

Cochlear™

Nucleus® cochlear implants

Physician's Package Insert

Hear now. And always



This document contains important information such as indications and contraindications that applies to the following cochlear implant systems:

- Cochlear™ Nucleus® CI500 Series cochlear implant
- Nucleus Freedom™ implant
- Nucleus 24 implant
- Nucleus 22 implant

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Device description

Cochlear Nucleus implant systems are designed to provide useful hearing and include both implanted and external components. The cochlear implant is surgically implanted under the skin behind the ear. It includes a receiver/stimulator to receive and decode the electrical signals and an electrode array to deliver these signals to the cochlea.

The external components include the following sound processors: SPrint™, ESPr™, ESPr 3G, Nucleus Freedom and CP800 Series with their associated accessories and cables. A cochlear implant system converts sound in the environment into electrical code and transmits this code to the auditory nerve, and on to the brain where it is interpreted as sound.

Indications

The cochlear implant is intended to restore a level of auditory sensation via the electrical stimulation of the auditory nerve.

Adults

Nucleus cochlear implants are intended for use in individuals 18 years of age or older who have bilateral, pre, peri or postlinguistic sensorineural hearing impairment and obtain limited benefit from appropriate binaural hearing aids.

These individuals typically have moderate to profound hearing loss in the low frequencies and profound (≥ 90 dB HL) hearing loss in the mid to high speech frequencies. Limited benefit from amplification is defined by test scores of 50% correct or less in the ear to be implanted (60% or less in the best-aided listening condition) on tape-recorded tests of open set sentence recognition.

Children

The cochlear implant system is intended for use in children 12 to 24 months of age who have bilateral profound sensorineural deafness and demonstrate limited benefit from appropriate binaural hearing aids. Children two years of age or older may demonstrate severe to profound hearing loss bilaterally. In younger children, limited benefit is defined as lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three to six month period. It is recommended that limited benefit be quantified on a measure such as the Meaningful Auditory Integration Scale or the Early Speech Perception test. In older children, limited benefit is defined as $\leq 30\%$ correct on the open set Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive and linguistic skills. A three to six month hearing aid trial is recommended for children without previous aided experience.

Contraindications

A cochlear implant is not indicated for individuals who have the following conditions:

1. Deafness due to lesions of the acoustic nerve or central auditory pathway
2. Active middle ear infections
3. Absence of cochlear development
4. Tympanic membrane perforation in the presence of active middle ear disease.

Warnings

Medical treatments generating induced currents

Some medical treatments generate induced currents that may cause tissue damage or permanent damage to the cochlear implant. Warnings for specific treatments are given below.

Electrosurgery

Electrosurgical instruments are capable of inducing radio frequency currents that could flow through the electrode array. Monopolar electrosurgical instruments must not be used on the head or neck of a cochlear implant patient as induced currents could cause damage to cochlear tissues or permanent damage to the implant. Bipolar electrosurgical instruments may be used on the head and neck of patients; however, the cautery electrodes must not contact the implant and should be kept more than 1 cm (~0.5 in.) from the extracochlear electrodes.

Diathermy

Do not use therapeutic or medical diathermy (thermopenetration) using electromagnetic radiation (magnetic induction coils or microwave). High currents induced into the electrode lead can cause tissue damage to the cochlea or permanent damage to the implant.

Medical diathermy using ultrasound may be used below the head and neck.

Neurostimulation

Do not use neurostimulation directly over the cochlear implant. High currents induced into the electrode lead can cause tissue damage to the cochlea or permanent damage to the implant.

Electroconvulsive therapy

Do not use electroconvulsive therapy on a cochlear implant patient under any circumstances. Electroconvulsive therapy may cause tissue damage to the cochlea or damage to the cochlear implant.

Ionizing radiation therapy

Do not use ionizing radiation therapy directly over the cochlear implant because it may cause damage to the implant.

Magnetic Resonance Imaging (MRI)

MRI is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The Nucleus CI500 Series cochlear implant, Nucleus Freedom cochlear implant, Nucleus 24 cochlear implant and some Nucleus 22 cochlear implants have a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 tesla, but not higher.

For patients with a Nucleus 22 cochlear implant without a removable magnet, MRI is contraindicated.

If uncertain, to verify that the patient has a Nucleus cochlear implant with a removable magnet, the physician should use an X-ray to check the radiopaque lettering on the implant. There are three platinum characters printed on each implant. If the middle character is a 'C', 'G', 'H', 'J', 'L', 'P', 'T', '2', '5' or '7' the implant has a removable magnet.

The CI500 Series cochlear implant has a removable magnet. Unlike other Nucleus cochlear implants, the CI500 Series does not have radiopaque lettering.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the processor before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (~2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

For more information about magnet removal, refer to the Surgeon's Guide or contact Cochlear.

