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# SURGICAL PROCEDURES AND BIOLOGICAL SAFETY IN COCHLEAR IMPLANT

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## Introduction

Cochlear implants are electronic devices that contain a current source and an electrode array that is implanted into the cochlea. Electrical current is then used to stimulate the surviving auditory nerve fibers (Wilson, 2000). Cochlear implantation has been an approved method of treating profound, bilateral, sensorineural hearing loss for persons since the mid-1980s (House and Berliner, 1991). Although the original cochlear implants were single channel devices, there are now several commercially available, multichannel cochlear implant systems. Additionally, over the course of the last two decades, technological developments in cochlear implant design have yielded substantial gains in spoken word recognition for the average multichannel cochlear implant user. Along with advances in engineering and speech processor design have come changes in the criteria for cochlear implant candidacy. For example, initially only adults with postlingual profound deafness were considered suitable candidates for cochlear implantation; now, audiometric thresholds are no longer a primary determinant of cochlear implant candidacy for postlingually deafened adults. Similarly, congenitally deaf children initially were not considered suitable candidates for multichannel cochlear implantation. When implantation of children was approved by the FDA it was limited to children 2 years of age and up; now, the FDA has approved the use of multichannel cochlear implants in prelingually deafened children as young as 12 months of age, and many children younger than 12 months of age have been implanted off protocol.

## Surgical Procedures

Of single-channel implants, the one designed by House and Urban has been the most widely used since it was first introduced in 1972. A robust electrode design, simple speech processing

strategy, transcutaneous transmission of the signal and straightforward, safe surgical technique enabled this implant to be developed early and manufactured relatively easily. By the early 1980s, once it had been proved by extensive use in adults, it was considered safe to apply the device to children. (Cochlear Implants – A Practical Guide by Huw Cooper, 1991; chapter 11 - John M. Graham & chapter 12 – Clark, Franz, Pyman & Webb).

The buried electronics are placed on the squamous temporal bone and platinum wire connects them with a ball electrode placed in the scala tympani or just outside it. An indifferent electrode is placed deep to the temporalis muscle or in the orifice of the eustachian tube where it enters the middle ear.

**Multichannel Implants**

The aim of a multichannel cochlear implant is to take advantage of the spatial representation of frequency in the cochlea so that spectral information in speech can be used to assist patients who are profoundly deaf or totally deaf to communicate (Cochlear Implants – A Practical Guide by Huw Cooper, chapter 12 – Clark, Franz, Pyman & Webb). To do this it is preferable to place an electrode array within the scala tympani of the basal turn of the cochlea. There is some biological evidence to indicate that it is better that this electrode array is free fitting (Sutton, Miller & Pfingst, 1980). It is also desirable that it is flexible, smooth & tapered so that it may be withdrawn and another reimplanted if necessary at a later stage (Clark et al., 1987b, Jackler, Leake & McKerrow, 1989). The electrode array is connected to a receiver-stimulator package & the package receives information transmitted through the intact skin by a radio frequency link.

**Earlier implant techniques**

**Preparation and incision**

For the UCH/RNID implant the patient is prepared for postaural mastoidectomy. There is minimal shaving of the scalp, 3 cm behind and above the pinna. Before an incision is made, the intended position of the receiver coil is marked on the scalp using a template. The coil must be well clear of the pinna itself to allow easy placement of the transmitter coil later, when the implant is in use; this is particularly important in patients who wear spectacles.

The incision is in or just behind the postaural sulcus. A generous amount of temporalis fascia is harvested, which will later be used to cover the electrode cables. Using an elevator, the temporalis muscle and underlying periosteum are lifted from the squamous part of the temporal bone to create a pocket for the receiver coil, between the periosteum and the bone.

The sulcus incision heals very reliably and lies anterior and inferior to the receiver coil and well in front of the part of the active electrode cable that passes from the coil over the rim of the mastoid bowl. All the superficial foreign material is thus placed safely behind the incision and under the well vascularized scalp.

