

Based on the results of the current study it is clear that the HiFocus SlimJ electrode array is the least traumatic lateral wall design tested in our program, or reported in the literature, to date. In addition, it is important to note that when trauma was observed it was noted in a very limited number of locations in almost all instances and that no trauma was observed in the extreme base in any of the specimens in this series. Based on the conclusions of previous studies which relate electrode position and intracochlear trauma to subject performance (e.g. Kamakura and Nadol, 2016, Wanna et al., 2015, Carlson et al., 2011, Finley et al., 2008, Aschendorff et al., 2007, Roland and Wright, 2006) optimizing each of the essential parameters described above should provide greater benefit for cochlear implant recipients.

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HiFocus™ SlimJ Electrode

Electrode Design Goals

The Advanced Bionics HiFocus™ SlimJ electrode array represents more than three years of meticulous development based on in-depth evaluation of surgical handling characteristics preferred by surgeons, the role of electrode mechanical characteristics in surgical insertion damage and optimum insertion location. This electrode incorporates the reduced profile and asymmetric stiffness features found in the pre-curved HiFocus Mid-Scala array. Multiple laboratory and clinical reports have shown that this technology significantly reduces, or eliminates, intracochlear trauma in both temporal bone studies and in cochlear implant patients (Boyle, 2016, Hassepass et al., 2014, Rebscher et al., 2008, Wright et al., 2005). Because all straight or slightly curved electrodes are in direct contact with the basilar membrane and/or spiral ligament throughout most of their insertion length either minor damage to these structures, or full translocation into the scala vestibuli, may be predicted for these arrays.



Figure 1. HiFocus SlimJ electrode

The design goal for the SlimJ electrode is to provide a lateral wall array that overcomes this inherent obstacle to optimum patient performance by protecting the most delicate structures of the cochlea. At the same time the SlimJ array meets the specific needs of individual patients with anatomical features favoring a slightly curved electrode and for surgeons that feel a lateral wall array is best suited to their surgical approach. The SlimJ electrode is equally well suited for insertion through either a round window approach or a cochleostomy. The smaller profile of the SlimJ occupies less than 20% of the volume of the scala tympani throughout its intended insertion depth. Multi-surgeon validation studies have demonstrated that the SlimJ array successfully reduces the severe trauma often reported with lateral wall electrodes currently in clinical use worldwide (DeSeta et al., 2017, Mosnier et al., 2017, Jeyakumar et al., 2013).

HiFocus SlimJ Electrode Design Stiffness Properties

Control of the mechanical properties of CI electrodes manufactured by Advanced Bionics has progressed in functionally significant increments with each generation since the introduction of the Clarion spiral array in the 1990's. The Clarion was the first commercially available intracochlear electrode to incorporate asymmetric flexibility to limit vertical movement of the array in the scala tympani. Since that time, several multicenter temporal bone and CT based studies have clearly demonstrated that electrodes which are inherently more stiff in the vertical axis are significantly less likely to bend vertically, resulting in trauma, during insertion. This upward bending often results in severe damage to the

osseous spiral lamina, basilar membrane or stria vascularis and ultimately deviation in to the scala media or scala vestibuli (Roland and Wright, 2006, Roland, 2005). To date, this result has been replicated in carefully matched studies of more than 12 commercial and prototype electrode designs by more than 30 surgeons in San Francisco, Los Angeles, New York, Miami, Hannover and other centers around the world.

The unique design of the SlimJ electrode incorporates the successful features of these previous models. Figure 2 illustrates the precisely controlled lead wire configuration used in the SlimJ array. The SlimJ also incorporates the specially tapered tip design that helps to guide the array through a small incision in the round window. Because the overall flexibility of an electrode is, in large part, determined by the lead wires molded into the assembly the precise arrangement of these lead wires can be used to predictably control electrode flexibility in three dimensions. In the SlimJ, this technique is used to produce an electrode which is 2.5 – 3x more stiff in the vertical plane while increasing flexibility in the horizontal plane, the natural plane of curvature for the cochlea. As described in the validation section below, these characteristics result in a slightly curved electrode array with a remarkably low rate of insertion trauma.