Nucleus CI500 Series cochlear implants

Non-clinical testing has demonstrated that the device can be scanned safely under the following conditions:

	Average Head SAR	Average Whole Body SAR		
		Landmark location above shoulder	Landmark location chest	Landmark location below chest
1.5 tesla	2.0 W/kg	0.5 W/kg	1.0 W/kg	2.0 W/kg

Table 1: Specific Absorption Rate (SAR) levels during MRI (non-clinical testing)

In non-clinical testing, the device produced a temperature rise of less than 2°C at a maximum Local Specific Absorption rate (SAR) of 2 W/kg for 6 minutes of MRI scanning in 1.5 tesla MRI scanners*. Temperature rise was measured using a Luxtron thermometer system and SAR was calculated using calorimeter method.

* MRI Equipment and coil

GE Signa whole body coil 46-258170G1 – Located at Purdue University, West Lafayette, Indiana, USA; s/n 10146MR9

GE 1.5 T Genesis. Signa whole body system – Located at Innervision in Lafayette, Indiana, USA; s/n 0065innermr; Software version 09

GE 3T Signa HDx whole body scanner – Located at Innervision in Lafayette, Indiana, USA; s/n 07654493T; Software version 14\LX\MR

Meningitis

Prior to implantation, candidates should consult their primary care physician and implanting surgeon regarding vaccination status against organisms that cause meningitis. Meningitis is a known risk of inner ear surgery and candidates should be appropriately counselled of this risk. In addition, certain preoperative conditions may increase the risk of meningitis with or without a cochlear implant. These conditions include:

- Mondini’s syndrome and other congenital cochlear malformations
- Concurrent Cerebrospinal Fluid (CSF) shunts or drains
- Recurrent episodes of bacterial meningitis prior to implantation
- Perilymph fistulas and skull fracture/defect with CSF communication.

Loss of residual hearing

Insertion of the electrode into the cochlea will result in complete loss of residual hearing in the implanted ear.

Long term effects of electrical stimulation

Most patients can benefit from electrical stimulation levels that are considered safe, based on animal experimental data. For some patients, the levels needed to produce the loudest sounds exceed these levels. The long-term effects of such stimulation in humans are unknown.

Small parts hazard

Parents and caregivers should be counselled that the external implant system contains small parts that may be hazardous if swallowed or may cause choking if inhaled.

Battery ingestion

Batteries can be harmful if swallowed. Ensure that batteries are kept out of reach of young children. If swallowed, seek prompt medical attention at the nearest emergency center.

Head trauma

A blow to the head in the area of the cochlear implant may damage the implant and result in its failure. Young children who are developing their motor skills are at greater risk to receive an impact to the head from a hard object (e.g. a table or chair).

Rechargeable batteries

In certain circumstances, rechargeable batteries can become VERY HOT, and could cause injury. Remove your processor immediately if it becomes unusually warm or hot, and seek advice from your clinician. Parents and caregivers should touch their child's or recipient's processor to check for heat if the child or recipient is showing signs of discomfort. Rechargeable batteries should NEVER be worn beneath clothing (including scarves and headwear covering the ears). Use of the rechargeable battery is contraindicated in patients who cannot remove the device by themselves, or notify a caregiver that the device has become hot.

Overheating

Remove your processor immediately if it becomes unusually warm or hot, and seek advice from your clinician. Parents and caregivers should touch their child's or recipient's processor to check for heat if the child or recipient is showing signs of discomfort.

The manufacturer only recommends the use of zinc air batteries as they have been determined to be safe in recommended use conditions and provide an appropriate power source for the CP810 sound processor.

The CP810 is not intended to be used with silver oxide batteries. In some circumstances, the use of these batteries could result in severe burns. A dangerous amount of heat can be generated by these batteries in conditions where heat cannot dissipate, especially if the device is being held against the skin by clothing or a retention device. In addition, use of silver oxide batteries may damage your processor.

Precautions

If you experience a significant change in performance or the sound becomes uncomfortable, turn off your processor and contact your implant centre.

Use the cochlear implant system only with the approved devices and accessories listed in the user guide.

The processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care. The processor must not be opened by anyone other than Cochlear's qualified service personnel or the warranty will be invalidated.

Each processor is programmed specifically for each implant. Never wear another person's processor or lend yours to another user. If you have two processors (one for each ear), always wear the processor programmed for your left ear on the left, and the processor programmed for your right ear on the right. Using the wrong processor could result in loud or distorted sounds that, in some instances, may cause extreme discomfort.

Do not operate the processor at temperatures above +40 °C (+104 °F) or less than +5 °C (+41 °F).

Do not store the processor at temperatures above +50 °C (+122 °F) or less than -20 °C (-4 °F).