The technique recommended for the House implant and the Vienna single-channel device places the incision 1 cm behind and above the coil with a large postaural flap and scalp shave. Once the flap has been raised, for the House device, part of the temporalis muscle is excised and a flat seating on the squamous temporal bone is prepared for the coil, using a 'butterfly' reaming drill.

**Mastoidectomy**

A cortical mastoidectomy is performed, and a generous posterior tympanotomy is cut, to expose the whole of the round window niche.

It is sometimes possible to preserve the chorda tympani in the dissection, but this should not compromise adequate surgical access. When the round window niche is posteriorly placed, it is safer to identify and skeletonise the vertical part of the facial nerve on the rim of the posterior tympanotomy; identifying the nerve in this way allows the surgeon to drill away the deeper margin of the tympanotomy, beyond the nerve, with greater confidence, to expose a posteriorly placed round window niche. Removal of the mastoid tip cells is not desirable. If the cortical mastoid cavity is kept fairly small, the cable for the active electrode spirals down its wall before passing through the posterior tympanotomy and approaching the round window membrane from below.

**Round window: electrode placement**

The House implant was originally deigned to pass 24 mm into the scala tympani; however, this distance was eventually reduced to 6 mm, mainly to reduce the risk of damage to the basilar membrane. The electrode of the Vienna single-channel implant can be placed outside the cochlea, on the round window membrane, or just inside the scala tympani.

Recently, intracochlear placement has proven preferable on the grounds that this gives a superior postoperative result (K. Burian, personal communication).

Similarly the UCH/RNID implant was designed to lie outside the cochlea, on the round window membrane, except in cases of bony obliteration of the round window.

Since 1989, it has also been found preferable to place the electrode tip a few mm inside the scala tympani in ears with no detectable residual hearing, but not in children and not in patients implanted for tinnitus suppression.

For extracochlear placement, where the round window niche is of normal size, no drilling of the niche is needed. The electrode cable passes through the inferior part of the posterior tympanotomy and approaches the round window membrane from below, so that the natural spring of the electrode cable holds the tip of the electrode securely in the round window niche.

Obliteration or narrowing of the round window niche will involve drilling with a diamond burr. There should only be enough drilling to allow access for the electrode. If there is no identifiable round window niche, the surgeon must drill in an anterior direction until either the endosteum of the scala tympani is encountered or the scala itself entered.

Any leakage of perilymph is sealed with a free graft of temporalis muscle. In view of the nature of the diseases causing profound acquired hearing loss, obliteration or narrowing of the round window niche is relatively common and may occur in up to 50% of cases.

For intracochlear placement, the round window membrane is exposed by drilling away the bony tip of the round window niche to which the lateral and superior rim of the membrane is attached.

A small diamond drill is used and care taken not to allow the rotating shank of the burr to touch and exposed vertical portion of the seventh nerve. For the same reason, the drill should not rotate when being passed through the posterior tympanotomy (House, 1982).

The anterior rim of the round window is displaced to allow the electrode to be passed into the cochlea. At present, intracochlear electrode placement technique is commonly used than the extracochlear placement as it results in more effective nerve stimulation.

House (1982) observed that, where the basal turn is obliterated by new bone formation, this new bone is very white in color and can be distinguished from the surrounding otic capsule. It may then be possible to drill along the core of white bone which may eventually lead to a patent part of the scala tympani.

A free graft of temporalis muscle is packed around the electrode cable where it enters the cochlea, to reduce the risk of perilymph leak and of infection entering the cochlea from the middle ear.

**Fitting the implant**

The receiver coil of the UCH/RNID implant is mounted on a square of thin, reinforced Silastic sheeting. This sheeting is trimmed, leaving a flange 0.5 - 1 cm inferiorly, to take an anchoring suture.