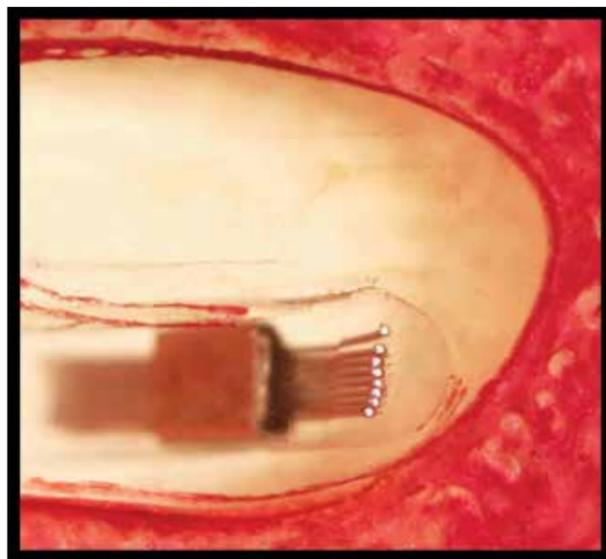


Figure 2. Vertical Rib

SlimJ Dimensional Specifications

The HiFocus SlimJ electrode consists of a tapered elastomer carrier holding 16 platinum stimulating contacts (see Figure 3). Each lead wire is individually insulated with fluorocarbon-polymer. The array length is 23.0 mm from the tip to the blue marker ring that is intended to be used as a reference marker for insertion depth. The active electrode length, from the apical stimulating contact to the most basal contact, is 20.0 mm. The spacing between each contact is 1.3 mm (c-c) with a length of 3.0 mm from the most basal contact to the marker ring. The predicted angular insertion depth for the SlimJ array is approximately 420° from the RW, matching the intended depth of the corresponding Mid-Scala electrode design. A 10 mm molded elastomer wing is located immediately proximal to the marker ring facing away from the modiolus. This feature provides a flat surface that can be reliably gripped with standard surgical forceps to guide the array into the scala tympani.

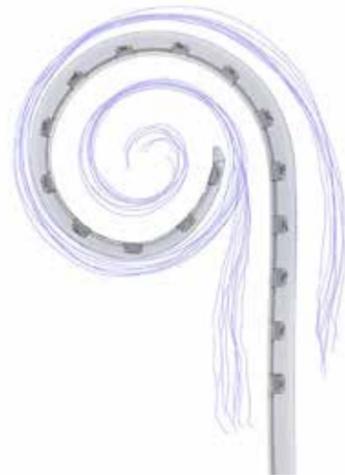


Figure 3. SlimJ Schematic in Top View Cochlear Outlines

Electrode Size

The shape and cross-sectional area of the SlimJ array was based on the database of human scala tympani profiles compiled at the University of California, San Francisco (USCF) (Rebscher et al., 2008), empirical testing in clear plastic scala tympani models and trial insertion tests in human cadaver temporal bones with the input of several groups of experienced cochlear implant surgeons. This iterative development protocol led to the design, fabrication and evaluation of nine specific prototype models resulting in the final

design of the SlimJ that combines optimum overall size, mechanical characteristics, flexibility and surgical handling properties.

Figure 4 illustrates the SlimJ electrode modeled within the UCSF profiles at representative cross-sections in the cochlear base (60° from the RW), first turn (240°) and lower second turn (420°) near the tip of the array. Design criteria for the SlimJ specified that the array, when fully inserted with the blue marker ring near the round window or cochleostomy, fit within all of the scala tympani cross-sections in the UCSF database. It is important to note that the cross-sectional area of these profiles varies by more than 100% at some locations. At the tip of the electrode (contact #1) the elastomer carrier measures 0.55 mm (H) x 0.26 mm (W). At the proximal stimulating contact (#16) the electrode measures 0.79 mm (H) x 0.61 mm.

