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A temporal bone study of insertion trauma and intracochlear position of cochlear implant electrodes. II: Comparison of *Spiral Clarion*™ and *HiFocus II*™ electrodes

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Abstract

In recent years, several new designs of cochlear implant electrodes have been introduced clinically with the goal of optimizing perimodiolar placement of stimulation sites. Previous studies suggest that perimodiolar electrodes may increase both the efficiency and performance of a cochlear implant. This is the second of two studies designed to examine the positioning of electrodes and the occurrence of insertion-related injury with these newer designs and to directly compare two perimodiolar electrodes to their predecessors. In our previous report we compared the Nucleus™ banded electrode with the Nucleus *Contour*™ perimodiolar electrode. In the present study, using the same protocol, we examine the *Spiral Clarion*™ electrode and its successor, the *HiFocus II*™ electrode with attached positioner.

Eight *Spiral Clarion*™ arrays and 20 *HiFocus II*™ electrodes with positioners were inserted into human cadaver temporal bones. Following insertion, the specimens were embedded in acrylic resin, cut in quarters with a diamond saw and polished. Insertion depth, proximity to the modiolus and trauma were evaluated in X-ray images and light microscopy.

The newer electrode was consistently positioned closer to the modiolus than the previous device whereas the angular depth of insertion measured for the two electrodes was similar. The incidence of trauma was minimal when either electrode was inserted to a depth of less than 400°. However, severe trauma was observed in every case in which the *HiFocus II*™ with positioner was inserted beyond 400° and in some cases in which the *Spiral Clarion*™ was inserted beyond 400°. To evaluate the possible role of electrode size in the trauma observed we modeled both devices relative to the dimensions of the scala tympani. We found that the fully inserted *HiFocus II*™ electrode with positioner was larger than the scala tympani in approximately 70% of temporal bones measured. The results suggest that both the *Clarion*™ spiral and *HiFocus II*™ with positioner can be inserted with minimal trauma, but in many cases not to the maximum depth allowed by the design.

Keywords: Cochlear implant; Insertion; Trauma; Electrodes

1. Introduction

Since the first series of experimental cochlear implants in human subjects began in the late 1960's the number of implant recipients each year and the benefits obtained have increased steadily (Schindler, 1999;

Abbreviations: OSL, osseous spiral lamina; BM, basilar membrane; SpG, spiral ganglion; SpL, spiral ligament; SM, scala media; St. V, stria vascularis; ST, scala tympani; SV, Scala Vestibuli; RM, Reissner's membrane; Elect, electrode; Pos, positioner

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Rebscher et al., 1999). The ''artificial cochlea'' as it was once known has exceeded virtually all initial expectations and has led to a worldwide collaboration of scientists, surgeons, manufacturers and those in the deaf teaching and rehabilitative professions serving a patient population of more than 85,000. The improvement in performance of cochlear implant recipients during this period resulted from advances in speech processing hardware and software, increased numbers of information channels delivered across multichannel electrode arrays and changes in selection criteria for cochlear implant candidates, allowing implantation of individuals with greater residual hearing.

With the goal of further improving overall performance, several manufacturers have introduced second-generation intracochlear electrodes. These designs are based on the concept that positioning stimulating electrodes nearer to the modiolus, which contains the surviving spiral ganglion cells, would increase the efficiency and selectivity of stimulation (Finley et al., 1990; Shepherd et al., 1992; Frijns et al., 1996, 2001; Briaire and Frijns, 2000; Rebscher et al., 2001). These electrodes have been termed ''perimodiolar'' designs. Although conceptually straightforward, the engineering strategies developed to produce such electrodes have led to very different designs from several manufacturers.