The coil is then slipped up under the temporalis muscle and periosteum. Irregularities on the surface of the squamous temporal bone are identified, the coil removed and the bone drilled smooth to allow the coil to lie flat without rocking. The tip of the active electrode is then carefully placed in the round window niche, with the electrode cable spiralling down the walls of the mastoid cavity.

The coil of the implant can be shifted in its pocket under the temporalis muscle to allow the cable to lie in a stable position.

After the cable to the active electrode leaves the receiver coil, a shallow trough is cut into the bone where the cable crosses the superior rim of the mastoid cavity. This draws the cable medially, as soon as it leaves the coil, and protects it from being moved by external pressure or by contraction of the temporalis muscle.

This trough can be undercut in the direction of the natural spring of the cable to hold the cable more securely.

A shallow groove is also drilled to accommodate the cable to the indifferent electrode; this cable ends in a flat plate which is tucked under the temporalis muscle towards the root of the zygoma.

The active electrode cable and the Silastic sheeting attached to the receiver coil are each anchored with a silk stitch to 'rat-bite' holes drilled in the mastoid bowl and squamous temporal bone respectively.

Before finally anchoring the implant it is important to check:

1. The position of the coil in relation to the pinna and the site previously marked on the scalp;
2. The position of the active electrode tip in the round window niche; and
3. That the active electrode cable sits comfortably in the mastoid bowl.

After tying the two silk stitches, the coil is further secured to the squamous temporal bone with Histoacryl glue. The electrode cables are covered by temporalis fascia. Free grafts of temporalis muscle can be used to support the active electrode cable in the mastoid cavity and a tiny piece of temporalis muscle is finally placed around the ball electrode in the round

window niche, taking care that this does not form a bridge of soft tissue between the electrode and the horizontal part of the VIIth cranial nerve.

The wound is closed in layers without a drain and a pressure dressing is applied for 48 hrs. If the ear canal skin was partly elevated, a bismuth iodoform paraffin paste (BIPP) pack is left in the canal for 7 days. The line of the postaural scar lies anterior to the superficial parts of the implant and reduces the risk of exposure should healing of the wound be delayed.

For the House implant, a circular shallow bed is drilled on the squamous temporal bone, and part of the temporalis muscle is excised to reduce the tissue between the buried receiver and the external coil. The receiver is prevented from slipping by the ring of its bed cut in the bone and by a single suture across its diameter secured to a pair of 'rat-bite' tunnels in the bone on either side of its bed.

**Frachet technique:**

There have been preliminary reports of a technique described by Frachet in Paris, using a gold 'cupula' electrode placed like a thimble on the tip of a stapedectomy piston, with wires passing from this gold electrode through the mastoid cavity and emerging through the skin of the ear lobe (Frachet et al., 1989).

This percutaneous connection uses relatively little power, provided by miniature batteries which can therefore be contained in an ear-level speech processor. It remains to be seen whether this ingenious technique will be free from complications associated with the percutaneous wiring.

**Advanced Surgical Techniques**

**Anesthetic & Preoperative preparation**

The anesthetist should be aware that the child may also have a syndrome associated with deafness that could lead to anesthetic difficulties.

Enquire specifically if the child has had a history of fainting or seizures as this may indicate the presence of Jervell & Lange-Nielsen syndrome. An EEG is needed to exclude this syndrome, which can lead to fatal cardiac irregularities developed during surgery.

Certain musculoskeletal abnormalities such as Klippel-Feil syndrome may result in difficulties with intubation, and an X-ray is required to determine the degree of fusion of the cervical vertebrae.

Either gaseous or intravenous induction of an anesthetic can be used & after the child has been induced in the anesthetic room, the hair is clipped and shaved over an area to provide a margin of at least 25 mm around the incision to ensure sterility.

The length of the operation is normally from 2 to 3 ½ hrs, and the total time taken up to 5 hrs. Fluid replacement will be needed over this period. Intravenous antibiotics are administered during and after the procedure and then orally when tolerated.