The processor's sound quality may be intermittently distorted when you are within approximately 1.6 km or 1 mile of a radio or television transmission tower. Additional sources of interference include, but are not limited to:

- Security systems
- Industrial machinery and power systems
- Mobile communications equipment (including cellular telephones)
- Certain kinds of hand-held, two-way radios (including Citizen Band, Family Radio Service, and Amateur Band).

To reduce or eliminate the interference, move away from the source. If your processor stops working, turn the power switch off and then back on. This effect is temporary and will not damage the processor.

Theft and metal detection systems

Devices such as airport metal detectors and commercial theft detection systems produce strong electromagnetic fields. Some cochlear implant recipients may experience a distorted sound sensation when passing through or near one of these devices. To avoid this, turn off the processor when in the vicinity of one of these devices.

The materials used in the cochlear implant may activate metal detection systems. For this reason, recipients should carry the Cochlear Implant Patient Identification Card with them at all times.

Electrostatic discharge

A discharge of static electricity can damage the electrical components of the cochlear implant system or corrupt the program in the processor.

If static electricity is present (e.g. when putting on or removing clothes over the head or getting out of a vehicle), cochlear implant recipients should touch something conductive (e.g. a metal door handle) before the cochlear implant system contacts any object or person.

Prior to engaging in activities that create extreme electrostatic discharge, such as playing on plastic slides, the processor should be removed. Clinicians should use an anti-static shield on the computer monitor when programming a cochlear implant recipient.

Mobile telephones

Some types of digital mobile telephones, e.g. Global System for Mobile communications (GSM) as used in some countries, may interfere with the operation of the external equipment. As a result, cochlear implant recipients may perceive a distorted sound sensation when in close proximity, 1–4 m (~3–12 ft), to a digital mobile telephone in use.

Adverse events

The following information summarizes adverse events for adults and children implanted with the Nucleus 24 cochlear implant.

Adults

Adult safety data are based on a total of 133 patients implanted with the Nucleus 24 during the adult clinical investigation at 27 U.S. sites. 20 patients experienced either a medical/surgical or device-related complication.

11 of the 20 complications were medical/surgical in nature and the remaining nine were device-related. 18 of the 20 adverse events resolved without surgical or extensive medical intervention.

Medical/Surgical complications

One patient experienced device migration which required revision surgery to reposition the device. One patient experienced a wound hematoma which required minor surgery to resolve. One patient experienced a slightly compressed electrode array and the surgeon elected to remove the device and replace it with a second one during the initial surgery. Four patients experienced facial nerve stimulation. All cases of facial nerve stimulation were resolved through reprogramming. Two patients experienced tinnitus related to cochlear implant use. One case resolved without intervention and the second case was resolved through reprogramming. One patient experienced short-term postoperative dizziness which resolved without medical treatment. One patient experienced fluctuating psychophysical levels related to a relatively thick (10+ mm) skin flap. This case was resolved through replacement of external equipment.

Device-related complications

No device failures or other serious device malfunctions occurred during this study. Four patients experienced electrode insulation faults (short circuits) that were resolved through reprogramming. Two patients were inadvertently overstimulated during device programming and one patient reported a nonauditory sensation during device programming. Two patients experienced a mild skin reaction to the processor cable. These were resolved completely with topical medical treatment.

Children

Pediatric safety data are based on a total of 150 children implanted with the Nucleus 24 during the clinical investigation. 24 patients experienced 27 medical/surgical or device-related complications. Nine of the 27 complications were medical/surgical in nature and the remaining 18 were device-related. 24 of the complications resolved without surgical or extensive medical intervention.

Medical/Surgical complications

One postmeningitically deafened child with bilaterally ossified cochleae failed to experience auditory stimulation through the fully functional cochlear implant. One patient developed streptococcal meningitis less than 24 hours following cochlear implant surgery. The infection was successfully managed with medical treatment. One patient experienced a wound infection that was resolved through surgical explantation of the device. One patient experienced extracochlear electrode placement related to a congenital malformation of the inner ear. This complication was resolved through surgical explantation of the device. Two patients experienced slight compression of the electrode array which resulted in two short-circuited electrodes in one case and no electrode anomalies in the other. The case with electrode short circuits was resolved through reprogramming. One patient experienced facial nerve stimulation related to a severe congenital malformation of the inner ear. This complication was resolved through reprogramming, however, the patient continues to experience occasional slight facial nerve stimulation. Two patients experienced mild short-term postoperative dizziness. Both cases resolved without medical intervention.

Device-related complications

No device failures or other serious device malfunctions were observed during this study. 13 patients experienced electrode faults (short-circuit or open-circuit electrodes) on one or more electrodes. All of these cases were resolved through reprogramming. One patient experienced non-auditory sensations during psychophysical testing. This case was resolved through reprogramming. One patient experienced an unanticipated overstimulation. This complication was resolved through replacement of external equipment.

