

Electromagnetic interference and cochlear implants

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Summary. This paper reviews the most common sources of electromagnetic interference (EMI) with cochlear implants (CI). Particular attention will be given to the description of the mechanisms of electromagnetic interaction with CI; main disturbances caused to CI; relevant scientific investigations; and existing requirements and tests for electromagnetic compatibility (EMC) immunity applicable to CI.

Key words: cochlear implants, electromagnetic interference, electromagnetic compliance, magnetic resonance imaging, non-ionizing radiation.

Riassunto (*Interferenze elettromagnetiche e impianti cocleari*). Questo articolo ha l'obiettivo di fornire una rassegna esaustiva delle principali sorgenti di interazione elettromagnetica con gli impianti cocleari. In particolare, per ogni tipologia di sorgente verranno riportati: i meccanismi di interazione con gli impianti cocleari; gli effetti che tali interazioni hanno sugli impianti; i principali studi scientifici pubblicati sull'argomento; le vigenti prescrizioni e prove di compatibilità elettromagnetica degli standard europei ed internazionali applicabili agli impianti cocleari.

Parole chiave: impianti cocleari, interferenza elettromagnetica, compatibilità elettromagnetica, imaging a risonanza magnetica, radiazioni non-ionizzanti.

INTRODUCTION

A cochlear implant (CI) is an active prosthetic device implanted into the inner ear, *i.e.*, the cochlea, and it is used to stimulate, through electrical impulses, the neural tissue of the spiral ganglion (*i.e.*, the inferior root of the acoustic nerve). The neural discharges resulting from the electrical stimulation induce auditory sensations at the level of the brain cortex area, which can restore partial hearing to severe to profound deaf people [1]. Most of the people with cochlear implants can communicate without lip-reading or signing, and some can even communicate over the telephone. Several cochlear implants have been designed over recent years, with slightly different specific characteristics, but all the devices share the common features described in the following. An ear level microphone picks up, amplifies, and converts the speech sound into an electrical signal. The electrical signal is transmitted, through appropriate cabling, to the speech processor. The speech processor analyzes and converts the speech into appropriate digital information about the pattern of the electrical stimulation that has to be delivered to the cochlea through the implanted electrode array. The speech processor delivers the digital information to the external transmitting coil, which is located on the head of the patient

over the implant site. The external transmitting coil, in turn, transmits both power and digital information through a radio frequency (RF) link to the receiver/stimulator of the implant, which is implanted in a depression of the skull bone, behind the mastoid. The external coil is held in place over the internal receiver/stimulator package (which contains the internal coil) with a pair of external and internal magnets. The receiver/stimulator decodes the digital information coming from the speech processor through the radiofrequency link and delivers the electric stimulation pulses to the electrode array (consisting of multiple electrodes) which is implanted in the inner ear. The electrodes implanted into the cochlea stimulate the ear nervous terminals by means of a series of bipolar current pulses, whose amplitude, width and frequency are controlled by the speech processor [2-5].

Adults and children can get a CI, even very young children and babies. In 1990, the United States Food and Drug Administration (FDA) lowered the approved age for implantation to 2 years, then 18 months in 1998, and finally 12 months in 2002, and special approval has been given for babies as young as 6 months in the United States and 4 months internationally. According to 2005 data reported by the United States National Institute

on Deafness and Other Communication Disorders, nearly 100 000 people worldwide have received a CI. Currently (as of 2006), the main three CI devices are manufactured by Advanced Bionics (United States) (a subsidiary from 2004 of Boston Scientific Corporation, United States), Cochlear Corporation (Australia), and MED-EL (Austria).

Sources of electromagnetic interference (EMI) with cochlear implants can be found not only in particular circumstances due to specific medical treatments, such as magnetic resonant imaging (MRI), therapeutic ionizing radiation, electrosurgery, diathermy, neurostimulation, and electroconvulsive therapy, but also and very often even in the everyday life of a CI patient. Examples of frequent sources of EMI are mobile phones, electronic article surveillance (EAS) systems, and metal detection systems, which may interfere with the operation of the CI speech processor and cause distortion of the sounds processed by the CI. Last but not least, electrostatic discharge such that generated by removing clothes over the head or by playing on plastic slides may damage CI components or corrupt the program in the CI speech processor.

