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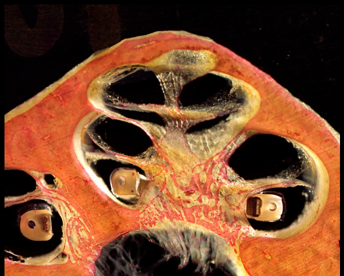
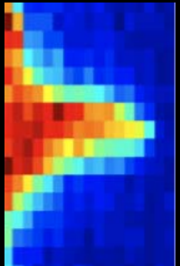
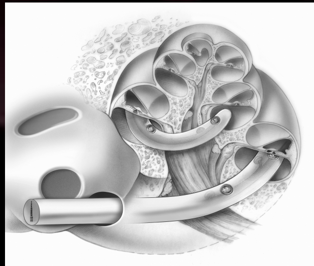
Improved Outcomes with Cochlear Implants: Electrode Design, Surgical Methods

Stephen Rebscher

Epstein Laboratory
University of California, San Francisco



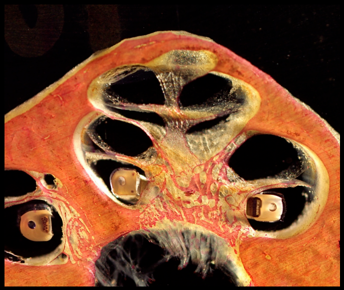


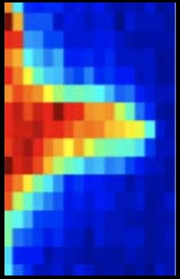
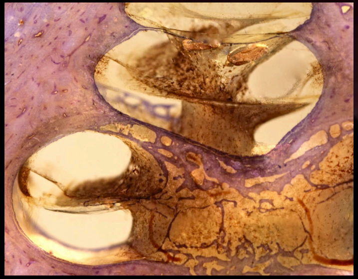
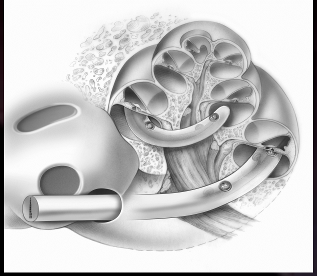


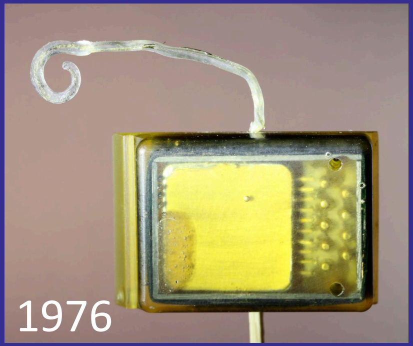

Major Collaborators:

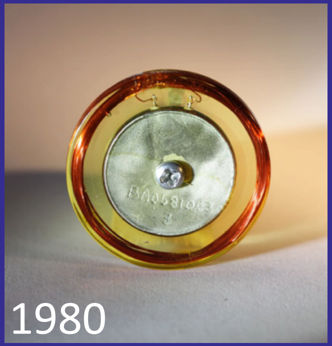
Dr. Patricia Leake, UCSF
Dr. Russel Snyder, UCSF
Dr. Larry Lustig, Columbia Univ.

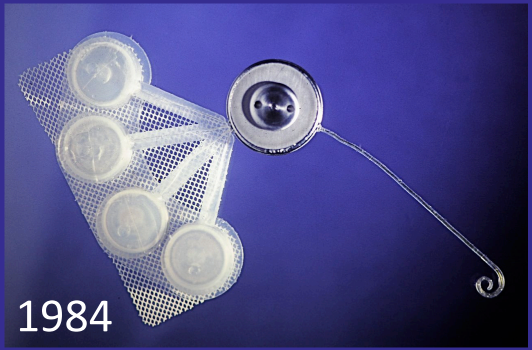
Dr. J.T. Roland, NYU
Dr. William Luxford, HEI, USC
Dr. Peter Wardrop, Scottish Nat. CI Center

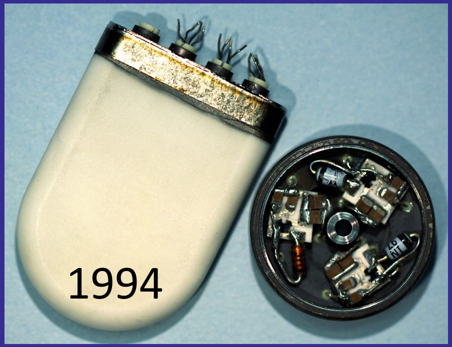


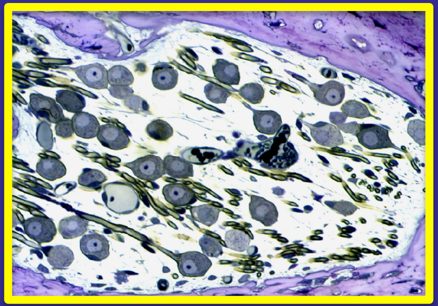
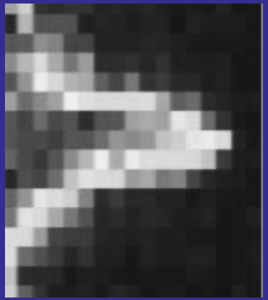
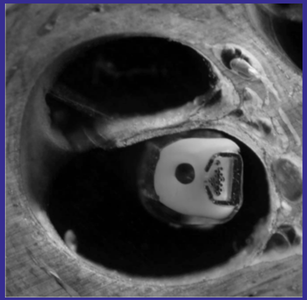




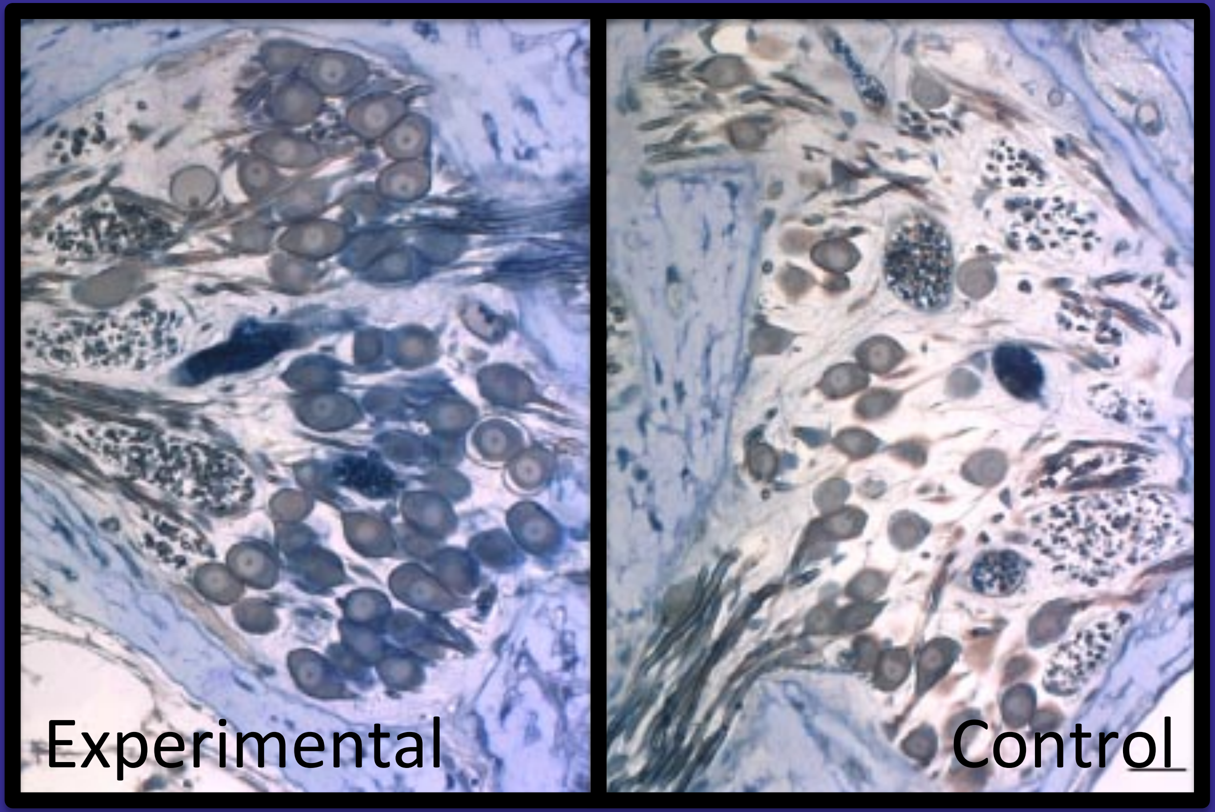


History of Cochlear Implant Research at UCSF

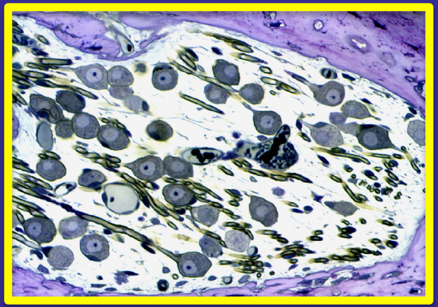
1. Early multichannel CI, 1970s, Dr. Robin Michelson
2. Chinese clinical exchanges began in 1970s
3. Electrophysiology, Dr. Michael Merzenich,
   F. and D. Russ Award, National Academy of Engineering, 2014
4. Safety of CI, Dr. R. Schindler, Dr. P. Leake
5. Multichannel clinical trials 1981
6. CI engineering lab at Peking Union Hospital, Dr. Z. Wang
7. IP transfer and clinical trials, Advanced Bionics 1990s
8. Nurotron Biotechnology shared development

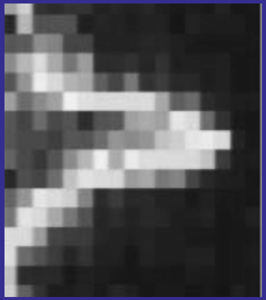




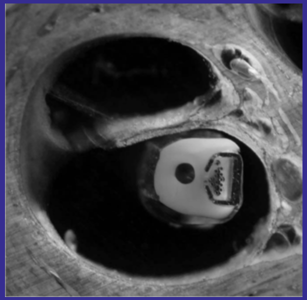
Current Studies:
Neural Survival



Ganglion cell survival







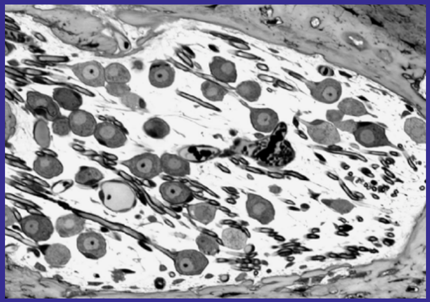
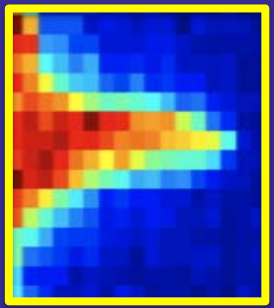
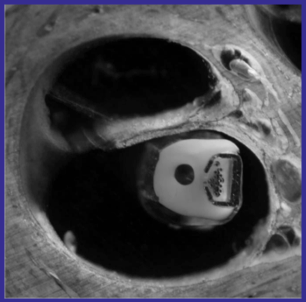
Current Studies:
Neural Survival

Long-Term Studies have shown:

