. There are four main degrees of hearing loss. These are categorized as mild, moderate, severe, and profound hearing loss.

http://www.babyhearing.org/HearingAmplification/HearingLoss/audiogram.asp

Normal hearing is considered anything better than 25dB as pictured in the green in the above diagram. Mild hearing loss is from 25dB – 45dB and is marked in the blue area above. Mild hearing loss can cause a person to have difficulty hearing quiet voices (Boothroyd, 1993). Moderate hearing loss is described as being from 45dB – 65dB and
is pictured in the purple above. Persons with a moderate hearing loss have a difficult time with group conversations (OSHA). Severe hearing loss is classified as 65dB – 85dB as pictured in the red above. Persons with severe hearing loss will have a great difficulty understand spoken language. Profound hearing loss is anything greater then 85db and is shaded in black in the picture above. Persons with profound hearing loss do not hear speech or other sounds unless they are very loud. The ‘speech banana’ is portrayed in the picture to the right above. The area that is shaded in yellow is the range in which average speech sounds are heard (NIDCD). Persons with a severe or profound hearing loss are not able to hear any of the sounds in this range with or without amplification.

**Educational Placements**

According to Med El (2006) there are six educational placements options for parents of deaf or hard of hearing children with regards to school placement. The first option is for deaf children to attend school with hearing children in a public or private school setting, which is often referred to as inclusion. This means that the child with a hearing loss will attend all of his or her classes with hearing children, usually in their home school district, and receives support services in the school as necessary (MedEl, 2006).

The next option for students with a hearing loss is a self-contained classroom. MedEl (2006) describes this as a class that is composed entirely of children with a hearing loss and is taught by a teacher of the deaf. This type of class is often found in a public school setting with typical hearing children (MedEl, 2006).
The third option for children who are deaf or hard of hearing is a partially mainstreamed program. In this type of program children with a hearing loss spend part of the day in a self-contained classroom with other children who have a hearing loss and part of the day in an inclusion setting with hearing children.

A fourth option is reverse mainstreaming. In this type of setting children with and without a hearing loss are educated together. Typically the class is usually team taught by a teacher of the deaf and a regular education teacher (MedEl, 2006).

Day schools are another option. These are schools that consist exclusively of children with a hearing loss (MedEl, 2006). The children are bussed to and from school everyday.

The last option is residential schools for the deaf. These are schools where students have the option to reside at the school during the week and only go home on the weekends. (MedEl, 2006). These schools are also exclusively setup for children who have a hearing loss. Such schools are on the opposite end of the spectrum from inclusion.

**Communication Options**

According to the MedEl website there are five different communication options for children with hearing loss and their families. The following information from MedEl’s “A Guidebook for Parents” defines these five options.

The first option, American Sign Language (ASL) is defined as a manual language that has a different syntax, structure and grammar from spoken English and is used extensively among the Deaf community. In this case, English usually is taught as a
second language through reading and writing. The primary goal of ASL is to allow deaf children to use this language as their primary means of communication without the use of speech. With this approach children do not need access to residual hearing however, parents should have access to the Deaf community and adults who are fluent in ASL.

The second communication method that MedEl discusses is total communication, which uses every means of communication with the children: formal sign system, fingerspelling, gestures, speechreading, body language, oral speech, and the use of amplification. The goal of this approach is to provide the least restrictive communication method between the deaf child and his or her family.

Cued Speech is another method that is used to communicate with deaf children. This is a communication system that uses eight different handshapes and placements on the body to represent the different speech sounds. This approach aids in learning to lip read by making the sounds of speech more visible.

Children with cochlear implants are often trained using either an oral or auditory verbal approach. With both of these approaches, early identification of the hearing loss as well as early amplification is critical. In an oral approach the children use their residual hearing, either with hearing aids or cochlear implants, along with speechreading. In an auditory-verbal approach children rely solely on their hearing. Speechreading is not encouraged in this approach. Parents also play an important role in learning to teach their children to listen and continue with the therapy outside of a formal setting, for example, at home (MedEl).
**Cochlear Implants – Background Information**

Advanced Bionics (2003) states that Cochlear implants are prosthetic devices with internal components that are surgically placed and components that are worn externally either on the ear or in a case on the waist. Cochlear implants are considered the only medical treatment for severe to profound hearing loss. Adults and children with a profound hearing loss may or may not benefit from traditional hearing aid technology. “While very powerful hearing aids exist, that increase intensity to very high levels, they may not improve hearing if there are too few or no remaining sensory cells to stimulate (Advanced Bionics, 2003 pg. 4)”. If this is the case, sound information cannot be properly delivered to the brain. This is when cochlear implant technology can be beneficial. A cochlear implant is different from a hearing aid in that it delivers the electrical signal directly to the nerve by bypassing the damaged structure of the inner ear (Advanced Bionics, 2003).

**Parts of the Cochlear Implant**

A cochlear implant consists of both internal and external parts. The internal parts of the cochlear implant system are placed under the skin behind the ear during an operation that takes between 2 – 4 hours. During the operation the surgeon threads the electrodes through the cochlea (Nucleus, 2004). The transmitter that is placed under the skin contains a magnet that helps to hold the external pieces in place.

(www.cochlearamericas.com)
The cochlear implant also includes externally worn parts. All three companies’ products look different however; they all include four basic parts, the headpiece (A), the battery (B), the processor module (C) and the microphone (D) as illustrated below. The headpiece transmits sound from the processor to the internal device. The battery is the power supply for the cochlear implant processor and can be regular batteries or rechargeable batteries. The processor transfers the sound into a digital signal that can be sent to the internal device. Finally, the microphone picks up the sound and sends it to the speech processor (www.bionicear.com).

