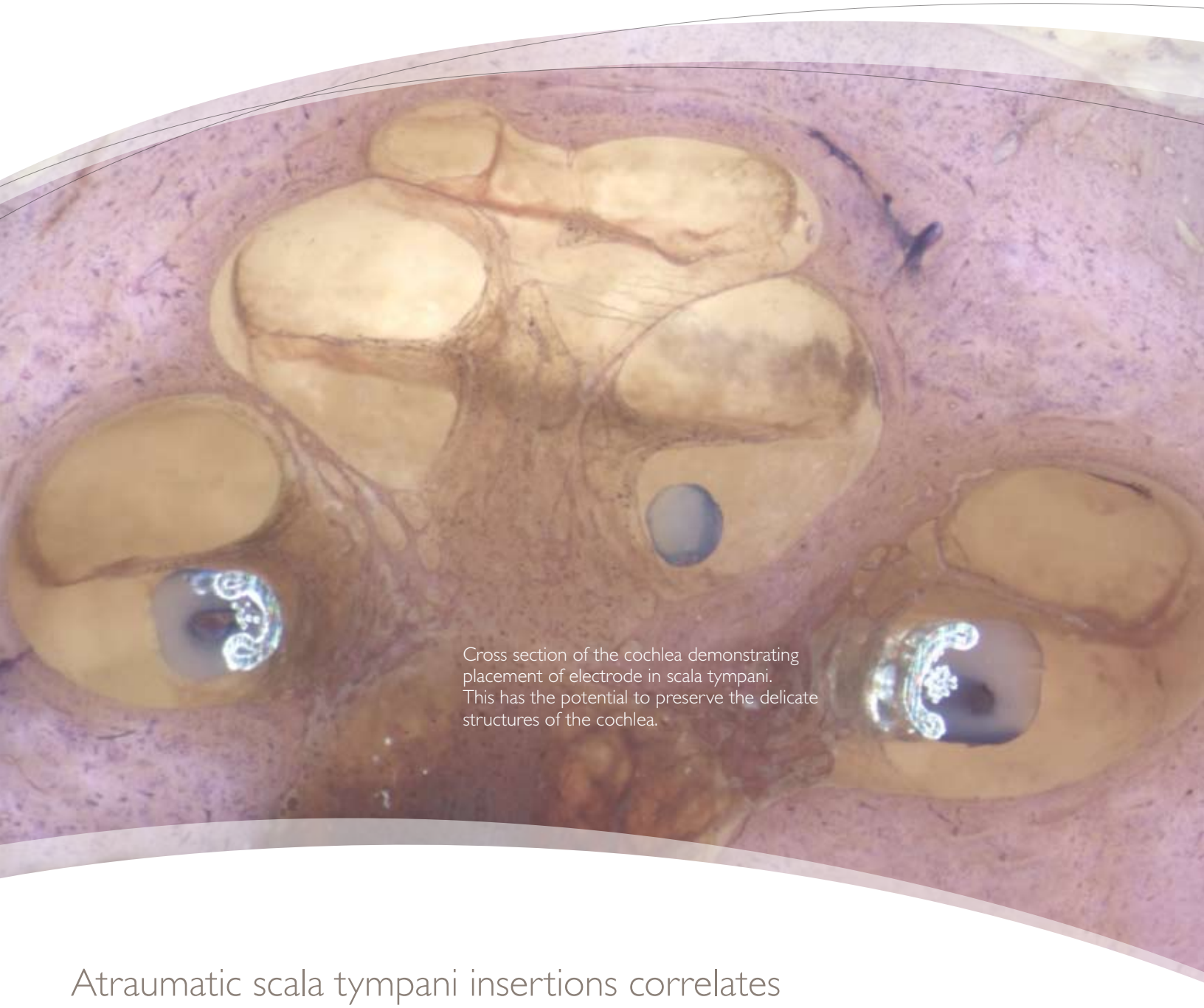
New Clinical Evidence Confirms the Importance of Perimodiolar Electrodes