The body temperature is usually well maintained as the child is completely draped except for the wound, so no active heating is required unless the ambient temperature is low. In this case, forced air warming is preferred.

Finally, to reduce bleeding during surgery, maintain an adequate depth of anesthesia, mild hypotension, and mild hypocapnia using controlled ventilation.

The CI surgery should be done with care to prevent infection. This requires good aseptic procedures and routine. When implanting a foreign body there is an increased risk of postoperative infection, and with cochlear implants this has occurred in 1.2 % of adults and 0.73 % of children (Hoffman & Cohen, 1995).

**Incision & preparation of flaps**

After demarcating the incision, the skin & deeper tissues are injected with a solution containing a vasoconstrictor to reduce bleeding. A steridrape is applied over the exposed skin and side drapes. The incision is made through the steridrape, skin & subcutaneous tissue down to the deep fascia. This is preferably done with a scalpel rather than cutting diathermy in line with good plastic surgical principles to facilitate skin healing.

The flap of skin and subcutaneous tissue is dissected inferiorly to expose the deeper tissues overlying the mastoid & inferior portions of the parietal and occipital bones.

An anteriorly based flap of deep fascia and periosteum is then created and dissected anteriorly to the EAM. In elevating the deep fascia and periosteal flap, surgical care should be taken in dissecting inferiorly to avoid cutting the facial nerve and the occipital artery or a mastoid emissary vein.

Some mastoid emissary veins can cause marked blood loss, and should always be looked for in the preoperative X-ray.

**Mastoidectomy & Posterior Tympanotomy**

When the landmarks of the mastoid bone are exposed and identified, and cartilaginous auditory canal dissected forward, the cortical mastoidectomy is commenced.

Using a large cutting burr, the cortex of the mastoid superior and posterior to the external meatus is removed. The excavation is deepened and air cells are removed superior and posterior to the meatus.

Care should be taken while drilling superiorly not to expose dura when there is a low lying middle fossa.

Drilling close to the posterior and superior walls of the bony meatus will ensure the safest approach to the mastoid antrum, by minimizing the risk of damaging the facial nerve, especially when there is a poorly pneumatized mastoid.

When the mastoid antrum is exposed, identify the horizontal semicircular canal and the short process of incus, which are the superior landmarks for the vertical section of the facial nerve. Extend the excavation of mastoid air cells inferiorly initially to the floor of the ear canal.

It is important to identify the facial nerve before making the posterior tympanotomy because it can swing laterally in a third of cases where it is at risk when extending the posterior tympanotomy inferiorly and the chorda tympani may be taken as the facial nerve, in which case the dissection will enter the ear canal.

If the bone is sclerotic and the nerve is not readily identified, a diamond paste burr should be used as it is less likely to damage the nerve if it is inadvertently exposed. However, good irrigation is important to prevent overheating of the nerve.

It is helpful with difficult posterior tympanotomy to drill the bone at the junction of the bony meatus and floor of the antrum to expose a small posterosuperior segment of the annulus of the TM. This landmark will assist in defining the boundaries of the facial recess for the completion of the posterior tympanotomy.

The boundaries are the fossa incudis superiorly, the chorda tympani laterally and anteriorly, and the facial nerve medially and posteriorly. Identifying these boundaries will help ensure the middle ear is exposed without damaging the facial nerve or entering the EAC.

Commencing the posterior tympanotomy and entering the middle ear is best done by following “sentinel” air cells lying inferior to the floor of the mastoid antrum into the middle ear. However, these cells are not always present, especially when the mastoid is sclerotic.

When the posterior tympanotomy is partially completed, identify the round window niche. Sometimes the niche is obliterated due to adhesions or with new bone following meningitis. In which case the center of its superior margin can be located on average 1.5 mm below the center of inferior margin of the oval window.