In the European Union, EMI or, more specifically, electromagnetic compatibility (EMC) in active implantable medical devices (such as CI) is regulated under the Council Directive 90/385/EEC [6] and its harmonized standard [7], as part of a family of safety standards in which EMC is viewed in terms of safety and clinical function of the device. In particular, the harmonized standard [7] is the primary standard containing general requirements applicable to all types of active implantable devices. As of December 2006, there is no product-specific standard for CI with the exception of the draft European standard [8] which is not yet active and is currently submitted to European Committee for Standardization (CEN) and European Committee for Electrotechnical Standardization (CENELEC) members for enquiry. This draft European standard has been prepared under a mandate given to CEN and CENELEC by the European Commission and will cover (when approved) essential requirements of Directive 90/385/EEC [6]. In absence of a CI-specific standard, usually most of CI devices are tested to be compliant with the international standard IEC 60601-1-2 [9] which is related to requirements and tests for EMC in medical electrical equipment. The text of the international standard IEC 60601-1-2 was approved without any modification by CENELEC as the European standard EN 60601-1-2:2001.

Despite the widespread diffusion of CI and the large number of interference sources, a relatively few studies were published on the topic of EMI and CI. Objective of this paper is to review the most important sources of EMI with CI, giving particular attention to: mechanisms of interaction with CI; main disturbances caused to CI; relevant scientific investigations; and existing requirements and tests for EMC immunity applicable to CI.

SOURCES OF EMI WITH CI

Magnetic resonance imaging

To ensure in CI a good transmission quality and exact alignment between the external transmitter and the internal receiver coil, usually a pair of magnets, one integrated into the transmitter coil of the external headset and the other integrated into the internal coil are applied. Although this is a very good solution for with regard to the quality of the transmitted message between external and internal coils, the presence of the two magnets creates serious problems with MRI. The electromagnetic fields produced during MRI (static, RF pulsed, and pulsed gradient magnetic fields) may interfere with the implant in several ways [10, 11]: eddy currents could arise in the conductive part of the implant and cause heating and damage of the surrounding tissues; magnetic field gradient could exert force and torque on ferromagnetic parts of the CI and dislodge the implant, thus damaging the device and surrounding tissues; electric field induced in conductive loops by RF magnetic field could seriously damage the electrodes and the stimulator of the implant; the CI internal magnet could be demagnetized thus reducing transmission functionality and, finally, could give raise to artifacts in MR images.

MRI is thus always contraindicated for patients with a CI except under specific circumstances, *i.e.*, when the implant is specifically designed for MRI compatibility and safety. Two different approaches are typically implemented to achieve MRI compatibility. In the first approach, CI internal magnet is enabled to be surgically removed before MRI. Examples of CI with removable magnets are the Nucleus 24 cochlear implant (Cochlear Corporation, Australia) and the HiResolution Bionic Ear System's HiRes 90K (Advanced Bionics, United States), which were approved by FDA to be safe for MRI up to 1.5 T [12] and at 0.3 and 1.5 T [13], respectively. In the second approach, the internal magnet is MRI safe and there is no need for removal before MRI. Example of this type of CI is the MED-EL Combi 40+ (MED-EL, Austria) in which the internal magnet is put in a robust ceramic case. This implant was approved in 2003 by FDA to be safe for MRI at 0.2 T [14].

