Hearing Research 348 (2017) 44–53

Contents lists available at ScienceDirect

Hearing Research

journal homepage: www.elsevier.com/locate/heares

Research Paper

The pattern and degree of capsular fibrous sheaths surrounding cochlear electrode arrays

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ARTICLE INFO

Article history:
Received 14 November 2016
Received in revised form
25 January 2017
Accepted 14 February 2017
Available online 17 February 2017

Keywords:
Cochlear implant
Fibrous tissue
Advanced Bionics
Nucleus
Impedance
Temporal bone

ABSTRACT

An inflammatory tissue reaction around the electrode array of a cochlear implant (CI) is common, in particular at the electrode insertion region (cochleostomy) where mechanical trauma often occurs. However, the factors determining the amount and causes of fibrous reaction surrounding the stimulating electrode, especially medially near the perimodiolar location, are unclear. Temporal bone (TB) specimens from patients who had undergone cochlear implantation during life with either Advanced Bionics (AB) Clarion ™ or HiRes90K™ (Sylmar, CA, USA) devices that have a half-band and a pre-curved electrode, or Cochlear ™ Nucleus (Sydney, Australia) device that have a full-band and a straight electrode were evaluated. The thickness of the fibrous tissue surrounding the electrode array of both types of CI devices at both the lower (LB) and upper (UB) basal turns of the cochlea was quantified at three locations: the medial, inferior, and superior aspects of the sheath. Fracture of the osseous spiral lamina and/or marked displacement of the basilar membrane were interpreted as evidence of intracochlear trauma. In addition, post-operative word recognition scores, duration of implantation, and post-operative programming data were evaluated.

Seven TBs from six patients implanted with AB devices and five TBs from five patients implanted with Nucleus devices were included. A fibrous capsule around the stimulating electrode array was present in all twelve specimens. TBs implanted with AB device had a significantly thicker fibrous capsule at the medial aspect than at the inferior or superior aspects at both locations (LB and UB) of the cochlea (Wilcoxon signed-ranks test, $p < 0.01$). TBs implanted with a Nucleus device had no difference in the thickness of the fibrous capsule surrounding the track of the electrode array (Wilcoxon signed-ranks test, $p > 0.05$). Nine of fourteen (64%) basal turns of the cochlea (LB and UB of seven TBs) implanted with AB devices demonstrated intracochlear trauma compared to two of ten (20%) basal turns of the cochlea (LB and UB of five TBs) with Nucleus devices, (Fisher exact test, $p < 0.05$). There was no significant correlation between the thickness of the fibrous tissue and the duration of implantation or the word recognition scores (Spearman rho, $p = 0.06$, $p = 0.4$ respectively). Our outcomes demonstrated the development of a robust fibrous tissue sheath medially closest to the site of electric stimulation in cases implanted with the AB device electrode, but not in cases implanted with the Nucleus device. The cause of the asymmetric fibrous sheath may be multifactorial including insertional trauma, a foreign body response, and/or asymmetric current flow.

1. Introduction

Cochlear implants (CI) have been considered a well-tolerated biocompatible device with a low rate of complications (Issa et al., 1983; Webb et al., 1988; Ray et al., 2004; Venail et al., 2008; Ding et al., 2009; Bennatti et al., 2013). A chronic local inflammatory

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http://dx.doi.org/10.1016/j.heares.2017.02.012
0378-5955/

reaction, which may result in CI failure, explantation, or reimplantation, has been reported in rare clinical CI cases. The causes for this chronic local inflammation might be a delayed hypersensitivity or a local tissue reaction to the CI electrode array (Bertuleit et al., 1999; Ho et al., 2003; Puri et al., 2005; Kunda et al., 2006; Nadol et al., 2008; Lim et al., 2011; Neilan et al., 2012; Bennatti et al., 2013). Several temporal bone studies have demonstrated fibrosis and new bone formation adjacent to the electrode track (Nadol and Eddington, 2004; Li et al., 2007; Somdas et al., 2007; Seyyedi and Nadol, 2014; Kamakura and Nadol, 2016), and have shown that this local inflammatory response is quite common. (Nadol and Eddington, 2004; Seyyedi and Nadol, 2014; Kamakura and Nadol, 2016). Seyyedi and Nadol (2014) demonstrated evidence of a chronic inflammatory reaction including inflammatory mediator cells, fibrous tissue and new bone formation in twenty-eight specimens (100%), from patients who during life underwent cochlear implantation.

They reported that these inflammatory effects were more severe at the basal turn of cochlea close to the cochleostomy, and suggested that trauma of electrode insertion (at the cochleostomy) and a foreign body response may initiate these inflammatory effects. However, determining factors of the amount and causes of fibrous reaction surrounding the stimulating electrode, especially medially at a perimodiolar location, are unclear. Moreover, the causal relation between fibrous tissue growth or new bone formation and hearing performance is still inconclusive (Li et al., 2007; Kamakura and Nadol. 2016).