An air cell inferior to the cochlea (hypotympanic air cell or tunnel of the cochlea) may appear very similar to the round window, and has been implanted on occasions by mistake. When the posterior tympanotomy has been completed, an adequate view should be obtained of the round window and the promontory anterior to this, so that a cochleostomy can be completed.

**Creation of a bed for the Receiver-Stimulator**

For the receiver-stimulator, there is a need to drill a round or an ovoid bed, respectively. The bed is made in the mastoid bone and mastoid angle of the parietal bone. The bed is fashioned initially with a cutting burr, and then completed with a diamond paste burr.

A template provided with the device assists in making this the right size. A diamond paste burr should be used when approaching dura and when dura is exposed to minimize the risk of tearing it. After the bed is created, drill a gutter anteriorly into the mastoid cavity to accommodate the lead wire assembly.

**Cochleostomy & Electrode insertion**

After completing the bed for the receiver-stimulator, preparations are then made for making the cochleostomy and inserting the electrode array. Gowns and gloves should be changed and the site is irrigated with a dilute antibiotic solution to minimize the risk of introducing infection into the cochlea.

It is now more usual to carry out a cochleostomy rather than incise the round window membrane and insert the electrode through it. The cochleostomy is made 1 mm anteroinferior to the round window.

In making the cochleostomy it is preferable to use a small diamond paste drill and drill from below upward. In this way there is less risk of any trauma to the spiral lamina which would lead to loss of auditory nerve fibers.

When the scala tympani is affected by new bone following labyrinthitis, it is often soft enough to remove with a needle and sucker but may require some burring.

The removal of the bone should continue for up to 8 mm from the round window region, not the cochleostomy, otherwise any further penetration could risk entering the internal carotid artery. The bone over the scala tympani can also be drilled to make a gutter.

After making the cochleostomy, the Silastic sheath slid over the array to protect the electrode when the tie is made.

When inserting an electrode array in an infant also remember the orientation of the cochlea within the temporal bone may appear different from that of the adult. The basal turn will often appear to pass more superiorly, and be rotated more medially than in the adult. A specially designed claw is used to direct the tip of the electrode to the cochleostomy opening, and then to ease the electrode along the scala tympani by stroking it gently forward.

The electrode should be inserted to the point where slight resistance is felt. Is it is pushed too hard; the tip may penetrate the basilar membrane or buckle in the basal turn near the round window which could cause a fracture of the spiral lamina.

In the uncomplicated case the electrode array can usually be inserted for a distance of 21 mm on average. The range is 15 mm to 27 mm. if an adequate depth of insertion has not been obtained before resistance if felt, this can often be rectified by slightly withdrawing the electrode and rotating it 90˚ counterclockwise in the right ear or clockwise in the left, before further advancing it.

A deeper insertion has also been reported if the electrode array is coated with Healon, which reduces the friction between the array and the outer wall of the scala (Donnelly et al., 1995; Laurent, Anniko & Hellstrom, 1991; Lenhardt, 1993).

When the electrode insertion is completed it is stabilized, and the platinum tie twisted around the protecting sheath to hold it in place or it is inserted into the titanium clip. A small fascial graft taken from the temporalis region is placed around the electrode entry point. This can provide significant protection from an infection from otitis media passing around the electrode entry point (Clark & Shepherd, 1984; Dahm et al., 1995).

**Fixation of package & wound closure**

The receiver-stimulator (CI-24M) can be flexed and bent at its center so that it can lie flat against the skull of an infant or young child. This is a distinct advantage over packages that are completely rigid.

Prior to the fixation of the package, some surgeons will have drilled small tunnels in the bone on either side of the package bed to place ties to hold the receiver-stimulator in place. In an infant this is not a good procedure as the bone is thin, the drill may abrade the dura, and bleeding could occur and be difficult to control.

In children it is best to tie the package down with ligatures that are placed through the temporalis and deep fascia, and also to stitch the anteriorly based fascial flap back over the package. It is important to release the retractors before this is done.