However, up to date, there is no standard procedure to assess MRI compliance and safety. Published scientific investigations are not homogeneous and differ greatly as to experimental setup (patients, cadaver specimens, and phantom models), tested MRI levels and protocols, and parameters measured to assess MRI safety. For example, Baumgartner *et al.* [15, 16] performed a retrospective study over patients with CI who underwent MRI at 1.0 T. No adverse effects were reported by the patients, and no damage nor malfunctioning was observed for all the implants. Also, all MR images were of diagnostic value (*i.e.*, image artifacts caused by the presence of the CI were small). Similar results were obtained by Youssefzadeh *et al.* [17] in patients who underwent MRI at 1.0 T: in particular there was no detectable movement of the electrode and receiver coil nor any

temperature change near the electrode. In the study by Weber *et al.* [18], a magnetless implant (*i.e.*, an implant where the receiver coil was held in place without a magnet) was tested for MRI safety at 0.3 and 1.5 T in 11 patients. Results revealed that the tested magnetless implant was MRI compatible. Gubbels *et al.* [19] evaluated the effect of MRI at 1.5 T on the Nucleus 24 cochlear implant without removing the internal magnet before MRI. A compression dressing was used to prevent magnet displacement. CI were implanted in four cadaver heads and exposed to MRI. In no case displacement occurred if the compression dressing was applied and no decrease in the strength of the magnet was observed after MRI. The authors concluded that surgical removal of the internal magnet may not be necessary before scanning at 1.5 T. Wackym *et al.* [20] measured the demagnetization of the internal magnet of the MED-EL Combi 40+ implant in two fresh cadaver heads exposed to MRI at 0.2 and 1.5 T and in three patients who underwent MRI at 0.2 T. In all cases, the magnet was not removed from the implant before MRI. In cadavers, sagittal T1-weighted, axial T1-weighted, and axial T2-weighted sequences were performed at different head orientations. No significant demagnetization of the internal magnet was observed in CI implanted in cadaver heads both at 0.2 and 1.5 T. The same result was obtained in the patients after a 0.2-Tesla-MRI. More extensive studies on MRI were done using cochlear phantoms. In the studies of Teissl *et al.* [21, 22] phantoms were used to measure demagnetization, movement, force and torque on the magnet, temperature increase, induced voltage due to switched gradients or RF pulse, artifacts and geometric distortion area of MR images at 0.2 and 1.5 T MRI. The tests were done with the MED-EL Combi 40+ implant. Except for the torque at 1.5 T, the measured electromagnetic interferences between the CI and the 0.2 and 1.5 T scanners remained within acceptable limits. The authors concluded that MRI at 0.2 should be safe; at 1.5 T MRI examination should only be performed if there is a strong medical indication. As a final example of published investigation on MRI safety with CI, the documentation accompanying the FDA Premarket Approval (PMA) [12] of the Nucleus 24 cochlear implant reported the results of the tests done by the manufacturer with a MRI scanner having 1.5 T static field, 64 MHz pulsed field, and pulsed gradient fields up to 20 T/s. Pulsed gradient fields did not produced any stimulus output from the implant; temperature rise in the neighbourhood of the implant was non significant (< 0.1 °C); under the worst case scan parameters, MR image could be distorted in the area around the implant (approximately 2 cm medial and 6 cm inferior). With MRI static field, the force exerted on the implant was small (less than the normal weight of the implant) and not harmful.

The various models of CI currently available are quite different and therefore no general conclusion can be drawn about MRI compliance. To this pur-

pose, CEN and CENELEC are currently working on the standardization of the procedures to be used to assess MRI compliance and to the definition of the main hazards (such as force, heat generation, unintentional output, etc.) of a subject implanted with a CI [8].

Mobile phones

Successful use of a telephone, at least with a familiar speaker, has been frequently reported in adults [23-29] and also in children [30] implanted with CI. Survey by Sorry *et al.* [26] showed that 27/61 respondents of Finnish postlingually deafened adult implantees used a cellular phone, a digital one in the vast majority of cases. However, in a subgroup ($n = 9$) of the respondents using a body-worn processor, EMI problems turned out to be common. Another report [28] also mentioned problems of CI users with sound quality over the ordinary telephone and/or cellular phone. EMI problems are caused by both electrical and magnetic components of electromagnetic fields in the audio and ultrahigh frequencies, with the magnetic components predominating at the audio frequencies [31].