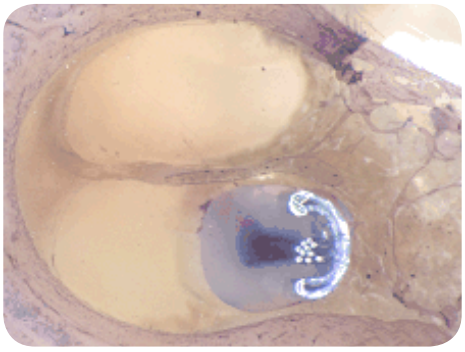
Cross section of the cochlea demonstrating placement of electrode in scala tympani. This has the potential to preserve the delicate structures of the cochlea.

Atraumatic scala tympani insertions correlates with improved hearing performance.

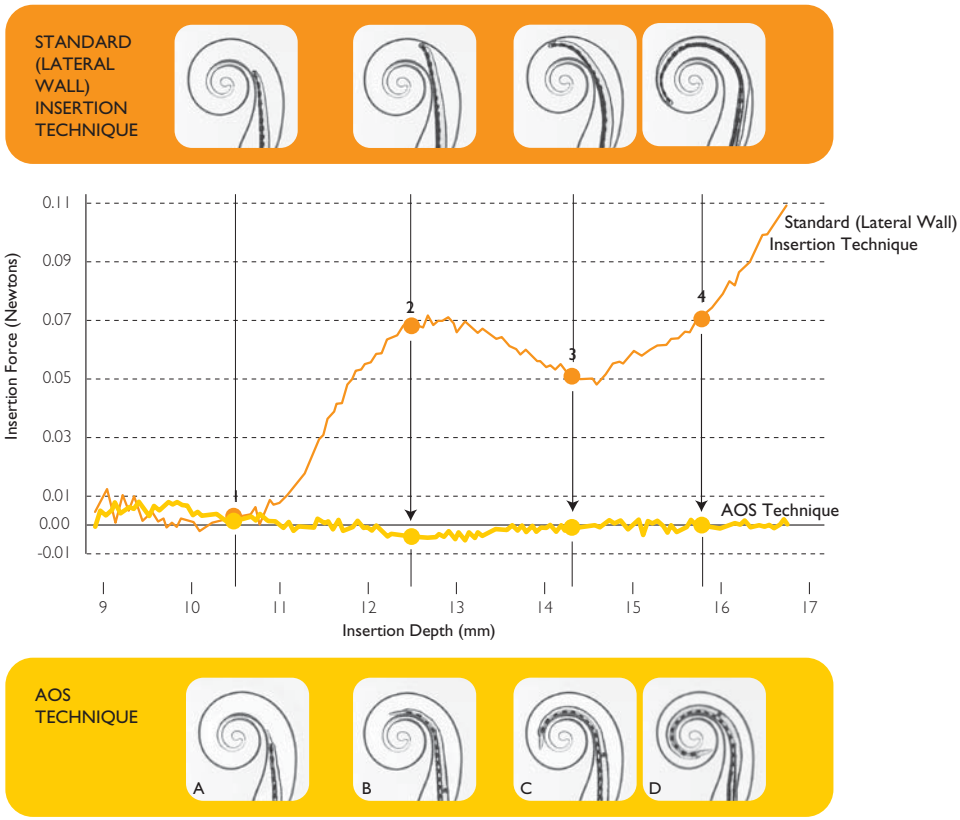
Recent peer-reviewed research studying the impact of electrode placement and cochleostomy position confirms that patient outcomes are optimized when an atraumatic scala tympani insertion is achieved. The proper combination of surgical technique and perimodiolar electrode mechanics significantly increases the chance of correct electrode placement and atraumatic insertion[1,2,3]. This leads to optimal speech perception performance[2,3]. It is widely believed to help increase preservation of residual hearing.