How a Cochlear Implant works

The microphone on the externally worn processor picks up the sound and changes it into digital signals. The processor then sends these signals to the internally implanted computer via radio waves. The internal computer transmits the digital signals to the electrodes that are implanted in the cochlea. The electrodes then stimulate the hearing nerve, which send signals to the brain where they are interpreted as sound (Nucleus, 2006).
Cochlear Implants – A Brief History

Cochlear implants have been in existence for less than 50 years. The Deafness Research Foundation (2006) says that in 1961 the first two American patients were implanted by Dr. William House for short term clinical trials. Over the next few years Dr. House worked on developing a workable/wearable implant. In 1984, the Food and Drug Administration (FDA) approved the House/3M unit for use in adults and by 1985 the Nucleus/Cochlear Corporation’s implant was approved. In 1989, the first child received the Nucleus multi-channel cochlear implant. Advanced Bionics first came onto the scene in 1991 and was FDA approved in 1996. MedEl was founded in 1989 and was FDA approved for use in adults and children in 2001 (Deafness Research Foundation, 2006). According to Fan-Gang Zeng (2004), “Functionally, the cochlear implant has evolved from the single-electrode device that was used mostly as an aid for lipreading and sound awareness to modern multi-electrode devices that can allow an average user to talk on the telephone” (pg. 3). The history of each cochlear implant company will be discussed in subsequent chapters.

Cochlear Implant Candidacy

“A host of factors determine whether a cochlear implant is likely to benefit an individual with sensorineural hearing loss” (Niparko, 2004, pg. 54). According to the Boys Town National Research Hospital cochlear implant candidacy has changed greatly over the years. When cochlear implants were first available the candidacy requirements stated that only adults who were postlingually deafened were candidates for implantation (Boys Town National Research Hospital). The FDA has since approved
Cochlear implant technology for adults and children over 12 months of age with severe to profound sensorineural hearing loss. Implant candidates must undergo a hearing aid trial to evaluate their benefit from hearing aids, as well as psychological assessments to assure that the parent or user’s expectations are reasonable. Dr. John Niparko comments on the guidelines for cochlear implantation:

Clinical guidelines for implant candidacy represent a composite assessment of an individual’s age, hearing status, unaided and aided audition, the circumstances of support surrounding the candidate (particularly patterns of use of spoken language) likely to influence use of the device, and an awareness of potential benefits and constraints of current implantable technologies (pg 54).

Niparko states, “As advances have improved implant performance, candidacy criteria have consequently reflected changes in the expected level of benefit” (pg. 54). Children and adults with cochlear implants are also benefiting greatly from their use in everyday listening environments.

**Cochlear Implant Companies**

Currently there are three FDA approved companies making cochlear implants for use in children and adults in the United States. These are Nucleus/Cochlear Corporation, MedEl Corporation, and Advanced Bionics Corporation. Each of these companies produces a product that is similar to the other products with slight variations. The following is a brief summary of the three companies and their products.
Nucleus/Cochlear Corporation

Nucleus/Cochlear Corporation, located in Australia, is currently marketing the Nucleus Freedom cochlear implant. “Freedom is the world’s first cochlear implant system to have adaptive Beam technology – a two microphone system designed to soften distracting background sounds allowing for focused listening in crowd” (Nucleus, 2006 pg. 5).

Freedom Body Worn Processor
(Freedom BTE)
(www.cochlearamericas.com)

MedEl Corporation

The MedEl cochlear implant system is manufactured in Austria. This company is currently marketing the Pulsar internal device and Tempo+ speech processor (www.medel.com). MedEl’s BTE processor can be worn in a variety of configurations making it the only BTE that can be worn by infants that does not need to be placed on their tiny ears.

Tempo+ BTE Angled Battery Pack
Baby BTE configuration
(www.medel.com)
**Advanced Bionics Corporation**

Advanced Bionics is the only American based cochlear implant manufacturer. They are currently marketing the High Resolution cochlear implant system, which includes the High Res 90K internally implanted device, the Auria BTE speech processor and the Platinum Series body worn processor ([www.bionicear.com](http://www.bionicear.com)).

![Platinum Series Body Worn Processor](image1.png) ![Auria BTE speech processor](image2.png)

**Cochlear Implant Failures**

As stated previously, cochlear implants are electronic devices and as such are subject to failure. The rate at which these cochlear implants fail is different for each manufacturer. Another difference is how each manufacturer deals with such problems. According to Cochlear Corporation in the last year 1 out of 1461 implanted Nucleus Freedom cochlear implants failed as compared to 1 out of 77 Advanced Bionics High Res 90K implants ([www.cochlear.com](http://www.cochlear.com)). There are no current statistics about the failure rate for MedEl cochlear implants in the last year. Cochlear implants are rated on the Cumulative Survival Rate (CSR), which is “a standard indicator of the likelihood of device functionality after a given period of use” ([www.medel.com](http://www.medel.com)). MedEl states that
their Cumulative Survival Rate (CSR) is 99.52% with the Pulsar and 98.91% with the Combi 40+ (www.medel.com). Advanced Bionics CSR is 97.5% and Nucleus Corporations CSR is 99.93% (www.cochlear.com).

**Conclusion**

As described in this chapter, there are different types and degrees of hearing loss and many options for teaching deaf and hard of hearing children language. With today’s enhanced technology children with profound hearing loss are able to access sound through improvements in both hearing aids and cochlear implants. Also discussed were the various cochlear implant parts and how each works, as well as the many factors that determine if a child or adult is a cochlear implant candidate. There are three different companies that manufacture cochlear implants that are available in the United States. Each of these companies has similarities and differences and each cochlear implant is subject to failure.

In the next chapter, we will discuss the history of cochlear implants and the future of the technology. More information will be provided on cochlear implant failures and how each company is dealing with these failures. Lastly, we will discuss how the companies are promoting their products and how it has changed from the past and how it is likely to change in the future.
Chapter 3 –

History, Failures, and Publications

from the three current cochlear implant companies
**Introduction**

As stated in previous chapters, cochlear implants are prosthetic devices that allow severely and profoundly deaf children and adults access to language. The enhancements in cochlear implant technology have made this technology accessible to more deaf children. This is in part due to the fact that with improvements in cochlear implant technology the criteria for candidacy have also changed. As addressed in the previous chapter, cochlear implants are now available to children who are 12 months of age, have a severe to profound hearing loss, receive limited benefit from hearing aids, and have parents with the right expectations as to the success of the cochlear implant. This chapter will further address the topic of how cochlear implants have changed over the last 20 years.

