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Research Paper

Intraoperative force and electrocochleography measurements in an animal model of cochlear implantation

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ABSTRACT

To preserve residual hearing, techniques for monitoring and reducing the effects of trauma during cochlear implant surgery are being developed. This study examines the relationships between intraoperative recordings (electrode insertion force and electrocochleography), trauma, and hearing loss after cochlear implantation. The study also evaluated the efficacy of intravenous steroids for reducing hearing loss after implantation. Thirty-two normal-hearing guinea pigs were randomly implanted with electrode arrays of differing stiffness ('hard' or 'soft'). These arrays used an intracochlear electrode to record electrode insertion force and electrocochleography responses to a multi-frequency acoustic stimulus during implantation. Additionally, sub-cohorts of animals were administered intravenous saline ('control') or dexamethasone ('steroid') prior to surgery. Subsequent hearing loss was assessed using electrocochleography recordings from the round window membrane prior to surgery and 4 weeks after implantation. After 4 weeks, cochleae were harvested and imaged with thin sheet laser imaging microscopy. After 4 weeks, compound action potential (CAP) thresholds did not differ between steroid and control groups. The CAP amplitude at low-mid frequencies decreased after implantation with a hard electrode, an effect which was partly negated by administering steroids. A decrease in the 'intraoperative' CAP amplitude preceded the reporting of insertion resistance by the surgeon by 5.94 s (± 4.03 s SEM). Intraoperative CAP declines were also correlated with higher grades of trauma ($r = 0.56$, $p < 0.01$) and greater hearing loss ($r = 0.56$, $p < 0.01$). This relationship was not repeated with intraoperative cochlear microphonics. A rise in intraoperative force, which preceded the reporting of resistance by 0.71 s (± 0.15 s SEM), was correlated with trauma ($r = 0.400$, $p = 0.04$) but not hearing loss ($r = 0.297$, $p = 0.27$). Preserving intraoperative CAP amplitudes during implantation was predictive of an atraumatic insertion and reduced post-implantation hearing loss. A rise in force usually preceded the reporting of resistance, although by less than 1 s. These results suggest that intraoperative CAPs may offer a more robust feedback mechanism for improving hearing preservation rates than cochlear microphonic and electrode insertion force recordings, especially considering the rapid changes in insertion force and relatively slow human reaction times. Pre-operative steroids were effective in reversing loss of CAP amplitude with hard electrodes and evoked by lower frequency tones, which suggests a possible role in reducing synaptopathy.

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1. Introduction

Preserving residual hearing to facilitate 'electroacoustic

stimulation' (EAS) is now a widely recognised goal of cochlear implantation surgery. EAS combines electric and acoustic hearing in the same ear and is particularly beneficial for perceptual tasks relying on pitch resolution, such as music appreciation and speech perception in background noise (Gantz et al., 2005; Santa Maria et al., 2013). Complete or partial preservation of residual hearing may be achieved by minimizing electrode insertion trauma

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(Eshraghi and Van de Water, 2006; O'Leary et al., 2013), and this has led to the exploration of intraoperative techniques that monitor the behaviour of the electrode.

Two potential intraoperative monitoring techniques are electrocochleography or ECochG (the electrical response of the cochlea to acoustic stimulation) and the force of the electrode insertion. Preserving the amplitude of electrocochleography responses like the compound action potential (CAP) (Mandala et al., 2012) and the cochlear microphonic (CM) (Acharya et al., 2016; Campbell et al., 2016) have shown promise in predicting the extent of hearing preservation. However, ECochG recordings have mostly arisen from observational studies that are yet to provide meaningful interpretations for surgeons performing cochlear implantation. Although recent findings for intracochlear measurements made both in animals (Choudhury et al., 2014; DeMason et al., 2012) and in humans with scalar translocation have shown ECochG to be predictive of some types of surgical trauma (O'Connell et al., 2017).

The magnitude of electrode insertion force as a feedback mechanism is widely believed to correlate with structural damage (Wade et al., 2014) and by extension, the level of post-implantation hearing loss (Kobler et al., 2015). However, these assumptions are yet to be explored experimentally because of difficulties measuring the relatively small force of electrode insertion from a sensor placed beneath the head (Miroir et al., 2012). Recently, insertional forces measured along the axis of the electrode have been shown to be similar to a conventional 6-axis sensor placed beneath a cochlear model (Miroir et al., 2012) and this may provide a more practical option for intraoperative recordings.