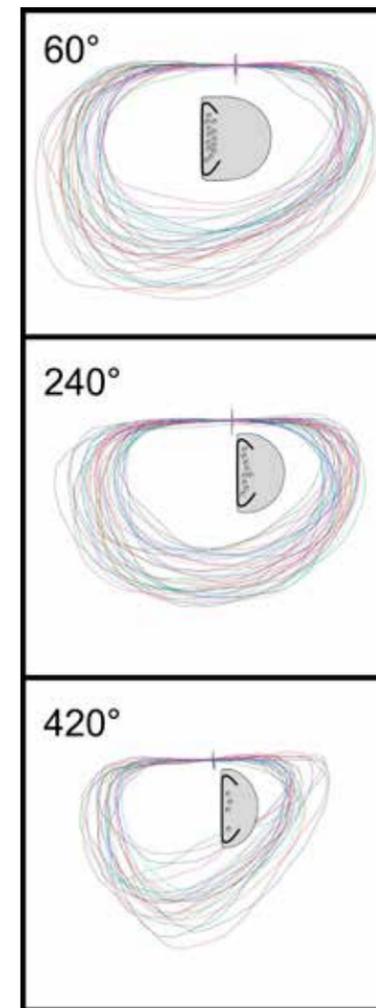


Figure 4. Electrode X-Sections in UCSF ST Profiles

The small dimensions of the electrode tip, and a specifically designed taper, facilitate insertion through either a small vertical slit in the RW membrane or a circular cochleostomy as small as 0.8 mm. Opening the RW membrane can be performed using a surgical laser, micro-cautery or fine hypodermic needle.

Prior to temporal bone validation testing each lateral wall prototype was extensively tested in the force measurement platform developed at Advanced Bionics. The slight curvature, decreased thickness and overall greater compliance of the SlimJ electrode results in a highly significant reduction in insertion force compared to previous lateral wall designs.

Electrode Design Validation

Methods

As described briefly above, the iterative development of the SlimJ electrode was based on the successful design framework of previous electrode arrays from Advanced Bionics including specific features to improve handling properties, significantly reduce insertion trauma and reduce the variability of insertion depth. Each of these interrelated parameters were evaluated with extensive bench testing, force measurement profiling and testing in clear models of the scala tympani followed by multiple hands-on temporal bone workshops with experienced cochlear implant surgeons at Advanced Bionics and research centers around the world. In all, nine design revisions were tested in each of these protocols and more than 100 trial insertions were performed in human cadaver temporal bones.

The final temporal bone validation series for the SlimJ electrode was conducted at the Advanced Bionics temporal bone training and research laboratory in Valencia, California. Five surgeons with cochlear implant experience, but without extensive previous temporal bone CI study experience, each prepared 8 human temporal bones and inserted the SlimJ array in accordance with their usual surgical practices and the specific anatomical requirements of each specimen.

To accurately evaluate the occurrence of trauma for a prototype cochlear implant design it is necessary to

recreate the clinical surgical approach as precisely as possible. Thus, in this validation study, the mastoid bone surrounding the channel drilled to the middle ear space was maintained to the level of the skull surface and the full facial recess was preserved as it is in the clinical procedure. This requirement assures that both the visual assessment of cochlear anatomy and the angular access for the electrode insertion are representative of the clinical environment. All specimens were minimally fixed in formaldehyde (24 hours) immediately after harvesting to minimize changes in the physical properties of the cochlear tissues. Left and Right temporal bones were randomized among the five surgeons.

In this study (n=40) 34 of the insertions were made through the round window, 4 electrodes were inserted through a cochleostomy and 2 electrodes were inserted via an extended round window approach. The preponderance of the round window, or extended round window, as the preferred location for electrode insertion is in keeping with current surgical trends toward this site for access to the scala tympani (Iseli et al., 2014, Celine et al., 2012). The mean size of the insertion opening was 0.98 mm for the round window, 0.86 mm for the insertions through a cochleostomy and 0.80 mm for the extended RW specimens. The surgeons reported that "ease of use" for the SlimJ electrode was 6.25 out of 7 overall with no difference in ease of use between specimens in which a round window vs. cochleostomy opening was used. The small number of extended RW openings used precluded comparison of ease of use for this method. Surgeons in the validation study group had the choice of using forceps specifically designed to hold the SlimJ array or standard surgical forceps during each insertion. Surgeons preferred to use the device specific forceps in 62% of the specimens.