As CI enable telephone communication, and as EMI problems are evident and common, new solutions are needed to provide CI users with the possibility of benefiting from modern mobile communication. Up till now, only few laboratory works have been conducted to address interference, listening comfort, and speech recognition [26-32]. According to Sorry *et al.* [26] some body-worn processors are highly susceptible to EMI problems. Because of their small size and their well performing signal processing features, behind the ear signal processors have become ever more popular, but body-worn processors are still in wide use all over the world. Some cochlear implant users themselves have tried to solve listening problems with cellular phones with custom-made adapter cords and jacks [28].

Qian *et al.* [32] proposed a wireless phone adapter that could be used to route the audio signal directly to the hearing aid or cochlear implant processor. This adapter was based on Bluetooth technology. The authors stated that the favourable features of this wireless technology made the adapter superior to traditional assistive listening devices. Three cochlear implant users were tested with the proposed phone-adapter and reported good speech quality. Sorri *et al.* [26] studied three new assistive listening device prototypes that eliminate or diminish EMC problems. Ten experienced CI users listened in quiet to running speech samples and a sentence test on a landline phone and a digital cellular phone with and without the three prototype phone-adapters. Subject performance was assessed using a sentence test, a subjective visual analog scale, and by ranking the best and the poorest listening condition. Compared to the other test conditions, the authors found that listening to a digital cellular phone alone revealed, on average, the poorest

sentence recognition scores (29%) and the poorest results in four different subjective judgments (the amount of disturbances, the clarity of the message, the quality of the sound, overall judgment) with all three phone-adapters tested. The authors concluded that the phone-adapters generally helped the implantees to recognize speech better on the cellular telephone (by 10-21 percent units, on average). Therefore, assistive listening devices could diminish the compatibility problems between CI and digital cellular phones. However, this statement should be interpreted with caution, because only one telephone model and three different phone-adapters with body-worn processors were tested in that study [26]. Nevertheless, both CI and digital cellular phone manufacturers should take EMI problems into consideration. Cochlear implant users could benefit more from existing and future assistive listening devices if the audio inputs (and possible induction coils of the processors) had uniform standards, preferably in common with hearing aids. Furthermore, both for scientific research and product development, international standards for measuring the immunity of hearing devices to EMI are needed. The process of harmonizing these standard assessment techniques is in progress [33].

In the US, the Federal Communications Commission (FCC) has set a final milestone (February 2008), when half of all digital cellular telephones offered by manufacturers and service carriers must produce less interference [34]. However, obviously all the problems probably cannot be eliminated with improved technology. Furthermore, the current digital cellular phones and implant systems, in particular, will be in use for several years.

Only recently, there have been published scientific investigations on the estimation of EMI in CI through phantoms or numerical simulations. Tarusawa *et al.* [35] proposed a test phantom to estimate cellular phone EMI with CI. This test phantom was constructed from a square tank filled with saline solution. The use of a flat phantom provided a level of consistency in duplicating the exposure conditions in the EMI tests. The measurement and calculation results showed that there is no difference in the electric field (E-field) strength near the surface of the phantom when comparing flat and head-shaped phantoms and that the flat phantom is sufficiently thick to disregard the influence of reflective waves near the surface of the phantom. The calculation results also indicated the appropriateness of using physiological saline (0.18 g/l) up to 3 GHz when comparing the E-field strength inside a phantom comprising physiological saline and in a 2/3 muscle model. The results of EMI testing of a CI showed that there is no difference in the maximum interference distance when using either the flat or head-shaped phantom. Based on these results, the authors sustained the validity of using the flat phantom in EMI tests from cellular phone for the CI.

