HiFocus™ Mid-Scala Electrode Design

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Electrode Design Goals

The HiFocus™ Mid-Scala electrode is intended to improve hearing for individuals with severe-to-profound hearing loss by providing extended electrical coverage of the cochlea while minimizing trauma related to insertion. Specifically, the design goals for this new array were to create a thinner electrode that:

1. "Free floats" in the scala tympani, thus avoiding the delicate structures of the cochlea.
2. Consistently locates the apical stimulating contacts adjacent to lower frequency neurons.
3. Facilitates insertion through the round window to enable more effective stimulation of the basal cochlear turn.

In addition, the electrode should be appropriate for use with a wide range of surgical techniques, including either cochleostomy or round window insertion, as described above, and the use of either a freehand or tool-assisted approach.

HiFocus Mid-Scala Electrode Design

The design of the HiFocus Mid-Scala electrode was based on these goals and was the result of an iterative optimization of each feature.

Shape. An electrode array with a relatively small cross section and correct spiral dimensions will accommodate the large variation observed in cochlea size because the mathematical equation that defines the cochlear spiral and its tonotopic distribution of neurons is common to all cochleae (Skinner et al., 2002; Stakhovskaya, 2008). Thus, while the variable lengths of the outer and inner walls of the scala tympani determine the angular insertion depth of traditional lateral wall and peri-modiolar electrode designs (Escude et al., 2006), a "free floating" electrode that does not follow either of these surfaces (as the curvature of the array is more open than traditional peri-modiolar arrays) should consistently assume its pre-molded shape, and associated tonotopic location, when fully inserted. In addition to greater consistency in angular insertion depth, the mid-scala location should result in an increased insertion depth as a function of electrode array length (described by Wardrop et al., 2005 as the "proximity factor" and by Holden et al., 2013 as the "wrapping factor") compared to lateral wall arrays, and this position is positively correlated with increased performance in human subjects (Holden et al., 2013 and Finley et al., 2008) and in computer modeling studies (Frijns et al., 2009). To illustrate this strategy, Figure 1 shows a schematic of the HiFocus Mid-Scala electrode modeled within a stacked set of nine human scala tympani outlines. The final size and geometry of the HiFocus Mid-Scala electrode was based on empirical data from a series of spiral electrodes that were fabricated and inserted in a set of temporal bones and clear scala tympani models that represented the range of anatomic variation observed in human subjects.

Figure 1. The spiral shape and smaller dimensions of the HiFocus Mid-Scala electrode locate the array near the center of the scala tympani. In this illustration, the array is modeled within outlines of 9 human scala tympani.

Size. The cross-sectional profile of the HiFocus Mid-Scala electrode is tapered to fit within the full range of scala tympani dimensions observed in the human population and is the smallest pre-curved array in the industry. The dimensions used for this analysis were based on outlines measured in 35 human temporal bones at the University of California, San Francisco (UCSF) (Rebscher et al., 2008). Figure 2 illustrates the HiFocus Mid-Scala electrode array modeled within these profiles at three insertion depths and a corresponding histological section at the same depth in a typical temporal bone from this study. The percentage in the lower right corner of each histological section indicates the proportion of scala tympani cross-sectional area that is occupied by the electrode array in each section.

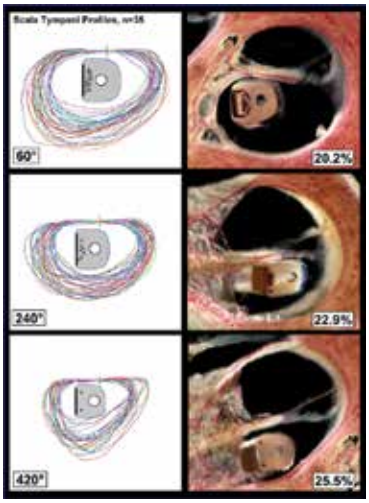

Figure 2. Electrode size is a critical factor in reducing insertion trauma. In this figure, cross-sections of the HiFocus Mid-Scala array are modeled within profiles of 35 human scala tympani (left) and are shown in corresponding histological sections (right). The area occupied by the array is shown as the percentage of scala tympani area in the lower right of each image.