**Discussion of Answers to Questions**

The following sections of this chapter will focus on answering the questions that were proposed in chapter one as well as giving the reader a better understanding of the enhancements that cochlear implant manufacturers have made to their products over the last 20 years.

**Question One:**

**What is the history of cochlear implants and how have the cochlear implant companies changed over the last 20 years?**

According to the Deafness Research Foundation (2006) Dr. House implanted the first two American patients for short-term clinical trials in 1961. After these trials, Dr. House began working on trying to develop a wearable speech
processor. In 1972 Dr. House along with an engineer, Jack Urban, created the first wearable speech processor that could be taken home by the clients.

http://www.hei.org/about/history/historyhouse.htm

In 1980 the Food and Drug Administration (FDA) began to regulate cochlear implants and in 1984 they approved the use of the 3M/House cochlear implant device for use in adults.

http://www.hei.org/about/history/historyhouse.htm
According to the House Ear Institute (2006), in 1989 they were the first to implant a young child with a multi-channel cochlear implant. The child pictured above was the first child to receive an implant at the age of 5.

After Dr. House and the House Ear Institute began developing cochlear implants several other companies followed in succession. In 1981 the Nucleus/Cochlear Corporation was founded and in 1985 the Nucleus/Cochlear Corporation implant was approved by the FDA (Deafness Research Foundation, 2006). This implant was approved for use in adults and included 22 electrodes. This internal device only allowed for users to have one option of a processing strategy called SPEAK. Many of the early users were able to use SPEAK to listen to more than just environmental sounds.

Internal receiver for the N22 Cochlear Implant.
http://www.earspecialtygroup.com/esg_cochlear_implants.html
The next generation of the Nucleus Cochlear Implant came out in 1998. This internal part was called the N24. This consisted of 22 electrodes and 2 ball electrodes (electrodes that are not placed inside the cochlea) for a total of 24 electrodes. With this new internal component came more options for listening quality. There were now three different listening strategies that users could try, SPEAK, MPEAK, and CIS. Each of these strategies changes the sound signal into different electrical impulses in ways that stimulate the hearing nerve differently.

![N24 internal components](www.cochlear.com)

This generation of internal components also provided the option of a removable magnet. This is useful in situations where the patient may need to have a MRI in order to diagnose other conditions.

In 2002, Nucleus/Cochlear Corporation introduced the N24C (Nucleus 24 Contour). This implant differed from the previous implants because it had a precoiled electrode array. This helped with easier insertion into the cochlea and provided the surgeon the ability to place the array closer to the hearing nerve. In addition to the three previously mentioned listening strategies this generation of internal devices introduced a fourth, ACE, which provided listeners with a faster processing speed. This
was helpful in providing better clarity to the users in difficult listening situations (for example, in noise or crowds).

The newest cochlear implant from Nucleus/Cochlear Corporation is the Nucleus Freedom. This provides 22 electrodes, a precoiled array, and a softtip, in order to maximize the closeness to the hearing nerve with the least amount of damage done to the cochlea (Cochlear, 2006). This internal device also has a removable magnet which allows for MRIs when necessary. This internal device allows for a variety of different listening situations. Along with the four listening strategies available before, SPEAK, MPEAK, CIS and ACE the Nucleus Freedom also provides listeners with a HiACE option, Beam listening option (which is for listening in crowds), ADRO (which is for listening to music and other rich environments) and Whisper (which is for listening to soft and distant sounds).
Nucleus has also manufactured 7 generations of external components. All of these have changed the way that people are using and wearing their cochlear implants. The first external device that Nucleus/Cochlear Corporation provided to its patients in 1985 was the Nucleus Mini22 Wearable Speech Processor. The second generation was the Spectra Speech processor, which was FDA approved in 1989.

In 1997 the SPrint speech processor was made available. This is the bodyworn speech processor that has been used for many adults and children implanted from 1997 – 2005.

Up until this time cochlear implant processors were all body born processors. In 1998, Nucleus/Cochlear Corporation introduced their first Behind The Ear (BTE) speech processor, the ESPrit BTE.
ESPrit BTE speech processor in beige, brown, and black.

www.cochlear.com

In 2000 the next generation of BTE was introduced. This was the ESPrit 22 BTE speech processor, followed by the ESPrit 3G speech processor in 2002. The ESPrit 3G speech processor was made compatible with all internal implants provided by Nucleus. This meant that people who were implanted in 1985 with the N22 internal device were able to use the 3G BTE speech processor.

ESPrit 22 BTE speech processor               ESPrit 3G BTE speech processor

www.cochlear.com

The Nucleus 3G processor was the first of its kind of offer FM capability with a BTE processor. The cochlear implant user purchases a separate FM boot to attach to the processor which allows the FM transmitter to be connected:
The newest generation of cochlear implant processors manufactured by Nucleus/Cochlear Corporation is the Freedom bodyworn and Freedom BTE speech processors. They are compatible with the Freedom internal component and have recently been made compatible with the N24C internal component.

This cochlear implant processor allows for direct FM use. The Freedom BTE was made with its own FM transmitter to attach to the bottom:
Or it can be directly connected to the bodyworn processor:

Nucleus has changed their product line dramatically throughout the past 20 years. They have created 4 generations of internal receivers that have increased the number of electrodes and the processing strategies that can be used for each as well as 3 generations of body worn processors and 4 generations of BTE processors. For the future they are working on making the Nucleus Freedom compatible with all of the existing internal devices as well as improving the current processor. They are also working on making some of the new implant strategies compatible with older internal components. Nucleus/Cochlear Corporation has just announced work on a new hybrid cochlear implant. This type of cochlear implant combines the use of a hearing aid and a
cochlear implant for people with profound high frequency hearing loss and with moderate low frequency hearing loss (NBCi.com, 2006).