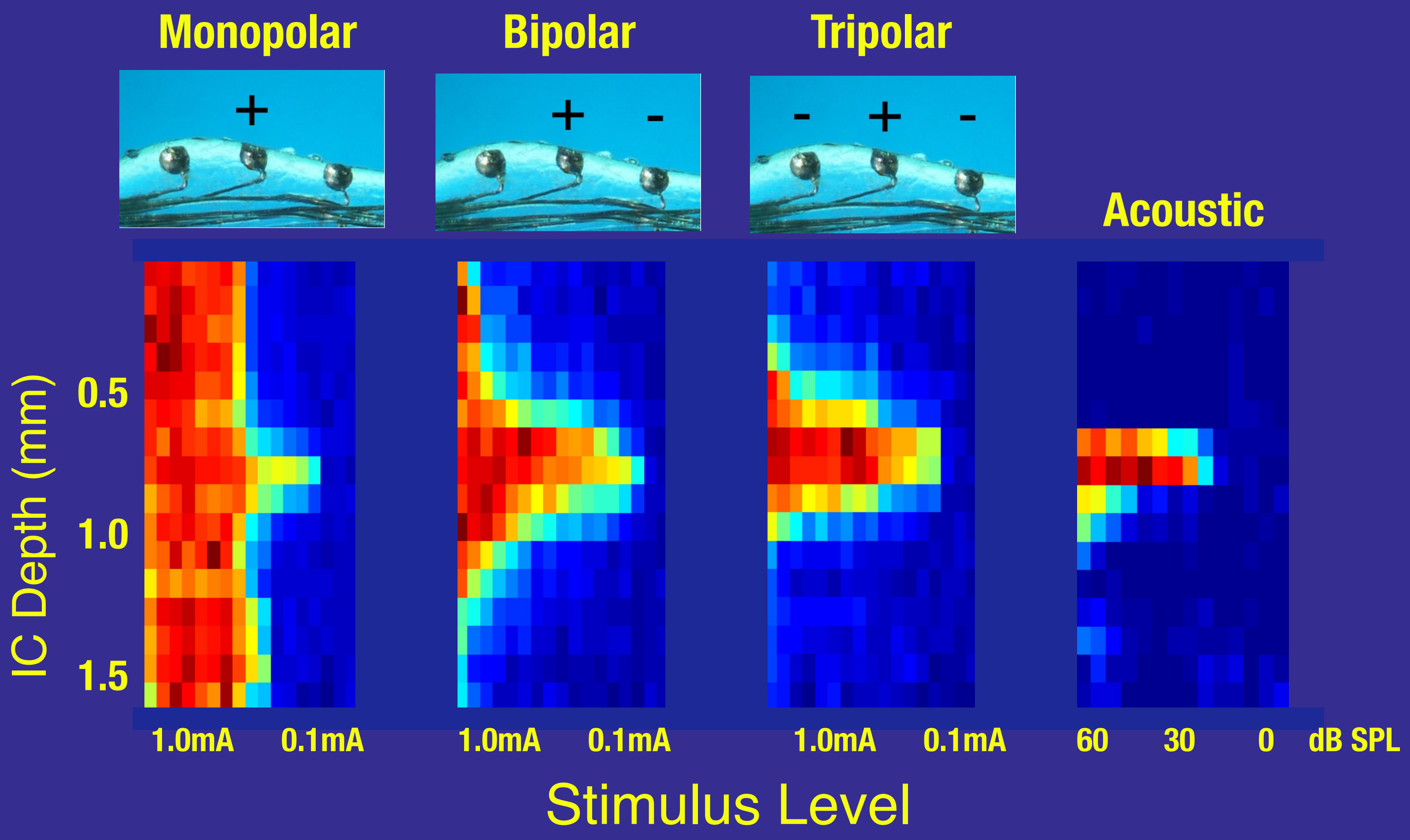
1. Electrical stimulation has protective effect in SG

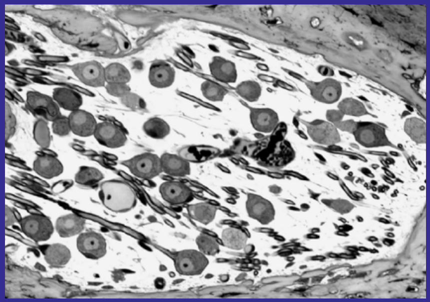
2. BDNF supports SG survival –osmotic pump or viral

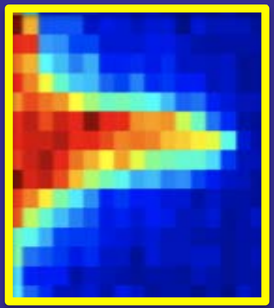
3. Trauma degrades function

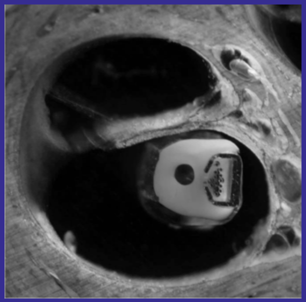
  

Current Studies: Electrophysiology









Current Studies:
Electrophysiology

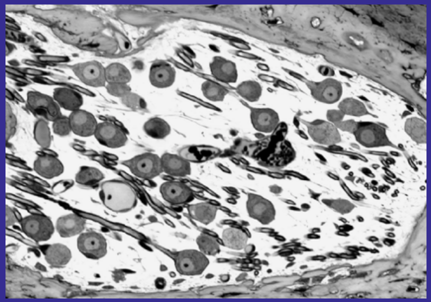
Electrophysiology Studies have shown:

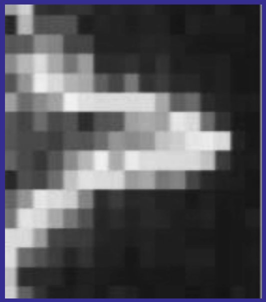
1. Central responses to E-stim can be very localized
   Monopolar – Bipolar – Tripolar

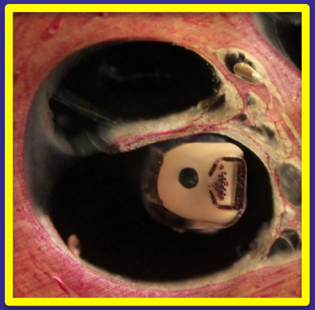
2. Chronic E-stimulation maintains tonotopic tuning

3. Chronic E-stimulation helps to maintain firing rate

4. Loss of spiral ganglion degrades function

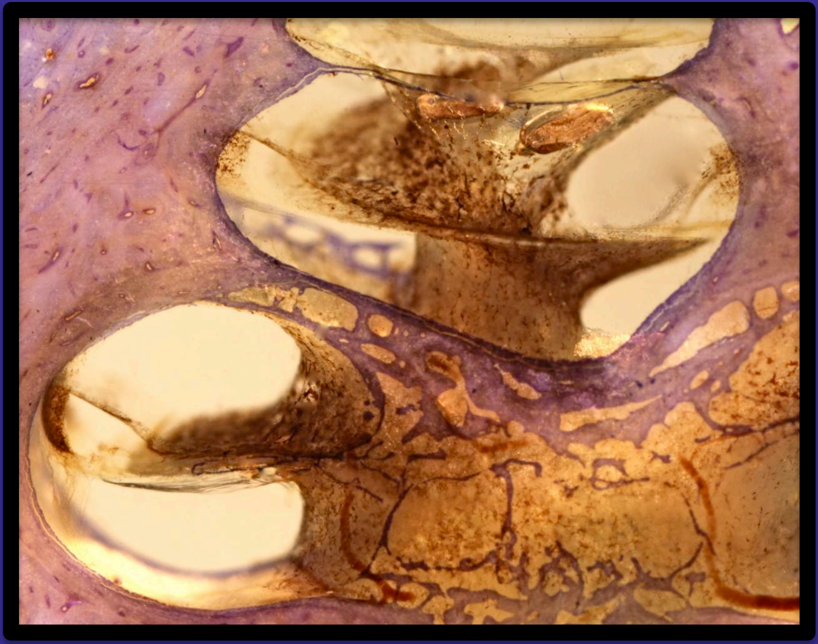






Current Studies: Insertion Trauma

Temporal Bone Studies



Purpose:

To evaluate the role of mechanical stiffness, electrode size and electrode shape in insertion trauma

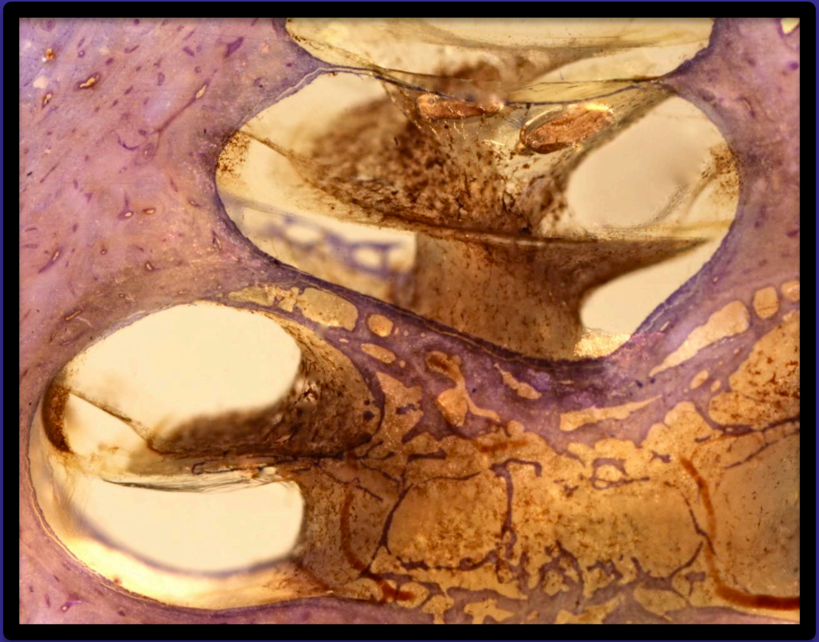
Manufacturers:

Advanced Bionics LLC, USA
Cochlear Corporation, Australia
Nurobiosis, Seoul, South Korea
Nurotron Biotechnology, China

Electrodes Studied:

Cochlear Banded - Cochlear Contour - Contour Advance - AB Spiral – AB HiFocus II w/ POS - AB HiFocus 1j AB Prototype Lateral Wall (3) – Nurotron CS10A – Nurobiosis

