Cochlear™ Nucleus® CI422 cochlear implant with straight electrode

Important Information: Warnings, Precautions and Electromagnetic Compatibility

United States of America

Symbols

Note

Important information or advice.

Caution

Special care to be taken to ensure safety and effectiveness.

Could cause damage to equipment.

Warning

Potential safety hazards and serious adverse reactions.

Could cause harm to person.

This document contains important information such as warnings, precautions and privacy that applies to the following cochlear implant systems:

- Cochlear™ Nucleus® CI422 cochlear implant with straight electrode

Read this document carefully to ensure that you understand the care of your system.

Discuss this information with your physician before undergoing any major medical procedure.

Contents

Warnings

Medical treatments generating induced currents

Some medical treatments generate induced currents that may cause tissue damage or permanent damage to the 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 an 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 (~½ 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 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 an implant patient under any circumstances. Electroconvulsive therapy may cause tissue damage to the cochlea or damage to the implant.

Ionising radiation therapy

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

MRI safety information

The Cochlear Nucleus CI422 implant is MR Conditional. MRI examinations can be performed safely on a person with this implanted device only under very specific conditions. MRI examinations performed under different conditions may result in severe patient injury or device malfunction.

Full MRI safety information is available:

- in the *Cochlear Nucleus Implants MRI Guidelines*
- by visiting www.cochlear.us/mri
- by calling your regional Cochlear office – contact numbers are available on the back cover of this guide

Refer to the *Cochlear Nucleus Implants MRI Guidelines* for a complete list of Warnings and Cautions.

All external components of the Cochlear implant system (e.g. sound processors, remote assistants and related accessories) are MR Unsafe. The recipient must remove all external components of their Cochlear implant system before entering a room where an MRI scanner is located.

What is an MRI?

Radiologists and MR technologists are medical specialists experienced in diagnosing disease and injuries using a range of imaging techniques. One of these imaging techniques is magnetic resonance imaging (MRI).

MRI is a diagnostic tool to obtain images of organs and tissues using a very powerful magnetic field measured in tesla (T). MRI scans can range in strength from 0.2 T to 7 T, with 1.5 T being the most common.

Safety concerns for medical device implants and MRI

Due to the powerful magnetic and radio-frequency fields, medical device implants with metallic or ferromagnetic components such as pacemakers, defibrillators, catheters, pumps and cochlear implants can create problems for MRI scans. The risks include the potential for device repositioning, localised heating, unusual sounds or sensations, pain or injury and distortion of the MR image.

Cochlear Nucleus implants and MRI compatibility

A Cochlear Nucleus implant is a medical treatment for moderate to profound hearing loss or single sided deafness. Inside each Cochlear Nucleus implant is a magnet.

To ensure MRI compatibility, Cochlear Nucleus implants feature a removable magnet. The magnet is easy to remove and replace if needed. In the rare case that a recipient needs serial MRI examinations, a non-magnetic plug is available to prevent fibrous tissue growing in the magnet recess.

Cochlear Nucleus implants are approved for MRI scans under specific conditions at 1.5 T with the magnet in place and at 3 T with the magnet removed.

Loss of residual hearing

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

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 ingested or inhaled.

Head trauma

A blow to the head in the area of the 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). For recommendations on how to minimise the chance of children experiencing head trauma see https://www.cdc.gov/traumaticbraininjury/prevention.html.

Use of batteries and battery ingestion

When using disposable batteries, only use battery types recommended by your clinician or Cochlear. Other types may not have sufficient energy to allow your processor to operate for a long time. Cochlear does not recommend the use of silver oxide or alkaline batteries.

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 centre.

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 of external devices

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 Cochlear rechargeable battery modules and zinc air disposable batteries.

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

Your processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care. The opening of your processor by anyone other than Cochlear's qualified service personnel invalidates the warranty.

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 your processor at temperatures above +40 °C (+104 °F) or less than +5 °C (+41 °F).

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

Your 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 your processor.

Theft and metal detection systems

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

The materials used in the 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 implant system or corrupt the program in your processor.

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

Air travel

Transmitting devices such as mobile/cell phones are required to be switched off on aircraft. If you have a remote control (remote assistant) for your processor, it should also be switched off because it is transmitting high frequency radio waves when switched on.

Scuba diving

Implant type	Maximum depth
CI422 implant	40 m (~131 ft)

Table 1: Maximum diving depths when wearing implants

Recipients should seek medical advice before participating in a dive for conditions that might make diving contraindicated, e.g. middle ear infection, etc. When wearing a mask, avoid pressure over the implant site.

