Clinical Trial on the Capacitive Component of Electrical Impedance in the Cochlea and the Effect of Topical Dexamethasone in Cochlear Implant Surgery

DI LELLA, FEDERICO A; FERNANDEZ, FLORENCIA; PARREÑO, MATIAS; BOCCIO, CARLOS

OTOLARYNGOLOGY DEPARTMENT
HOSPITAL ITALIANO DE BUENOS AIRES
ARGENTINA

federico.dilella@hospitalitaliano.org.ar
Disclosure

F. Di Lella is a Latin-American Medical Consultant for:

- Cochlear Ltd.
- Advanced Bionics
Cochlear implants  The first medical device to restore a human sense

- Feasible and secure treatment for severe to profound SNHL
- Speech perception outcomes may vary due to:

Biographical factors
- Age
- Genetics
- Immunological response
- Cochlear anatomy

Audiological factors
- Onset of Hearing impairment
- Etiology of HL
- Residual hearing
- Cochlear approach (RW, eRW, Co)
- Insertion trajectory
- Insertion speed
- Electrode (flexibility, dimensions)
- Depth of insertion
- Blood / Bone dust
Potential Damages inside the Cochlea with a CI

Surgical Approach

- Opening of the cochlea: endosteal lesions, bleeding, bone dust, perilymph suction (ACTIVATE THE COCHLEAR INFLAMMATORY CASCADE)
- Insertion of the electrode array: damage to the lateral wall, modiolar damage, damage to the basilar membrane, scala dislocation (INTRACOCHLEAR STRUCTURAL DAMAGE)

Acute inflammatory reaction

- Cytokines and free radicals
- Hair cells and neuronal damage: apoptosis - necrosis

Chronic inflammatory reaction

- Labyrinthitis, progressive intracochlear fibrosis, ossification
There are evidences that cochlear damage is not good...

M. L. CARLSON ET AL.

Implications of Minimizing Trauma During Conventional Cochlear Implantation


Department of Otolaryngology Head and Neck Surgery, Mayo Clinic School of Medicine, Rochester, Minnesota, U.S.A.

...focusing on the incidence and sustainability of postoperative preserved hearing and the benefit of EAS. However, in the present study, we test the hypothesis that patients sustaining less intraco cochlear trauma during implantation with a conventional length electrode will demonstrate improved speech understanding in the electric-only condition. If substantiated, the results of this study would support the argument.

A. DALBERT ET AL.

Hearing Preservation After Cochlear Implantation May Improve Long-term Word Perception in the Electric-only Condition

*†Adrian Dalbert, *‡Alexander Huber, *§Naeni Baumann, *‖Dorothe Veraguth, *‖Christof Roosli, and *‖Flurin Pflügger

*University of Zurich, and †Department of Otorhinolaryngology—Head and Neck Surgery, University Hospital Zurich, Zurich, Switzerland...
Introduction

The electrode array in the cochlea:

A BENEFIT for the patient & a PROBLEM for the cochlea

How the cochlea reacts to the implant inflammatory response → fibrosis → ossification

The Electro-Neural Interface:

- The electrode surface
- The stimulus parameters
- The nature of the medium

Impedances

- Assess electrode functioning
- Calculate power consumption
- Kinking of flexible electrodes
- Mapping

May vary over time (protein adsorption, cellular inflammatory reaction, fibrosis, ossification)

Cochlear implants are unable to directly assess impedance.

Impedances can be obtained by measuring voltage, as provided by Ohm's law. \( Z = \frac{V}{i} \)

The current clinical method of monitoring electrode impedance in patients can only determine the overall electrode impedance \( (Z_t) \)

\[
Z_t = Z_a + Z_p
\]

\[
Z_t = \frac{V_a}{i} + \frac{R_p \left[ 1 - e^{-\frac{t}{R_p C_p}} \right]}{i}
\]

Objective

Evaluate the effect of the use of a single dose topical dexamethasone during CI surgery with a novel daily in-vivo real-time remote method to measure and calculate overall electrode impedance and its subcomponents in cochlear implant recipients.
**Material & Methods**

**Clinical Trial**
Randomized, double-blind, placebo-control study

- **Control Group**
  - n = 10
  - Saline Solution

- **Intervention Group**
  - n = 10
  - Dexamethasone 20 mg/ml

- **20 patients**
  - Profound SNHL
  - CI candidates

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This study was approved by the Human Research and Ethics Committee at the Hospital Italiano de Buenos Aires, IRB00010193

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Cochlear Implant Data Collector Software (CIDC)

Patients are instructed to measure themselves 2 times per day from the day of surgery to the day of activation.