The purpose of this animal-based study was to determine correlations between intraoperative cochlear implant-based ECochG, electrode insertion force recordings and post-implantation hearing loss. Two electrode arrays of differing stiffness were validated in an epoxy cochlear model for their insertion force and depth, and then implanted into the cochleae of guinea pigs. A hand-held insertion tool was designed and implemented for performing uni-axis force measurements. Systemic steroids were administered pre-operatively in a placebo controlled manner to assess their relative efficacy (Connolly et al., 2011; Lee et al., 2013; Rah et al., 2016) in reducing the effects of specific types of electrode insertion trauma (Lo et al., 2017b). Correlations between steroid pre-treatment, the level of surgical trauma and post-implantation hearing loss were examined.

2. Materials and methods

2.1. Cochlear implant array

The cochlear implant was a single channel electrode array, 15 mm in length and with a single platinum ring at its tip. This ring was welded to a straight internal platinum wire 25 μm in diameter. The ring and internal wire were embedded in a silastic carrier comprised of one of two types of silicone: hard (MDX4-4880 Dow Corning Products, USA) or soft (MDX4-4210 Dow Corning Products USA). Both electrodes used undyed materials and did not differ in their appearance. The maximum diameter of the implant was 0.45 mm, narrowing to 0.41 mm towards the tip, which models the tapering and tip diameter of contemporary human electrode designs (Mukherjee et al., 2012). At the basal end of the electrode array, the internal platinum wire was welded to a platinum contact that ran perpendicular to the array (Fig. 1). This enabled intra-cochlear ECochG recordings from the ring electrode at the tip of the array to be conducted to the platinum contact that remained outside of the cochlea.

2.2. Replica model force measurements

Force measurements on the two electrode designs were performed by advancing electrodes attached to a load cell in to a guinea pig scala tympani model. Firstly, a 3-D epoxy model of the basal turn was created by molding a silicone cast in crystal epoxy resin (Fig. 2). The silicone cast of scala tympani was produced by dislocating the stapes to open the oval window, followed by the injection of silicone through an opening in the round window (RW). After hardening, the silicone was removed to produce a caste of a full basal turn of scala tympani, commencing at the RW. This segment was molded in crystal epoxy resin and the silicone was then withdrawn. A cochleostomy was drilled into the epoxy model by an experienced surgeon using a 0.8 mm diamond bur and after anatomical orientation.

Insertion forces were recorded with an Instron 5543 Force Measurement System (Instron; Deutschland GmbH, Pfungstadt, Germany). The scala tympani (ST) model was attached to the lower gripping jaw and oriented with the cochleostomy and insertion axis directed vertically. The upper gripping jaw, connected to the load cell, was used to fix the test electrode and direct it downwards into the model. Four electrodes made of hard or soft silicone (2 each) were inserted twice in to the scala tympani model. The model was filled with normal saline and electrodes were pre-inserted into the opening of the cochleostomy. Electrodes were inserted at a constant speed of 15 mm/min (Rajan et al., 2013) until buckling of the basal portion of the electrode was observed. Force measurements were captured every 4 ms and all insertions were video recorded (see Appendix 1). The angular depth of insertion was determined as degrees of rotation around the modiolus, commencing at the mid-point of the RW and finishing at the electrode tip (Lo et al., 2017a). These depths were analysed from still photographs (Fig. 2) in the axial orientation (Lo et al., 2017a) using the 2D angle tool in Amira 5.4 (Visualization Sciences Group, France).

Supplementary video related to this article can be found at <https://doi.org/10.1016/j.heares.2017.11.001>.

2.3. Hand-held insertion tool

A hand-held insertion tool (Fig. 1) was developed that was based upon a previous instrument capable of sensitive and accurate force recordings (Miroir et al., 2012). During insertions, the electrode array pushed a blunt pin into a dextran-filled tube comprised of carbon fibre (Engineering Supplies, QLD, Australia). Dextran fluid and carbon fibre tubing were chosen to lower frictional forces (Kontorinis et al., 2011; Miroir et al., 2012). Abutting the other end of the blunt pin to the electrode was a uni-axis force sensor (milli-Newton force sensor, EPFL, Lausanne, Switzerland). The force sensor has a range of 0–0.4 N, with 4 mN resolution, and has been shown to record similar measurements to a conventional 6-axis sensor placed beneath a cochlear model (Miroir et al., 2012). Sensor data was recorded at a sampling rate of 1000 Hz and acquired with a DT9847 (Data Translation GmbH, Germany) USB data acquisition. Before every fifth implantation, the force sensor was re-calibrated using 1.5-, 5- and a 10-g weights.

2.4. Experimental procedure

All procedures in this study were approved by and performed in accordance with the Animal Research Ethics Committee of the Royal Victorian Eye and Ear Hospital (project 15\335AU). Thirty-two adult Dunkin-Hartley tricolour guinea pigs, weighing >400 g, were used in this study. Animals underwent left sided cochlear implantation with one of two electrode types (hard or soft) after receiving either intravenous dexamethasone ('steroid') at 2 mg/kg

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