Advanced Bionics Corporation has been manufacturing cochlear implants since 1991. They began clinical trials in 1992 and became FDA approved in 1996 for use in adults. In 1997 the FDA approved Advanced Bionics CLARION implant for use in children as well. The first internal device manufactured by Advanced Bionics was the CLARION 1.2 in 1996. This device was made out of ceramic material and contained 8 electrodes. This internal device only allowed for two different listening strategies to be used. These were CIS and SAS. CIS is a faster sound processing strategy where SAS is slower.

C1.2 internal device with S-Series Bodyworn Processor.

www.bionicear.com

Advanced Bionics then came out with the CII internal device in 2002 (www.bionicear.com). This device had 8 electrodes and could process sound in the same way as the C1.2, using either CIS or SAS.
Both of these previous internal devices were made out of ceramic. If a child or adult was to get hit in the head on the side where they had their cochlear implant it was possible to break the internal device. The next generation the HiRes90K internal device is different because it is made of titanium. It is also the first Advanced Bionics internal device that contains 16 electrodes. This allows for more programming strategies to be used, CIS processing and two different HiResolution processing strategies which allow for more in depth listening and better quality. These are HiRes S and HiRes P.
The first Advanced Bionics speech processor was the C1.2 bodyworn processor. This was introduced in 1996 and was compatible with the C1.2 internal component.

C1.2 Bodyworn speech processor

www.bionicear.com

The next speech processor that Advanced Bionics introduced was in 1999 with the introduction of the CLARION S-Series bodyworn speech processor. With this new technology the use of rechargeable batteries was introduced.

S-Series bodyworn speech processor

www.bionicear.com

Shortly after the CLARION S-Series was introduced Advanced Bionics manufactured the Platinum Speech Processor. This was introduced in 2000 and contained a smaller speech processor that was easier to wear. This generation of bodyworn processors from
Advanced Bionics also had the option of using either rechargeable or standard AA batteries.

Platinum Speech Processor (PSP)

www.bionicear.com

In 2002, Advanced Bionics introduced their first BTE processor. The Platinum BTE processor was the first BTE processor, from any company, that also used rechargeable batteries.

Platinum BTE

www.bionicear.com

The next generation of BTE processors that come out for Advanced Bionics was the CII BTE. This was compatible with the CII internal device and used smaller batteries then the Platinum BTE. The batteries were also rechargeable.
The newest generation of speech processors available from Advanced Bionics is the Auria BTE. This was first developed in 2003 and was made commercially available in 2004. This BTE is used with the HiRes90K internal device and provides a new low profile headpiece as well as some other features. With this BTE the battery life is greatly increased allowing for almost a full day on one battery. The Auria also has the option of a AA battery pack that can be worn on the shoulder and provides up to two days of battery life.

Advanced Bionics has had a rapid growth in their product line since they were first FDA approved in 1996. They are currently working on a 120-channel processing strategy that would be compatible with the HiRes90K internal device. This will allow for
more clarity while listening as well as a better appreciation for music (www.bionicear.com). Along with this new processing strategy, Advanced Bionics is also working on a new BTE. The Harmony BTE has been in FDA trials since the beginning of 2006 and is expected to be released in early 2007. This would be the only BTE that is capable of handling the 120-channel software.

MedEl Corporation was first introduced in Europe in 1989. Med El Clinical trials began in the United States in 1995 and MedEl became FDA approved in 2001 for use in both adults and children (MedEl, 2006). The first internal device that they manufactured was the COMBI 40+. The COMBI 40+ had 24 electrode and was available in a variety of options for different hearing needs.

COMBI 40+ internal components

www.medel.com

The next generation of internal components that MedEl manufactured and is currently manufacturing in the United States is the PULSAR device. This device also has 24 electrodes and allows for a variety of different options for different listening needs.

PULSAR internal components

www.medel.com
For example, the PULSAR comes in a standard array which is used by most cochlear implant users. However, the PULSAR also comes in a compressed array and a medium array for patients who have incomplete cochlea due to Mondini Syndrome (a malformation of the cochlear in which patients have only 1 ½ turns of the cochlea instead of the usual 2 ½ turns making cochlear implantation sometimes difficult) (www.medel.com). MedEl also has a split electrode array for use in patients that have ossification due to meningitis. Another option that MedEl has is for patients with tumors on their auditory nerve where a standard cochlear implant would not work. This is the auditory brainstem implant which bypasses the auditory nerve also allowing patients with damaged or missing auditory nerves to also get benefit from a cochlear implant.

MedEl developed the world’s first BTE in 1991. The current BTE that Med El is marketing here in the United States is the TEMPO+ BTE. This BTE has several different
wearing options making it the only BTE that infants and children can wear (www.medel.com).

TEMPO+ BTE: Angled BTE, Child’s BTE, and Straight BTE configurations.

www.medel.com

TEMPO+ Baby BTE wearing option

www.medel.com

MedEl is currently working on a variety of new technologies and enhancements in cochlear implants. In Europe, MedEl is marketing the SonataTI100 internal device along with two different BTE options: The OPUS 1 and OPUS 2. The SonataTI100 is a cochlear implant that allows for 100 channels to be used with 24 electrodes. This enhances listening in music and other difficult listening situations. The OPUS 1 BTE is very much like the TEMPO+ BTE. It also allows for a variety of configurations and wearing options for all ages. This can be used with the SonataTI100 internal device.
MedEl’s newest speech processor is the OPUS 2 BTE speech processor. This is available in a variety of configuration and wearing options and is compatible with the SonataTI100 internal device.

MedEl is the first cochlear implant manufacturer to begin marketing a hybrid cochlear implant used in patients that have a profound high frequency hearing loss and a moderate to severe low frequency hearing loss. This type of device uses the PULSAR
internal device that is only partially threaded through the cochlear where the high
frequency sounds are heard. This allows for the user to use the cochlear implant
technology to listen to high frequency sounds and a built in hearing aid to amplify low
frequency sounds (www.medel.com).

