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Nucleus Multichannel Auditory Brainstem Implant Consumer Update

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What is the Nucleus 24 ABI multichannel auditory brainstem implant?

The Nucleus 24 Auditory Brainstem Implant (ABI) is designed to provide sound to people with Neurofibromatosis Type II (NF2) who become deaf when tumors are removed from their auditory (hearing) nerves. The Nucleus 24 ABI is a surgically implanted device that bypasses the damaged auditory nerves by providing electrical stimulation to the cochlear nucleus of the brainstem. This stimulation produces a response that can be interpreted by the brain as sound.

What is Neurofibromatosis Type II?

Neurofibromatosis Type II is a genetic condition that affects one in 40,000 people in the United States and affects both genders, males and females, equally. The offspring of an affected parent has a 50% chance of inheriting the gene and the average life expectancy is 40 years.

People with NF2 have tumors that grow on both the right and left auditory nerves, and sometimes in other places in the body. When these tumors are surgically removed, often it is necessary to remove parts of the auditory nerves along with the tumors. These nerves are the pathways for sounds to reach the brain. This results in total deafness. Hearing aids and cochlear implants are not beneficial when parts of the auditory nerves have been removed.

How was the Auditory Brainstem Implant developed?

Dr. William House and Dr William Hitselberger at the House Ear Institute (HEI) developed the first ABI in 1979. It was a single-channel device, with a ball-type electrode, with a percutaneous plug used to transmit the signal thru the skin to the implant. The original device was powered by a modified hearing aid. HEI implanted 13 NF2 patients with this first device in 1979.

In 1986, the single-channel device was redesigned and HEI started using a device with platinum plate electrodes. The implant was powered by a modified 3M/House Cochlear Implant Speech Processor. In

addition, the percutaneous plug was changed to a transcutaneous design, which means they did away with the plug and sent the signal through the skin by a FM radio signal. With this new device, which was still a single channel, they implanted about 25 NF2 patients.

In 1989, the House Ear Institute (HEI), Cochlear Ltd., and Huntington Medical Research Institute began working together to develop a Multichannel ABI. Many years of research resulted in a new ABI, which was based on the Nucleus 22 cochlear implant system. The first 3 patients were implanted with the Multichannel ABI in 1992. Since that time, over 100 NF2 patients have received the device.

What Centers in the U.S. offer the Nucleus 24 ABI System?

- House Ear Institute
- New York University
- Ear Consultants of the Southwest
- Midwest Ear Institute
- Indiana University
- Pittsburgh Ear Associates
- Medical College of Wisconsin
- University of Iowa
- Carolina Ear and Hearing Institute
- The Otology Group
- California Ear Institute
- University Medical & Dental Hospital, New Jersey
- Chicago Otology
- Duke University
- Methodist/Baylor

Who is a candidate for the Nucleus 24 ABI?

To be considered a candidate for the Nucleus 24 ABI, an individual must:

- Be diagnosed with Neurofibromatosis Type II.
- Be at least twelve years of age.
- Have appropriate expectations and be prepared to participate in a follow-up program.

Prospective implant recipients who have undergone gamma knife radiation should be considered with extreme caution, due to possible injury of the cochlear nucleus.

How does an Auditory Brainstem Implant differ from a cochlear implant?

Although there are many similarities between an ABI and a cochlear implant, there are also some important differences. The cochlear implant electrode array is placed in the inner ear of an individual with an intact and functioning auditory nerve. The ABI electrode array is placed on the surface of the cochlear nucleus in the brainstem, bypassing the inner ear and auditory nerve. Both devices have the potential to provide a variety of hearing sensations that can be helpful for understanding speech.

What are the components of the Nucleus 24 ABI system?

The Nucleus 24 ABI consists of both internal and external components. The internal components, including the receiver/stimulator and the electrode array, are surgically implanted. The external components, the speech processor and the headset, are worn on the body or clothing and can be removed every day.

Nucleus 24 ABI Internal Components

The receiver/stimulator is made of a very rugged titanium case covered by a silicone capsule, providing both durability and flexibility to the implant. This part of the implant is surgically placed under the skin in a shallow “bed” made in the bone behind the ear.

The receiver/stimulator contains a small magnet that usually is removed before the device is implanted. Once the magnet is removed, the remaining materials used in the implant are non-magnetic, which allows magnetic resonance imaging (MRI). The implant can withstand MRI strengths up to 1.5 Tesla when the magnet is removed.

The electrode array extends from the receiver/stimulator and is placed on the surface of the cochlear nucleus in the brainstem. The array is made up of 21 platinum disk electrodes arranged on a PET-mesh backing, and can stimulate multiple sites on the cochlear nucleus. There is a separate ball electrode that is placed underneath the temporalis muscle as a ground.



Nucleus 24 ABI External Components

The SPrint speech processor is a sophisticated microcomputer that converts sound into electrical information. It is programmed with a computer, allowing the audiologist to fine-tune the listening programs for each individual’s hearing needs.

The speech processor is connected to a headset that transmits electrical information and instructions across the skin to the implant. The headset consists of:

- **Microphone** – The microphone is worn at the ear like a small behind-the-ear hearing aid.
- **Transmitting coil and cables** – Two thin cables connect the transmitting coil and microphone to the speech processor. The transmitting coil contains a magnet, which holds it securely in place over the implant.
- **Small magnetic retainer disk** – A retainer disk is used to hold the transmitting coil over the receiver/stimulator. This disk is placed on the side of the head like a small Band –Aid. The magnetic retainer disk attracts to the magnet in the transmitting coil to hold the coil in place.