N= 9/166

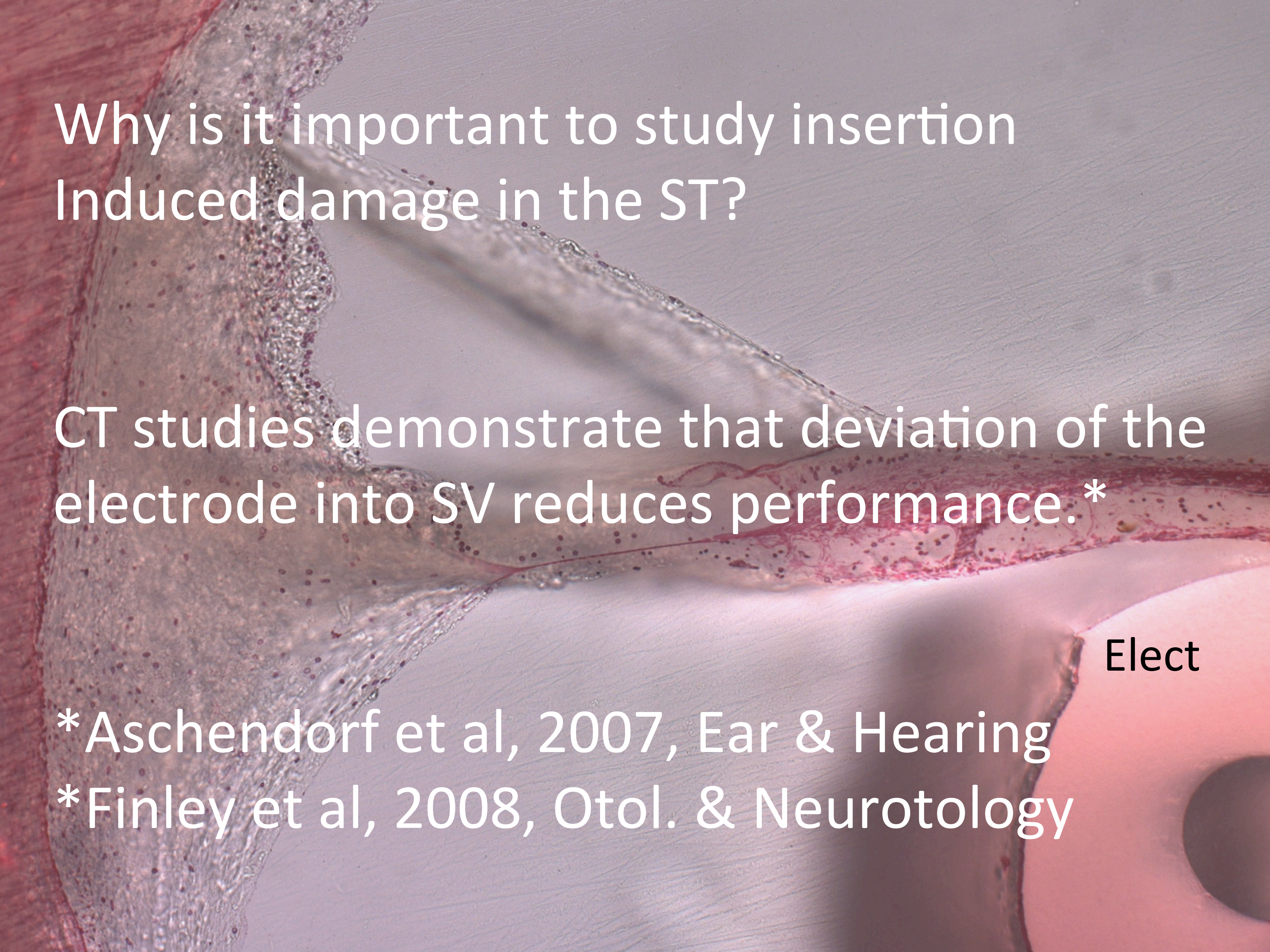


Participating Surgeons (n=19):

Dr. A. Eshraghi, USA– Dr. Fu Yong, China – Dr. Haynes, USA
Dr. Hu Baohua, China - Dr. Labbadie, USA – Dr. T. Lenarz, Germany
Dr. Li Jianan, China – Dr. L. Lustig, USA – Dr. W. Luxford, USA
Dr. Manrique, Spain - Dr. Peng Shaopeng, China – Dr. Rivas, USA
Dr. J.T. Roland, New York – Dr. Shi Ziquang, China
Dr. W. Slattery, USA – Dr. Sun Shuping, China – Dr. Wanna, USA
Dr. David Whinney, UK - Dr. Peter Wardrop, Scotland

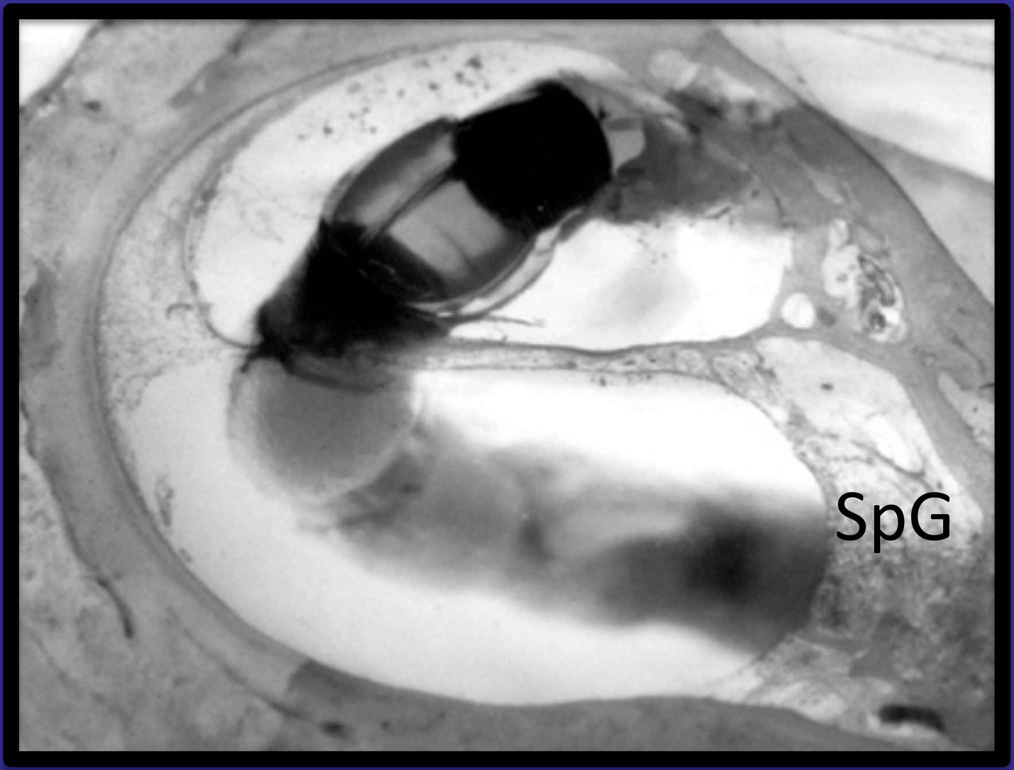
Why is it important to study insertion Induced damage in the ST?

CT studies demonstrate that deviation of the electrode into SV reduces performance.*



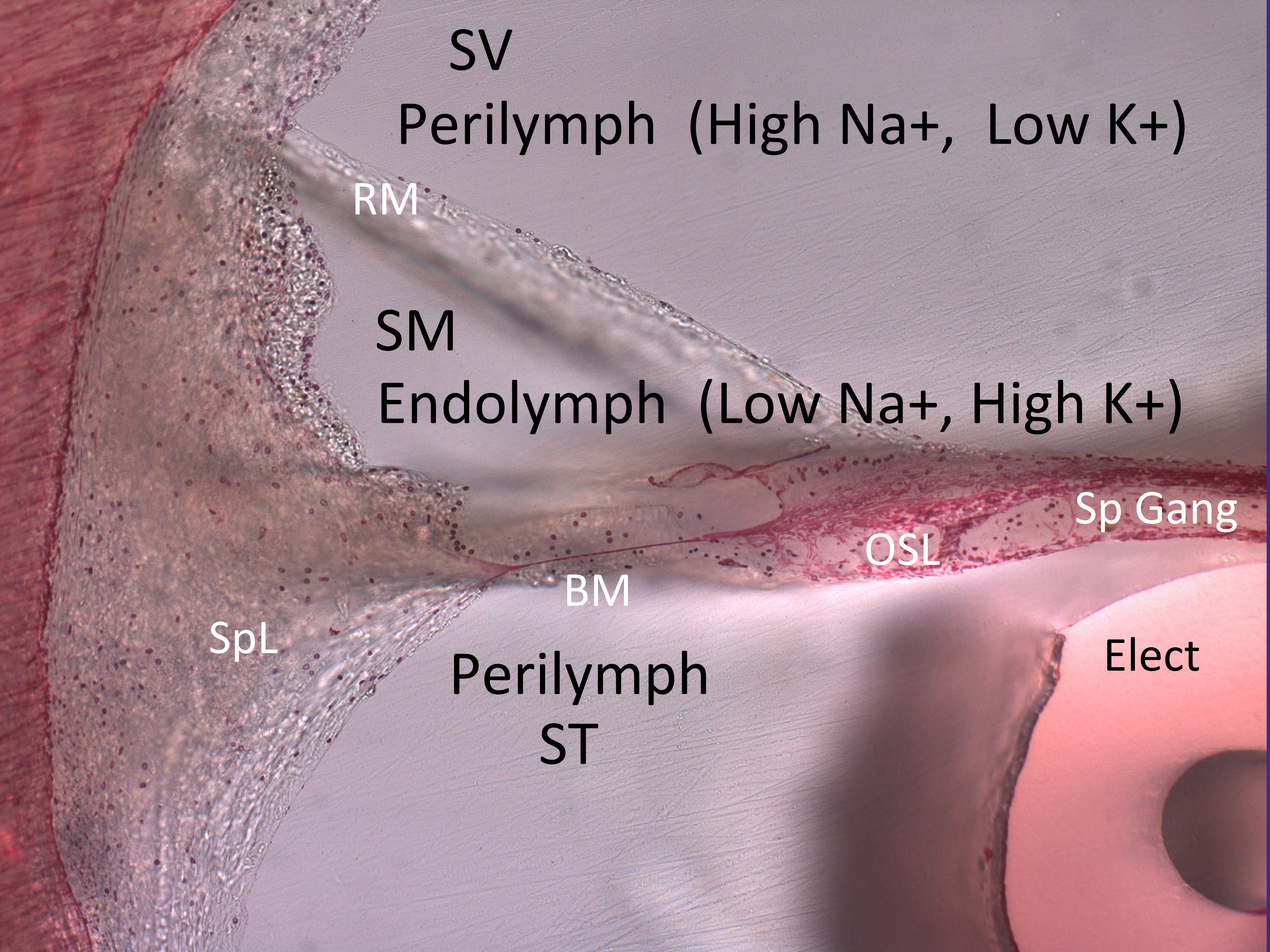
*Aschendorf et al, 2007, Ear & Hearing
*Finley et al, 2008, Otol. & Neurotology