DUET Hearing System BTE

www.medel.com

MedEl is the only cochlear implant manufacturer to manufacture a middle ear
hearing implant. “The Vibrant Soundbridge is not a hearing aid; it is a new category of
implantable middle ear hearing devices” (www.medel.com). This type of hearing device
directly vibrates the bones in the middle ear and is used in adults with a moderate to
severe sensorineural hearing loss who do not want to use conventional hearing aids.
Patients who use this device say that it has less feedback than traditional hearing aids
and is easier to take care of than traditional hearing aids (www.medel.com).
How the Virbate Soundbridge works

www.medel.com

The implanted Vibrant Soundbridge is placed in the middle ear and vibrates the sounds that are picked up by the audio processor which is worn on the head.

Picture of a man using the Vibrant Soundbridge

www.medel.com

MedEl has worked hard to continue improving their implants since they began manufacturing cochlear implants in 1989. They have had 3 generations of internal components and 3 generations of external speech processors along with many other new hearing devices for patients who have more than just profound sensorineural hearing loss.
Cochlear implant companies have made great strides in the enhancement of quality of listening for patients. These companies all strive to be the leaders in cochlear implant technology and continue to be motivated to enhance and improve the technology. Throughout the last 20 years cochlear implants have greatly enhanced the lives of many deaf and hard of hearing individuals and will continue to do so well into the future.

**Question Two:**

**What is the rate of failure for each company? How do the companies address these problems?**

Cochlear implants are electronic devices that are subject to failure. However, the rate of this failure and the handling of the internal device failures differs greatly between the three companies. According to the European Consensus Statement on Cochlear Implant Failures and Explantations (2005), there are several reasons that a cochlear implant can fail. A device failure is stated as, “a device with characteristics outside the manufacturer’s specifications resulting in a loss of clinical benefit” including but not limited to complete loss of sound, pain during listening, popping or cracking sounds during stimulation, and intermittent sounds. There are also other reasons for cochlear implants to be removed and replaced. One of these is performance decrement, which is, “the unexplained but documented decrement in performance or a device that causes non-auditory sensations necessitating explanation.” An example would be when a child stops responding to sounds or speech that they were able to hear before. In this
case testing of the device does not show any failure through testing completed by the company.

If re-implantation restores function or abolishes non-auditory sensations, the implant should be considered to have had a device failure and should be reported to the competent authority. If the new device fails to do so, the episode should be considered as a medical explantation (European Consensus Statement on Cochlear Implant Failures and Explantations, 2005).

The other two reasons that the European Consensus (2005) gives are loss of follow up and medical reasons. If a cochlear implant recipient does not receive adequate follow-up care after receiving their cochlear implant they may not have the appropriate outcome with their cochlear implant. Cochlear implants that need to be removed due to infection or for biological failures but are functioning normally are considered to be removed for medical reasons.

Cochlear Implant failures are currently measured in terms of the Cumulative Survival Rate (CSR). The CSR is “a standard indicator of the likelihood of device functionality after a given period of use” (MedEl, 2006). In other words, if a company has a CSR of 98.7% at one-year, out of 1000 devices, 987 of them are still working properly. The CSR refers to device failures and does not include cochlear implants that are removed for surgical or medical complications. The three current cochlear implant manufacturers CSR’s are as follows:

<table>
<thead>
<tr>
<th>Manufacturers</th>
<th>CSR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cochlear/Nucleus Corporation</td>
<td>99.93%</td>
</tr>
</tbody>
</table>
According to Jamie Berke (2003), there are several reasons why people need to be reimplanted. Several of these are, skin flap can become infected, the body can reject the implant, the implant receiver can extrude, the electrode array can get damaged or the electrodes were not put in correctly, the electrode array can migrate out of place, and the implant simply stops working the way it had before (Berke, 2003).

“Approximately two percent of all cochlear implant devices experience device failure and have to be removed” (www.cochlearimplant.org). All of the devices that must be removed need to be reported to the Food and Drug Administration (FDA) (Berke, 2003). According to the FDA the number of cochlear implants that failed from 2001-2002 are:

<table>
<thead>
<tr>
<th>Implant</th>
<th>Number that failed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cochlear Corporation – Nucleus 22</td>
<td>249</td>
</tr>
<tr>
<td>Cochlear Corporation – Nucleus 24</td>
<td>227</td>
</tr>
<tr>
<td>MedEl Corporation – Combi 40</td>
<td>16</td>
</tr>
<tr>
<td>Advanced Bionics – Clarion</td>
<td>215</td>
</tr>
</tbody>
</table>

(Berke, 2003)

Cochlear implants are made to be used for many years. The failure rate for long term cochlear implant use differs for each company. Advanced Bionics states that the CLARION 1.2 cochlear implant is still used by 92.0% of the recipients after 5 years and the CLARION CII is still in use by 97.7% of the patients after 3 years (Greiner, 2004).
According to Cochlear (2006) the reliability of their cochlear implants has been exceptional:

<table>
<thead>
<tr>
<th>Product</th>
<th>Adults</th>
<th>% that has failed</th>
<th>Children</th>
<th>% that has Failed</th>
<th># of years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom</td>
<td>5,232</td>
<td>0.0%</td>
<td>4,767</td>
<td>0.2%</td>
<td>2 years</td>
</tr>
<tr>
<td>N24C</td>
<td>15,743</td>
<td>0.5%</td>
<td>19,942</td>
<td>1.3%</td>
<td>6 years</td>
</tr>
<tr>
<td>N24</td>
<td>7,272</td>
<td>0.5%</td>
<td>10,968</td>
<td>3.4%</td>
<td>9 years</td>
</tr>
<tr>
<td>N22</td>
<td>9,940</td>
<td>3.8%</td>
<td>8,225</td>
<td>8.6%</td>
<td>19 years</td>
</tr>
</tbody>
</table>

Cochlear implant failure rates do not appear to be the same for adults and children. The failure rate of cochlear implants in children is much greater than that of cochlear implants in adults (Chute & Popp, 1996). “The overall failure rate reported by Cochlear Corporation notes that whereas only 3% of adults have had this type of problem, 9% of children have had failed internal receivers” (Chute & Popp, 1996).

