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#### **Research** paper

### Correlation between word recognition score and intracochlear new bone and fibrous tissue after cochlear implantation in the human

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#### ABSTRACT

Cochlear implantation is an effective, established procedure for patients with profound deafness. Although implant electrodes have been considered as biocompatible prostheses, surgical insertion of the electrode induces various changes within the cochlea. Immediate changes include insertional trauma to the cochlea. Delayed changes include a tissue response consisting of inflammation, fibrosis and neo-osteogenesis induced by trauma and an immunologic reaction to a foreign body. The goal of this study was to evaluate the effect of these delayed changes on the word recognition scores achieved post-operatively. Seventeen temporal bones from patients who in life had undergone cochlear implantation were prepared for light microscopy. We digitally calculated the volume of fibrous tissue and new bone within the cochlea using Amira® three-dimensional reconstruction software and assessed the correlations of various clinical and histologic factors. The postoperative CNC word score was positively correlated with total spiral ganglion cell count. Fibrous tissue and new bone were found within the cochlea of all seventeen specimens. The postoperative CNC word score was negatively correlated with the % volume of new bone within the scala tympani, scala media/vestibuli and the cochlea, but not with the % volume of fibrous tissue. The % volume of new bone in the scala media/vestibuli was positively correlated with the degree of intracochlear insertional trauma, especially trauma to the basilar membrane.

Our results revealed that the % volume of new bone as well as residual total spiral ganglion cell count are important factors influencing post-implant hearing performance. New bone formation may be reduced by limiting insertional trauma and increasing the biocompatibility of the electrodes.

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#### 1. Introduction

Cochlear implantation is an effective procedure for auditory rehabilitation of patients with severe to profound deafness (Somdas et al., 2007; Benatti et al., 2013; Seyyedi and Nadol, 2014), and implant electrodes have been considered as biocompatible prostheses with a low complication rate (Seyyedi and Nadol, 2014). However, surgical insertion of the electrode induces immediate and delayed changes within the cochlea (Li et al., 2007; Somdas et al., 2007; Fayad et al., 2009). Immediate intracochlear changes are due to trauma during surgical insertion of the electrode including fracture of the osseous spiral lamina, disruption of

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the basilar membrane, dissection into the spiral ligament and stria vascularis, and injury to the lateral cochlear wall and modiolus (Li et al., 2007; Somdas et al., 2007). Delayed changes are due to both insertional trauma and to a host tissue response to the electrode consisting of inflammation, fibrosis and neo-osteogenesis (Li et al., 2007; Somdas et al., 2007; Fayad et al., 2009). These changes have been reported in several histopathological studies of temporal bone specimens from patients who in life had undergone cochlear implantation (Nadol and Eddington, 2004; Nadol et al., 2008, 2014; Fayad et al., 2009; Seyyedi and Nadol, 2014). Nadol and Eddington (2004) reported a robust fibrous and bony tissue response in all 21 ears at the cochleostomy site and an inflammatory cellular response in 12 of the 21 temporal bones. Nadol et al. (2008) have suggested an immunologic response to the electrode as a possible explanation in some cases of "soft failure" of cochlear implantation. Nadol et al. (2014) have suggested that a foreign body response may in certain cases result in migration or even extrusion of the electrode. Sevvedi and Nadol (2014)









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reported fibrosis and new bone formation in all 28 temporal bones and a foreign body giant cell infiltration and granulomatous reaction in 27 of 28 temporal bones. Somdas et al. (2007), Li et al. (2007), and Fayad et al. (2009) have reported quantitative assessments of fibrosis and new bone formation in the cochlea following cochlear implantation in the human, but Li et al. (2007) have reported that the total volume of intra cochlear new tissue did not correlate with word recognition scores. However, other studies suggest that fibrous tissue and new bone may affect patterns of stimulation around the electrode (Kawano et al., 1998; Choi and Oghalai, 2005; O'Leary et al., 2013). Kawano et al. (1998) demonstrated that auditory thresholds of individual electrodes were increased and dynamic ranges were decreased with increasing amounts of fibrous tissue and new bone in a temporal bone study of five patients with Nucleus 22-channel cochlear implants. Choi and Oghalai (2005) and O'Leary et al. (2013) have suggested that the severity of local tissue response may be negatively correlated with both performance after implantation and preservation of the residual acoustic hearing using mathematical (Choi and Oghalai, 2005) and animal (O'Leary et al., 2013) models. However, other than the report by Li et al. (2007) there have been few quantitative studies of correlations between postoperative hearing performance and the volume of fibrous tissue and new bone in human subjects.