Sleeping

Do not wear your processor while sleeping, as you may not become aware of your processor becoming unusually warm or hot.

Do not allow children or recipients with disabilities to wear their processor while sleeping.

Retention aids

When using retention aids such as the Snugfit or LiteWear, be aware that it may take longer to remove the processor if the processor becomes unusually warm or hot.

Do not attach the LiteWear beneath layers of clothing.

Electromagnetic compatibility (EMC)

Guidance and manufacturer's declaration

The Nucleus CP800 Series Sound Processor, Nucleus Freedom, Nucleus Hybrid, Nucleus ESPrit 3G, Nucleus SPrint processors and the CR100 Series Remote Assistant are intended for use in the electromagnetic environments specified in this document.

They have been tested and found to be in compliance as shown. You should take care to use your processor as described.

Electromagnetic emissions

Emission test	Compliance	Guidance
RF emissions CISPR 11	Group 1	RF energy is only used for its internal function. The RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3		

Table 2: Electromagnetic emissions

Electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV air, ±4 kV, ±8 kV and ±15 kV air	±8 kV contact ±2 kV air, ±4 kV, ±8 kV and ±15 kV air	Refer to *Electrostatic discharge*(ESD) on page 10
Electrical fast transient/burst IEC 61000-4-4	Not applicable		
Surge IEC 61000-4-5			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	1200 A/m	Power frequency magnetic fields be at levels characteristic of a typical location in a typical commercial or hospital environment
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	Not applicable 10 V/m 80 MHz to 2.7 GHz	Not applicable 20 V/m 80 MHz to 3.0 GHz	See *Warnings* on page 5, *Precautions* on page 9 and *Guidance* on page 14.

Table 3: Electromagnetic immunity

Guidance

Portable and mobile RF communications equipment should be used no closer to any part of the devices, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance (d):

$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz

$d = 2.3\sqrt{P}$ 800 MHz to 3.0 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol:

Note

1. At 80 MHz and 800 MHz, the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Explanatory notes:

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the processor is used exceeds the applicable RF compliance level above, the processor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the processor.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances

Your processor is intended for use in an electromagnetic environment where the radiated RF disturbances are controlled.

To prevent electromagnetic interference, maintain a minimum distance between the portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 3.0 G Hz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Table 4: Recommended separation distances

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note

1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Adverse effects

Prospective Cochlear Nucleus cochlear implant recipients should be advised of the following possible effects of receiving an implant:

- Normal risks associated with surgery and general anaesthesia.
- Increased surgical and anaesthetic risks for certain populations.
- Complications most frequently associated with this surgical procedure - stimulation of the facial nerve, taste disturbance, and tinnitus.
- Complications that may require additional medical treatment, surgery, and/or removal of the device, such as:
  - Acute Otitis Media (AOM)
  - facial nerve injury leading to temporary facial nerve weakness
  - perilymph fistula
  - Concurrent Cerebrospinal Fluid (CSF) leakage
  - vestibular dysfunction
  - subdural injury
  - subcutaneous haematoma
  - irritation, inflammation or breakdown of the skin flap; infection; and in some cases, extrusion of the device caused by the presence of a foreign body under the skin
  - decreased hearing ability caused by the electrode array migrating partially or completely out of the cochlea
  - perforation of external ear structures, such as the tympanic membrane or canal wall, by the electrode lead
  - perception of non-auditory sensations and poorer performance than expected from misplacement of the electrode array.

- Electrical stimulation may result in increased tinnitus, temporary facial nerve stimulation, temporary dizziness, or temporary pain.
- 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 an uncomfortably loud sound sensation, intermittent sound, or no sound.
- Failure of various component parts of the implanted device could require removal or replacement of the implant, or a reduction in the number of electrodes used.

Meningitis

Before implantation, candidates should consult their primary care physician and implanting surgeon regarding vaccination status against micro-organisms that cause meningitis.

Meningitis is a known risk of inner ear surgery and candidates should be appropriately counselled of this risk. Certain preoperative conditions may increase the risk of meningitis with or without an implant. These conditions include:

- Mondini's syndrome and other congenital cochlear malformations
- CSF shunts or drains
- recurrent episodes of bacterial meningitis before implantation
- perilymph fistulas and skull fracture/defect with CSF communication.

