LES PATIENTS MUNIS D'IMPLANTS COCHLÉAIRES EN SALLE D'OPÉRATION – ENJEUX ET PREOCCUPATIONS

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RÉSUMÉ

Les normes de sécurité pour les patients munis d'implants cochléaires sont difficiles à trouver. En fait, ces dernières sont en constante évolution à mesure que sont diffusés des renseignements supplémentaires. Cet article vous propose un aperçu des philosophies et des lignes directrices actuelles pour la plupart des interventions médicales/chirurgicales, avec une importance particulière accordée à l'environnement des salles d'opération, tel qu'indiqué par les trois fabricants autorisés à commercialiser les implants cochléaires au Canada.

INTRODUCTION

Le personnel des blocs opératoires rencontrent de plus en plus de patients munis d'implants cochléaires étant donné que les dispositifs sont plus répandus.[1,2] Les implants cochléaires nécessitent en tout temps un traitement soigneux, plus particulièrement en salle d'opération. À défaut de comprendre les risques et de minimiser les précautions, les patients pourraient souffrir d'une incapacité grave. Le but de cet article est de fournir de l'information de base sur ce qu'est un implant cochléaire et de résumer les recommandations actuelles quant à la sécurité des patients munis d'implants cochléaires en salle d'opération et en milieu hospitalier. Cet article ne traite pas de la chirurgie pour les implants cochléaires, des appareils de correction auditive implantables ni de tout autre type d'implants auditifs.

Les normes de l'AIISOC relatives à cet article figurent dans la publication Normes, lignes directrices et énoncés de positions pour la pratique de soins infirmiers périopératoires autorisés (9e édition) de l'Association des infirmières et des infirmiers de salle d'opération du Canada (AISSOC) de juin 2009, section 3, p. 173, Normes 2.28 et 2.2.9.

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PATIENTS WITH COCHLEAR IMPLANTS IN THE OR – ISSUES AND CONCERNS

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ABSTRACT

Safety standards for patients with cochlear implants are difficult to find. Safety standards are, in fact, constantly evolving as more information becomes available. This article provides an overview of current philosophies and guidelines for most medical/surgical interventions, with emphasis on the operating room environment, as indicated by the three manufacturers authorized to market cochlear implants in Canada.

INTRODUCTION

Operating room staff are encountering more patients with cochlear implants as the devices are becoming more common.[1,2] Cochlear implants require careful treatment at all times and particularly in the operating room. Failure to understand the risks and take simple precautions can result in severe disability to patients. The purpose of this article is to provide basic information on what a cochlear implant is and to summarize the current recommendations for operating room and hospital safety for patients with cochlear implants. This article does not discuss cochlear implant surgery, implantable hearing aids or other types of implants used in the ear.

What is a cochlear implant and why is it special?

The cochlea changes sound into nerve impulses and is the organ in the ear responsible for hearing. For those with some types of hearing loss that are too severe to benefit from a conventional hearing aid a cochlear implant can be effective in restoring communication ability. The cochlear implant is the first device that can uses electrical stimulation to replace a natural sensation in humans.[2] A cochlear implant is not a hearing aid – it stimulates the inner ear differently. A hearing aid picks up sound with a microphone, amplifies the sound and stimulates the ear with louder sound. A cochlear implant picks up sound with a microphone but stimulates the cochlea with electrical impulses. The main difference between a cochlear implant and a hearing aid is that the implant stimulates the cochlea electrically rather than with sound as in a hearing aid.

Currently there are three companies authorized to manufacture and market cochlear implants in Canada. All three companies are marketing cochlear implants with similar components. Individuals with newer cochlear implants use a device that looks similar to a behind-the-ear hearing aid but patients with older models utilize a sound processor (also called a speech processor) worn on the belt. Cochlear implant systems have both internal and external components that are hard-wired together. The internal and external components communicate via FM electrical signals transmitted across the skin[2] (See Figure 1).

INTERNAL components are surgically implanted, not visible externally, and not removable without surgery.

1) The receiver system includes an internal magnet to match the external magnet in the transmitter system. The internal and external magnets on each side of the skin hold the receiver coil in place to pick up the FM electrical signals from the external transmitter; and
2) The implant itself is worn under the skin and conducts electrical stimulation down into the cochlea through many electrodes. The number of electrodes in the cochlea varies and may be up to 24.[3-7]

EXTERNAL components are removable and worn externally.

