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Histopathology of the Clarion Cochlear Implant Electrode Positioner in a Human Subject

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Abstract

A silastic electrode positioner was introduced by the Advanced Bionics Corporation in 1999 and it was designed to achieve a perimodiolar position of the stimulating electrode. The positioner was voluntarily recalled in the United States in July 2002 due to an apparent higher risk of bacterial meningitis in patients in whom the electrode positioner had been placed. A detailed histopathologic study of the positioner in the human has not previously been published. The histopathologic findings in a 74-year old woman who underwent bilateral cochlear implantation using the positioner are presented. Findings including a large track caused by the combined electrode and its positioner with considerable disruption of the basilar membrane and osseous spiral lamina. Although there was a fibrous sheath around the electrode and positioner at the cochleostomy in both ears, this fibrous sheath did not extend deeply into the cochlea except at the apical end of the electrode beyond the positioner. This resulted in a large fluid space around and between the positioner and electrode within the cochlea and presumably in fluid continuity with the CSF space. Possible clinical implications are discussed.

Keywords

Histopathology; Clarion Cochlear Implant; Positioner; Human

Introduction

The manufacturers of the Clarion® cochlear implant system (Advanced Bionics Corporation) introduced the concept of an electrode positioner in 1999. This silastic positioner was designed to lie between the actual stimulating electrode and the lateral cochlear wall to position the electrode closer to the modiolus, in order to improve frequency selectivity and to reduce power consumption.

Electrophysiologic studies of the electrode system with positioner have demonstrated reduction in the evoked auditory brainstem response threshold compared to the electrode

without positioner [Lenarz et al 2000]; [Eisen and Franck, 2004] and also lower psychophysical thresholds (T levels), and most comfortable loudness levels (M levels) in patients using the positioner [Donaldson et al, 2001]. Anatomic evidence of a more perimodiolar location of the electrode array was demonstrated in several temporal bone studies using cadaveric human specimens [Gstoettner et al, 2001]; [Fayad et al, 2000]; [Wardrop et al, 2005]; [Richter et al, 2002]; [Tykocinski, et al, 2000] and also by radiographic imaging [Yang et al 2000]; [Richter et al, 2002]. However, despite success in achieving a more perimodiolar position of the electrode array, considerable trauma to the basilar membrane and osseous spiral lamina was also identified in these cadaveric specimens [Richter et al, 2002]; [Tykocinski, et al, 2000]; [Wardrop et al, 2005]; [Aschendorff et al, 2003]. The positioner was voluntarily recalled in the United States in July 2002 due to an apparent higher risk of bacterial meningitis when the electrode positioner was used [Reefhuis et al, 2003].

Arnold et al [2002] hypothesized two possible etiologies for an increased risk of otogenic meningitis, firstly a perilymphatic leak at the cochleostomy site, and secondly the creation of a space between the positioner and the electrode which remained unsealed. To date there has been one human temporal bone histopathologic study of a positioner implanted during life [Makarem et al, 2008]. However, the main thrust of this manuscript was the possible role of a biofilm in meningitis, and there was little detail concerning the induced pathology within the human cochlea.

The Temporal Bone Laboratory at the Massachusetts Eye and Ear Infirmary recently acquired human temporal bone specimens from a patient who had undergone bilateral cochlear implantation using the positioner device eight years prior to death. Although this patient never suffered meningitis, given the relevance of the findings as to possible mechanisms of meningitis, and clarification of trauma induced by the positioner and electrode array in the living patient, this case report of a bilateral cochlear implantation with positioner is presented.