According to Nucleus (2006), the CI22M cochlear implant that was implanted in an estimated nine thousand people, is still in use by 95.9% after 19 years.

As discussed previously, cochlear implants are subject to failure and there are many reasons why cochlear implants fail. However, some cochlear implants fail more than others for manufacturing errors. These errors result in products being recalled. The first time a cochlear implant was recalled was in April of 1995. The Nucleus Mini 22 channel cochlear implant was recalled due to a power supply inside the implanted part of the cochlear implant malfunctioning and causing device failure (FDA, 1995). The next major cochlear implant recall occurred in September of 2004. This recall by the FDA
involved several hundred cochlear implants because of moisture contamination (Greiner, 2004). According to the FDA (2004), “The recalled devices included all unimplanted CLARION and HiResolution models. The Company initiated the recalls after a review of the internal complaint records and analysis of returned product revealed the potential problem.” This has not been Advanced Bionics only recall due to the problem of moisture in the device. In March of 2006 Jeffery Greiner, President and Co-Chief Executive Officer, and James Miller, President, Auditory Division, wrote a letter to Advanced Bionics cochlear implant users stating the voluntary recall of their devices. The HiResolution90K cochlear implant was recalled due to moisture-related problems. The reason for this recall was said to be caused by the use of implants from a particular supplier.

Implants manufactured with a particular component from Supplier A are highly reliable demonstrated by a one-year Cumulative Survival Rate (CSR) greater than 99.5%. A 99.5% CSR means that of every 1000 implanted devices, 995 continue to work properly at the end of one year. Devices manufactured with a particular component from Supplier B have a one-year CSR of 97.5% (Greiner & Miller, 2006).

Due to this fact, Advanced Bionics decided to recall all devices made with the part from Supplier B.

Another reason that cochlear implants have been recalled or replaced was the risk of meningitis. “Meningitis is an infection in the cerebrospinal fluid around the brain and spinal cord” (FDA, 2003). There are two different type of meningitis, viral and
bacterial. Bacterial meningitis, which is more serious than viral meningitis, is the type that is typically seen among cochlear implant patients.

The FDA/CDC (Center for Disease Control) study of children with cochlear implants did show that cochlear implants with electrode positioners were associated with a greater risk of developing meningitis than implants without positioners. The study was unable to determine how the positioner increased the risk for developing meningitis (FDA, 2003).

At the time of this announcement it was not known if explantation of the cochlear implant would help reduce the risk of meningitis in patients who were implanted with an implant that contained a positioner.

Each company deals with cochlear implant failures in different ways. According to the FDA in 2004 when Advanced Bionics recalled their CLARION and HiResolution cochlear implants it was a voluntary recall. This meant that if the implants were already implanted no action was to take place (they were not to be explanted), however for any internal implants that were in doctors offices or in stock at the company they were to be recalled and taken back. This has happened several times to Advanced Bionics with the most recent being in March of 2006 (FDA, 2006). The MedEl cochlear implant was not approved for use by the FDA until they worked out some of their problems also relating to moisture. When a cochlear implant fails the company has policies on how they will deal with the failed device. All companies will replace a failed device with their own device free of charge if they are still under warranty. A cochlear implant is under
warranty for ten years (www.cochlear.com). This means that if the device is an
Advanced Bionics device, Advanced Bionics will replace it with another Advanced Bionics
device and cover all of the cost if the device is still under warranty.

**Question Three:**

**What are cochlear implant companies doing to promote their product? What type of materials do the cochlear implant companies provide for parents and teachers?**

The cochlear implant companies advertise their implants through a variety of
different means. All three companies provide doctors and hospitals with brochures
describing their products and all of the benefits of their products. Each company also
puts out at least one videotape documenting the progress of several patients, both
adults and children, who use that specific company’s cochlear implant. All three
cochlear implant companies have websites that are accessible for patients and
prospective cochlear implant users. Cochlear implant companies are also providing more
and more information for parents, teachers and professionals who work with children
and adults who use cochlear implants.

With the enhancements in cochlear implant technology many children today are
being implanted younger and younger. With children receiving cochlear implants at a
younger age they are able to begin school with much less support then even before
(www.cochlear.com). Therefore, many regular education teachers are working with
children who use cochlear implants in the regular education classroom. Many of the
cochlear implant companies are providing information for schools to better assist the
students who cochlear implants in the classroom (Neault, 2006).

Nucleus/Cochlear Corporation provides information for teachers online that can
be printed by parents or teachers and provided to assistance in the classroom
(www.cochlear.com). One of the information packets that Nuclues provides is a list of
classroom suggestions for teachers to make listening in the classroom better for the
child with a cochlear implant (DeConde-Johnson, 2006). This list includes
troubleshooting checks to make sure that the equipment is working properly, classroom
acoustics, use of a classroom amplification system (FM system), writing key words or
ideas on the board, using visual supplements to aid in teaching, use preferential
seating, discuss the cochlear implant with the class so that they can better understand
what the child needs, and use a buddy system to help the student catch any work or
directions that were missed (DeConde-Johnson, 2006). Nucleus also provides
information on classroom acoustics, captioning, FM systems, and working with families
(www.cochlear.com).

Nucleus provides Cochlear’s HOPE (Habilitation Outreach for Professionals in
Education) Program. This is a program that provides online learning opportunities for
teachers and other professionals who come in contact with children who use cochlear
implants. They provide workshops, online learning opportunities, and a toll free phone
number for teachers or parents to call with questions or concerns (www.cochlear.com).