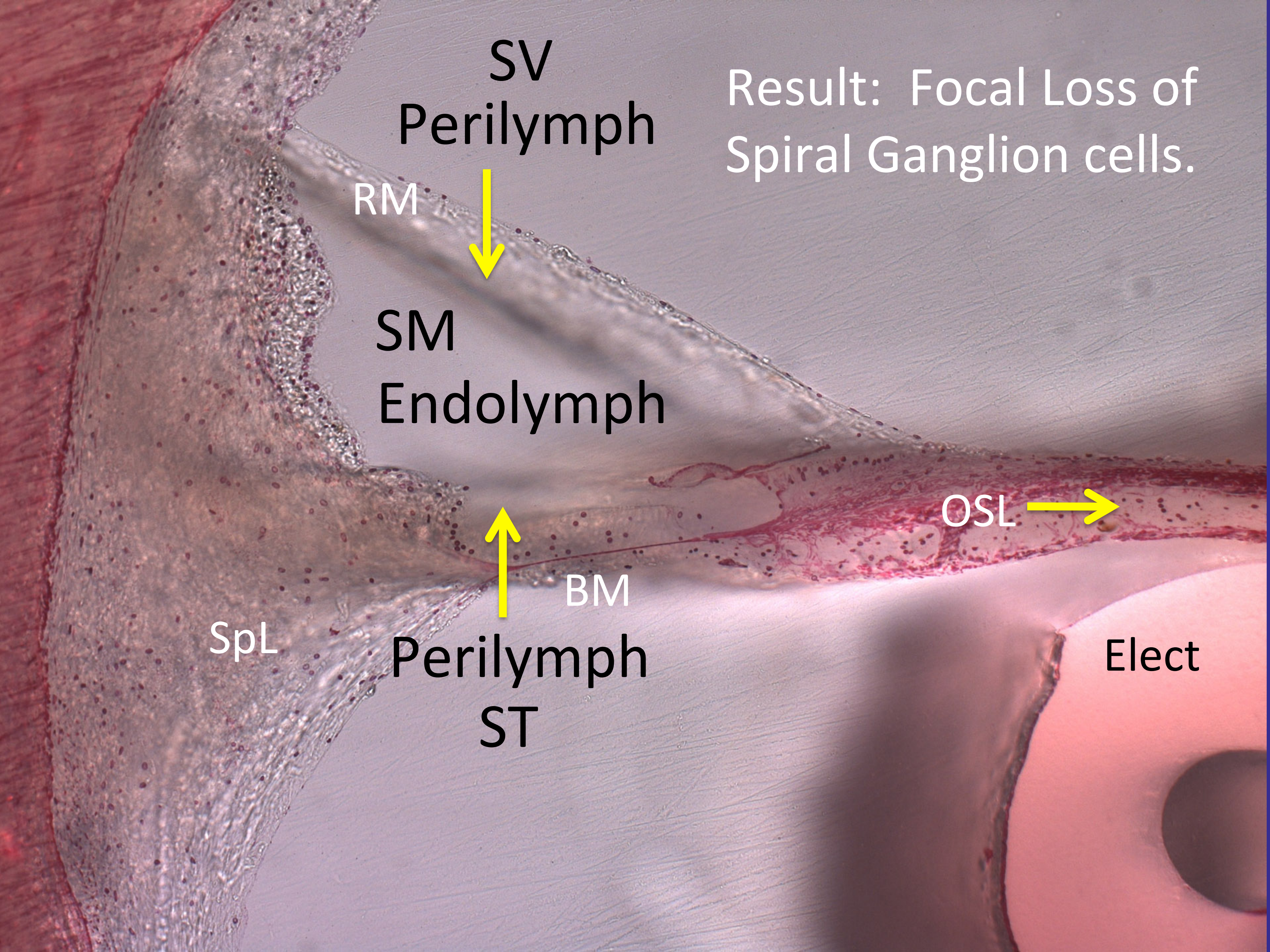
- physically damaged, neural loss
- distorted frequency mapping
- shallow insertion



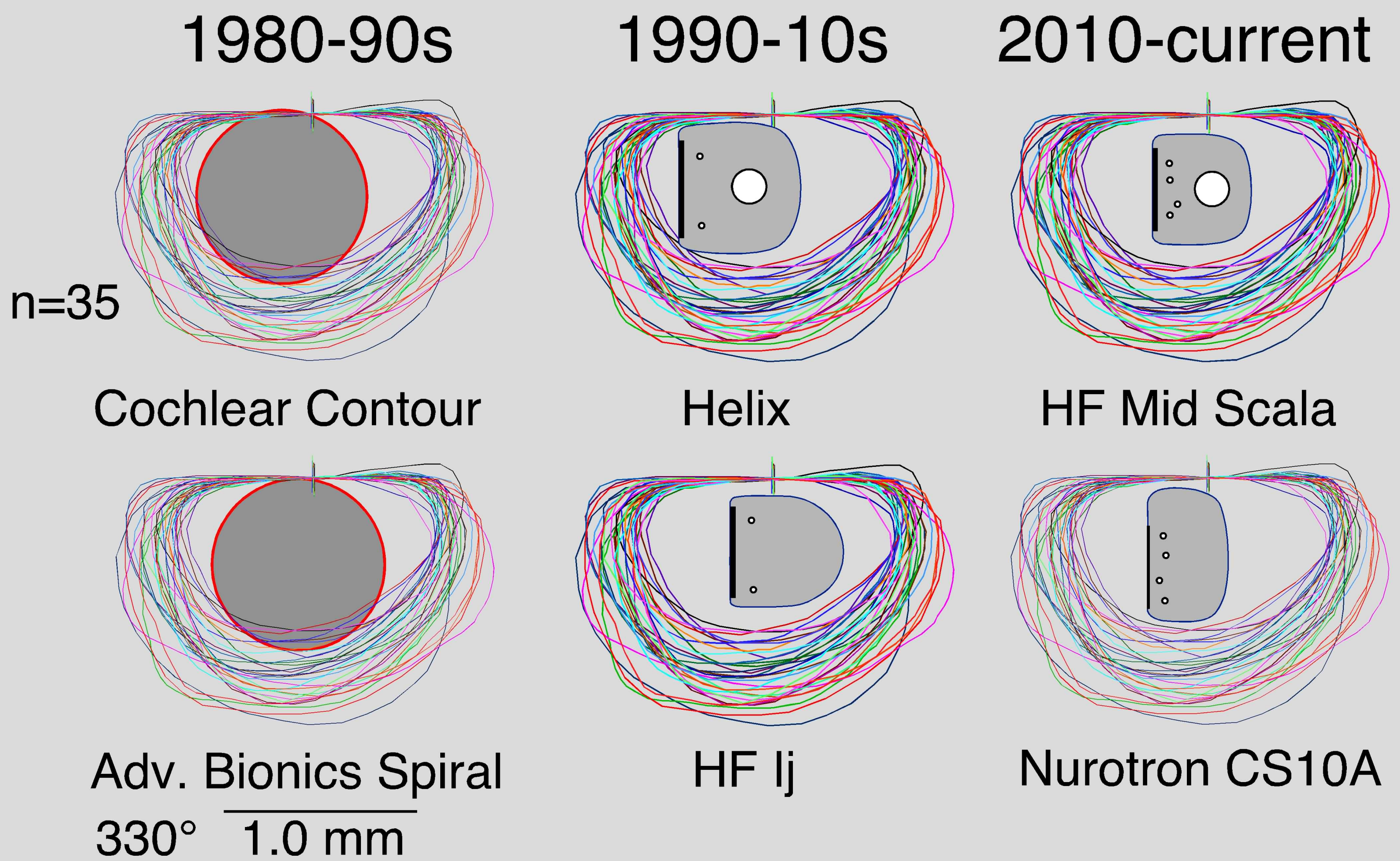
Intracochlear Damage

- high thresholds
- poor DR
- high channel interaction

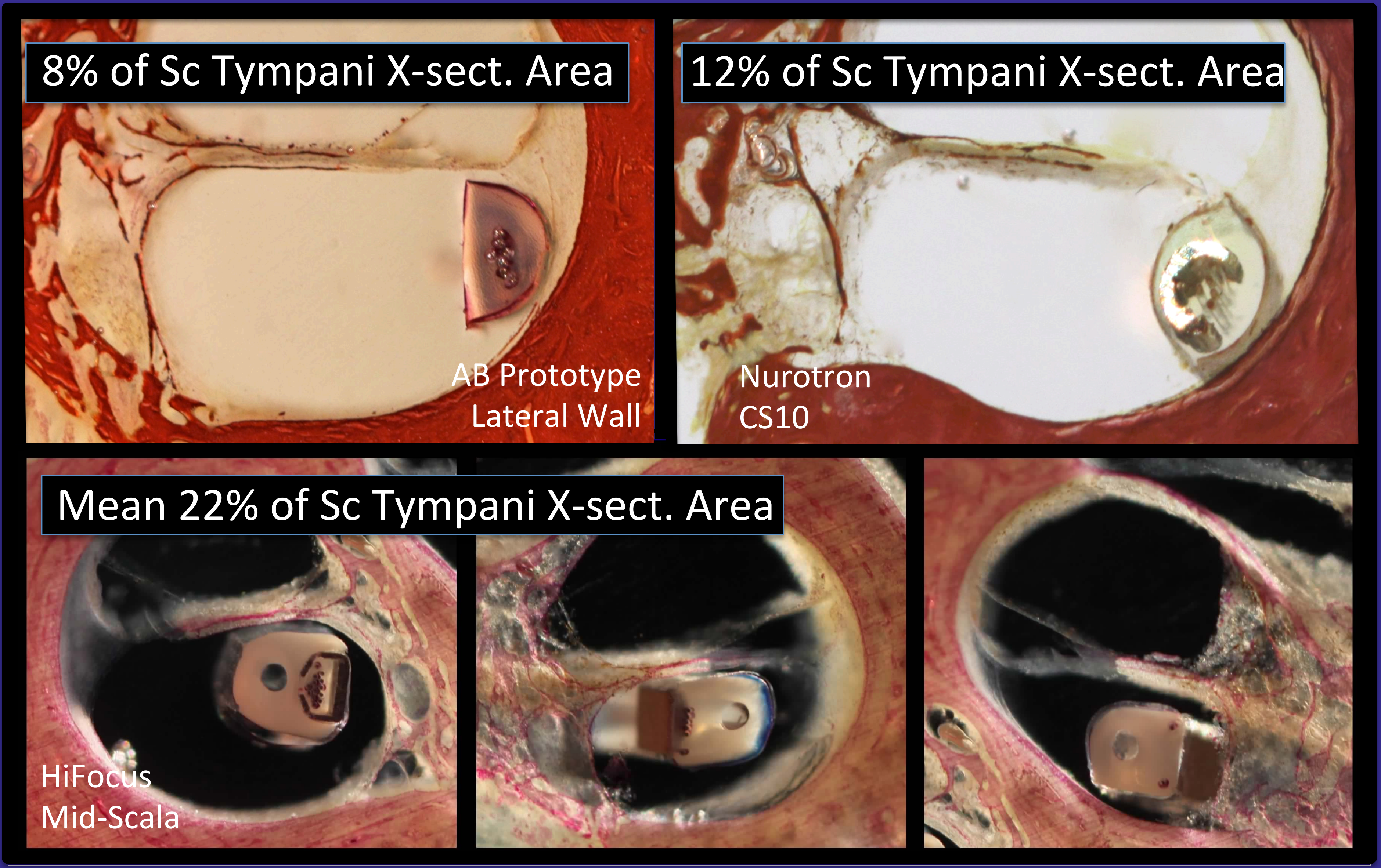

SV
Perilymph (High Na+, Low K+)
RM
SM
Endolymph (Low Na+, High K+)
Sp Gang
OSL
BM
SpL
Elect
Perilymph
ST


SV
Perilymph
Result: Focal Loss of
Spiral Ganglion cells.
RM
SM
Endolymph
OSL
BM
SpL
Perilymph
ST
Elect