When the package has been fixed in its bed, it is useful to stimulate the package and record compound action potentials (CAPs), EABRs, and electrode impedances. This will indicate the placement is satisfactory, the auditory nervous system is being stimulated, and provide some baseline data on the thresholds that may be appropriate when the child is stimulated postoperatively.

It is necessary to take a lateral or Stenver's plane X-ray view in the operating room to see if the electrode has been placed satisfactorily within the cochlea.

The wound is then closed in layers and a firm dressing applied.

**Special problems during Surgery**

Hemorrhage is likely to be a problem only if there is a large mastoid emissary vein. This should always be looked for on the X-rays. Bleeding can usually be controlled with bone wax, crushed muscle, or absorbable packing. In a severe bleed, absorbable gauze may have to be stitched in place to apply compression and the operation abandoned.

A perilymph gusher is managed by letting fluid drain off before inserting the electrode and then sealing around the entry point with fibrous tissue or absorbable packing. Perforation of the tympanic membrane or tearing of dura should be repaired at the time of surgery with fascia.

**Biological Safety**

It is important to ensure that the materials used for the electrode array, lead wire and receiver-stimulator used by each cochlear implant manufacturer are biocompatible. To do this for the cochlear device, candidate materials were implanted in the subcutaneous tissue and muscle of the experimental animal and, in the case of the material for the electrode array in the cochlea.

It is also essential that the particular materials used in fabricating devices are tested because their composition may differ or be affected by the manufacturing process.

The biocompatibility of the materials used in the cochlear banded array has subsequently been confirmed in a patient who had an implant and died from unrelated causes (Clark et al., 1988).

The electrode array should be atraumatic and, in particular, there should be no damage which could lead to a significant loss of neural elements. In addition, there should be minimal tissue reaction, e.g., new bone growth, because this may result in reduced performance over time. Fractures of the spiral lamina are one of the causes of new bone formation (Simmons,

1967; Clark, 1973, 1977; Clark, Cranz & Nathar, 1975; Schindler et al., 1977; Sutton, Millar & Pfingst, 1980).

In another experimental study, it was shown that a free fitting electrode caused less histopathological reaction than a moulded array (Sutton, Millar & Pfingst, 1980). Furthermore, a moulded array cannot readily allow for variations in anatomy and pathology.

The cochlear multi-electrode array has been inserted in human temporal bones to determine the presence of any trauma. Shepherd et al. (1985 a) examined the bones histologically and found that a tear of the spiral ligament occurred quite commonly at a point approx. 10 mm from the round window.

It was also found that a tear of the basilar membrane or a fracture of the spiral lamina only occurred if force was applied to the electrode array after resistance was felt (Clark et al., 1988).

Further studies on the human temporal bone were also carried out to reduce the chance of the electrode tip perforating the basilar membrane. It was found that if the electrode array was rotated (anticlockwise for the right and clockwise for the left ear) this would direct the tip of the electrode down and away from the basilar membrane (Franz & Clark, 1987). This is a procedure now recommended to help ensure the atraumatic insertion of the cochlear electrode array.

It has been shown that single electrodes made from wire with a diameter of 0.21 mm can cause trauma when inserted for a distance of about 20 mm (House & Edgerton, 1982; Johnsson, House & Linthicum, 1982).

A comparative study of cochlear multi-electrode array, and the thicker single wire has shown that the multi-electrode array, which is made from thinner wires is 10 times more flexible and will buckle with a force that is 25 times less than that required to make the single wire buckle (Patrick & MacFarlane, 1987).

**Otitis Media:**

The incidence of OM in children implanted with a single channel intracochlear electrode was not higher than normal, and that none developed meningitis or other evidence of inner ear infection (House & Luxford, 1985).

Studies on the experimental animal have shown that the spread of infection from staphylococcus aureus or streptococcus pyogenes is limited by the tissue at the electrode entry

point and by the sheath that develops around the electrode (Clark & Shepherd, 1984; Franz, Clark & Bloom, 1984, 1987a; Brennan & Clark, 1985; Cranswick et al., 1987).