After insertion of each electrode a small drop of cyanoacrylate adhesive was applied between the RW and the facial recess to secure the electrode and the wire lead fantail was removed to further protect the array from accidental movement. Initial x-ray images were taken of each array to provide a pre-embedding

comparison to ensure that electrodes are not disturbed during histologic processing.

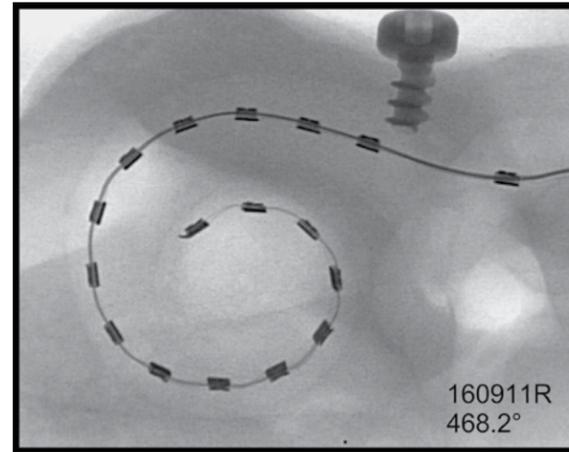


Figure 5. X-ray view of typical specimen

Each temporal bone was then blue lined to isolate the cochlea, embedded in epoxy, x-ray imaged a second time and sliced using an ultra-fine diamond blade in a slow speed saw. Slices were stained, mounted and imaged. Representative cross-section images are shown in Figure 6. Insertion depth was measured from the x-ray image for each specimen.

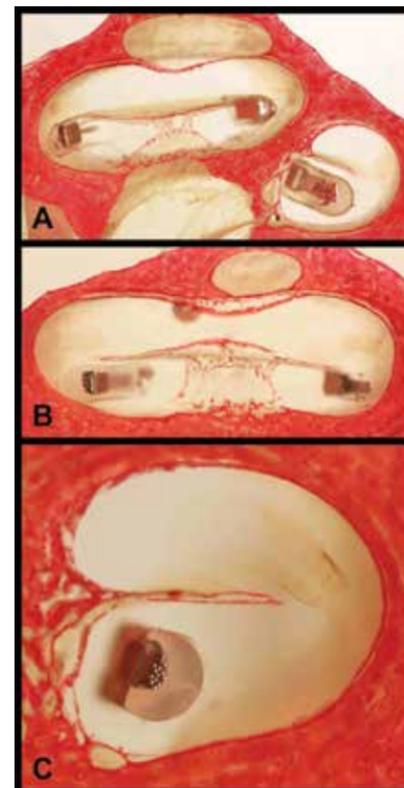


Figure 6. Slice views of histology

Validation Study Results — Histology

Specimen slices were evaluated at a magnification of 5x – 50x and any observed damage was scored using the system developed by Eshraghi (Eshraghi et al., 2003) with a score of 0 = no visible trauma, 1 = elevation of the basilar membrane, 2 = rupture of the basilar membrane, 3 = electrode in the scala vestibuli and 4 = fracture of the osseous spiral lamina, modiolus or torn stria vascularis. One specimen in this series had severe trauma (trauma grade of 4) and one specimen had a tear in the basilar membrane at one confined location (trauma grade of 2). The majority of the remaining specimens (55%) had no visible trauma (trauma grade of 0). Slight to moderate elevation of the basilar membrane (trauma grade 1) was observed at one or more locations in the remaining 45% of the specimens. As noted earlier, lateral wall electrodes, by their nature, are in contact with the basilar membrane and/or stria vascularis through most of their intracochlear length. With the SlimJ electrode array this contact resulted in no damage in a majority of the specimens tested and more severe trauma (trauma score of 3 or 4) in only two specimens. No difference in the frequency of damage was observed based on the location of the opening to the scala tympani.