Reduction in electrode size over time

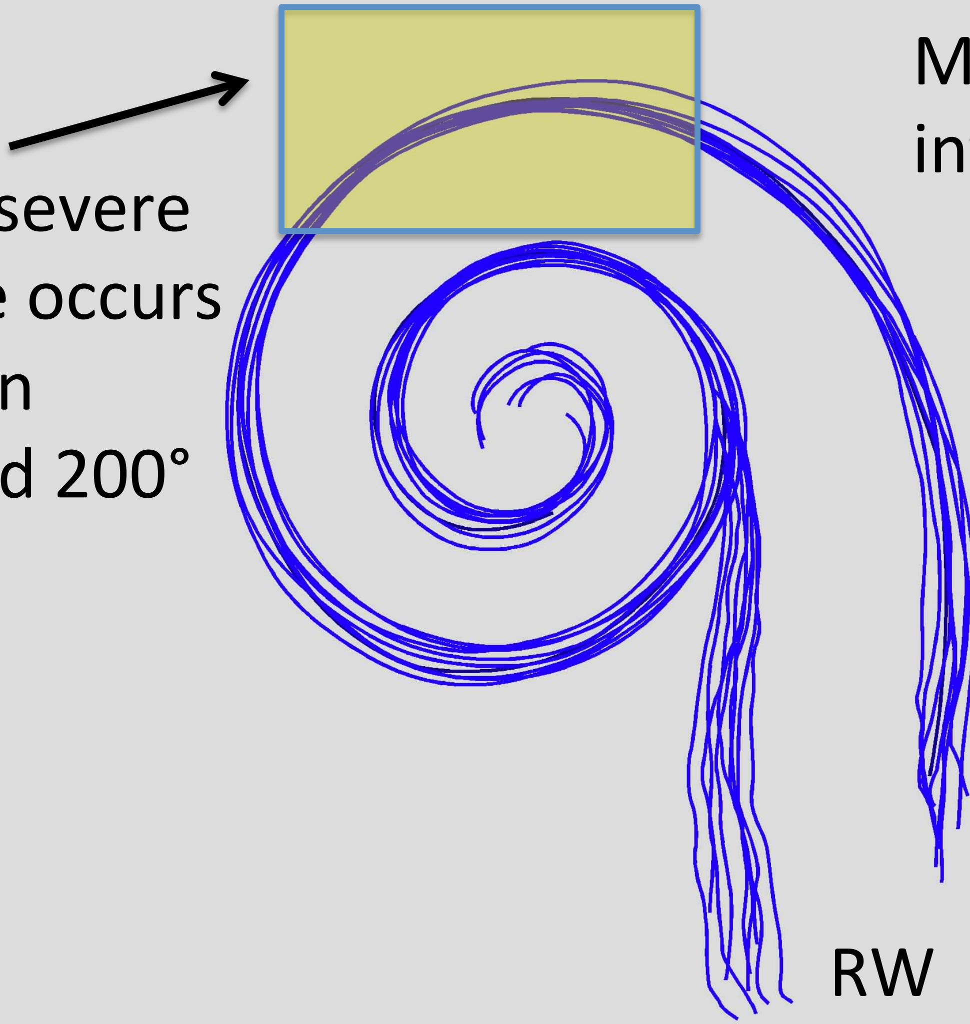


Current Examples



Where, and how, does damage most often occur?

75% of severe damage occurs between 160° and 200°

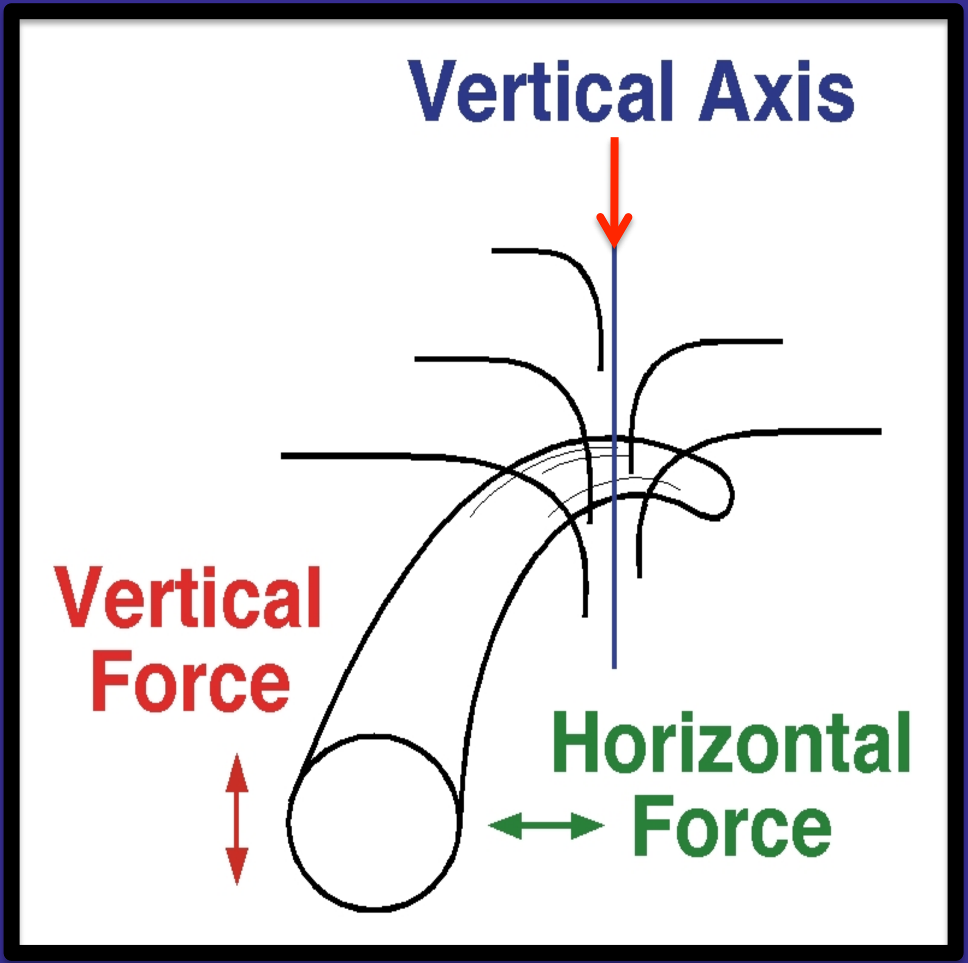


Mean Location of deviatio
into Sc. Vest. 181° from RV

How do mechanical properties effect the rate of trauma?

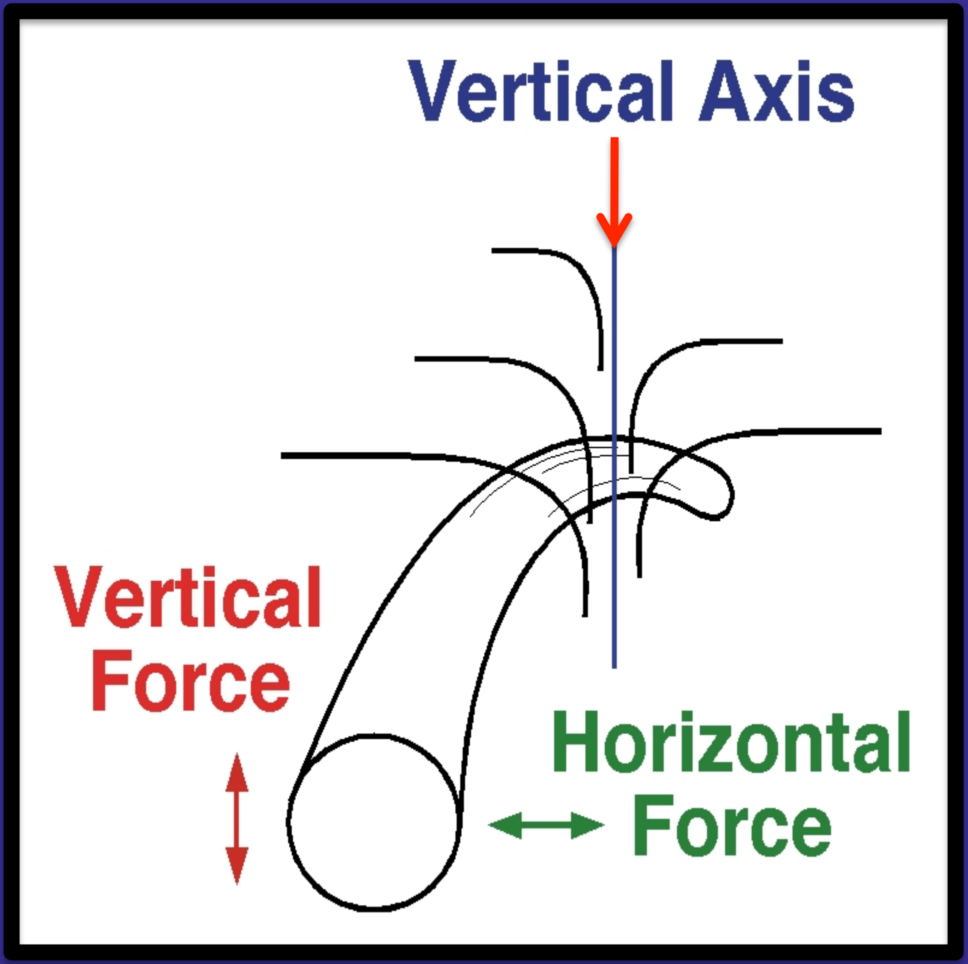
We hypothesize that an electrode which is more stiff in the vertical plane will be less likely to deviate from the scala tympani upward in to the scala vestibuli.

To test this hypothesis we measured:



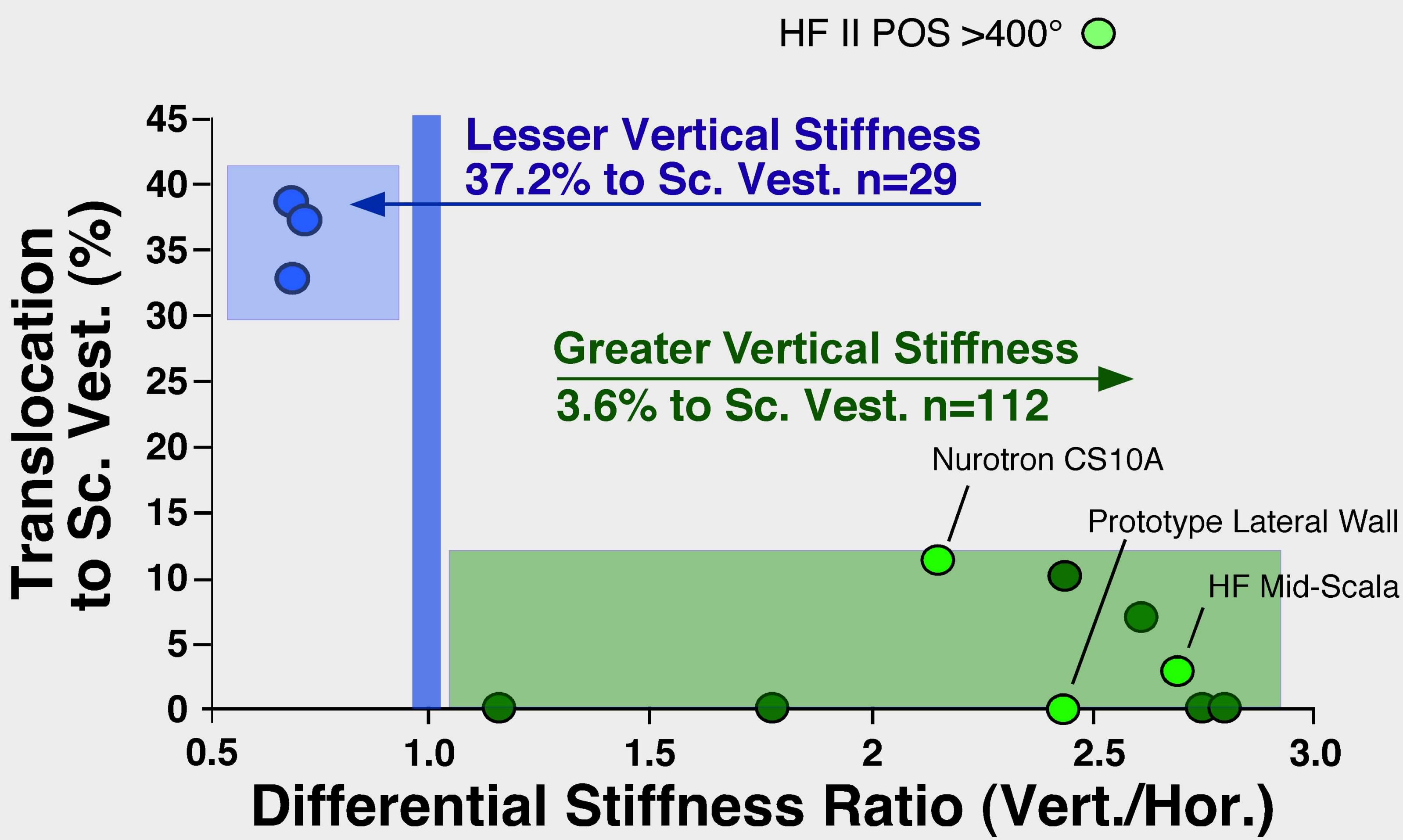
1. The vertical and horizontal stiffness of each electrode design.