Three patients experienced mild skin reactions to the processor cable. One case was resolved through covering the cable, one case was resolved through an alternative polyurethane coating of the cable, and one case resolved spontaneously without intervention.

In addition to the adverse events experienced during the clinical study, the following potential adverse events could occur:

- Individuals are exposed to the normal risks associated with surgery and general anesthesia. In addition, this procedure may result in infection or bleeding, numbness or stiffness about the ear, injury to or stimulation of the facial nerve, taste disturbance, dizziness, increased tinnitus, neck pain and perilymph fluid leak. Perilymph fluid leak may result in meningitis.
- The cochlear implant results in a palpable lump under the skin behind the ear. The presence of a foreign body may cause irritation, inflammation, or breakdown of the skin and, in some cases, extrusion of the device. The electrode array may migrate partially or completely out of the cochlea, resulting in decreased hearing ability. The electrode lead may perforate structures of the external ear, such as the tympanic membrane or canal wall. Misplacement of the electrode array may result in the perception of non-auditory sensations. Such complications may require additional medical treatment, surgery, or removal of the device.
- Electrical stimulation may result in increased tinnitus, facial nerve stimulation, dizziness, or pain. Individuals who have residual hearing in the ear selected for implantation have a slightly greater risk of short-term postoperative dizziness than individuals with no residual hearing in that ear.
- The long-term effects of electrode insertion trauma or chronic electrical stimulation are unknown. Such effects may include new bone growth in the cochlea or deterioration of the nerve cells. These effects may preclude replacement of the electrode array or may lead to eventual deterioration of cochlear response.
- Failure of component parts (both external and internal) could result in the perception of uncomfortably loud sounds or no sound. Failure of various parts of the implanted device could result in removal, replacement of the implant, or a reduction of the number of electrodes in use.

Results of clinical studies

The clinical study results contained in the Physician's Package Insert reflect clinical trials conducted with the Nucleus 24 straight array.

Adults

SPrint™ (body worn) processor

Effectiveness of the Nucleus 24 system using the SPrint body worn processor was assessed by comparing the speech perception abilities of 67 postlinguistically deafened adults preoperatively in the best-aided condition (implanted ear aided, non-implanted ear aided or binaurally aided) with their postoperative performance in the implanted ear alone, after three months of device use. Postoperatively, the body worn SPrint processor was programmed to implement the Spectral-peak (SPEAK) speech processing strategy. Recorded measures of open set sentence recognition were presented in quiet using City University of New York (CUNY) and Hearing in Noise Test (HINT) Sentences. CUNY Sentences also were presented in background noise at a level that was moderately difficult for the typical cochlear implant recipient (+10 dB signal-to-noise ratio). Open set speech recognition was also assessed over long-distance telephone lines using Central Institute for the Deaf (CID) Everyday Sentences of Speech Test and the Psycho-Acoustic Laboratory Sentences (PAL). Recorded measures of open set, monosyllabic word recognition (Consonant-Nucleus-Consonant (CNC) Words) were presented in quiet. Due to the high levels of performance exhibited by adults using the Nucleus 24, more simple measures of lipreading enhancement and closed set speech perception were not included in the evaluation battery. Individual subject results were analyzed using a binomial statistical model.

Hearing-only, open set sentences in quiet

- After three months of experience with the Nucleus 24, almost all recipients (66/67; 98.5%) demonstrated significant improvement in open set sentence recognition (CUNY) compared to their preoperative performance with hearing aids. All individuals demonstrated significantly above-chance sentence recognition. Recipients recognized an average of 78% of words in sentences, with a median score of 87%. Approximately half of the recipients (49.3%) recognized 90% or more words and approximately two-thirds (62.7%) recognized 80% or more words.

- Recipients rapidly developed high levels of open set speech perception after limited experience with the Nucleus 24. Average sentence recognition (CUNY) increased from 56% to 65% to 78% and median scores increased from 58% to 72% to 87% after two weeks, one month and three months of device use, respectively. After only two weeks, approximately one-third (31.3%) of the recipients recognized 80% or more words. After only one month, approximately half (47.8%) of the recipients recognized 75% or more words.
- After three months of experience with the Nucleus 24, almost all recipients (63/67; 94.0%) demonstrated significant improvement in the recognition of more difficult open set sentences (HINT) compared to their preoperative performance with hearing aids. Almost all individuals demonstrated significantly above-chance speech recognition. Recipients recognized an average of 60% of the words in these more difficult sentences, with a median score of 63%. Approximately one-third of the recipients (35.8%) recognized 75% or more words.