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Stimulation Modes & Measurement Sequences

Stimulus parameters:
- Current level: 80 (74.21 uA)
- Pulse width: 60 uS
- Inter-phase gap: 12 uS
- Period: 333.4 uS (freq. 3 KHz)

Voltage measurements:
- 22 measurements / input pulse
- 4 modes
- 22 electrodes

1936 values
~5 minutes
Cochlear Implant Data Analyzer Software (CIDA)

Automatic calculation of Access Resistance and Polarization Impedance


\[ V_a = i \cdot R_a \quad \rightarrow \quad R_a = \frac{V_a}{i} \quad (1) \]

\[ \tan \theta = \frac{V_c - V_a}{t_2 - t_1} \]

\[ C_p = i \cdot \frac{(t_2 - t_1)}{V_c - V_a} \quad (2) \]

\[ V_t = i \cdot R_a + i \cdot R_p \left[ 1 - e^{-\frac{t_2}{R_p \cdot C_p}} \right] \quad (3) \]

Ra, Cp, Rp

In Vivo Real-time Remote Cochlear Implant Capacitive Impedance Measurements: A Glimpse Into the Implanted Inner Ear

Fabrizio Alberto Di Lella, Diego de Mora, Florencia Fridman, Mario Parmeles, and Carlos Mario Borco

Odontopediatría 01:01-01:01, 2019
Results: Definite pattern progression

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PLACEBO

DEXAMETHASONE

Values progression for Electrode #2 - Placebo Group

Values progression for Electrode #2 - DEX Group
Changes are more important at the level of the basal turn of the cochlea (electrodes 1 & 2), which resulted in dividing the cochlea into 5 zones for the study.
Results

- Groups comparison using Shen & Faraway test.
- There seems to be significant differences in basal electrodes (1 & 2) between both groups for both $Ra$ and for $Cp$ ($p < 0.05$).
- This difference seems to be only observable during the first 10 days postimplantation, to later reach similar values in both group.
The inflammatory response produced after cochlear implantation promotes fibrotic tissue deposition around the electrode array which can also impair electrode impedance and post-implantation hearing outcomes.

Protein adsorption onto the material surface is the first reaction that occurs to medical devices implanted in the body (Tang and Eaton 1999, Shen and Horbett 2001), and same reaction is observed for electrodes implanted into the fluid-filled scala tympani of the cochlea. Such adsorption of protein is also likely to increase electrode impedance. Newbold et al (2010) demonstrated that protein adsorption increased the polarization component of electrode impedance when measured with biphasic current pulse. Franks et al (2005) showed that coatings of laminin and poly-l-lysine on platinum electrodes resulted in a reduction of the capacitance measure, thereby increasing the overall electrode impedance.

Choi et al. (2017) reported that a rise of electrode impedance would likely start in the basal turn of the cochlea.
The highest levels of fibrous tissue growth were detected in the basal region of the cochlea, in the vicinity of the round window niche.
Conclusions

- This method has proven to be useful for the safe and remote assessment of the electrical impedance components in cochlear implant recipients.

- Single dose of topical dexamethasone during CI surgery seems to be useful to modulate the inflammatory reaction only in the basal turn of the cochlea and only for the first postoperative week.

- Ra values could help to better understand the fibrosis reaction inside the cochlea. We confirm a significant increase in Ra from the surgery to the CI activation, specially on the basal turn of the implanted cochlea.

- Polarization impedance, specially measured by Cp, may provide important information about the initiation of the complex inflammatory response that occurs inside the implanted cochlea.
Further developments

• Use of patient-administered impedance tests for long term cochlear health assessment after cochlear implants is a promising field to improve outcomes and also for drug effect monitoring.

• A multi-center clinical trial to evaluate daily impedance changes with the use of systemic steroids and also the correlation with hearing preservation is currently on development at our center. Results will be available shortly.
Thank you for your attention

Di Lella, Federico A; Fernandez, Florencia; Parreño, Matias & Boccio, Carlos M

federico.dilella@hiba.org.ar