The effect of different types of seals at the electrode entry point in preventing the spread of Streptococcus Pneumoniae infection from the middle ear to the inner ear is presently being studied (Berkowitz et al., 1987; Shepherd et al, 1989).

In carrying out multi-electrode intracochlear stimulation, it is very important that the electrical stimulus parameters do not lead to damage of nerve fibers or ganglion cells. Studies have shown that with pure platinum the charge density should be less than 50 μC/ sq. cm per phase (Agnew et al., 1981; Walsh & Leake-Jones 1982).

Furthermore, it is essential that there be no charge imbalance between pulses, otherwise there will be a direct current (d.c.) which can damage neurons.

The stimulus parameters used do not damage the neural elements or electrodes for periods of up to 2000 hrs of continuous stimulation (Shepherd, Clark & Black, 1983; Shepherd et al., 1985b).

In addition, the temporal bone of a patient who died from cardiac disease has shown no adverse effects after 10000 hrs of stimulation (Clark et al., 1988).

**Asepsis:**

The prevention of infection is important when implanting any foreign body in a patient, and this applies to single and multi-channel implants as well as to the pedestal or plug and socket for percutaneous stimulation.

If there are pathogens on the skin in and around the ear as well as in the upper respiratory tract, treatment is instituted to remove them. The operating room should meet high standards of asepsis and this includes the use of an air filtration system.

In preparing the area, it is necessary to shave the scalp for at least two-thirds of the side involved. It is essential to leave a 6-mm margin between the wound edge and the hair. The area is prepared by the application of antiseptic solution and sterile plastic drapes are then applied.

Antibiotics are given parenterally at the beginning of the operation and for one day postoperatively. They are continued parenterally or given orally if there is an infection. Amoxycillin and Cloxacillin are used. Also the wound should be irrigated with a dilute solution of Amoxycillin and Cloxacillin (Cochlear Implants – A Practical Guide by Huw Cooper, chapter 12 – Clark, Franz, Pyman & Webb).

**Magnetic Resonance Imaging (MRI)**

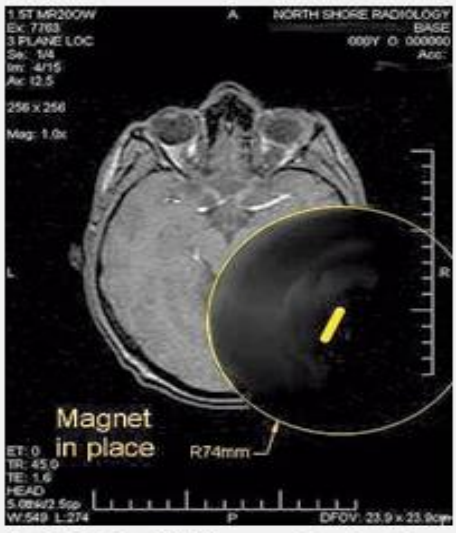
**Importance of MRI compatibility**

MRI uses a very powerful magnet to provide detailed images of a person's internal organs and tissue. It is often used to provide early detection of many different conditions so that treatment can be more effective.

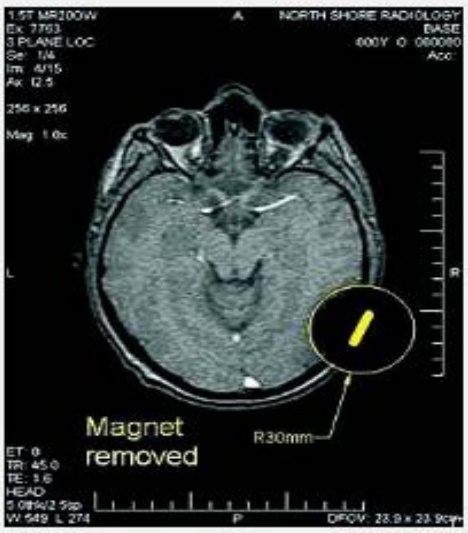
As implanted medical devices can interfere with MRI scans, it's important to consider the compatibility of this increasingly popular technology with your choice of cochlear implant.