> Contour Advance™ Electrode with Advance Off-Stylet (AOS) technique is designed for atraumatic scala tympani insertion

The mechanical properties of the Contour Advance electrode due to its distinct selected geometry, softness and flexibility combined with the AOS technique is designed to facilitate smooth perimodiolar movement through the scala tympani (ST). The perimodiolar introduction of electrode with AOS technique minimizes insertion force on the lateral wall of the cochlea[1] which reduces scalar dislocation[2]. Roland (2005)[1] evaluated the insertion characteristics of the Contour Advance electrode using real-time fluoroscopic imaging and mechanical insertion dynamics, and histologic evaluation of electrode position and trauma results. The study concluded, "The Contour Advance electrode, inserted with the AOS technique, represents significant improvement over the Contour™ electrode, inserted with standard insertion technique."



This picture of the Contour Advance electrode inserted in the Scala Tympani shows excellent preservation of all structures and optimal perimodiolar electrode positioning.



The Advance Off-Stylet Technique

Step A
The electrode is held with the AOS surgical forceps and introduced into the cochlea until the white marker is at the cochleostomy.

Steps B & C
The stylet is held still with jeweller's forceps, with one hand. The array is advanced off the stylet while holding the stylet still.

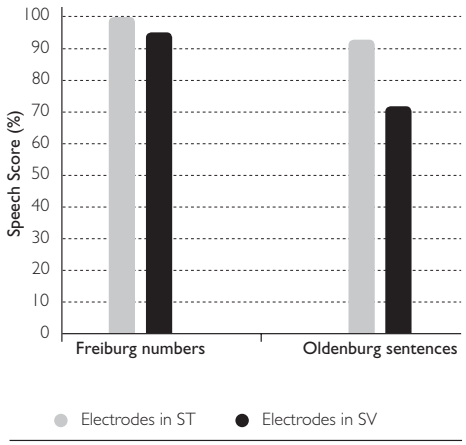
Step D
The electrode array is advanced into the cochlea until the middle rib is at the cochleostomy. The remaining portion of the stylet that is still within the electrode is withdrawn.

The graph quantitatively depicts the benefit of the AOS technique by measuring the force that the electrode exerts on the walls of the cochlea model during a standard insertion and an electrode inserted with the AOS technique. Four phases of insertion of the electrode as it moves into the cochlea are depicted. The AOS technique shows dramatically reduced lateral wall forces. Courtesy of Dr. J Thomas Roland Jr., New York University School of Medicine.

> Optimum scala tympani position correlates with better hearing performance

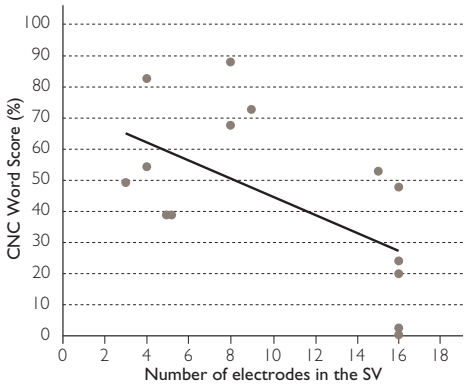
Recent independent, peer-reviewed research confirms electrode insertion in the ST is essential in cochlear implant surgery because it results in better speech understanding[2,3].

Aschendorff et al (2007)[2] evaluated the quality of electrode insertions with the Contour electrode with standard insertion techniques and the Contour Advance with the AOS technique using 3D reconstruction of CT images. They correlated speech perception performance with radiographic measurements. Their results confirm the advantages of electrode placement in the ST. Their study concluded that, "Speech tests results varied with respect to the location of the intracochlear electrode position, with insertions into the scala tympani being significantly superior to the scala vestibuli."



Data adapted from Aschendorff et al (2007)[2]. ST placement results in significant ($p<0.05$) improvement in speech perception performance for subjects with less than 15 years duration of hearing loss. While the same trend was demonstrated in subjects with more than 30 years' of hearing loss, it was not statistically significant.