Nucleus also provides a variety of different rehabilitation software programs for
teachers and parents to use with children who have cochlear implants. Listen, Learn
and Talk is a program designed for preschool children with cochlear implants and can be used at home or in school. Start Listening is another program that is for infants and preschool children who are beginning to learn to listen. This is a videotape that provides listening activities that children can use with their parents or and watch alone (www.cochlear.com). Nucleus Hear We Go is a program for teenagers who are deaf or hard of hearing and can be used at home or in school to provide some additional listening practice. Sound and Beyond is another program that Nucleus provides for adults and teenagers that is self-paced and can be used alone or with other people (www.cochlear.com). All of these programs are provided by Nucleus/Cochlear Corporation and can be purchased online or through an audiologist/speech pathologist and provide cochlear implant users more practice that is essential for learning how to use their device.

Advanced Bionics also provides information for parents, teachers, and other professionals that work with children and adults who have cochlear implants. They provide information for school in a program called Tools for Schools. The Tools for Schools program provides parents with information relating to cochlear implants and education, helps cochlear implant centers in providing information for schools, and assists school professionals, early intervention specialists, auditory verbal therapists, speech and language therapists, and other professionals who work with children with cochlear implants (www.bionicear.com). They provide a variety of handouts and information packets relating to cochlear implant equipment, tips for teaching children with cochlear implants, ling sound cards, troubleshooting guides, information on FM
systems and a newsletter. All of this information can be found on the website at http://www.bionicear.com/professionals/tools.asp.

Advanced Bionics also provides an Educators Kit that includes information about what a cochlear implant is, how it works, how it is used in the classroom, having appropriate expectations for children with cochlear implants in the classroom, information about auditory, speech, and language goals, and other resources for educators (www.bionicear.com). They provide cochlear implant users, parents, and teachers with a variety of different rehabilitation software. A free assessment tool for infants and toddlers is called the IT-MAIS (Infant Toddler – Meaningful Auditory Integration Scale) which is a “structured interview schedule designed to assess the child’s spontaneous response to sound in his/her everyday environment” (www.bionicear.com). This is done by asking the parents a variety of questions relating to the child’s listening and vocal patterns that they observe at home.

Bringing Sound to Life is another program from Advanced Bionics. This program was created at The Listening Center at Johns Hopkins University Hospital by Mary Koch. This program provides information about listening with a cochlear implant in steps that children go through. It is a video based program that parents and teachers can use to gather language and information needed to provide the child with the appropriate therapy and listening environments (www.bionicear.com). Mary Koch also created the WASP (Word Association for Syllable Production) program that provides children with the visual and auditory information that is needed to understand speech. This program provides cards with pictures and sounds in an order that allows children to progress
through the stages of listening beginning with the sounds and working their way to listening and understanding words (www.bionicear.com).

Advanced Bionics also provides two rehabilitation programs for teenagers and adults. Hearing Your Life rehabilitation software is a computer based listening program that is self paced and allows the user to work from simple auditory skills to more complex listening activities (www.bionicear.com). Making the Connection is a workbook and auditory CD that provides listening practice. This can be completed alone or with a friend or teacher serving as a “listening coach” (www.bionicear.com).

MedEl Corporation also provides a great deal of information to parents, teachers and other professionals about cochlear implants and listening. MedEl provides a handbook for teachers working with children with cochlear implants that provides information on cochlear implants, how they work, and what can be done in the school to maximize the listening and understanding ability of children with cochlear implants (www.medel.com). Along with this information packet comes a troubleshooting guide for teachers when an unexpected problem is encountered during the school day. MedEl also provides something they call EarGear which is a troubleshooting kit for parents and educators. This kit provides some of the essentials for troubleshooting a device that might not be working properly including batteries, spare cables, a troubleshooting guide, and a speech processor test device (www.medel.com).

MedEl also produces three assessment and training tools. Littleears is an auditory development assessment that is for children three years of age and younger and was developed to assess the auditory behaviors of children who are not yet verbalizing
Another tool that MedEl has is Identifying Early Phonological Needs in Children with a Hearing Loss, which is designed to “assess spontaneous use of first level phonological patterns in children with hearing loss, utilizing a list of 25 words that are typically within the speaking vocabulary of young children with hearing loss” (www.medel.com). Finally, MedEl provides AudiTrain which is a program designed for adults who want to practice their auditory skills. It consists of both a synthetic and analytic approach and contains 22 individual lessons that allow the user to work through a variety of listening tasks (www.medel.com).

All three cochlear implant companies provide parents and educators with a great deal of information as well as auditory training options for adults and children to use on their own time. They also provide brochures and videos that explain how a cochlear implant works and when they can be beneficial. Many companies are providing information to consumers through the internet and information is readily available to teachers and other professionals.

Criteria Used to Select Articles

The articles and information that were used to answer the previous questions in this paper were chosen by the researcher using a variety of different means. First, the researcher looked for articles that included factual data and relevant statistics. Also used were a variety of online resources from the companies or other creditable sources. Many of the other resources that were used were provided by the three cochlear implant companies which allowed the researcher to take an in depth look at their
products and the information that they are providing to the parents, clients and other professionals as well as how their companies have grown over the last 20 years.

**Summary**

In this chapter we discussed the information that was collected relating to the history of cochlear implants, statistics and other information about cochlear implant failure and what type of information the companies use to promote their products as well as the information they are providing to the parents and educators. We also briefly discussed several auditory training assessment tools that can be used for children and adults with cochlear implants. Pictures were provided as an aid in understanding the developments that cochlear implant companies have made over the last 20 years.

In the next chapter a brochure will be created in order to provide parents with concise, clear information relating to all three companies in that they may use to help make the decision of which cochlear implant company to choose. In this packet information will also be included relating to follow up care and information that can be provided to schools as well as tools that can be used at home to provide listening opportunities for children with cochlear implants.
Chapter 4 –

Cochlear Implants:

A guide for parents and teachers
**Introduction**

Chapter four has been created as a guide for parents, teachers and other professionals working with students who have or are considering cochlear implants. This guide takes the form of an informational packet and a brochure and compiles all of the information discussed in the previous three chapters. In the guide you will find information relating to the history of each cochlear implant company, contact information for the companies, and other resources that the companies provide for parents, teachers, and other professionals. The brochure will consist of a summary of the information packet that can be distributed to hospitals, clinics, schools, and audiologists to clearly lay out the information that each company is currently being distributed.