Hearing-only, open set sentences in noise (+10 dB Signal-to-Noise Ratio (SNR))

After three months of experience with the Nucleus 24:

- Almost all recipients (61/66; 92.4%) demonstrated significant improvement in the recognition of recorded, open set sentences (CUNY) in the presence of background noise, compared to their preoperative performance with hearing aids. All but one recipient demonstrated significantly above-chance speech recognition.
- When tested in an environment designed to represent 'real world' listening situations (background noise), recipients recognized an average of 59% of the words, with a median score of 67%. One-third of the recipients (36.3%) recognized 75% or more words and approximately one-half of the recipients (47.0%) recognized 70% or more words.

Hearing-only, open set words in quiet

After three months of experience with the Nucleus 24:

- 88% of recipients (59/67) demonstrated significant improvement in the recognition of recorded, open set monosyllabic words compared to their preoperative performance with hearing aids. Monosyllabic word recognition ranged from 0% to 80%.
- Recipients recognized an average of 37% of the words, with a median score of 36%. 18% of the recipients (12/67) recognized 60% or more words and 28% of recipients (19/67) recognized 50% or more words.

Telephone testing

All telephone testing was administered over long-distance telephone lines using recorded, open set sentence measures (CID and PAL sentences). Under these difficult listening conditions, after three months of experience with the Nucleus 24:

- 91% of the recipients (61/67) demonstrated significant improvement in the recognition of open set sentences (CID) compared to their preoperative performance with hearing aids. Almost all recipients (65/67; 97%) recognized these sentences at significantly above-chance levels. 79% (53/67) demonstrated significant improvement in the comprehension of open set sentences (PAL) compared to their preoperative performance with hearing aids.
- Recipients scored an average of 60% and 58% on CID and PAL Sentences, with median scores of 66% and 65%, respectively. Approximately half of the recipients (47.8%) recognized 70% or more of recorded words in sentences (CID), and 21% of recipients recognized 90% or more words. Approximately a quarter (23.9%) of the recipients correctly answered 90% or more of recorded questions (PAL), and approximately half (50.8%) correctly answered 70% or more questions.

ESPrin™ (ear level) processor

After a minimum of three months experience with the SPrin processor, 36 subjects were fitted with the ESPrin ear level processor (programmed to implement the SPEAK speech processing strategy) and speech perception was evaluated following one month of ESPrin use. Recorded measures of open set sentence recognition were presented in quiet and in the presence of background noise (+10 dB SNR), at a level that was moderately difficult for the typical cochlear implant recipient. Recorded measures of open set word recognition were presented in quiet. ESPrin performance was compared with each subject's preoperative baseline, as well as with the SPrin postoperative baseline. The evaluation measures for the ESPrin were the same as those used to assess the SPrin, except that telephone use with the ESPrin was not assessed. Individual subject results were analyzed using a binomial statistical model.

Hearing-only, open set sentences in quiet

- Almost all recipients (34/36; 94.4%) demonstrated significant improvement in the recognition of open set sentences (CUNY) using the ESPrin compared to their preoperative performance with hearing aids. Recipients recognized an average of 79.6% of the words in sentences, with a median score of 91%.
- All recipients tested (35/35; 100%) demonstrated significant improvement in the recognition of more difficult open set sentences (HINT) using the ESPrin compared to their preoperative performance with hearing aids. Recipients recognized an average of 63.4% of the words, with median score of 65%.

Hearing-only, open set sentences in noise (+10 dB SNR)

- Almost all recipients (32/36; 88.9%) demonstrated significant improvement in the recognition of open set sentences (CUNY) in the presence of background noise using the ESPrin compared to their preoperative performance with hearing aids. All but four recipients demonstrated significantly above-chance speech recognition.
- When tested in an environment designed to represent 'real world' situations (background noise), recipients recognized an average of 57.9% of words in sentences, with a median score of 64%.

Hearing-only, open set words in quiet

- 89% of recipients (32/36) demonstrated significant improvement in the recognition of open set monosyllabic words using the ESPrIt compared to their preoperative performance with hearing aids. Recipients recognized an average of 38.3% of the words, with a median score of 40%.

Communication Profile for the Hearing-Impaired (CPHI) communication performance scale

The 18 item Communication Performance Scale of the CPHI was completed pre- and postoperatively by 59 of the 67 clinical trial subjects. The CPHI uses a five point rating scale to assess respondents' ability to communicate effectively in a variety of social, work-related and home settings. An improvement of one level rating is considered by the authors of the CPHI to represent a clinically significant difference. Not all of the communication environments assessed by the CPHI were experienced by all subjects. The following statements summarize self-reported changes in communication abilities as assessed by the CPHI. When using the Nucleus 24:

- Three-quarters (45/59; 76.3%) of the respondents reported communicating more effectively when driving in a car with family members.
- Three-quarters (40/54; 74.1%) of the respondents reported communicating more effectively when ordering in a restaurant.
- Three-quarters (42/55; 76.4%) of the respondents reported communicating more effectively at a dinner party.
- Three-quarters (36/46; 78.3%) of the respondents reported hearing religious services more effectively.
- Over three-quarters (41/48; 85.4%) of the respondents reported communicating more effectively in meetings.