Case Report

This 74-year old woman had a history of bilateral hearing loss starting at approximately age 6. A diagnosis of bilateral otosclerosis was made, and she underwent bilateral stapedectomy and bilateral revision stapedectomy later in life. Audiometry performed at age 66 demonstrated anacusis of her left ear and a severe to profound sensorineural loss on the right (Figure 1). Word recognition at age 35 was 0% on the right. At age 66 she underwent bilateral cochlear implantation using an Advanced Bionics High Focus CII cochlear implant with positioner (Figure 2). At 54 months postoperatively her word recognition score (CNC word list) was 66% on the left and right sides and 68% binaurally. At 63 months postoperatively her binaural CNC word score was 74%. Postoperatively she suffered a few episodes of what were described as positional vertigo and disequilibrium. Her past medical history included hypertension and chronic obstruction pulmonary disease.

At 26 hours postmortem, both temporal bones were removed and fixed in 10% buffered formalin. The electrode array had been removed after death but before histologic preparation, and the positioner had been retained within the cochlea during the period of

histologic preparation and sectioning. After decalcification in ethylene diamine tetra-acetic acid the specimens were embedded in celloidin and sectioned at a thickness of 20 micrometers in a horizontal plane. The specimens were stained in hematoxylin and eosin and mounted on glass slides. Every tenth section was studied by light microscopy.

Findings

On 2-dimensional reconstruction both cochleas possessed 2-1/2 turns. The length of the cochlear duct on the right side was 27 mm and 27.8 mm on the left. Histopathologic findings in both ears were similar and hence will be described together.

Cochlear Duct

There were no remaining hair cells within either cochlea, either along the course of the electrode track or apical to it. The number of remaining spiral ganglion cells was 51% of normal corrected for age on the right side and 55% of normal corrected for age on the left. There was endolymphatic hydrops of the entire cochlea on both sides but not of the vestibular apparatus. There was collapse of the saccular wall in both ears.

Track of Implanted Electrode and Positioner

The implant electrode and attached positioner entered the cochlea in the lower basal turn (approximately 2.5 mm from the round window on the right and 1.5 mm from the round window on the left side). The electrode track extended apically to 21 mm from the round window in both ears. Although the electrode had been removed prior to histologic preparation and the positioner remained in situ during sectioning, the silastic positioner fell out of each section as it was cut. Nevertheless, the electrode track could be easily followed using tissue reaction and trauma induced by the electrode array. In Figure 3, the track of the positioner can be seen both in the scala tympani and scala vestibuli. Apical to the positioner, where the implant electrode extended beyond the positioner, the track of the electrode only could be seen at mm 21. Figure 4 demonstrates a higher power of the basal and middle turn of the cochlea. The positioner created a track of large diameter which remained near the lateral cochlear wall. It also caused considerable disruption of the basilar membrane and osseous spiral lamina. There was no distinct fibrous track around the electrode array that was visible except where the electrode was sectioned apical to the positioner track (mm 21). Here the electrode track was at the lateral cochlear wall and was surrounded by a fibrous sheath.

Figure 5 demonstrates the track of the positioner in the left ear at mm 11 from the round window. With the condenser of the microscope defocused, the outline of the positioner could be seen as well as disruption of the basilar membrane. There was no continuous fibrous sheath surrounding the positioner within the cochlea. Reissner's membrane was visible and its anatomy was consistent with endolymphatic hydrops in all turns of the cochlea.

Tissue reaction to the presence of the positioner and electrode array

There was a fibrous sheath surrounding the electrode array and positioner track at the cochleostomy (Figure 6A). The fibrous sheath, however, did not extend to any significant

degree within the cochlear duct around the electrode track (Figure 6B). Within the cochlea there was little in the way of a fibrous sheath around the positioner and none discernible around the electrode itself except where the electrode extended apical to the positioner (Figure 4). In some sections, a foreign body reaction could be seen adjacent to the electrode array (Figure 7) in the form of multinucleated foreign body giant cells and a lymphocytic cell infiltration.