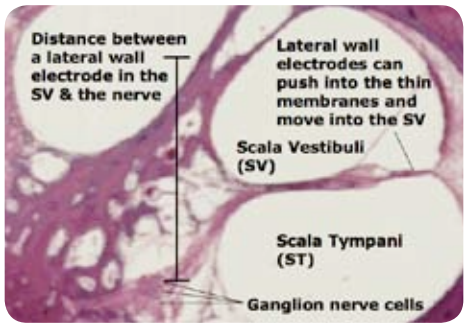
Skinner et al (2007)[3] also used specialized 3D imaging software of CT scans to identify the position of electrode arrays in the cochlea and compared this data with speech perception performance. Their results demonstrate similar findings that electrodes inserted in the scala vestibuli (SV) result in significantly ($p<0.05$) poorer speech recognition in patients. "That is, the more electrodes in the SV, the lower the score."



Data adapted from Skinner et al (2007)[3]. SV placement results in a significant ($r = -0.59$, $p < 0.05$) decrement in speech perception performance.

Positioning the electrode in the ST provides closer and more direct stimulation of the spiral ganglion cells. Furthermore, reducing trauma to the intracochlear structures is widely believed crucial for preserving residual hearing.

SV placement and dislocation of the electrode from the ST to SV can damage Reissner's membrane, the organ of corti, and the integrity of the scala media.



Cross section of the cochlea, demonstrating the position of the scalae and relative placement of the electrode.

> Minimal insertion trauma and scala tympani placement is a prerequisite for the preservation of residual hearing[2,4]

As indications for cochlear implantation expand and candidates present with increasing amounts of residual hearing, the preservation of this residual hearing becomes even more important. Fraysse et al (2005)[4] assessed the preservation of residual hearing following implantation with the Contour Advance electrode and evaluated the benefits of combined electric and acoustic stimulation. They found that hearing was preserved in 75% of recipients implanted with the Contour Advance electrode using a soft surgical approach and AOS technique. Use of residual low frequency hearing may enable better speech in noise and pitch perception, and may improve subjective benefits such as sound quality, listening effort and greater enjoyment of music.

> Cochleostomy placement and electrode mechanics determine electrode position and hearing outcomes

A recent publication reporting on the results of a survey performed amongst North American surgeons by Adunka and Buchman (2007)[5] found a great deal of variation in cochleostomy location. Citing the Aschendorff[2] and Skinner[3] papers, the authors state: "Overall, uniformity in scala tympani cochleostomy placement is lacking. This probably has resulted from the general feeling that precise electrode location within the cochlea is unnecessary. Recent studies now suggest that electrode location should be within scala tympani, and that dislocations or placement of the array into scala vestibuli may result in worse outcomes."

Briggs et al (2005)[6] demonstrated how cochleostomy location determines in which scala the electrode will be inserted by review of electrode insertion studies and post-mortem anatomical study of implanted human temporal bones[6].

Skinner et al (2007)[3] and Aschendorff et al (2007)[2] both found a large number of direct SV insertions. Aschendorff reported that after modifying cochleostomy location to one positioned more inferior and anterior to the round window niche, the SV insertions reduced from 62% to 14%[2].

In the Skinner publication, 100% of HiFocus® electrodes introduced into the ST also dislocated into the SV[3]. These HiFocus electrodes are a laterally placed array. In the Aschendorff publication, by changing from the Contour with standard insertion

technique to the Contour Advance with AOS technique, a reduction in dislocation from 75% to 16% was reported[2]. Electrode dislocations are primarily the result of electrode mechanics within the cochlea[1,2].

In summary, the Contour Advance electrode with AOS technique combined with correct cochleostomy position provides the greatest chance for an atraumatic scala tympani electrode insertion which has now been confirmed to support the optimization of cochlear implant patient outcomes.

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