If the reduced size and optimized spiral shape of the HiFocus Mid-Scala™ array results in a true mid-scala position, it is hypothesized that this will significantly reduce the risk of cochlea damage typically seen with lateral wall or peri-modiolar electrodes by minimizing contact between the electrode tip and the boundaries of the scala tympani during insertion (e.g., Adunka et al., 2004; Aschendorff et al., 2007; Briggs et al., 2001; Roland, 2005). The "free floating" design will also reduce or eliminate ongoing contact pressure between the array and the structures surrounding the scala tympani.

Mechanical Stiffness Properties

Electrodes that are stiffer in the vertical plane compared to the horizontal plane of the cochlear spiral are far less likely to bend upward resulting in damage to the cochlear partition and deviation into the scala vestibule (Rebscher et al., 1999; Wardrop et al., 2005b; Rebscher et al., 2008). The majority of the inherent stiffness in an electrode array comes from the lead wires held in the elastomer carrier. Using these lead wires as structural elements in the array permits the fabrication of electrodes with predetermined three-dimensional stiffness. Figure 3 illustrates the electrode lead arrangement in the HiFocus Mid-Scala electrode. Molding the leads in a vertical column imparts greater resistance to bending in the vertical plane.

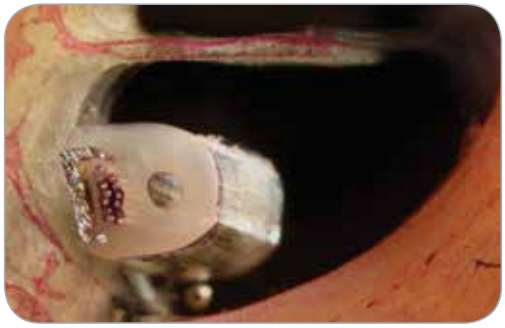

Figure 3. The vertical arrangement of lead wires in the HiFocus Mid-Scala electrode resists vertical deflection of the array.

Specifications

The HiFocus Mid-Scala electrode array consists of 16 platinum contacts with fluorocarbon-polymer-insulated lead wires molded in a spiral-shaped silicone carrier (Figure 4). The electrode is 18.5 mm from the proximal blue marker to the tip with a target insertion depth of 1¼ turns. This allows the apical contacts to reach lower-frequency neurons (Stakhovskaya et al., 2007) without the increased risk of trauma and perceptual distortions associated with deeper insertions (Adunka et al., 2006; Baumann et al., 2006; Gani et al., 2007). The electrode cross section is approximately 0.5 by 0.5 mm at the first contact and 0.7 by 0.7 mm at the most basal contact. Under the distal blue marker is a non-stimulating contact, providing a radio-opaque reference to the blue marker. The tip of the HiFocus Mid-Scala electrode is specifically tapered to facilitate insertion of the array through the round window membrane after the membrane has been perforated using a surgical laser, micro-cautery or the tip of a fine-gauge hypodermic needle (Figure 4).

Figure 4. The HiFocus Mid-Scala electrode is shown above. The array is 18.5 mm in length, 0.5 x 0.5 mm in cross section at the tip and 0.7 x 0.7 mm at the base. The tip of the array is specifically tapered to allow insertion through the round window after perforation.

A dedicated insertion instrument was developed to improve consistency and repeatability of electrode insertion (e.g., Briggs et al., 2011). The stylet, which extends down the lumen of the electrode to the first electrode contact, is also relatively stiff, holding the electrode straight and allowing good visibility of the surgical space. It is coated to minimize friction as the electrode is released. When using the insertion tool, the depth of the stylet within the scala tympani is limited to 6 mm to allow the electrode array to begin to assume its pre-molded spiral shape before it contacts the outer wall of the first turn.

Electrode Design Validation – Methodology

A team of experienced surgeons, residents and engineers evaluated several prototype electrodes in over 150 temporal bones to arrive at the final HiFocus Mid-Scala electrode design. A unique aspect of the Advanced Bionics (AB) development process was the use of a force measurement system (Agilent

Universal Test Measurement System) that allowed three-dimensional measurement of forces within the cochlea during insertion of each prototype electrode. Surgeons experienced audio feedback that changed pitch in real time depending upon the magnitude of the resultant insertion force. At the same time, fluoroscopy and microscopy were synchronized and captured to provide a complete description of the position of the electrode and 3D forces exerted against cochlear tissues during the insertion process. Traditional histology was also performed.