In summary, where the electrode array consisted of both the positioner and electrode, the positioner seem to occupy space between the electrode and the lateral cochlear wall and therefore presumably displaced the electrode itself closer to the modiolus. There was surprisingly little in the way of a fibrous sheath around the electrode array except near the cochleostomy and distal to the positioner, suggesting a patent fluid space between the positioner and the electrode array. There was surprisingly little new bone and fibrous tissue except near the cochleostomy despite dissection of the lateral cochlear wall in contrast to what would have been expected by the findings of Li et al [2007] as described around electrode tracks without a positioner. There was significant fracture/dislocation of the osseous spiral lamina and basilar membrane induced by the positioner. There was bilateral cochlear endolymphatic hydrops and saccular collapse.

Discussion

Perimodiolar location of electrode array

As shown previously by Gstoeetner et al [2001] and Richter et al [2002] in cadaveric human specimens, the positioner was successful in displacing the electrode array to a more perimodiolar position which would confirm the electrophysiologic data of Lenarz et al [2000] demonstrating a decrease in thresholds for auditory brainstem responses with a positioner, that of Eisen and Franck [2004] demonstrating a decrease in the threshold of evoked response action potentials using the positioner and that of Donaldson and Peters et al [2001] demonstrating a decrease in T and M levels with the use of the positioner. Although a more perimodiolar position had been achieved using the positioner, this was done at the cost of significant trauma to the cochlea in the form of fracture or dislocation of the basilar membrane and osseous spiral lamina as shown in this study in both ears confirming findings in cadaveric specimens previously reported by Gstoeetner et al [2001] and Richter et al [2002].

Risk of meningitis

There had been no history of meningitis in this patient. However, although there was a fibrous sheath around the electrode and positioner at the cochleostomy on both sides, this fibrous sheath did not effectively separate the electrode array from the positioner resulting in a large fluid space around the positioner and electrode when adjacent to each other within the cochlea, including much of the scala tympani and scala vestibuli. In addition the electrode array (electrode plus positioner) did not have a circumferential fibrous sheath. Such an expanded peri-electrode fluid space, within the cochlea and presumably in fluid continuity with the CSF space, conceivably could predispose to an increased risk of infection within the cochlea and otogenic meningitis.

In addition significant trauma to the osseous spiral lamina was seen along the track of the positioner which has been shown to increase the risk of bacterial meningitis in an animal model [Wei, BRC, et al, 2007].

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Figure 1.
Preoperative audiogram at age 66. Speech discrimination on the right tested 31 years previously was 0%. The left ear was anacusic.

Figure 2.

An Advanced Bionics Hi-Focus CII cochlear implant with attached positioner. Notice that the positioner does not extend to the tip of the electrode array.

Figure 3. Mid-modiolar section of the implanted right temporal bone. The track of the electrode apical to the positioner is shown at millimeter 21 (*), and the track of the positioner is seen at millimeter 11 (***) and at millimeter 17 (**). The track of the positioner at millimeter 11 is shown better in Figure 4.

Figure 4.

The track of the electrode apical to the positioner at millimeter 21(*) is seen at higher power. At millimeter 21 there was a characteristic fibrous sheath around the track of the electrode array, whereas at millimeter 11(***), where the positioner had been located, there was little evidence of a fibrous sheath. The positioner and electrode combination filled most of the scala vestibuli and tympani. There was fracture dislocation of the osseous spiral lamina (OSL).

Figure 5. Millimeter 11 of the left temporal bone. The entire circumference of the positioner and electrode combination is better shown in this micrograph taken with the microscope condenser defocused. The margin (M) of the track of the positioner at the celloidin-silastic interface was easily seen. There was no circumferential fibrous sheath surrounding the positioner or electrode at this location.

Figure 6. Temporal bone section near the cochleostomy (C) in the right temporal bone. The positioner and electrode track was surrounded by a fibrous sheath (FS) in the extracochlear segment and in part of the intracochlear segment (6A). However, the positioner and electrode were surrounded by only a partial fibrous sheath (FS) which was not circumferential (6B).

Figure 7.

Track of the cochlear implant near the cochleostomy in the left temporal bone. There were both foreign body giant cells (FBGC) and a lymphocytic infiltrate (MI) adjacent to the electrode track (T).