This series of 40 temporal bone insertions, by 5 surgeons, represents one of the most in-depth evaluations of realistic surgical implantation of a cochlear implant electrode array reported prior to clinical introduction. The finding that only one specimen had an observed translocation into the scala vestibuli (2.5% of the specimens tested) and one specimen had a tear in the basilar membrane (2.5% of specimens) is remarkable when compared to the results of other lateral wall electrodes. In these evaluations, even in the most recent studies with shorter electrodes designed to minimize trauma, the rate of translocation in to the scala vestibuli was up to 50% (De Seta et al., 2017, Mosnier et al., 2017, De Seta et al., 2016, G. Martins et al., 2015, Jeyakumar et al., 2013, Le Breton et al., 2015, Ketten et al., 1998).

Electrode Size

The SlimJ electrode is shown modeled in the UCSF scala tympani profile series in Figure 4. Figure 7 illustrates

corresponding images of the array in representative sections of the scala tympani from the temporal bones study described above. In the first turn (approximately 60° from the RW) the mean cross-sectional area of the SlimJ electrode occupied 18.6% of the volume of the scala tympani. The range of volume occupied by the electrode at this level in the scala tympani was 13.5% to 28.2% (n=40). The mean area occupied in the upper first turn (approx. 240°) was 13.4% (9.4 – 18.6%, n=40) and at 420°, near the tip of the electrode, the area occupied by the electrode was 12.8% (7.25 – 21.6%, n=30). As seen in the modeled electrode fit illustrated in Figure 4, the temporal bone insertion study for the SlimJ confirmed that the reduced dimensions of this electrode will accommodate both the shape and dimensional variation commonly seen across the human population.

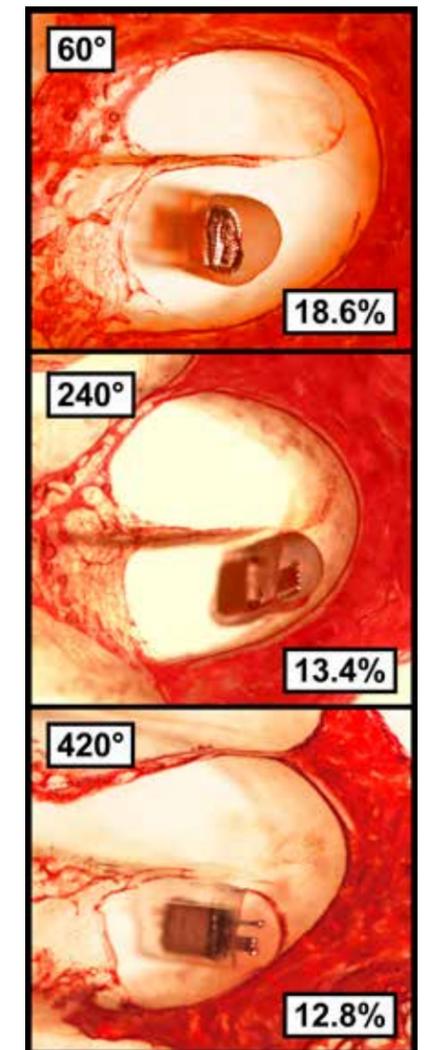


Figure 7. 3 Panel Electrodes in ST Profiles

Depth of Insertion

The mean depth of insertion for the specimens in this validation series was 413.9° (n=40) from the RW (for measurement criteria see Stackovskya et al., 2007 and Verbist et al., 2010) with a range of 338.7° - 509.8°. The standard deviation of the insertion depths for these 40 specimens was ~42°. The distribution of insertion depths is shown in Figure 8. It is important to note that the variation in insertion depth for the SlimJ electrode is lower than seen for most other lateral wall electrodes in previous studies. More consistent insertion depth may result in greater efficiency in establishing sound processor

fitting parameters for cochlear implant subjects and improved overall performance (Baskent et al., 2005) and may reduce the time required for adaptation and learning after device fitting (Reiss et al., 2007). This mean insertion depth corresponds to a tonotopic spiral ganglion frequency location of approximately 685 Hz or 85% of the spiral ganglion (Stakhovskaya et al., 2007) and is sufficient to access the frequency ranges necessary for high levels of speech recognition without increasing the risk of trauma or perceptual distortions reported with deeper insertions (Gani et al., 2007, Adunka et al., 2006, Baumann et al., 2006).