A printed copy of the brochure and informational packet can be found in Appendix A.

**Significance**

Cochlear implants allow many deaf children to learn spoken language and listening skills, however parents of these children are faced with several different decisions that need to be made during some crucial periods for their child. Parents have many decisions that need to be made including how they will teach their child language and if the decision is made to teach their child using an oral approach residual hearing needs to be accessed to the fullest extent. The parents then need to decide if a cochlear implant is right for their child and if so how they will begin the process. Parents then must choose an implant center and an audiologist and surgeon that will be
used for the evaluation. After the decision is made that the child is a candidate for cochlear implant surgery and the parents decide that is what they want for their child, the next step in the decision process is deciding on which implant company to choose. This decision can be a very difficult one because all three FDA approved cochlear implant companies have features that make them different from each other. Often this information from the companies is presented in a way in which parents can easily become overwhelmed. This departmental paper and the information packets and brochures that were created presented research relating to the three companies as well as the products they produce.

**Continuing Development**

The research throughout this paper shows that cochlear implants have changed greatly over the last 20 years. As technology continues to improve, cochlear implants will become smaller and be able to do much more than they can now. Along with this will come the ability to implant children younger than 12 months of age with a variety of hearing losses. It is important the parents of deaf children be given all of the information from the companies relating to their devices so that they can make a decision that is right for their child and their family.

**Conclusion**

This information packet and brochure was created to assist parents in making the decision about which cochlear implant company to choose as well as provide information for parents and teachers working with children who already have cochlear implants, whether in a mainstreamed classroom, self-contained classroom for the deaf,
or at a school for the deaf. The information provided here can help to provide some suggestions that will allow the children to better utilize their cochlear implant technology.

In the final chapter of this paper, the author reflects on her experience with writing the paper. It also includes more areas of concern that have been sparked by this research.
Chapter 5 –

Personal Growth and Recommendations
Introduction

This chapter will reflect on the researcher’s personal growth and development. Recommendations will also be made regarding other areas of research relating to cochlear implants, as well as how the researchers perspectives have changed throughout writing this paper.

Personal Development

This departmental paper has given the researcher the opportunity to grow as a researcher as well as a teacher of the deaf. It has also allowed the researcher to gain knowledge that will be useful to share with parents during her future employment and working with children and families. The researcher has personal experience with cochlear implants through being a cochlear implant user herself as well as teaching at a school for children with cochlear implants for one year. Due to this basic understanding about cochlear implants as well as experiencing several cochlear implant failures, the researcher wanted to gain more information that could help future children who will receive cochlear implants and also learn more about what each cochlear implant company offers.

During the researching of information for this paper, the author found a great deal of information provided by the companies that manufacture cochlear implants. The information found included: the history of cochlear implants, how they have changed over the last 20 years, the current products that the companies are marketing, cochlear implant failure rates, and information that each company provides to its consumers
about their products as well as information for teachers and other professionals working with children with cochlear implants.

Much of the research that was found and used by the researcher was provided by the companies as well as through a variety of books and the internet. Throughout the research, the researcher found information that allowed her to answer the questions that were presented in the first chapter of this paper.

The researcher found the information that each company provides for its clients as well as for teachers and other professionals to be useful in her daily interactions with parents of young deaf children. Each company that manufactures cochlear implants also provides several information sheets relating to adapting a classroom for a child with a cochlear implant and troubleshooting cochlear implants. The researcher feel that it is very important to provide all of this information to regular education teachers who might be working with children with cochlear implants in the mainstreamed setting. That will allow for help with the student in case a problem arises.

**Recommendations for Future Research**

After conducting her research, the researcher developed several ideas and considerations for future research relating to cochlear implants and the impact that they have on children, families, and professionals. These include the following:

- The effect on cochlear implantation on language development in children implanted prior to the age of 12 months.
Will the FDA change the candidacy criteria due to the new technology that the implant companies are creating? Will this affect how long children with cochlear implants are receiving specialized services?

A study of children with cochlear implants in the mainstream and how they are relating to their hearing peers.

A look at regular education teachers and how they feel about educating children with cochlear implants in the regular education classroom as well as what kind of adaptations need to be made for such students.

A study of the siblings of children with cochlear implants who are hearing as compared to a study of siblings of children with cochlear implants who are also cochlear implant users.

A study of families that have one child who uses a cochlear implant as compared to families with more than one deaf child who use cochlear implants.

**Perspectives**

Throughout conducting the research for this paper the perspectives of the researcher have changed somewhat. Prior to beginning her research, the researcher was familiar with cochlear implants as well as cochlear implant failures, due to the fact she had experienced two internal device failures. However, throughout her research, the researcher discovered several things related to cochlear implant failures that surprised her, one of which was how some companies cover up their failures. During the research, the researcher found that one company was adapting the numbers included in their Cumulative Survival Rate (CSR) by only including the implants that
were manufactured through one manufacturer. This specific company has two manufacturers that make their internal devices, and one of the manufacturers, supplier B, manufactures the devices that fail more frequently. The CSR for this company only includes the devices manufactured by supplier A, therefore adapting the actual numbers that the company is advertising. If the company produces 100 cochlear implants by supplier A and 100 cochlear implants by supplier B and in the end 1 implant from supplier A fails and 4 from supplier B fail the total CSR should be 97.5%. However, when this company was reporting their CSR they were only looking at the implants provided by supplier A and the CSR changed to 99%. This was surprising to the researcher as well as how many parents did not know that this was happening.

**Summary**

This chapter reflected on the growth and development that the researcher experienced during the writing of this paper. It also included several areas of future research focusing on cochlear implants and how they affect children and families. The more parents and families that are aware of cochlear implants and what their abilities and limitations they provide to deaf children, the better decisions can be made by the families during this time.
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Appendix A

Cochlear Implants – A Comparison of Three Companies