To date, two perimodiolar electrode designs have been evaluated in clinical trials. These devices are the Nucleus *Contour*™ electrode produced by Cochlear Corporation (Englewood, CO) and the *HiFocus*™ array manufactured by Advanced Bionics Corporation (Valencia, CA). The *Contour*™ is a spiral electrode that is temporarily held straighter during insertion by an internal wire stylet (Tycocinski et al., 2001). The stylet is retracted after, or during, insertion of the electrode allowing the electrode to return to its molded spiral shape and assume a final position closer to the modiolus. Two versions of the *HiFocus*™ electrode design use a separate space-filling positioner to move the active electrode closer to the modiolus (Lenarz et al., 2000). In the first clinical version of this electrode, the *HiFocus I*™, the positioner is inserted after full insertion of the electrode. In a subsequent version, the *HiFocus II*™, the positioner is attached to the electrode at either 4 or 6 mm from the tip. The *HiFocus II*™ electrode with attached positioner uses a custom insertion tool in which the positioner is loaded over a stylet and is pushed off the stylet as the insertion tool actuator is advanced. Thus, the electrode is pulled into the scala tympani by the positioner, in contrast to the original version in which the positioner pushed the previously inserted electrode toward the modiolus. At the time of this study the *HiFocus I*™ electrode was approved for clinical use and the *HiFocus II*™ electrode with attached positioner was approved for investigational use. It should be noted that subsequent to the completion of our study, the *HiFocus II*™ electrode with attached positioner was voluntarily withdrawn by the manufacturer due to concerns of increased incidence of bacterial meningitis (Reefhuis et al., 2003). The *HiFocus*™ electrode with no positioner is currently being applied clinically and a new coiled version of this electrode (Helix™) is being tested in a clinical trial.

This report is the second in a series of temporal bone insertion trials with subsequent histologic evaluation. The goals of these studies include documenting electrode position and assessing the frequency, severity and nature of trauma associated with insertion of these electrodes in comparison to the previous electrode design from each manufacturer. In the first report (Wardrop et al., 2005) we compared the original *Nucleus* 22™ banded array to the perimodiolar Nucleus *Contour*™ electrode. In the present study we compare the *Spiral Clarion*™ with its successor the *HiFocus II*™ (see Fig. 1). The electrodes were inserted in human temporal bones by three surgeons, an experienced implant surgeon and two otology fellows with specialized cochlear implant training in both the temporal bone laboratory and clinical setting. The implanted cochleae were evaluated using radiographic and histological techniques. Although temporal bone analysis does not allow evaluation of the reaction of the living cochlea to implantation, e.g., inflammation, fibrosis and neuronal degeneration, it does allow detailed assessment of the position of the electrode in the cochlea and the acute trauma caused by insertion.

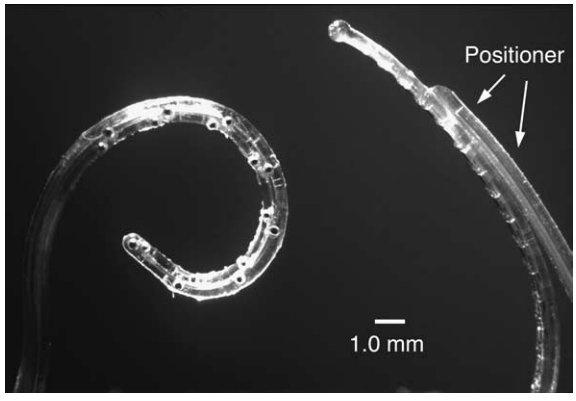

Fig. 1. The two electrodes evaluated in this study are shown. The original *Spiral Clarion*™ electrode is shown on the left. This electrode has 16 stimulation sites arranged in eight offset radial pairs, such that the apical contact in each pair is oriented to face the basilar membrane or osseous spiral lamina and the second contact is located 500 μm basal to the first contact and rotated 90° downward toward the modiolus. The *HiFocus II*™ electrode with attached positioner (right) is designed to position stimulating contacts closer to the spiral ganglion cells in the modiolus and to access more apical, lower frequency regions of the cochlea. The *HiFocus II*™ electrode has 16 longitudinally spaced stimulation sites facing the modiolus. Because the *HiFocus*™ electrode is radially symmetrical, different versions for implantation in a left versus right cochlea are not required.