To validate the final design, four experienced surgeons in the US and Europe inserted the HiFocus Mid-Scala™ electrode in a series of 32 temporal bones for regulatory qualification and a subsequent series of 5 temporal bones under identical conditions (total temporal bones, n=37). The specimens for this study were harvested within 24 hours and briefly fixed to minimize changes in the mechanical properties of the cochlear membranes. Surgeons used a realistic facial recess approach and a variety of insertion techniques (round window and cochleostomy, freehand and insertion tool) with saline as the only lubricant. Evaluation of each specimen was made through x-ray, histology, and trauma ranking (Eshraghi et al., 2003). Each surgeon also completed a questionnaire about their experience with the electrode and tool options.

To validate clinical reliability, an insertion/reloading/reinsertion protocol was followed in specimens to verify the robustness of the HiFocus Mid-Scala electrode against mechanical damage and to verify ease of use. This protocol involved securing an implant to the bone bed and following standard surgical practice in manipulating the electrode during insertion and reloading.

Electrode Design Validation – Results

Appropriate electrode size, shape, and mechanical characteristics minimize trauma. The data generated in the extensive bench testing and temporal bone studies described above verify that the HiFocus Mid-Scala electrode represents significant improvement in cochlear implant electrode design.

Data from additional force measurement experiments to compare electrode designs indicate that there was minimal force applied to cochlear structures during the insertion process for the HiFocus Mid-Scala electrode (Figure 5). The average insertion force for the HiFocus Mid-Scala electrode (n=4) inserted in this comparative study, using the dedicated insertion tool into a plastic cochlea model, is below 20 mN. Histological sections showed that the HiFocus Mid-Scala electrode was located mid-scala in most sections and fit easily in all scala tympani in the UCSF cochlear dimensional database along the entire length of the array (as illustrated in Figure 2). Moreover, 77% of all histologic specimens measured showed no contact between the electrode and either the inner or outer wall of the scala tympani throughout the entire length of insertion, a significantly greater proportion of specimens than any previous electrode design we have tested.

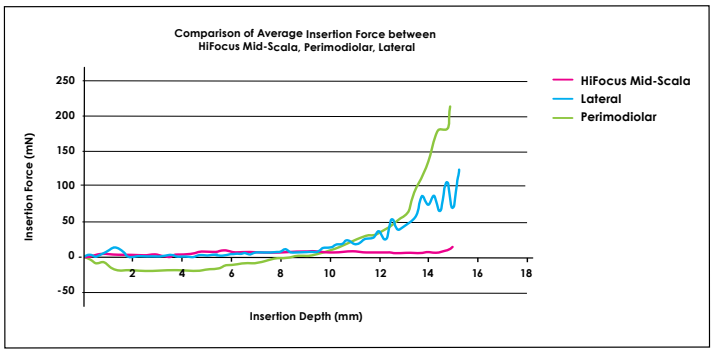

Figure 5. The shape of the HiFocus Mid-Scala electrode was optimized with data from a customized 3D force measurement system with micro-newton accuracy. Due to reduced contact, the insertion forces for the HiFocus Mid-Scala array are the lowest measured with this system.

The multicenter temporal bone trial confirmed that reducing the incidence and force of contact between the electrode array and the surrounding margins of the scala tympani resulted in a significant reduction in cochlear trauma. A typical hemicochlear view of a HiFocus Mid-Scala temporal bone insertion is shown in Figure 6. As described above, the HiFocus Mid-Scala array was inserted in 37 human temporal bones, histologically prepared and evaluated using the Eshraghi trauma grading scale (0 = no observable trauma, 1 = elevation of basilar membrane, 2 = rupture of basilar membrane, 3 = electrode in scala vestibuli, and 4 = fracture of the osseous spiral lamina, modiolus, or torn stria vascularis). Thirty five (35) of these specimens were rated as having no trauma in any of the histological slices (rating = 0). In the remaining two specimens, one electrode was inserted directly into the scala vestibuli with a slight deviation of the basilar membrane noted, but with no damage. As such, it could be scored with a rating of 1, but was classified as a rating of 3

because it was within the scala vestibuli. In the second specimen with observed damage, the proximal blue marker was located approximately 2 mm outside of the round window. The surgeon noted that the round window approach had not presented well and a cochleostomy would have been a better choice for this specimen. In this case, the electrode had translocated from the scala tympani into the scala vestibuli and was conservatively rated as a 4 on the trauma scale. Histology results are summarized in Table 1.