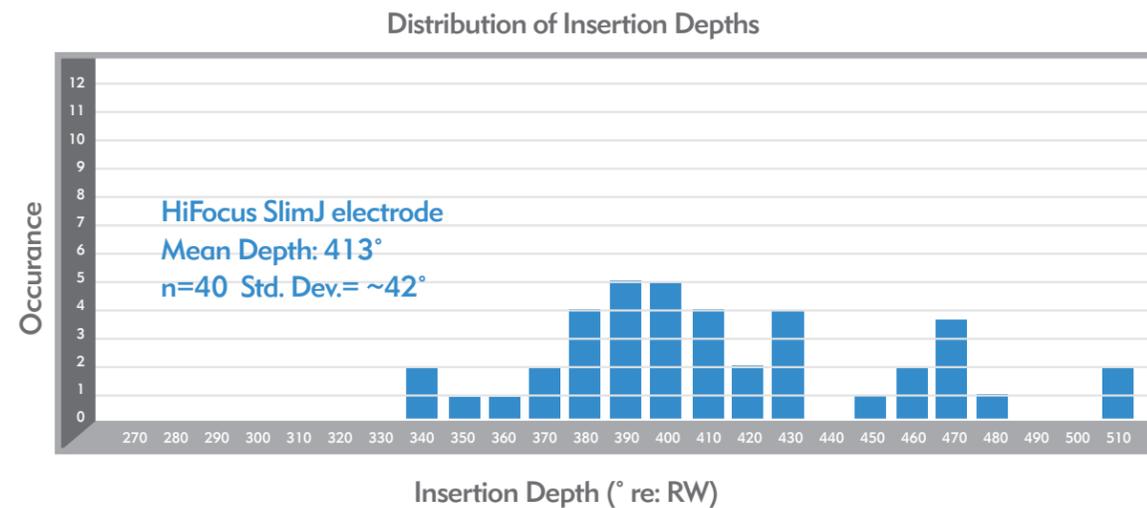


Figure 8. Graph showing angular insertion depths of HiFocus SlimJ across 40 samples

Round Window vs. Cochleostomy Insertion

As detailed above, surgeons in this validation study were instructed to utilize the surgical approach that they would choose in the clinical setting based on the anatomical presentation of each patient. As a result, 34 of the 40 insertions were made through the round window membrane, 2 were made through an extended round window and 4 electrodes were inserted through a cochleostomy (mean size 0.86 mm). No trauma was observed in the specimens that were inserted through an extended RW opening and minor damage (a trauma score of 1) was observed at one location in the four specimens in which the electrode was inserted via a cochleostomy. Due to the low frequency of trauma and the small number of specimens in which a cochleostomy

or extended round window approach was used no statistical comparison can be made between the three approaches to the scala tympani. However, it is clear that the handling characteristics of the SlimJ array are appropriate for use with all of these surgical options. It should also be noted that the tapered tip of the SlimJ electrode was specifically designed to simplify insertion through a small incision in the round window membrane. The overall proportions of the elastomer SlimJ appears to minimize trauma in the highly variable geometry of the extreme basal scala tympani (see Figure 9 and Atturo et al., 2014). No trauma was observed in this region in any of the 40 specimens evaluated in this study.

Clinical Reliability

Full validation testing has confirmed that the HiFocus SlimJ electrode array meets all medical device requirements for global markets controlled by U.S. and European regulatory standards (ISO, EEC, ASTM, AAMI, EN and CFR regulations).