To test this hypothesis we measured:



2. Correlated with the incidence of trauma observed with each design.

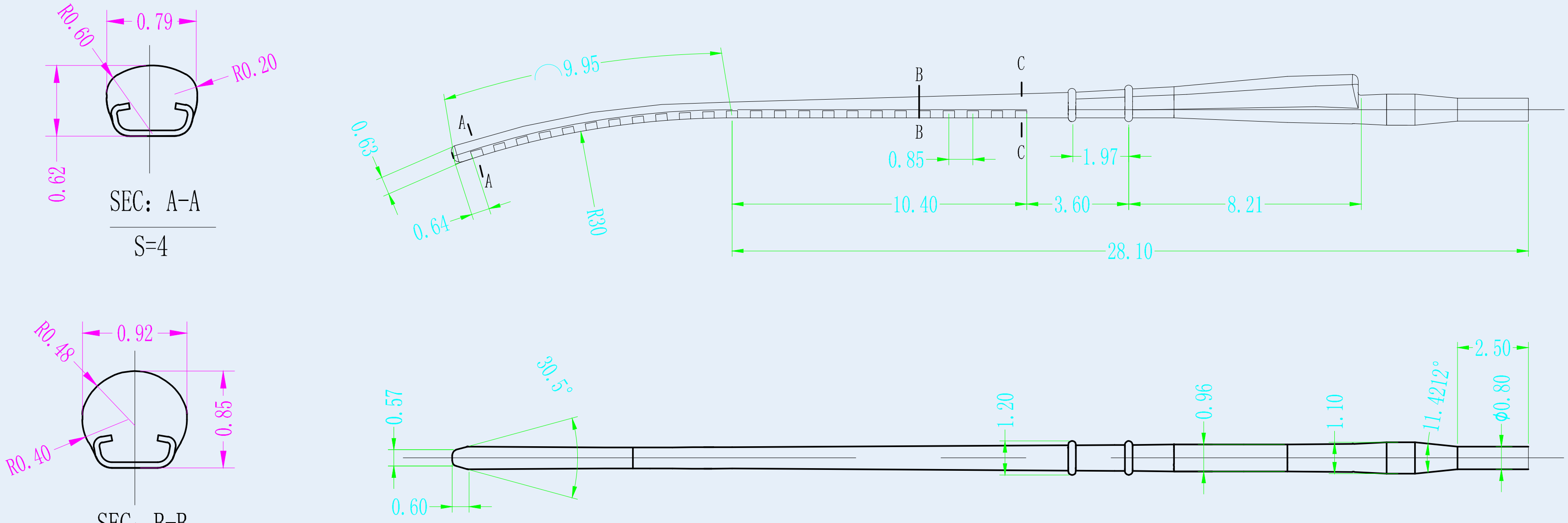
Vertical stiffness effects the rate of trauma



SHALL NOT BE DISCLOSED, DUPLICATED WITHOUT THE PRIOR WRITTEN PERMISSION OF NUROTRON

A4

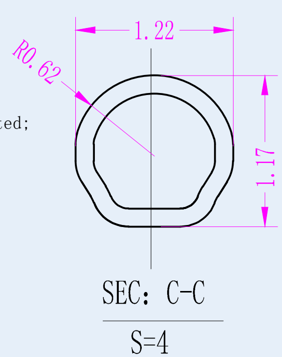
Change record				
REV.	ECN	Description	Date	name
1		First issue	2012/08/05	paul
2	E0000595	Change Tolerance	2013/08/05	paul
3		The replacement of the frame	2015/09/29	paul



24, 20, 16 mm Lengths
Smaller Profile

NOTE:

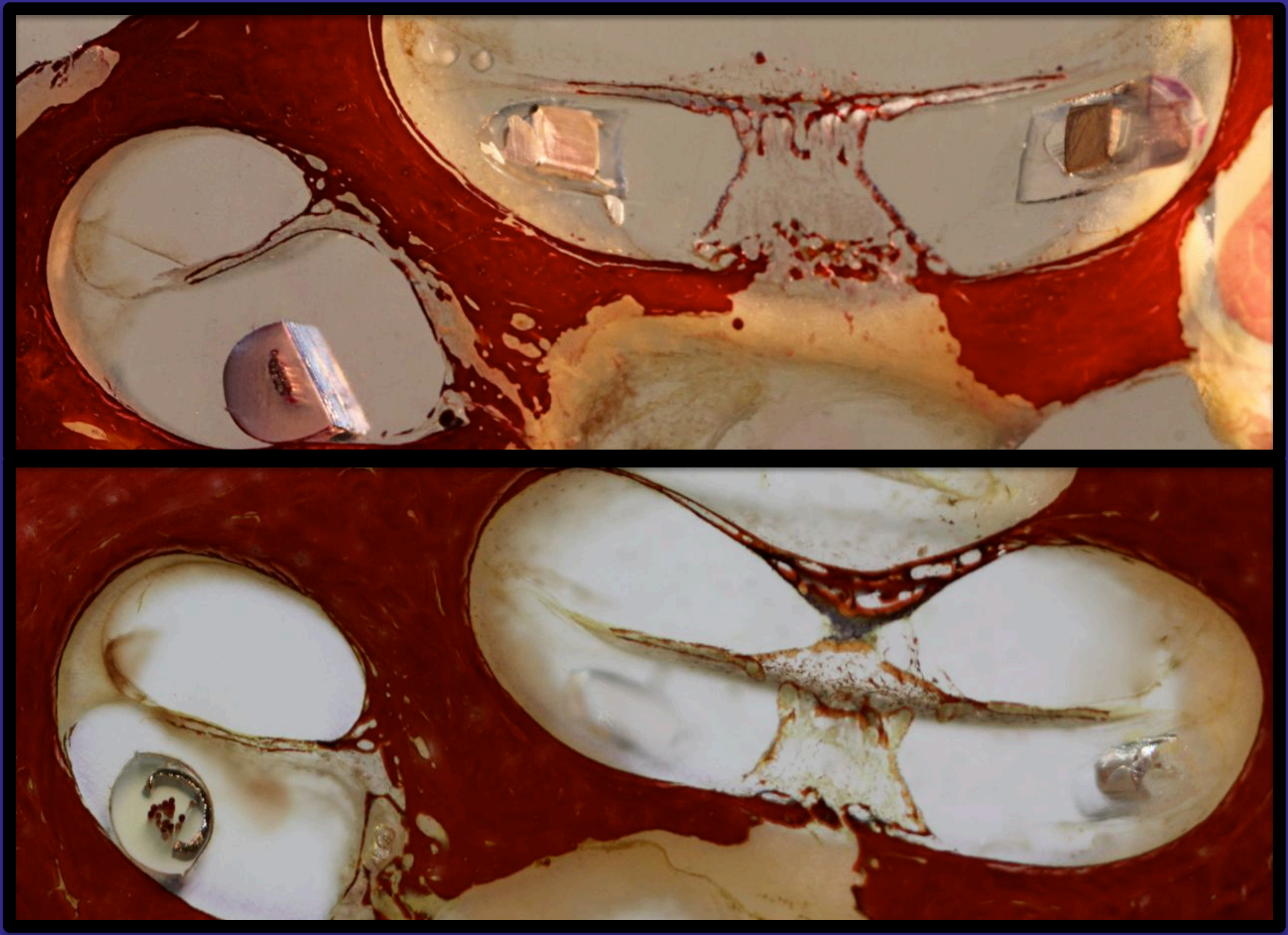
1. Please check 3D diagram if dimension not indicated;
2. EL array length:20.5±0.25mm;
3. Pitch of contacts:0.85±0.1mm;
4. Number of contacts: 24PCS
5. All of the tolerance within ±0.05mm;



NO:	Drawing number	Description	Number	Remarks
2		Silica:MED-4244		YL00.0001
1	CS4.010.100	Contact with wire (72)	24	EL injection

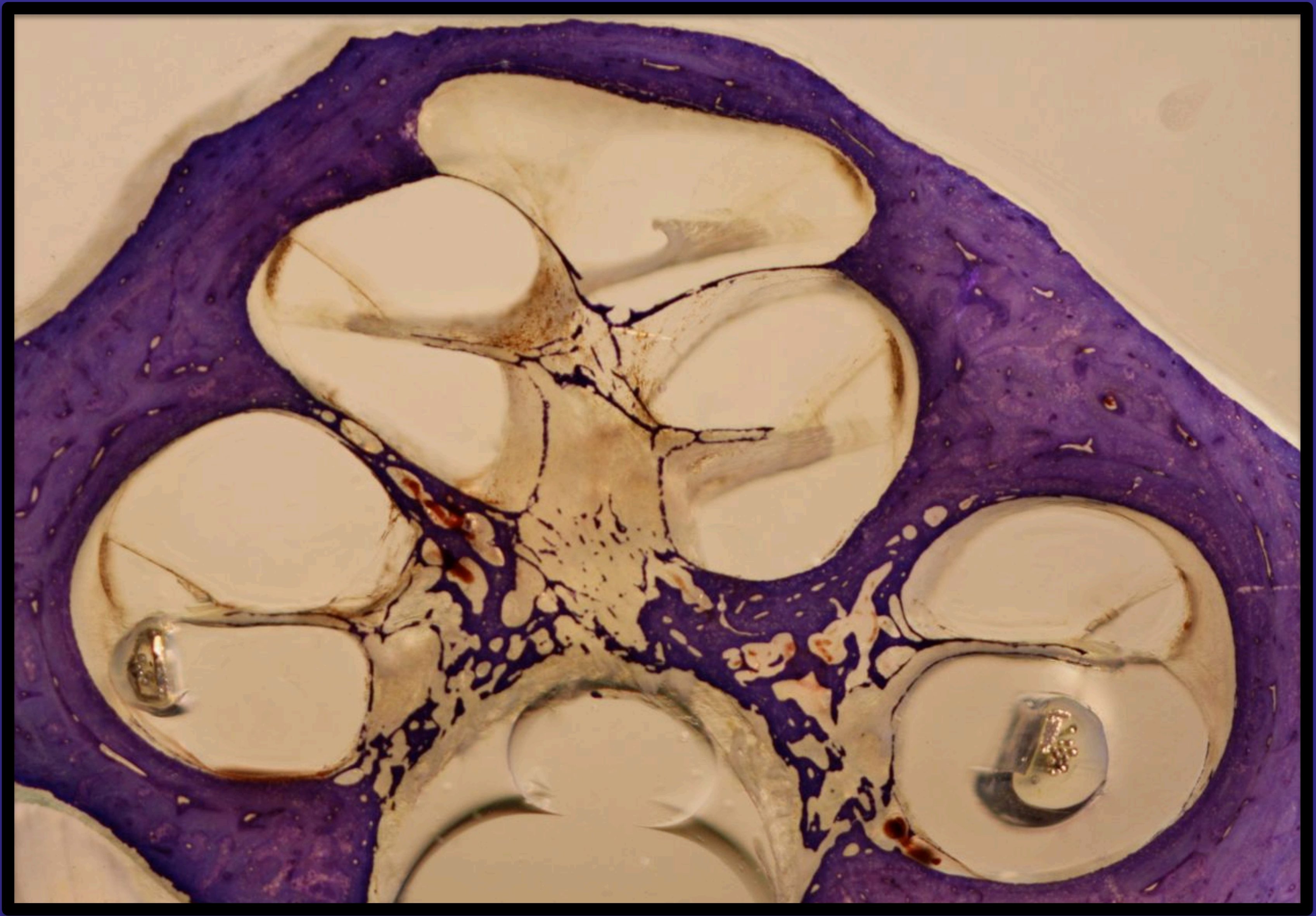
Tolerance: X.X ±0.15; X.X X ±0.10; X.XXX ±0.05; Angle tolerance: ±2°	NUROTRON 诺尔康		浙江诺尔康神经电子科技股份有限公司 ZheJiang Nurotron Biotechnology Co., LTD		
		Name	Date	DESCRIPTION: EL CS-10A(DS)	Scale	NA
	DRAWN	Zhiping tan	2015/09/29	DEVICE: CS-10A	REV.	3
	CHECKED		See Agile	DWG NO: CS4.010.104	SHEET 1 OF 2
	ENG APPRI		See Agile	Material: : NA	Unit: mm