For information on the use of vaccines to prevent meningitis in persons with cochlear implants refer to:
https://www.cdc.gov/vaccines/vpd/mening/hcp/dis-cochlear-gen.html

How we studied the Cochlear Nucleus cochlear implant system

Clinical studies were performed to test whether the Cochlear Nucleus cochlear implant system was safe and effective for use. Participants who were part of the studies had either bilateral sensorineural hearing loss or single sided deafness (SSD). Safety data and effectiveness data from the clinical studies are provided below.

Summary of safety data

The following information summarises adverse events for adults and children implanted with the Cochlear Nucleus 24 cochlear implant system. Safety data apply to all patients receiving a cochlear implant and are not specific to individuals with bilateral sensorineural hearing loss or single sided deafness/unilateral hearing loss.

Adults

Adult safety data are based on a total of 133 patients implanted with the Cochlear Nucleus 24 cochlear implant during the adult clinical investigation at 27 US sites. Twenty patients experienced either a medical/surgical or device-related complication. Eleven of the 20 complications were medical/surgical in nature and the remaining nine were device-related. Eighteen 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 haematoma 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 non-auditory sensation during device programming. Two patients experienced a mild skin reaction to the processor cable. These were resolved completely with topical medical treatment.

Children

Paediatric safety data are based on a total of 234 children implanted with the Cochlear Nucleus cochlear implants for two clinical investigations.

For the first clinical investigation, 150 children were implanted with Cochlear Nucleus 24 cochlear implants. Twenty four patients experienced 27 medical or surgical or device related complications. Nine of the 27 complications were medical or surgical in nature and the remaining 18 were device-related. Twenty four of the complications resolved without surgical or extensive medical intervention.

Medical/surgical complications[1]

For the first study, 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.

1 Medical/surgical complications would be classified today as a procedure related adverse event.

Device-related complications

No device failures or other serious device malfunctions were observed during the first study. Thirteen 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.

Additional summary of safety for children

Cochlear performed a prospectively-designed, retrospective analysis from its own registry data to establish a reasonable assurance of safety of implantation with the Cochlear Nucleus 24 cochlear implant system for paediatric patients aged 9 months to 12 months. The retrospective review of 84 children that were between 9 months and 12 months of age and implanted with Cochlear Nucleus cochlear implants was completed for this analysis. Twenty four patients experienced 28 medical or surgical complications and 26 of the complications were resolved without major surgical or medical intervention. Device-related complications (i.e. electrode faults) were not captured in this study. Six patients experienced minor post-operative complications, four of which were resolved without medical intervention. Two patients experienced cerebral spinal fluid leakage perioperatively. These were repaired during the cochlear implant surgery, and one patient required a revision surgery with reimplantation. Two patients experienced postoperative infections including mastoiditis, post-auricular abscess, and surgical site infection. All the infections were medically managed. Two patients developed seromas and one of these patients was reimplanted. Two patients experienced temporary facial weakness which resolved with steroid administration. There were no reports of postoperative meningitis. Overall, the above adverse events are typical surgical, procedure or device events observed in children implanted in relatively young age.

As of February 2020, Cochlear performed a systematic literature search in PubMed and EMBASE databases to assess safety of implantation with a Cochlear Nucleus cochlear implant in infants aged between 9 months and 12 months. A multi-step literature search process resulted in a final set of studies (49 peer-reviewed articles) representing additional relevant research on cochlear implantation for patients less than 12 months old. Safety studies that included children implanted at less than 12 months old covered a broad range of topics from surgical complications including anaesthesia and blood loss, to postoperative pain and dizziness, wound healing problems, and infections. The research literature reviewed on surgical and postoperative outcomes reported specific to the population under the age of 12 months at implantation did not identify an elevated incidence of complications.

Summary of effectiveness data

Adults

Unilateral Hearing Loss (UHL) / Single Sided Deafness (SSD)

Cochlear analysed existing data to demonstrate the effectiveness of cochlear implantation in adult participants with single sided deafness, or SSD. In the analysis, data from a Cochlear sponsored multicentre study was combined with data gathered from two cochlear implant centres. Data was analysed from 42 participants.

Effectiveness testing included speech recognition testing using:

- The Hearing in Noise Test (HINT) and
- Bamford Kowall Bench Sentences in Noise test (BKB-SIN).

Localisation testing was also completed.

Effectiveness testing also included outcomes reported by the participant. These patient reported outcomes included the:

- Speech, Spatial, and Qualities (SSQ) Questionnaire
- Iowa Tinnitus Handicap Questionnaire.