What benefits can be expected from the Nucleus 24 ABI?

Nucleus ABI Clinical Trail Summary:

- 82% of the implanted subjects were able to perceive sound and use the device postoperatively.
- 85% of the subjects demonstrated statistically significant improvements in open-set sentence understanding, when using the Nucleus ABI in conjunction with lipreading.
- 80% of the respondents reported receiving benefit from the auditory brainstem implant and 84% indicated that the decision to get the Nucleus ABI was the right one.
- 73% of the respondents would recommend a Nucleus ABI to others.

Data from a “Device Use and Satisfaction Survey” obtained from 15 ABI Centers and 163 ABI patients in the U.S.:

The Nucleus 24 ABI has 21 electrodes or channels of stimulation. On average, 8 of those channels are programmed, though it ranged anywhere from 3 channels, all the way up to 18 channels. There are 3 modes of stimulation: monopolar, bipolar, and variable mode. The majority of patients are programmed in the monopolar mode (58%) of stimulation with (12%) in the bipolar mode and (30%) in the variable mode. Almost all of the patients are using the SPEAK (94%) coding strategy with only (6%) programmed in other strategies.

We have found that the majority of patients (71%) implanted during first side tumor removal do not use the ABI (i.e. too much hearing in the opposite ear) as compared to (36%) implanted during second side tumor removal. Therefore, the majority of patients are now implanted during second side tumor removal.

What are we looking at for the future?

- High-rate encoders (ACE and CIS) and the ESPrIt 3G ear-level speech processor are being investigated on subset of patients.
- A penetrating electrode array has been developed to take advantage of the tonotopic organization of the Cochlear Nucleus.
- The use of NRT is being evaluated as an intraoperative tool.

Questions from the Audience:

Audience Member: Will someone already implanted be able to upgrade or be re-implanted with the new electrodes?

Thomas Mitchell: If you are already implanted and the device is functioning, it would be too risky to remove that implant to put the new implant in. If you have not yet been implanted in the opposite ear, then you could be implanted in that ear with the new device.

Audience Member: When you talk about improvement with an implant what is your baseline?

Thomas Mitchell: The primary benefit of the ABI is lipreading enhancement. Like with cochlear implants, improvements in technology have continued to improve patient performance with the device, but only about 12% of patients are able to demonstrate significant open-set sentence recognition scores in the auditory only condition. However, prior to surgery these patients were totally deaf and their scores were zero, so this is a significant improvement over the pre-op condition.

Also, remember that there are about 18% of patients who non-stimulable after implantation and end up being non-users because they received no benefit at all. The reason patients are non-stimulable is that the tumor growth either distorted brainstem anatomy, which made placement of the electrode difficult, or the electrode migrated postoperatively. That is the reason why we redesigned the original electrode and added the mesh pad, so that we could try and prevent the electrode from migrating postoperatively. Now with the redesigned electrode, as the tissue grows around the mesh pad it fixes the electrode pad against the Cochlear Nucleus. The new penetrating needle design may also help to hold the electrodes in place further.

Audience Member: If you have radiation to one side, can you still be implanted?

Thomas Mitchell: Yes, if the other ear hasn't been radiated. However, prospective implant recipients who have undergone gamma knife radiation should be considered with extreme caution, due to possible injury of the cochlear nucleus.

Audience Member: What are the risks with this surgery?

Thomas Mitchell: It is a very delicate surgery, since they are removing a tumor right at the brainstem, so there are some risks involved. I don't have percentages but one complication can be damage to the facial nerve, either temporary paralysis or permanent paralysis, if the nerve is severed.

There is also the possibility of dysphagia or difficulty swallowing. During the evaluation process, they go through all these possible complications with a candidate. Surgical risk may vary from patient to patient depending on medical history, size of the tumors, and length of the surgery.

Audience Member: Are there any other options for us other than an ABI?

Thomas Mitchell: At the current time, not that I know of. The ABI is pretty much it and if it doesn't work, I don't know of anything else that's available.

Audience Member: Generally, the bigger the tumor the less successful the patients have been?

Thomas Mitchell: That is what the data shows us. But we have also seen benefit for those patients that did have larger tumors.

Audience Member: How long does it take to recuperate from the surgery?

Thomas Mitchell: The ABI is usually implanted during the surgery to remove an auditory nerve tumor. The recuperation period is the same as it would be for the tumor removal surgery alone. After this type of surgery, most patients stay in the Intensive Care Unit for two to three days and then in the surgical unit of the hospital for three to four more days. Then there is a waiting period of four to six weeks before hook up can be done in order to allow the incision to heal.

Thomas Mitchell has a Masters' degree in Audiology and Speech-Language Pathology from the University of North Texas. Thomas began his career as a clinical audiologist at Owens Ear Center in Dallas, TX. Thomas was instrumental in starting the cochlear implant program at Owens Ear Center, which led to his position as Regional Manager with Cochlear Corporation in July of 1988. He has been with Cochlear Americas 14 years, seven years as the North Central Regional Manager, six years as the Mid-Central Regional Manager and in June 2001 was promoted to Area Director - Eastern U.S. In this position Thomas is responsible for leading a staff of three Regional Managers and seven Clinical Application Specialists that support the centers and patients throughout the Eastern area of the U.S., in areas of educational training to professionals, recipients and consumers, marketing support, clinical support and any other business issues related to operating an effective implant program.

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