General performance questionnaire

The General Performance Questionnaire was administered pre- and postoperatively to 51 of 67 clinical trial participants. The 14 item, self-report questionnaire evaluated possible device-related benefits, such as enjoyment of music, ability to monitor individual voice quality, improvements in communication ability and general quality of life issues.

The following statements summarize these self-reported benefits. When using the Nucleus 24:

- Three-quarters (35/51; 69%) of the respondents reported they enjoyed listening to music (at least to some degree) compared to one-third of the respondents (15/51; 29%) preoperatively.
- Two-thirds (32/51; 63%) of the respondents recognized (at least occasionally) songs and tunes that were familiar to them before losing their hearing, compared to 35% (18/51) preoperatively.
- Over one-third (20/51; 39%) of the respondents recognized familiar songs and tunes at least half of the time.
- 86% of the respondents (44/51) reported they could frequently or almost always monitor the loudness and quality of their voice compared to only 35% (18/51) preoperatively.
- 90% (46/51) of the respondents reported an overall improvement in communication ability without lipreading.

Regarding general quality of life issues

- 88% (45/51) of the respondents indicated that they were satisfied with the cochlear implant system after three months of experience.
- 92% (47/51) of the respondents were happy they made the decision to undergo surgery and receive the implant.
- 92% (47/51) of the respondents indicated that the quality of their lives improved after receiving the Nucleus 24.

Nucleus 24 and advanced speech processing strategies

The effectiveness of three advanced speech processing strategies, CIS, SPEAK, and ACE™, was assessed in a sample of 51 postlinguistically deafened adults. Prior to the study, all participants had at least three months of experience with the Nucleus 24 cochlear implant, using the SPEAK speech processing strategy. Study participants represented a broad range of postoperative outcomes and were randomly assigned to one of two experimental groups. Following a baseline performance evaluation using SPEAK, 27 subjects assigned to Group A were fitted with an optimized CIS strategy, and 24 subjects assigned to Group B were fitted with an optimized ACE strategy. After six weeks of experience with CIS (Group A) or ACE (Group B), each subject's performance was re-evaluated and compared to his or her SPEAK baseline, using a binomial statistical model. Tests of open set speech recognition included CNC Monosyllabic Words, CUNY Sentences, and HINT Sentences administered in quiet. CUNY Sentences also were presented in background noise at a level that was moderately difficult for the typical cochlear implant recipient (+10 dB signal-to-noise ratio). A comparative questionnaire was administered to each subject at the six week interval, to evaluate strategy preferences in a variety of listening environments.

Matrix of CIS and ACE™ programming parameters

As shown in the following matrix, the 51 investigational subjects and their audiologists selected different combinations of CIS and ACE programming parameters as optimal. For each participant, the optimal stimulation rate (per channel) is displayed along the x-axis and the optimal number of stimulation sites (channels for CIS and maxima for ACE) is displayed along the y-axis.

As illustrated, study participants selected:

- A wide range of CIS and ACE programming parameters
- Optimal stimulation rates ranging from 720 Hz – 2400 Hz per channel
- Optimal total stimulation rates ranging from 5,760 Hz – 14,400 Hz
- A minimum of six and up to 20 channels (CIS) or maxima (ACE) of stimulation, as optimal.

The 24 adults who converted from the baseline SPEAK strategy to ACE (Group B) recognized an average of:

- 80% of words in CUNY Sentences when using SPEAK, compared to 81% when using ACE. For both strategies, median open set scores were 92%.
- 65% of words in open set HINT Sentences when using SPEAK, compared to 66% with ACE. Median scores were 68% and 66% for SPEAK and ACE, respectively.
- 63% of words in CUNY Sentences in the presence of background noise using SPEAK, and 67% with ACE. Median noise scores were 65% for SPEAK and 74% for ACE.
- 42% of open set CNC Words with SPEAK, and 41% of the words with ACE. Median scores were 37% (SPEAK) and 35% (ACE).

Speech perception results for individual subjects

- No single speech processing strategy provided optimal performance for all study participants. When evaluated with CUNY Sentences presented in background noise, ten of the 27 subjects (37%) who tried SPEAK and CIS performed best with SPEAK, eight (30%) with CIS, and nine (33%) performed equally well with both strategies. Of the 24 subjects who tried SPEAK and ACE, seven (29%) performed best with SPEAK, nine (38%) with ACE, and eight (33%) performed equally well with both strategies.
- Postlinguistically deafened adult cochlear implant recipients derived significant benefit from access to multiple speech processing strategies and a broad choice of implementation options.