We wished to systematically evaluate the pattern of fibrous tissue formation around different types of CI electrodes in an attempt to determine the potential causes of fibrous tissue, including trauma, inflammation, and the possible role of electrical stimulation. This study also examined whether there is a clinical correlation between the thickness of the fibrous tissue and hearing performance or duration of implantation.

2. Materials and methods

2.1. Subjects

Temporal bone specimens were selected from the collection of the Otopathology Laboratory of the Massachusetts Eye and Ear from patients who in life had undergone cochlear implantation. These specimens were categorized by CI device in two groups: (1) Advanced Bionics (AB) Clarion ™ or HiRes90K™ (Sylmar, CA, USA) devices, which have 16 half-band contact electrodes, and a precurved configuration (HiFocus I, HiFocus IJ, HiFocus Helix and HiFocus with positioner) to achieve a more perimodiolar position, and (2) Cochlear ™ Corporation Nucleus (Sydney, Australia) devices, which have 22 full-band contact electrodes with a straight configuration. Demographic and clinical data including sex and age, duration of implantation, cause of deafness, type of CI device and electrode array and post-implantation last-recorded word recognition scores [CNC (Consonant- Nucleus-Consonant Word Test score) or NU6 (Northwestern University Auditory Test No. 6)] are presented in Table 1. When available, longitudinal CI impedance data from the manufacturer programming software were evaluated.

2.2. Histological methods and 2-D reconstruction of the cochlea

The temporal bone specimens were removed and fixed in 10% buffered formalin solution. The specimens were scanned, using computerized tomography with the intra-cochlear electrodes left in place, and decalcified in ethylene diamine tetra-acetic acid (EDTA). Electrodes were removed from the specimens after decalcification, and the specimens were then embedded in celloidin. The specimens were sectioned at a thickness of 20 μm in an axial plane, and every tenth section was stained with hematoxylin and eosin (H&E), and mounted on a glass slide. Every tenth section was studied using light microscopy for 2-D reconstruction based on the method described by Schuknecht (1953) and Otter et al. (1978).

2.3. Quantification of intra cochlear fibrous sheath

The dense fibrous sheath enveloping the electrode array was studied at two locations of the cochlea: the lower and upper basal turns (LB and UB respectively). The most orthogonal section at each location was selected to avoid bias caused by oblique section angle (Fig. 1A). Specimens in which a fibrous sheath was not seen at both locations of the cochlea were excluded. A standard light microscope (Olympus BX51) and a camera (Olympus DP71) were used to identify the morphology of dense fibers that formed a sheath or capsule around the electrode, as seen in H & E staining. Image J software (http://rsbweb.nih.gov/ij/) was used to measure the thickness of this dense fibrous sheath at three locations: medial, inferior, and superior to the track of the electrode array, with reference to the plane of the osseous spiral lamina (Fig. 1B). Lateral measurements were excluded in order to eliminate the possible influence of the juxtaposition of the lateral boney cochlear wall to the forming fibrous capsule. The loose fibrous tissue was not measured since its unorganized fibers spread diffusely in the cochlea, and therefore their quantification, as assessed by 2-D

Table 1
Clinical history of the implanted patients.

No.	Case/side	Sex	Age (yr.)	Diagnosis	C.I. usage (yr.)	Device	Electrode type	Electrode shape	C.I. WRS (%)
1	1 L	F	82	PSNHL, SSNHL	8	AB Clarion CII	HF I	Perimodiolar	44(CNC)
2	2 L	F	93	PSNHL	8	AB HR90K	HF 1J	Perimodiolar	NA
3	3 L	F	89	PSNHL	9	AB Clarion CII	HF I	Perimodiolar	10(CNC)
4	4 R	F	94	PSNHL	12	AB Clarion CII	HF II w/p	Perimodiolar	10(CNC)
5	5 R	M	89	PSNHL	3	AB HR90K	HF Helix	Perimodiolar	74(CNC)
6	6 R	M	64	SSNHL	2	AB HR90K	HF 1J	Perimodiolar	60(CNC)
7	6 L	M	64	SSNHL	2	AB HR90K	HF 1J	Perimodiolar	50(CNC)
8	7 R	M	80	Genetic	24	Nucleus 22	Banded	Straight	46(CNC)
9	8 R	F	84	PSNHL	13	Nucleus 22	Banded	Straight	34(NU6)
10	9 R	M	83	Meniere's sd., PSNHL	12	Nucleus 24	Banded	Straight	57(CNC)
11	10 L	M	76	PSNHL	18	Nucleus 22	Banded	Straight	0(NU6)
12	11 L	M	88	Acoustic trauma	11	Nucleus 22	Banded	Straight	NA

No, number; L, left; R, right; M, male; F, female; yr., year; PSNHL, progressive sensorineural hearing loss.
SSNHL, sudden sensorineural hearing loss; sd, syndrome; AB, Advanced Bionics; HR, Hi Res.
HF, HiFocus; w/p, with positioner; NA, not available; C.I., cochlear implant.
WRS, word recognition score (monosyllabic).