The objectives of this study were to quantitatively evaluate the % volumes of fibrosis and of new bone within the cochlea of patients who in life had undergone cochlear implantation using threedimensional reconstruction software, to assess correlations between the calculated volumes and postoperative word recognition scores, and to evaluate the factors which may influence the generation of fibrous tissue and new bone.

#### 2. Materials and methods

#### 2.1. Subjects

Seventeen human temporal bones from the collection of the Otopathology Laboratory of the Massachusetts Eye and Ear Infirmary from patients who in life had undergone cochlear implantation using various electrode designs were evaluated. Cases with new bone formation before implantation based on evaluation of preoperative CT scans and operative records were excluded. Postoperative last-recorded word recognition scores (CNC [Consonant-Vowel Nucleus-Consonant Word Test] scores) were available in all cases except in Case 1 and Case 7. In Case 1, the CNC word score was estimated based on the postoperative lastrecorded HINT (Hearing In Noise Test) score, and in Case 7, NU6 (Northwestern University Auditory Test #6) was used. The word recognition score, cause of deafness, age at onset of hearing loss and deafness, implant type and ear, age at implantation, and duration of implantation in all seventeen specimens are presented in Table 1.

#### 2.2. Histological techniques

All temporal bones were removed and fixed in 10% buffered formalin. After decalcification in ethylene diamine tetra-acetic acid (EDTA) the electrode array was removed and, in two cases with a positioner (Case 1 and Case 16), the positioner was retained within the cochlea during the remainder of the histologic preparation. The specimens were dehydrated in alcohol, embedded in celloidin, and sectioned at a thickness of 20  $\mu$ m in a horizontal plane. Every tenth section was stained with hematoxylin and eosin, and mounted on a glass slide for subsequent reconstruction and study.

#### 2.3. 2-D reconstruction of the cochlea

Every tenth section was studied by light microscopy. The serial sections of the temporal bones were reconstructed, and the numbers of spiral ganglion cells in Rosenthal's canal were calculated by conventional 2-D methods (Guild, 1921; Schuknecht, 1993). The most apical section of the cochlea containing the electrode tip in which there was histologic evidence, such as fibrous sheath around the electrode (Li et al., 2007; Lee et al., 2011), and the entry point into the cochlea were determined. The electrode length within the cochlea and the electrode length located in the scala media/vestibuli or spiral ligament were also determined using the 2-D reconstructions.

#### 2.4. 3-D reconstruction of the cochlea

The technique for 3-D reconstruction has been described previously (Li et al., 2007; Somdas et al., 2007). Digital images of each mounted slide were captured at low power (1.25×) under a light microscope fitted with a high-resolution camera (Olympus BX51, Olympus DP71). These images were cropped, resampled, registered, and segmented using the Amira<sup>®</sup> reconstruction and modeling software (ver. 6.0.0., FEI, Hillsboro, OR). Every tenth section was captured for all seventeen cases, and there was an average of 40 images per case. To determine the dimensions of the voxels, we used an image of a scale taken with the same objective, uploaded it with ImageJ software (http:/rsbweb.nih.gov/ij), and used Set Scale of ImageJ software to determine the distance per pixel.

Each 2-D image was segmented by identifying and tagging the different structures within the cochlea duct as follows: purple was used for shading of the scala tympani; green for the scala media/vestibuli; brown for the spiral ligament; yellow for fibrous tissue; blue for new bone; black for the electrode of the implant (Fig. 1A, B). Surface renderings of the segmented materials were generated and used to visualize the 3-D reconstruction (Fig. 2A–E). Using surface rendering, the volume of each material (scala tympani, scala media/vestibuli, new fibrous tissue, and new bone) was edited with the Amira's Volume Edit Tool, and measured using the Amira's Surface Area/Volume Tool, and the % volume of the electrode, fibrous tissue, new bone and total new tissue (total of new fibrous tissue and new bone) within the scala tympani, scala media/vestibuli, and the cochlear lumen were calculated.

## 2.5. Quantification of intracochlear damage caused by electrode insertion

The degree of electrode insertional trauma was assessed by adapting a method previously described (Li et al., 2007; Lee et al., 2011) and presented in Table 2. Damage to the osseous spiral lamina, lateral cochlear wall and basilar membrane was used as markers for insertional trauma. To provide an overall index of damage in each temporal bone, in every tenth section along the electrode track a score was assigned indicating the severity of insertional trauma from 0 to 2 as described and illustrated in Fig. 3A–J. These values were summed along the cochlear duct to generate a total damage score for each subject.

#### 2.6. Statistical analysis

Bivariate analyses and Pearson's coefficients of correlation were performed to investigate relationships between clinical and histologic variables, using Mini StatMate software (ATMS Co. Ltd., Tokyo, Japan). P < 0.05 was considered significant.

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