Questionnaire results

Following six weeks of experience with the new speech processing strategy, a questionnaire was administered to 49 of the 51 study participants. Respondents rated the ease with which they adjusted to the new strategy and also expressed relative preferences for one of the two strategies in a variety of listening environments. For preference-related items, participants were asked to indicate whether they (1) preferred SPEAK, (2) preferred the new strategy (i.e. CIS for Group A and ACE for Group B), (3) perceived SPEAK and the new strategy as equivalent or, (4) were not sure of their preference. The following statements summarize this self-reported information.

Of the 27 adults who converted from SPEAK to CIS:

- One-third (9/27; 33%) of the respondents rated the conversion process as 'easy'.
- Almost half (13/27; 48%) of the respondents preferred SPEAK when listening in quiet, 30% (8/27) preferred CIS, and 19% (5/27) rated the two strategies as equivalent.
- Two-thirds (18/27; 67%) of the respondents preferred SPEAK when listening in background noise, compared to 26% (7/27) who preferred CIS.
- When listening to music, 26% (7/27) and 33% (9/27) of the respondents preferred SPEAK and CIS, respectively.
- When using the telephone, 41% (11/27) of the respondents preferred SPEAK, 7% (2/27) preferred CIS, and 26% (7/27) rated the two strategies as equivalent.
- Over half (14/27; 52%) of the respondents selected SPEAK as their preferred strategy 'overall'.
- One-third (9/27; 33%) of the respondents selected CIS as their preferred strategy 'overall'.

Of the 24 adults who converted from SPEAK to ACE:

- Over half (13/22; 59%) of the respondents rated the conversion process as 'easy'.
- 27% (6/22) of the respondents preferred SPEAK when listening in quiet, 32% (7/22) preferred ACE, and 27% (6/22) rated the two strategies as equivalent.

Results of clinical studies

- 36% (8/22) of the respondents preferred SPEAK when listening in background noise and 32% (7/22) preferred ACE.
- When listening to music, 18% (4/22) of the respondents preferred SPEAK and 18% (4/22) preferred ACE. 23% (5/22) rated the two strategies as equivalent.
- 36% (8/22) of the respondents preferred SPEAK when using the telephone. 18% (4/22) preferred ACE, and 18% (4/22) rated the two strategies as equivalent.
- Almost one-third (7/22; 32%) of the respondents selected SPEAK as their preferred 'overall' strategy.
- 23% (5/22) of the respondents selected ACE as their preferred 'overall' strategy.

After only six weeks of experience using either CIS or ACE:

- Almost three-quarters (35/49; 71%) of the respondents reported an overall preference for one strategy over the other (i.e. Group A: SPEAK or CIS, Group B: SPEAK or ACE).

Children

Effectiveness of the Nucleus 24 system in older (five years and above) children was assessed by comparing the speech perception abilities of 23 pre- and postlinguistically deafened subjects preoperatively in the best-aided condition (implanted ear aided, non-implanted ear aided or binaurally aided) with their postoperative performance in the implanted ear alone, after six months of device use. Postoperatively, the Nucleus 24 system was programmed to implement the SPEAK speech processing strategy. Recorded versions of various pediatric speech perception measures were presented at 70 dB SPL. Individual subject results were analyzed using a binomial statistical model and group means were analyzed using paired t-tests and the non-parametric Wilcoxon Signed Ranks tests.

Of the children five years of age and older who were capable of being tested on open set word recognition tasks:

- 61% (14/23) demonstrated significant improvement on the Glendonald Auditory Screening Procedure (GASP).
- 44% (10/23) demonstrated significant improvement on the MLNT.
- 57% (13/23) demonstrated significant improvement on the LNT.
- 48% (11/23) demonstrated significant improvement on the Phonetically-Balanced Kindergarten (PBK) monosyllabic word test.

Group mean performance was significantly higher after six months of experience with the Nucleus 24, on all 11 measures of speech perception administered to children five years of age and older. These measures ranged from simple closed-tests to more difficult open set word and sentence recognition tests.

Device effectiveness for older children also was assessed through parental ratings of their child's auditory behaviors in a variety of everyday listening situations on the Meaningful Auditory Integration Scale (MAIS). For 19 children, preoperative ratings in the best-aided condition (implanted ear aided, non-implanted ear aided or binaurally aided) were compared with postoperative ratings after six months of implant use. Ratings describing the frequency of occurrence of the child's auditory behaviors ranged from 0 (Never) to 4 (Always). Results were analyzed as the proportion of children rated who demonstrated the specific behavior either 'frequently' or 'always'.