1) Microphone;
2) Sound processor containing a small computer to analyse sound from the microphone; and
3) Transmitter system that is a circular disk containing a magnet to hold the device in the proper place, and an electrical coil to transmit FM electrical signals across the skin to the internal components.

The implant itself must be placed surgically and requires the external components in order to function. If the external components are removed the patient cannot hear but the internal components are still present and at risk. This is important in the operating room.

Who uses a cochlear implant?

The general indication for cochlear implantation is sensorineural or nerve-related hearing loss that is too severe to benefit significantly from a hearing aid.[1] There are specific criteria from hearing test data and evaluations and these vary for adults and children. For some patients, inability to understand speech even when sound is loud enough is the main reason for the implant. Some

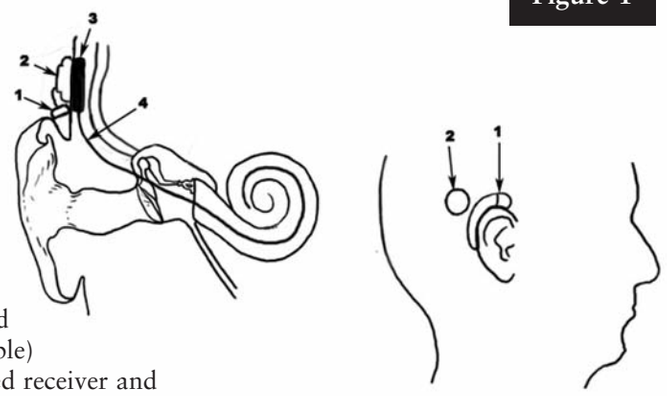
cochlear implant patients have rudimentary hearing.

Unlike with a hearing aid patient, if the external components of a cochlear implant are removed the patient is essentially deaf and no further communication is possible. This can be frightening for patients in the strange environment of the operating room. It is no longer possible for the patient to hear reassurances or explanations from the OR staff. For this reason the external components should be left in place as long as possible in the OR. External components should be removed only after, or just prior to, induction

TYPICAL COCHLEAR IMPLANT — **Figure 1**

Cochlear implants vary in appearance, but all currently have:

a) **External** (removable) components:
1) sound processor and microphone,
2) transmitter system and
b) **Internal** (non-removable) components; 3) implanted receiver and
4) electrodes entering the cochlea.



of general anaesthesia. Local or regional anaesthesia may present problems particularly if electrosurgery is being used near the implant area. Removal of the external device precludes auditory communication during the procedure. General anaesthesia might, in some situations, be preferable for patients with cochlear implants.

Preparation for and Risks of Surgery:

It seems wise to start in the pre-op holding area by having the patient show the staff how to remove and turn off the device. This is not difficult or dangerous although it can be strange to handle a device that attaches to a patient with a magnet. Individuals with cochlear implants are experts in the removal and care of their devices and are usually happy and willing to show care-givers what to do. They will want to be sure that the device will be removed before the possible use of electrocautery (or other situations that pose a risk, as outlined below). Individuals with cochlear implants are generally intelligent (reasonable cognitive ability is required to learn to use the device) and will usually be aware of some of the risks they face in surgery. As trauma, intubation, and other situations may impair the ability of the patient to communicate it is important that staff are also familiar with the device.

What situations are risky for patients with cochlear implants? Cochlear implants are electromagnetic devices so any medical intervention that involves magnetism or electrical stimulation, or any combination of both, requires careful consideration. Following the path of least resistance, an electrocautery current may travel down the electrode array. The large electrical energy burst will usually destroy any of the remaining delicate cochlear hair cells. This destruction may make the implant useless, or at best reduce its effectiveness, thus creating a disability for the patient. Bipolar cautery is less risky but still of concern. Radioactive isotopes (particularly gamma-rays), magnetic resonance imaging (MRI) scans, and any possible physical movement of the device also pose potential problems. Ordinary X-rays, blood work, and drugs are safe for implants.

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See Table 1 for the current recommendations for precautions during medical procedures.