Discussion

The specific anatomy of some patients makes a straight, or slightly curved, electrode the preferred choice for these individuals. The goal in developing the SlimJ electrode array was to refine the lateral wall electrode concept to provide both optimized surgical handling characteristics and to minimize the occurrence of surgical insertion trauma. To accomplish this goal, scientists and engineers at Advanced Bionics collaborated with more than 20 experienced cochlear implant surgeons to design, fabricate and evaluate the functionality, handling and occurrence of trauma in nine design iterations of this lateral wall array.

For more than two decades UCSF has worked with almost 30 cochlear implant surgeons, including all levels of experience, and 4 cochlear implant manufacturers to evaluate the occurrence and consequences of trauma that often results from the insertion of a cochlear implant electrode. During this time, we have completed detailed evaluations of more than 200 human cadaver temporal bones using 12 different electrode designs at UCSF (Wardrop et al., 2005, Wardrop et al., 2005a, Rebscher et al., 2008). These studies have identified three key elements that directly affect the frequency and severity of intracochlear trauma. The first of these factors is the size and shape of the electrode array. Because there is very little tactile feedback during insertion, and no direct correlation has been shown to relate tactile resistance to trauma, the surgeon cannot depend on the sensation of resistance to avoid damaging the cochlea. It is also well known that the size and shape of the cochlea, and particularly the scala tympani beyond the first turn, is highly variable (Aturro et al., 2014, Escude et al., 2006, Rebscher et al., 2008, Ketten et al., 1998). Thus, the cross-sectional shape and overall dimensions of an electrode array must accommodate the range of scala tympani

dimensions in the human population. Second, from the wide range of electrode designs evaluated in our studies at UCSF it is clear that electrodes with increased stiffness in the vertical axis of the array are far less likely to deviate vertically within the scala tympani with resulting damage to the cochlear partition or translocation into the scala vestibuli. Finally, diversion of an electrode into the scala vestibuli very close to the entry point to the cochlea is a common phenomena (Skinner et al., 2007, Aschendorff et al., 2007). The rapidly changing relationship of the cochlear partition to the axis of the modiolus in this region is illustrated in Figure 9 of this report. Appropriate selection of the insertion site, optimum electrode size, the shape of the electrode tip and electrode handling characteristics may all play important roles in avoiding this mode of trauma.

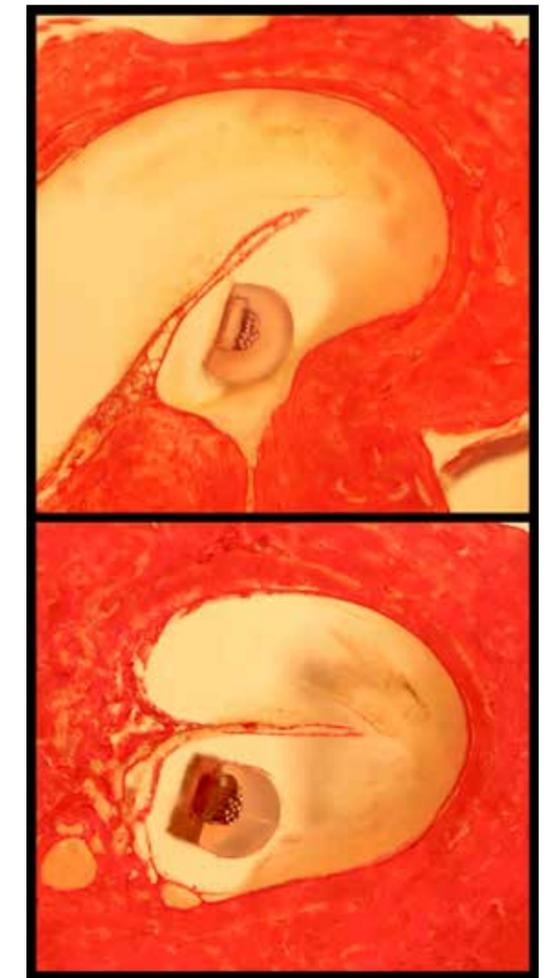


Figure 9. Extreme Basal Scala Tympani , 2 Panels