After six months of experience with the Nucleus 24:

- 83% (15/18) of the children frequently or always responded to their name in quiet compared with only 47% (9/19) preoperatively with hearing aids.
- 47% (9/19) of the children frequently or always responded to their name in noise compared with only 11% (2/19) preoperatively with hearing aids.
- 79% (15/19) of the children frequently or always spontaneously recognized common sounds in the classroom compared with 26% (5/19) preoperatively with hearing aids.

Younger children (ages 18 months to 4 years, 11 months)

Effectiveness of the Nucleus 24 system in younger children was assessed in part through parental ratings of their child's auditory behaviors in a variety of everyday listening situations on the MAIS. For 22 children, preoperative ratings in the best-aided condition (implanted ear aided, non-implanted ear aided or binaurally aided) were compared with postoperative ratings after six months of implant use. Postoperatively, the Nucleus 24 system was programmed to implement the SPEAK speech processing strategy. Ratings describing the frequency of occurrence of the child's auditory behaviors ranged from 0 (Never) to 4 (Always). Results were analyzed as the proportion of children rated who demonstrated the specific behavior either 'frequently' or 'always'.

After six months of experience with the Nucleus 24:

- 68% (15/22) of the children frequently or always responded to their name in quiet compared with only 27% (6/22) preoperatively with hearing aids.
- 45% (10/22) of the children frequently or always responded to their name in noise compared with only 14% (3/22) preoperatively with hearing aids.
- 41% (9/22) of the children frequently or always spontaneously recognized common sounds in the classroom compared with 14% (3/22) preoperatively with hearing aids.

Neural Response Telemetry (NRT™)

The Neural Response Telemetry (NRT™) system of the Nucleus 24 is capable of detecting physiological responses of elements of the auditory nerve within the cochlea.

Clinical considerations

Adult and pediatric patients deafened from birth to two years of age are considered to be prelinguistically deafened, while those with an onset of deafness from two to five years of age are considered to be perilinguistically deafened. Postlinguistically deafened patients typically are deafened after the age of five and present with age-appropriate speech and language skills.

Optimized hearing aid fitting and evaluation procedures are critical to the selection of suitable cochlear implant candidates. In order to ensure selection of appropriate candidates, hearing healthcare professionals should utilize state of the art amplification and diagnostic instruments, and clinically accepted hearing aid evaluation and fitting procedures.

Adults with severe to profound, postlinguistic, sensorineural hearing loss commonly present with asymmetrical audiometric profiles. When clinically appropriate, it is recommended that the poorer ear be selected for implantation, as surgical placement of the device will result in complete loss of residual hearing in the implanted ear. When selecting the ear for implantation, open set sentence recognition scores with hearing aids should be considered over more conventional audiological measures, as appropriate clinical indicators of preoperative auditory function.

Prelinguistically and perilinguistically deafened adults who do not have functional oral speech and language skills, and who are not highly motivated to participate in the rehabilitation process, are more likely to become non users of the device than are other adult patients. Prospective patients and their families should be counseled extensively regarding the limited nature of expected postoperative benefits, and should understand that prelinguistically and perilinguistically deafened adults are at risk for device non use.

Many prelinguistically and perilinguistically deafened adults demonstrate improved detection of medium to loud environmental sounds, including speech. A few individuals demonstrate improved lipreading abilities, following extensive rehabilitation. (Average test scores improved by less than 10%, when the device was used in conjunction with lipreading.)

There was no significant difference in performance between the SPrint (body worn) and the ESPrit (ear level) processors on any measure of open set speech perception in quiet or in noise.

Other information

Patient counseling

Preoperative counseling

Prospective cochlear implant candidates should be counseled regarding potential benefits, warnings, precautions and adverse effects of cochlear implantation, using the information in this document.

Storage, handling and sterilization

Implants should be stored at normal room temperature. Implants may be stored at temperatures between -4 °F and +120 °F (-20 °C and +50 °C). The 'use by' date is stamped on the outside package. If it has expired, return the device to Cochlear.

Handle the implant packages with care. Severe impact may rupture the inner sterile package.

Cochlear implants are supplied sterile in gas-permeable packaging. The titanium plugs and replacement magnets are supplied separately in sterile gas-permeable packaging. These are single use items. The sterile package contains information indicating ethylene oxide processing. Before opening the sterile package, inspect it carefully. If the package is ruptured, or exposure to ethylene oxide processing is not indicated, please return the package to Cochlear.

Information for use and recommended training

Physicians should be very experienced in mastoid surgery and the facial recess approach to the round window. It is important that physicians be trained in the implantation procedure for the CI500 Series and Nucleus 24. It is strongly recommended that the surgeon work with an experienced team of audiology, speech-language, rehabilitation, education and psychology professionals. It is recommended that audiology professionals attend a training program for this device. Cochlear Americas conducts periodic training courses.

For product-specific information, refer to the Surgeon's Guide supplied with each implant.

Notes

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