SOME OF THE COMMON OPERATING ROOM OR MEDICAL INTERVENTIONS THAT MAY BE OF CONCERN FOR COCHLEAR IMPLANTS INCLUDE THE FOLLOWING:

Electrosurgery means the cutting or destruction of tissue by electrical current. The concern with electrosurgery is the powerful current needed to achieve haemostasis, or cut tissue, may flow down the implant into the cochlea and damage the remaining, delicate remaining functional cochlear tissue. With monopolar electrocautery, a current passes from an electrode to ground through the patient's body by the path of least electrical resistance.[8] A cochlear implant, as it is an electronic device, may provide the path of least resistance. For this reason, monopolar electrocautery should not be used above the clavicle in patients with cochlear implants. Bipolar electrocautery uses high frequency current passing between two poles that are typically close together. One manufacturer recommends that bipolar cautery not be used closer than 3 cm[6] and another manufacturer recommends it not be used closer than 1cm from the implant.[7,8] The grounding pad should be placed on the torso or thigh and the patient's head should be electrically isolated from the operating room table.[7] Chemical haemostatic agents, for example silver nitrate ($AgNO^3$), do not pose a risk to cochlear implants.

Ultrasound is the application of high frequency sound waves that are well above the frequencies detectable by human hearing (250-2000 kilohertz).[5] All sound, including ultrasound, consists of the movement of molecules so there may be concern with cochlear implants. Ultrasound waves are reflected off soft tissue structures to image tissues under the skin surface. Diagnostic ultrasound can be used to image structures such as pregnant uteri, abscesses, and soft tissue masses. Ultrasound is also used therapeutically, with much greater energy, to stimulate tissues as an adjunct to physical therapy, to clean teeth in dental labs, in lithotripsy to break up kidney stones, and in cataract surgery (phacoemulsification).[8] Ultrasound should not be used in the area of the implant site but is otherwise safe for cochlear implants.

Neurostimulation, in this article, refers to the implantation of an electrical stimulation device for the purpose of relieving pain.[9] Most often the hardware, electrodes, and batteries are surgically implanted. In other cases radio-frequency stimulators are implanted and have some external components. Electrical stimulation of a cochlear implant would be undesirable so neurostimulation should not be used over the implant site. Otherwise it is safe for patients with cochlear implants.

Diathermy. There are three types of diathermy in medical practice:

1) radio frequency (shortwave) diathermy;
2) microwave diathermy; and
3) ultrasound.

Diathermy produces heat in various locations in the body in order to treat a variety of conditions such as muscle pains, strains and arthritis. Shortwave diathermy is often used to treat areas with large tissue mass such as a hip. Microwave diathermy is applied to superficial areas because its waves do not penetrate as deeply as shortwave. Ultrasound diathermy is probably most commonly used to treat athletic injuries and in physiotherapy. In some countries the word "diathermy" may be used to refer to what is called "electrocautery" in North America.

Manufacturers' recommendations regarding diathermy differ. Two of the Canadian companies recommend that diathermy not be used at all in cochlear implant patients.[7,8] The third recommends that diathermy not be used within 3 cm of implant.[6] Ultrasound diathermy may usually be used below the clavicles.

Electroconvulsive therapy (**ECT**) refers to the delivery of a large electrical stimulus to the brain in order to treat psychiatric disorders such as depression. This electrical stimulus can be dangerous to cochlear implant devices and

cochlear tissue. All 3 manufacturers recommend avoiding the use of ECT on cochlear implant patients.[6,7,8]

Radiation therapy utilizes ionizing radiation to treat cancer. Ionizing radiation is dangerous for cochlear implants so the manufacturers recommend that radiation therapy not be used within 3 cm of implant.[10-12] Gamma knife therapy is of particular concern because gamma rays are destructive to the atomic grid of cochlear implants but are commonly used to treat acoustic neuromas. Acoustic neuroma is a common cause of deafness. Some models of cochlear implant are safer for radiation than others but they vary. When this therapy is to be used the gamma knife team should contact the manufacturer and discuss the situation for that model.

Radioisotope therapy is commonly used to treat some cancers, particularly with brachytherapy. Medical radioisotopes usually emit gamma-, beta-, or alpha-rays depending on the isotope[4] Gamma-rays can damage the implant. Do not use gamma-rays in the head and neck of patients with cochlear implants. Beta- or alpha-rays may be used if they are not brought physically close to the implant.[4,6-8] This concern would be particularly important in the use of radioisotope therapy, such as brachytherapy for tongue or head and neck tumours that may be delivered intra-operatively, because gamma-radiation is produced. The area of the implant should not be exposed to gamma-emitting situations such as placing an open brachy therapy radioisotope source, intended for another body area, near the ear. These situations would also violate accepted standards for handling isotopes.