Description of Tests

Hearing in Noise Test (HINT)

The Hearing in Noise Test or HINT (Nilsson et al., 1994) is a test made up of 25 10-sentence lists used to test how well an individual understands in noise. The sentences are presented in noise which is filtered to match the long-term average spectrum of the sentences. The HINT is an adaptive test whereby the signal-to-noise ratio (SNR) is increased or decreased by a fixed amount based on the listener's ability to repeat the sentences correctly or not.

Bamford Kowall Bench Sentences in Noise test (BKB-SIN)

The BKB-SIN Test (Etymotic Research, 2005) includes 18 lists of sentences. The sentences are spoken by a single male talker, are 5-6 words in length and are at a 1st grade reading level. The sentences are presented in noise using 4-talker babble. The test starts out easy where the sentences are presented much louder than the noise and depending on a listener's ability to correctly repeat the words in the sentence, the sentences are either made softer or louder until a level is reached where 50% of the words in a sentence are repeated correctly.

Localisation Testing

Localisation is the ability to tell where a sound is coming from. Localisation testing was assessed by delivering a noise from one of 12 locations. The locations are numbered one through 12 on a response sheet, from right to left. The sound comes from a speaker positioned to represent an arc from 97.5° (on the right) to 262.5° (on the left) of the participant. There is a 15° separation between each speaker. The participant selects one number to indicate the perceived location of the sound.

Speech, Spatial, and Qualities (SSQ) Questionnaire

The SSQ is a validated self-assessment metric commonly used in hearing aid and cochlear implant research. It is designed to measure self-reported auditory disability across a wide variety of domains, reflecting the reality of hearing in the everyday world. There are 49 questions (SSQ-49) scored by the participant using a scale of 0 through 10, where 0 corresponded to minimal ability and 10 corresponded to complete ability. There are three specific hearing domains assessed:

- Speech hearing scale – This includes hearing speech in quiet and in noise, in one-on-one conversation and in groups/meetings.
- Spatial hearing scale – This includes hearing where sounds are coming from, distance, movement, and ability to segregate sounds.
- Qualities of sound scale – This includes ease of listening, naturalness, clarity, identification of different speakers, musical pieces and instruments, as well as everyday sounds.

Iowa Tinnitus Handicap Questionnaire

The Iowa Tinnitus Handicap Questionnaire was used to assess tinnitus. Tinnitus was assessed before and after the cochlear implant was turned on. There are 27 questions that fall into 3 factors:

- Factor 1 examines social, physical and emotional wellbeing.
- Factor 2 examines hearing abilities.
- Factor 3 examines an individual's view of tinnitus.

Understanding Speech in Noise – Speech Recognition Results

Comparison 1: Performance using a cochlear implant and normal hearing ear compared to performance before surgery

Cochlear compared performance before surgery to performance after 6 months of cochlear implant use. Before surgery, the participant used a hearing aid in the ear to be implanted and their normal hearing ear for testing. Six months later, the participant used their cochlear implant and their normal hearing ear for testing. During testing, speech was presented from a speaker in front of the participant. At the same time, noise was presented from a speaker that was on the side of the normal hearing ear. Twenty three participants are included in this analysis.

Results showed that after 6 months of cochlear implant use there was an improvement. Participants had an average improvement of 2.8 dB.

Comparison 2: Performance using a cochlear implant and normal hearing ear compared to the normal hearing ear alone

Cochlear compared performance for participants using a cochlear implant and the normal hearing ear to performance in the normal hearing alone. Both tests were completed after the participant had used a cochlear implant for at least 3 months. When normal hearing alone was measured, the cochlear implant was off. Thirty eight participants are included in this analysis.

Results showed that there was improvement when a cochlear implant was used for speech understanding in noise. Participants had an average 1.5 dB improvement.

To help determine the proportion of participants with 6 months of cochlear implant use who are performing to the same as or better than before receiving a cochlear implant, the following comparisons are provided.

When performance before cochlear implant surgery is compared to performance after cochlear implant surgery, it is found that:

- 18/23 (78%) participants demonstrated a clinically meaningful preoperative to post-activation improvement of 1.0 dB (10% improvement), with a range of -1.2 dB to -9.5 dB, (note that a negative score connotes improvement),
- 3/23 (13%) participants scored equal to their preoperative performance, with a range in difference scores from 0.0 dB to +0.8 dB, which suggests no change, and
- 2/23 (9%) participants had a difference score ≥ +1.0 dB, consistent with a decline in performance.