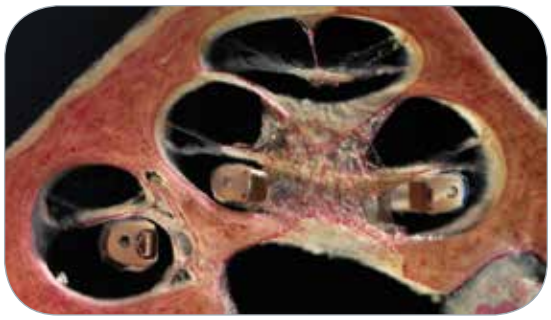

Figure 6. The HiFocus Mid-Scala™ array is shown above following a typical insertion in a human temporal bone. In this multicenter validation study, no trauma was observed (trauma score of 0) in 35 of the 37 implanted specimens.

Trauma Observed

		Insertion Site	
		Round Window	Cochleostomy
Method of Insertion	Insertion Tool	0 of 6	0 of 7
	Freehand/Stylet	1 of 16	1 of 8

Table 1. Histological study results. The number of specimens with trauma observed and the total number of specimens are given for each group studied.

More Consistent Insertion Depth, Lower Frequency Coverage

The "free floating" HiFocus Mid-Scala design, which assumes its original spiral shape after insertion, should be located at a more consistent angular insertion depth than an electrode that hugs the modiolus or follows the lateral wall of the cochlea. The average insertion depth for the HiFocus Mid-Scala array was 420°, with a range of 370° to 480° using the methods described by Stackovskya et al., (2007) and Verbist et al., (2010) (Figure 7). As expected, insertion depths were notably more consistent than has been reported with other electrode designs. For comparison, the standard deviation (SD) for all HiFocus Mid-Scala insertion depths was 20.7° while the SD of insertion depths reported for lateral wall designs was 35.5° to 171° and the SD for peri-modiolar designs was 34.5° to 61° (Adunka and Kiefer, 2006; James et al., 2006; Radeloff et al., 2008; Stover et al., 2005; Tykocinski et al., 2001; Wardrop et al., 2005b). More consistent insertion depth may offer benefits in establishing optimum processor parameters for clinical subjects (Baskent et al., 2005) and minimizing learning and adaptation required after fitting (Reiss et al., 2007). Insertion depth was independent of the insertion technique used. A 420° insertion angle corresponds to the tonotopic location of spiral ganglion neurons with frequencies of approximately 640–675 Hz (Stakhovskaya et al., 2007).

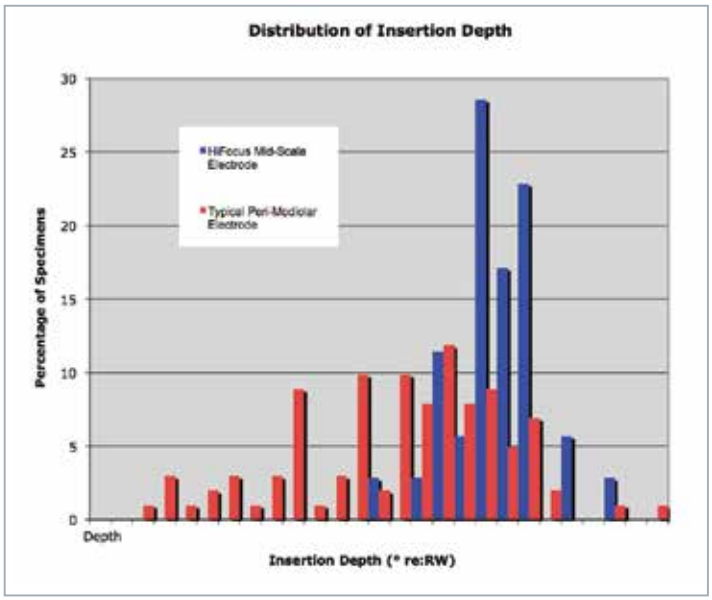

Figure 7. Insertion depths for the HiFocus Mid-Scala electrode were more consistent than for any other electrode previously studied. In this histogram, the distribution of insertions depths for the HiFocus Mid-Scala array are shown in blue and compared to the distribution of insertion depths for a typical peri-modiolar array in red.