Plasma knife / coblation involves the creation of a plasma field, near tissue, by applying radiofrequency electromagnetic stimulus to a bipolar electrode array adjacent to a conducting medium such as saline.[13] Recommendations for coblation are similar to bipolar electrocautery. One manufacturer recommends that coblation not be used within 3 cm[6] of the implant, the other two recommend a distance of 1 cm.[7,8] Tonsillectomies may be performed with coblation in patients with cochlear implants.[14,15]

Radiofrequency ablation refers to the use of a bipolar stimulation of tissue.[5] Tumours of the liver, and sometimes the kidney and bone, may be treated in this way using a minimally invasive procedure. Under CT-guidance a needle is inserted into the tumour. Then the tumour is heated by the bipolar electrodes. Radiofrequency ablation is also used to ablate tissue in the heart, such as abnormal conducting pathways, to correct arrhythmias. The device consists of a housed needle electrode delivered via catheter. One electrode is the needle and the other is the housing. In cochlear implant patients, radiofrequency ablation should not be used in the head and neck. The grounding pad should be on the torso or thigh.[16]

Magnetic resonance imaging (MRI) scans pose significant potential problems for patients with cochlear implants. The MRI is a strong magnetic device and the cochlear implant is an electromagnetic device so we should expect that MRI on a patient with a cochlear implant would result in problems. This is a challenge as the need for an MRI scan arises frequently because tumours such as acoustic neuromas cause deafness and the MRI is the most useful way to diagnose these benign tumours. Other brain pathology is often suspected in persons with profound hearing loss and can best be diagnosed with MRI. Manufacturers have been trying to solve MRI/cochlear implant problems with varying degrees of success. The best advice for routine use is to check with the manufacturer before each use. Most cochlear implants are safe in MRI scans up to 1.5 tesla.[17] Even if the MRI is safe, the magnet in the cochlear implant causes degradation of the MRI image up to 5 cm around the implant. Some, but not all, models have surgically removable magnets.[6,17-23]

Usually the patient is well aware of the manufacturer and type of implant, but situations could arise where the patient is unable to communicate this information. A simple lateral skull X-ray may help locate this information as many implants are designed so that information on the implant can be read on an X-ray.[6]

CONCLUSION:

In summary, cochlear implants should not be feared but they should be understood. They are the first of many high-tech devices that more patients are now utilizing. For many people they are wonderful devices that add to the quality of life. Thoughtful consideration in the areas of device care and safety may prevent a serious misfortune. As with everything in the operating room, common sense is important in this area. There may be unanticipated situations where precautions are unknown. Knowledge changes over time so it is important to always err on the side of caution in order to prevent a serious complication.

Further information on this topic can be found at www.medel.com, www.advancedbionics.com and www.cochlear.com.

Table 1 SUMMARY OF OPERATING ROOM SAFETY RECOMMENDATIONS FOR COCHLEAR IMPLANTS [6-8]

Modality	Current Recommendations, cautions regarding cochlear implants*
Monopolar cautery	Do not use above the clavicles. Grounding pad on torso or thigh
Bipolar cautery	Do not use within 3 cm of a Med-El or 1 cm of Cochlear Corp or Advanced Bionics implant
ultrasound	Do not use in the area of the implant
Neurostimulation (ie. For pain control)	Do not use near the implant site
Diathermy – electromagnetic	Electromagnetic or microwave – Do not use at all (Cochlear Corp). not use within 3 cm of implant (Med-El and Advanced Bionics).
Diathermy ultrasonic	May be used below the clavicles as for ultrasound
Electroconvulsive therapy (ECT)	Do not use in cochlear implant patients. ECT damages the implant and tissues.
Radiation therapy – external beam	Do not radiate within 3 cm of the implant For gamma knife call manufacturer of the implant
Radioisotope therapy (eg. Brachytherapy)	Do not use γ-rays in head and neck. γ-rays can damage the implant. β- or α-rays are OK but do not bring them close to the implant.
Plasma knife - coblation	Do not use within 3 cm of implant.
Radiofrequency ablation	Do not use in head and neck. Place grounding pad on torso or thigh.
MRI scans	Check with manufacturer for each case. Remember that the image will likely be degraded. Some internal magnets can be surgically removed.
Any procedure	Consider the possibility of damage to the implant and use caution if unsure.

**Information as of January, 2010 - B.W. Blakley*

ORNAC Standards pertaining to this article can be found in the Operating Room Nurses Association of Canada (ORNAC) (June 2009). *Recommended Standards, Guidelines, and Position Statements for Perioperative Registered Nursing Practice* (9th edition). Section 3, pg 173, Standards 2.28 and 2.2.9.

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