When performance with the cochlear implant on was compared to performance with the cochlear implant off, it was found that:

- 25/38 (66%) participants demonstrated a clinically meaningful improvement with cochlear implant on of 1.0 dB (10% improvement) with a range of -1.0 dB to -6.2 dB, (note that a negative score connotes improvement),
- 11/38 (30%) participants scored equal to their normal hearing when the cochlear implant was on, with a range of difference scores from -0.7 dB to +0.8 dB, which suggests no change, and
- 2/38 (5%) participants had a difference score > +1.0 dB, consistent with a decline in performance.

In the clinical study, 8/38 (21%) experienced a decrease in speech understanding when speech was presented in front and noise was directed to the cochlear implant side. This suggests potential interference with the hearing from the normal ear and the hearing from the cochlear implant. Additionally, a few published studies (Speck et al., 2020, Deep et al., 2021, and Zeitler et al.,2019) reported that very few people with SSD stop using their cochlear implant. Given these results, it is reasonable to conclude that a small number of recipients experience interference.

Cochlear performed subgroup analyses to see if subgroups were different for the co-primary effectiveness endpoints. The following subgroups were examined:

- Gender
- Median age at implant
- Median duration of hearing loss at baseline
- Cause of hearing loss
- Evaluation interval
- Median baseline/preoperative speech in noise score
- Median baseline CI off speech in noise score
- Preoperative pure tone average (PTA)

Results indicated that the only characteristics that affected the primary endpoint 1 outcomes were:

1. Duration of hearing loss.

   The mean score for participants below or equal to the median duration of hearing loss of 2 years was significantly poorer than that for duration of hearing loss above 2 years.

2. Cause of hearing loss.

   It was found that those participants with a sudden sensorineural hearing loss performed significantly better than those with any other cause for hearing loss in the participants.

3. Pre-operative speech in noise score.

   It was found that those participants who had poorer preoperative speech in noise scores demonstrated significantly greater improvement.

For coprimary effectiveness endpoint 2 outcomes, the only baseline characteristic that affected the endpoint was when speech was presented from the front and noise was directed to the normal ear while the cochlear implant was off. Participants with poorer speech understanding in noise in this condition demonstrated significantly more improvement when measuring listening with both the cochlear implant and normal ear.

There were no differences in the consistency of primary endpoints across investigational sites.

Localisation

Twenty four participants had localisation data available for analysis. Data showed an improvement when a participant had a cochlear implant turned on, compared to when the cochlear implant was turned off. Participants were more able to accurately identify the sound source. There was an average improvement of 18.8 degrees.

Patient reported outcomes

Speech, Spatial, and Qualities of Hearing Scale (SSQ)

There were 14 participants who completed the SSQ before surgery. There were 10 participants who completed it after 6 months of cochlear implant use.

The Speech Hearing Scale addressed how well participants could hear and understand speech in various quiet and noisy situations. These included one-on-one conversations and speech in small and large groups of people.

- After 6 months of cochlear implant use, scores on the speech and hearing rating scale increased by an average of 2.09 points.

Spatial Hearing Scale

The Spatial Hearing Scale addressed how well participants could judge directionality of sound. This included where a sound was coming from, how far away the sound was, and movement of sound (e.g., whether a sound was coming toward them or away from them).

- After 6 months of cochlear implant use, scores on the spatial hearing rating scale increased by an average of 2.38 points.

Sound Qualities Scale

The Sound Qualities Scale addressed how well participants could separate and sort out sounds and how well they could recognise different sounds. It also addressed how clear or natural sounds were, and how much effort listening required.

- After 6 months of cochlear implant use, scores on the sound qualities scale increased by an average of 1.04 points.

A total score for the SSQ, which reflected the average scores over the 3 subscales, was also reported at each test interval.

- After 6 months of cochlear implant use, total scores on the SSQ increased by an average of 1.84 points.

There was a significant average improvement on each subscale. The largest difference was found on the Spatial Hearing subscale.

Iowa Tinnitus Handicap Questionnaire

Data were available for 10 participants. After 6 months of cochlear implant use, 6 of the 9 (67%) participants with scores reported an improvement in their tinnitus. After 12 months of cochlear implant use, 7/10 (70%) participants reported an improvement in their tinnitus.

Children

As of February 2020, Cochlear performed a systematic literature search in PubMed and EMBASE databases to assess effectiveness of implantation with a Cochlear Nucleus cochlear implant in infants aged between 9 months and 12 months. A multi-step literature search process resulted in a final set of studies (49 peer-reviewed articles) representing additional relevant research on cochlear implantation for patients less than 12 months old. Effectiveness outcomes from the literature data support that implantation before 12 months of age supports paediatric cochlear implant recipients' improved speech and language development.

Notes

Hear now. And always

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