Electrodes stiffer in the vertical plane seldom deviate to Sc V



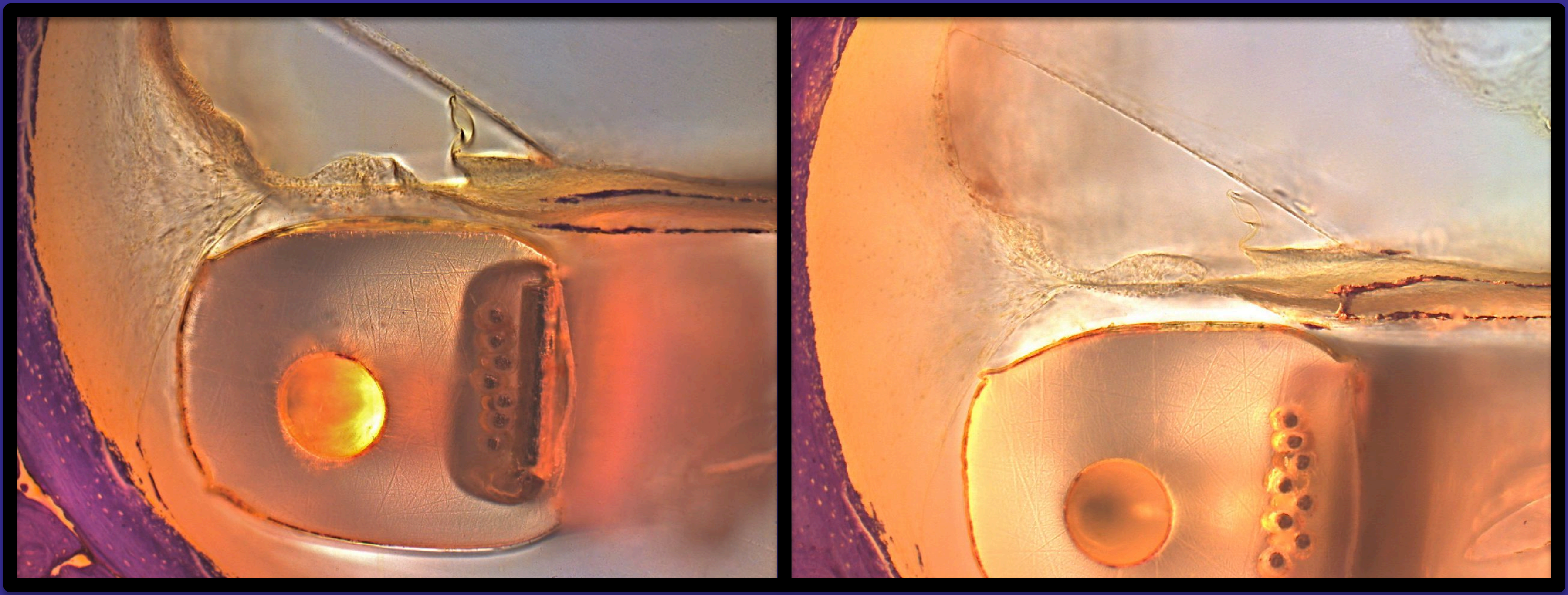
Nurotron CS10A

Straight arrays are located more lateral in the upper turns

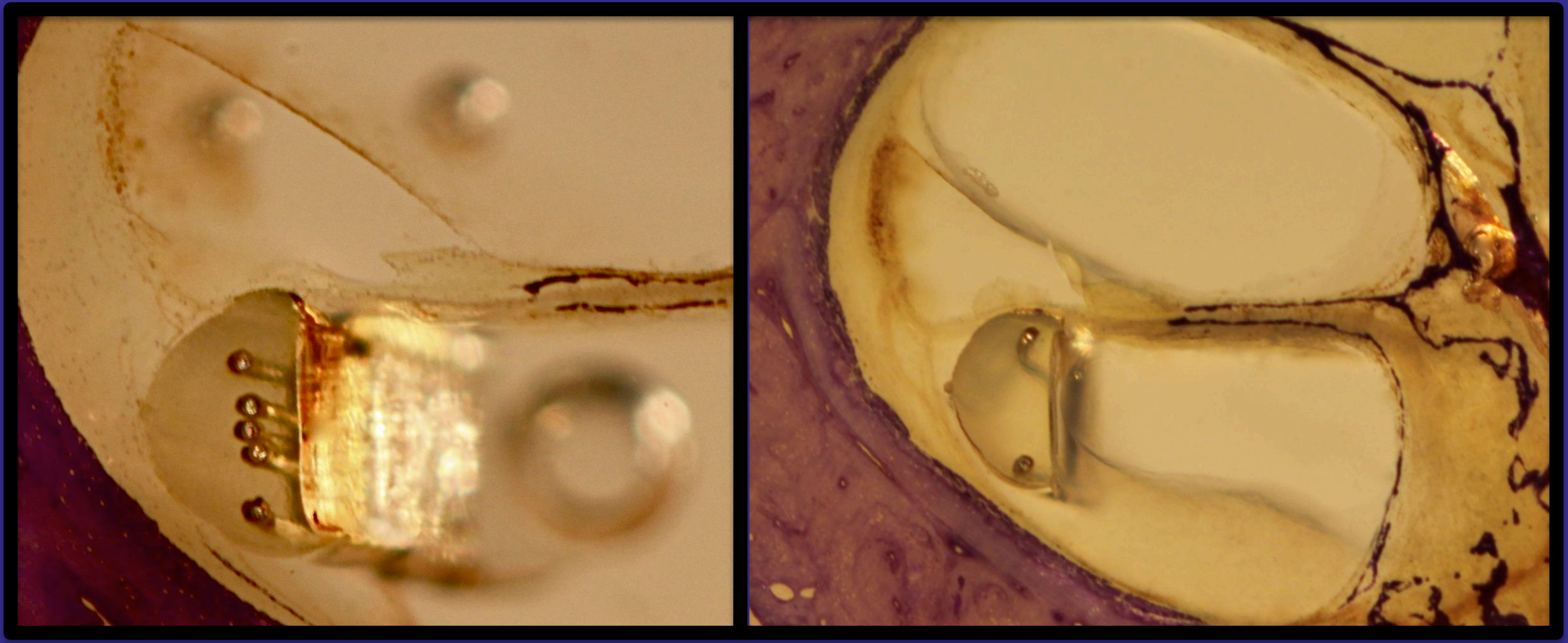


AB Lateral Wall Prototype

Lateral located electrodes may contact the Sp Ligament or Basilar membrane, in many cases without damage.



When distortion is observed it is most often minimal (Eshraghi Scale = grade 1), particularly with arrays that are stiffened in the vertical plane.



The effect of this distortion on residual hearing is unknown.

Other Observations:

We see no difference in trauma between RW insertion and Cochleostomy

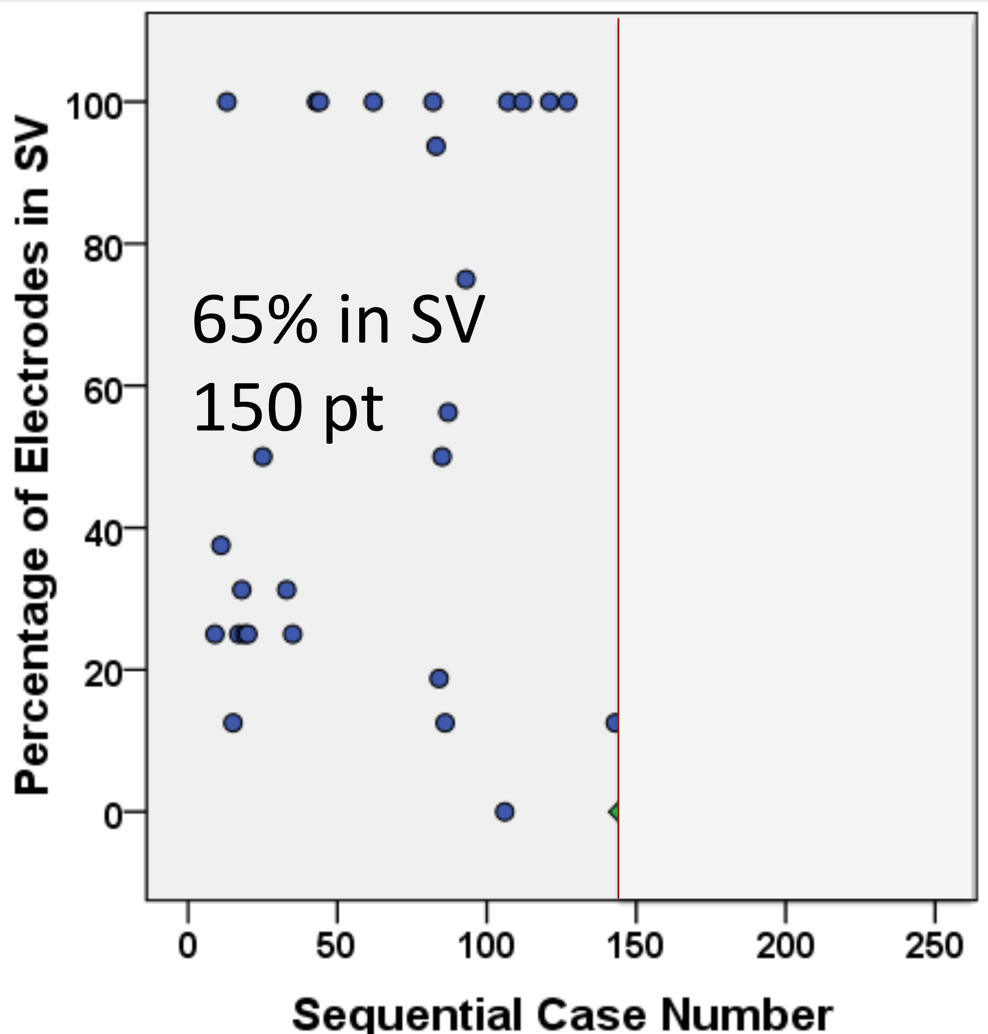
We see no difference in trauma between spiral shape and straight arrays

Do these improvements, i.e. reduced size and increased vertical stiffness, mean we will no longer see intracochlear trauma?

Do these improvements, i.e. reduced size and increased vertical stiffness, mean we will no longer see intracochlear trauma?