**How does a Cochlear Implant affect MRI?**

The internal implant contains a magnet, which holds the external sound processor coil in place. When placed in an MRI scanner, this magnet can cause a blur or 'artifact' over the medical image, which may hinder the Doctor's ability to make an accurate diagnosis of brain scans. As a quarter of all MRI scans are performed on the brain, having the flexibility to remove the internal magnet if required is an important consideration when choosing a cochlear implant.

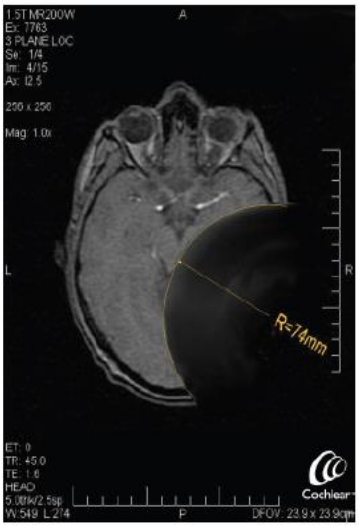



A 1.5 Tesla MRI scan of a Nucleus implant recipient with the magnet in place. The yellow line represents implant placement. The implant magnet creates a large blur on the image, hindering an accurate diagnosis.

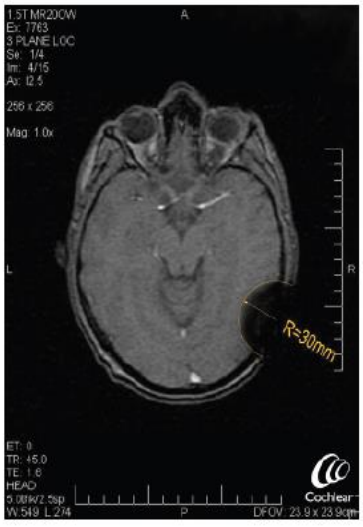



A 1.5 Tesla MRI scan of a Nucleus implant recipient with magnet removed. The yellow line represents implant placement. The blur on the image is significantly reduced and does not interfere with diagnosis.[2]

With the magnet in place, shadowing may extend as far as 11cm or 4.3 in. from the implant




With magnet removed, shadowing may extend as far as 6 cm or 2.5 in. from the implant




This means that recipients may be limited by older MRI technology or may need their entire implant removed, even for a scan of a different part of the body such as the knee.

Implant removal requires surgery. Once an implant is removed, it cannot be re-used, meaning a new implant is required. Recipients will also require further rehabilitation once the new implant is in place.

**Importance of compatibility with high strength MRI**

1.5 Tesla strength MRIs are considered standard at present; however 3.0 Tesla scans are becoming increasingly popular due to their superior image quality. With the continuing trend towards higher strength MRIs, the compatibility of cochlear implants with MRI is an important lifetime decision.

MRI compatibility differs between cochlear implant manufacturers. Nucleus implants from Cochlear are approved for MRI scans at 1.5 Tesla with the internal magnet in place and 3.0 Tesla with the magnet removed.

**Removing the magnet *before implantation***

If a new recipient has a condition that requires future MRI examinations over 1.5 T soon after implantation, the magnet may be replaced with a non-magnetic titanium plug before the device is implanted.

**Removing the magnet *after implantation***

Remove the magnet in sterile conditions, using general or local anesthetic: Make a small incision, ensuring there is good access to the magnet. The incision must be to the side of the

implant (not over the coil). Cut through any fibrous growth around the implant and expose the magnet. Use an elevator (or similar instrument) to lift the lip of the silicone recess around the magnet and remove the magnet. If a retaining suture runs across the magnet, move the suture out of the way.

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