Flexible Insertion Options

Participating surgeons indicated that the electrode could be inserted easily across the range of approaches (freehand vs. insertion tool, round window vs. cochleostomy), that the electrode could be reloaded easily, and that the cochleostomy gauge was useful and provided good visualization of the insertion point. The histologic data (Table 1) demonstrates that

the HiFocus Mid-Scala™ electrode can be inserted using either the tool provided or freehand with a very low incidence of damage when the array is inserted either through the round window or through a cochleostomy placed inferior and anterior to the round window. The path of the array through the extreme basal scala tympani can be seen in three specimens following round window insertion in Figure 8. Although the angle of the partition between the scala tympani and the scala vestibuli is highly variable in this region, the trajectory of the electrode from the round window to the first turn does not increase the likelihood of insertion damage.

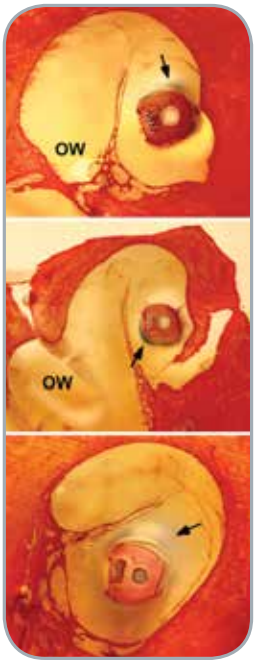

Figure 8. The HiFocus Mid-Scala array was inserted through the round window (RW) without trauma in the three examples shown above. Although the angle of the cochlear partition is highly variable in the extreme cochlear base, insertion through the RW does not increase the incidence of damage observed with the Mid-Scala array. The margins of the RW (arrows) and the oval window (OW) can be seen in this view from approximately 1.5 mm inside the RW.

Clinical Reliability

All participating surgeons confirmed that there was no significant visual damage to the electrode array (at 10–30x magnification) after each insertion. No electrodes suffered measureable electrical damage (open and/or shorted contacts) during the simulated use case in the specimens.

Discussion

Human temporal bone studies at UCSF over the past 15 years have evaluated insertion trauma for eight different electrode designs from three manufacturers and correlated the incidence and severity of cochlear damage with the characteristics of each model. These trials were conducted with a group of eight surgeons having a wide range of cochlear implant experience. The results of these studies have identified three critical factors in atraumatic insertion of cochlear arrays. First, the overall profile of the electrode must fit within the highly variable dimensions and shape of the scala tympani for all subjects. Second, electrodes that are more stiff in the vertical plane than in the horizontal plane are far less likely to deviate vertically into the scala vestibuli than electrodes without this mechanical characteristic. Last, direct insertion of cochlear implant electrode arrays through the basilar partition and into the scala vestibuli is still a common phenomenon (Skinner et al., 2007; Aschendorff et al., 2007) that can be avoided through appropriate location of a cochleostomy or use of the round window as the electrode insertion site (Aschendorff et al., 2007).

The multi-center temporal bone studies described here demonstrate that the HiFocus Mid-Scala electrode represents a significant advance in the design and manufacturing of cochlear implant electrode arrays. By combining small cross-sectional dimensions with a spiral shape that avoids contact with either the inner or outer wall of the scala tympani, the HiFocus Mid-Scala electrode was inserted to a more consistent depth and with less documented damage than other electrodes studied at UCSF. Several studies at other laboratories indicate that these attributes should improve performance for HiFocus Mid-Scala implant recipients with severe-to-profound hearing loss (e.g., Roland and Wright, 2006; Aschendorff et al., 2007; Finley et al., 2008).

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