Electrostatic discharge

Large amounts of static electricity could cause the implant memory to reset or, in general could damage its electrical components. For this reason, all implant manufacturers [12-14] warn CI recipients be cautious (or, when possible, to avoid) in situations in which static electricity is created, such as when pulling on and off clothes or when getting out of a vehicle. Children with CI are also advised to avoid plastic playground slides because this creates very high electrostatic discharge (ESD). If static electricity is present, patients should touch something conductive, such as a metal object, before the CI system contacts any object or person. Before a CI recipients take part in activities that create high ESD, such as playing with plastic playground slides, they should remove the speech processor and the headset containing the transmitter coil.

All CI models were subjected by the manufacturers to ESD test. Test procedures used for ESD compliance are different among the manufacturers. For example, for the Nucleus 24 cochlear implant, ESD testing [12] was conducted according to the requirements and indications given in the international standard IEC 801-2 [36]: the implant and the speech processor were tested both for common mode and differential mode discharge at the levels of ± 8 kV for contact discharge and ± 16 kV for air discharge. The implant was compliant (*i.e.*, the testing indicates normal performance within the manufacturer's specification limits) with IEC 801-2 test level 4 for both contact and air discharge; the speech processor was compliant with IEC 801-2 test level 1 for contact discharge and test level 2 for air discharge. The MED-EL Combi 40+ implant was tested for ESD immunity [14] according to the EN60601-1-2 [9] at the ESD levels of ± 6 kV for contact discharge and ± 8 kV for air discharge. All applicable requirements of the standard [9] were fulfilled. For the Clarion multi-strategy cochlear implant (Advanced Bionics, United States) [13], the implant, speech processor, and battery charges were subjected to ESD testing at levels of 5, 10, 15, 20 and 25 kV. No loss of performance (soft failure) was observed up to 15 kV and no component damage (hard failure) was observed up to 25 kV.

Radiotherapy

Ionizing radiation cannot be used directly over the CI system as it may damage the device [12-14]. According to the European standard EN 45502-1 [7] (which is applicable to all active implants), the accompanying documentation of the device shall warn, if appropriate, that electronic components in the implant may be damaged by therapeutic ionizing radiation, and warn that any damage to the device may not be immediately detectable. Compliance shall be checked by inspection. The CI-specific European standard prEN45502-2-3 [8] will provide (when approved) details on the procedure (number of exposures and radiation dose at each exposure)

to follow to test compliance to therapeutic ionizing radiation and the amount of change of the implant output signal (*i.e.*, the stimulating signal) from its value before the first irradiation.

High powers electrical fields applied directly to the patient

Some medical treatments generate induced currents that may cause damage to the tissue or the CI device. Electrosurgical instruments are capable of producing RF voltages of such magnitude that a direct coupling can effectively exist between the cautery tip and the CI electrode array. For all implant models, monopolar electrosurgical instruments must not be used on the head or neck of a CI patient [12-14]. In some implant models [12] bipolar electrosurgical instruments may be used on the head or neck of a CI patient provided that the cautery electrode is not in contact with the implant and is kept more than 1 cm from the extracochlear CI electrodes. Similar warnings are given for diathermy or neurostimulation and electroconvulsive therapy: all implants models warn to use none of these therapies directly over the CI to prevent tissue and implant damage [12-14]. Up to now, there is no standard procedure to test immunity of CI to high power electrical fields applied to the patient. The CI-specific European standard prEN45502-2-3 [8] will provide (when approved) details on the procedure (such as, implant external loads and type of signal generator used) to simulate the effect of high power electrical fields) to assess test compliance.

As to scientific investigations on this type EMI, there is only one study which is focused on the compatibility of dental appliances with CI [37]. The electromagnetic field created by dental instruments may present a potential hazard to CI patients. Damage to the electrodes in the cochlea, which lie within 6 cm of the maxillary second molar, would not only irreparably damage the implant, but would also necessitate a surgical procedure to replace it. In fact, not only the implant could be permanently damaged, requiring replacement, but sufficient electrical energy could necrotize vital cells of the basilar membrane, making re-implantation futile. Even if these cells were not damaged, re-implantation would involve significant expense to the patient plus the hazards of another surgery. The study by Roberts *et al.* [37] investigated the effects of EMI with a CI during the operation of the electric pulp tester, apex locator, electrocautery unit, electrosurgery unit and panoramic radiograph machine. A mastoidectomy and cochleostomy were performed on a cadaver, and a CI was implanted. The dental devices were used intraorally and the implant's circuitry was tested after each trial. A second CI was implanted in a human skull, which was then exposed to 50 panoramic radiographs, testing the implant's circuitry after each exposure. The authors [37] concluded that the probability of damage to the CI by any of the devices was negligible, except for the electrosurgery

unit operated at level 7, which destroyed the CI's circuitry. Therefore, although the other devices seem safe, they concluded that it is recommended that the electrosurgery unit not be used on a CI patient.

Generic sources of electromagnetic radiation

In addition to the specific EM sources already reviewed in the sections above, non-ionizing radiations from generic sources may affect CI functionality. All CI models are tested by the manufacturers for susceptibility to electromagnetic fields. For two CI models [12-14], EM compliance was tested according to the requirements given in the international standard IEC 60601-1-2 [9]. In particular, immunity to conducted disturbances induced by RF EM fields were assessed at the test level of 3 Vrms (root-mean-squared value) in the range from 150 kHz to 80 MHz; immunity to radiated RF EM fields were assessed at the test level of 3 V/m in the range from 80 MHz to 2.5 GHz. The test results indicate that exposure of the CI device to EM fields will generate some unwanted stimuli but not will result in interference with the normal operation of the device. Exposure will not induce damage to the implant and will not result in intermittent or ceased operation for the duration of the exposure. In other CI models, EM susceptibility was tested according to specific procedures developed directly by the manufacturer. For example, the Clarion multi-strategy cochlear implant was tested [13] with an electric field of 340 V/m in the frequency range 2-500 MHz. Susceptibility at magnetic field was assessed by placing the implant in a magnetic field in the frequency range 2-500 MHz; the strength of the field was increased until the implant stopped working. Susceptibility levels for this implant model ranged from 1.3 to 10.3 A/m. In addition, this implant model was immersed in saline solution to simulate body tissue characteristics. A monitoring system made by a fiber-optic line measured the testing field. Testing was conducted from 10 kHz to 1 GHz at electric field strengths of 0.5 to 7.0 V/m in a shielded room. The implant was properly electrically functioning at the completion of the test.

Examples of EMI from non-ionizing radiation are EAS and metal detection systems, which produce strong electromagnetic fields that may disturb CI functionality. In particular, all CI manufacturers warn that in some cases implant recipients may hear distorted sound when passing near or through these devices. To avoid this disturbance, it is recommended to switch off the speech processor. Also, the materials use in the CI may also activate metal detection systems.

As to scientific investigations on CI compatibility with non-ionizing EM fields, there is a study dealing with EMI with CI in work environment. Hocking *et al.* [38] tested CI patients working in electromagnetic fields. They found that mono-channel implants are more sensitive than multi-channel devices. Interference is also more likely to occur if the frequency of the electromagnetic field is in the

same range of the RF signal transmitted from the external CI transmission coil. The patient should be informed of the possibility of hearing artefacts in order to avoid potentially dangerous situations in the work environment.

CONCLUSIONS

The number of CI recipients as well as the use of EM sources for different applications are increasing very rapidly. EM interaction with CI is very common not only in specific medical treatments (such as with MRI) but also in the everyday life. The most investigated source of EMI in CI is the MRI, due to its dangerous effects both on the patient and on the implant if the implant is not specifically designed for MRI compatibility

and safety. The main three manufacturers of the CI devices here reviewed made changes in the design of their implants in order to make them to some extent safe at specified MRI levels. For all implant models and all types of sources of EMI with CI, safety measures were recommended in the implant accompanying documentation. Specific standards on EMC testing in CIs should be provided soon in the European standard prEN45502-2-3 [8] which is currently not yet approved. It will be necessary to perform deeper investigations to achieve more profound knowledge of EMI in CI.

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