Unfortunately, the answer is “No”

Surgical technique can strongly affect the rate of trauma

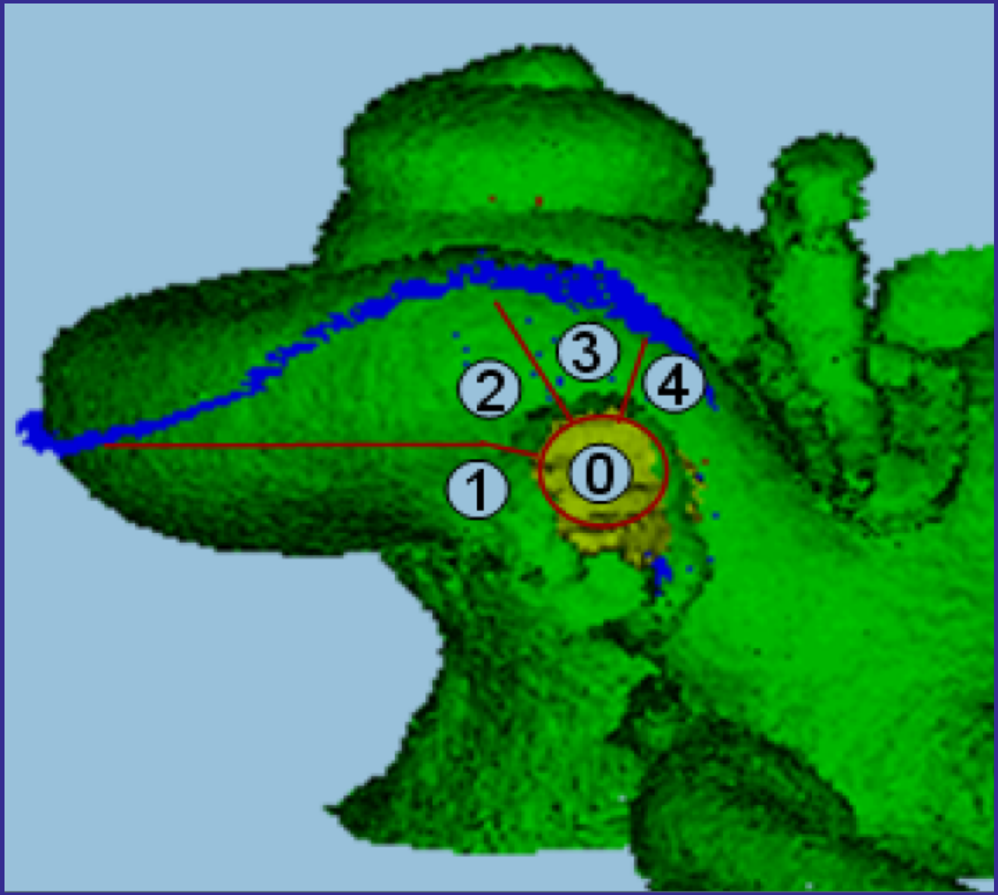


HiFocus 1j &Helix

Finley, et al

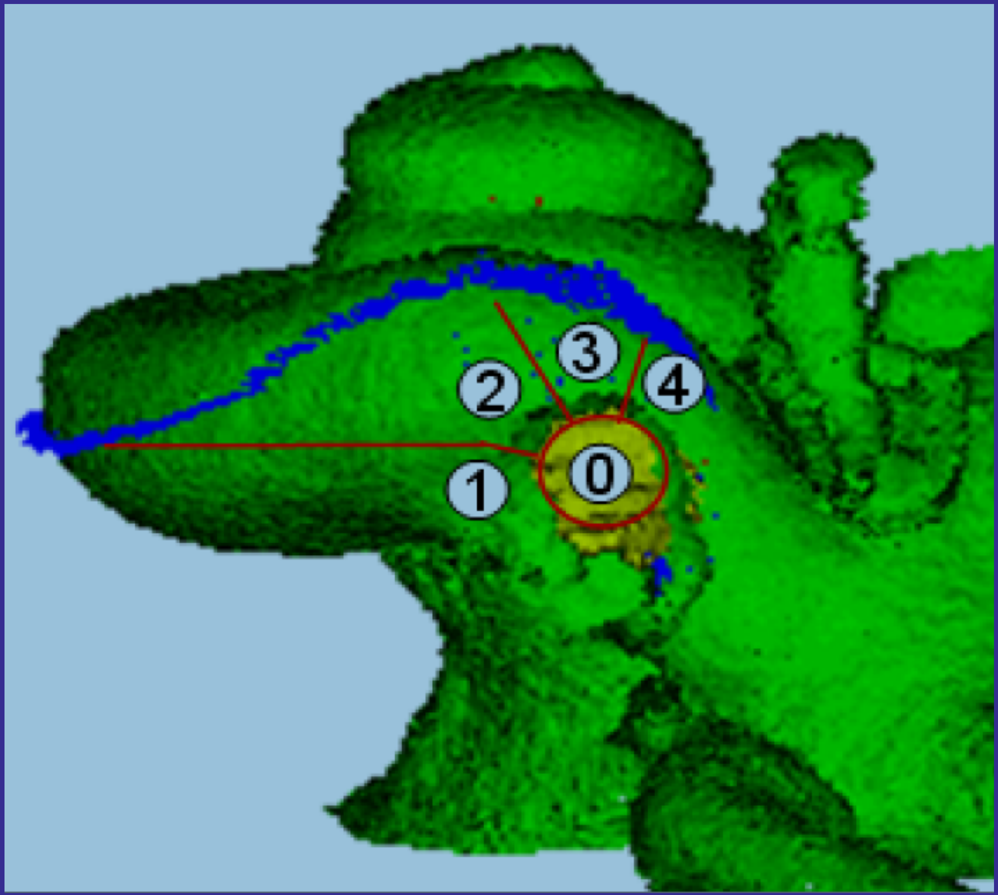
*6 other studies averaged 4.5% in SV, same arrays

Does cochleostomy location affect the percentage of electrodes in Scala Vestibuli?



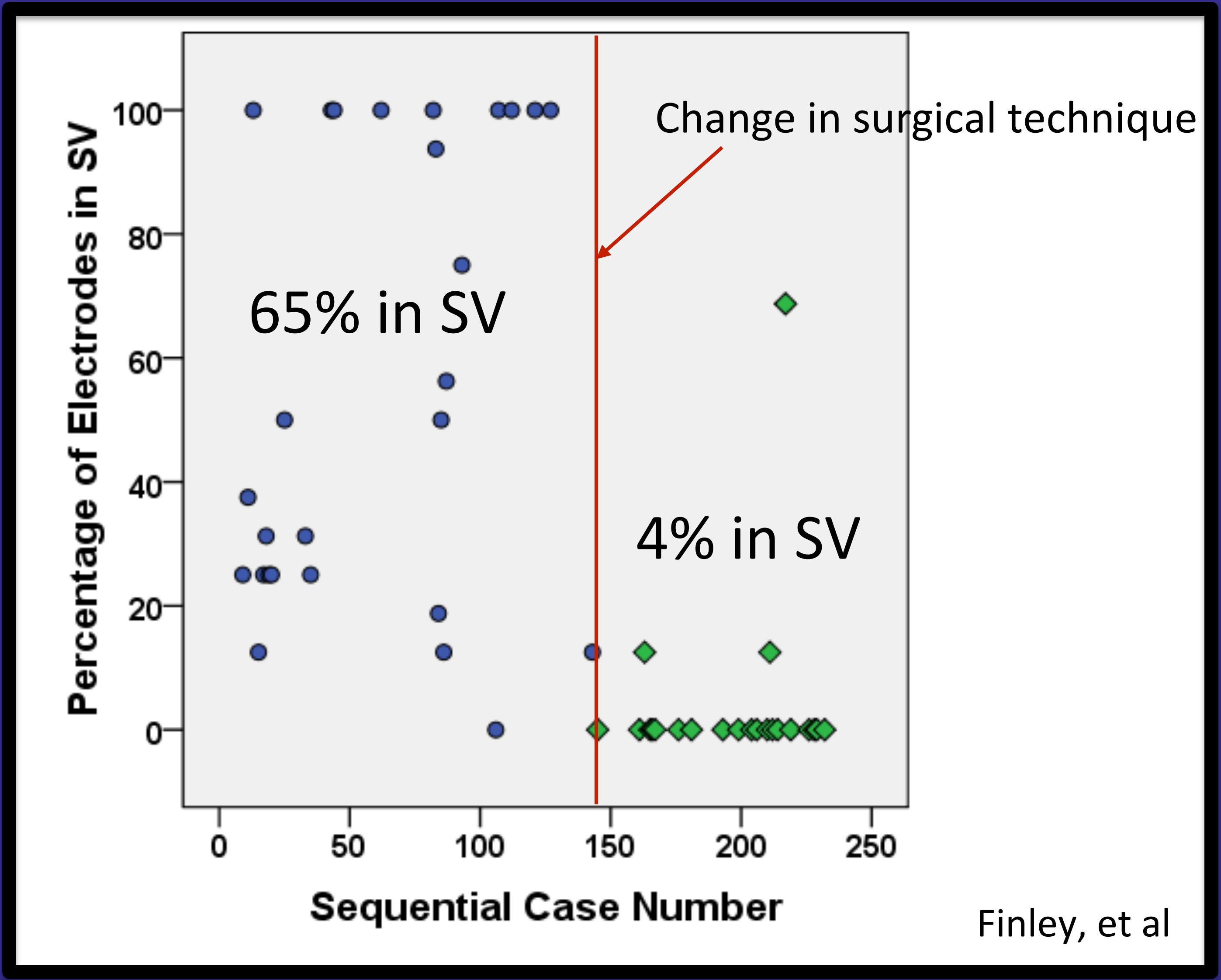
Finley, et al

What would happen if the surgeon made a concerted effort to place all cochleostomies in region #1?

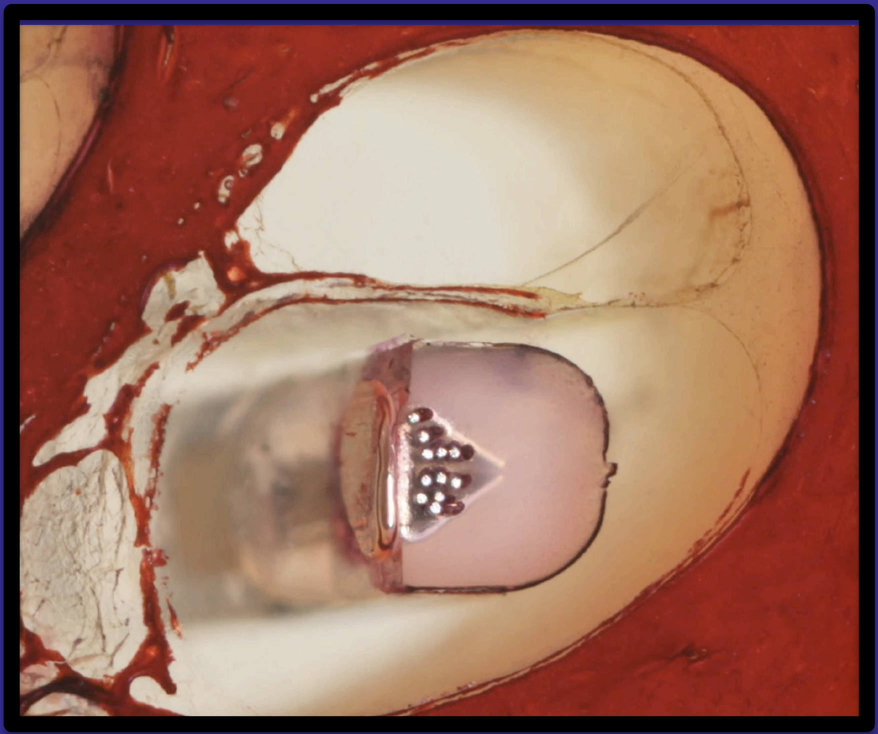


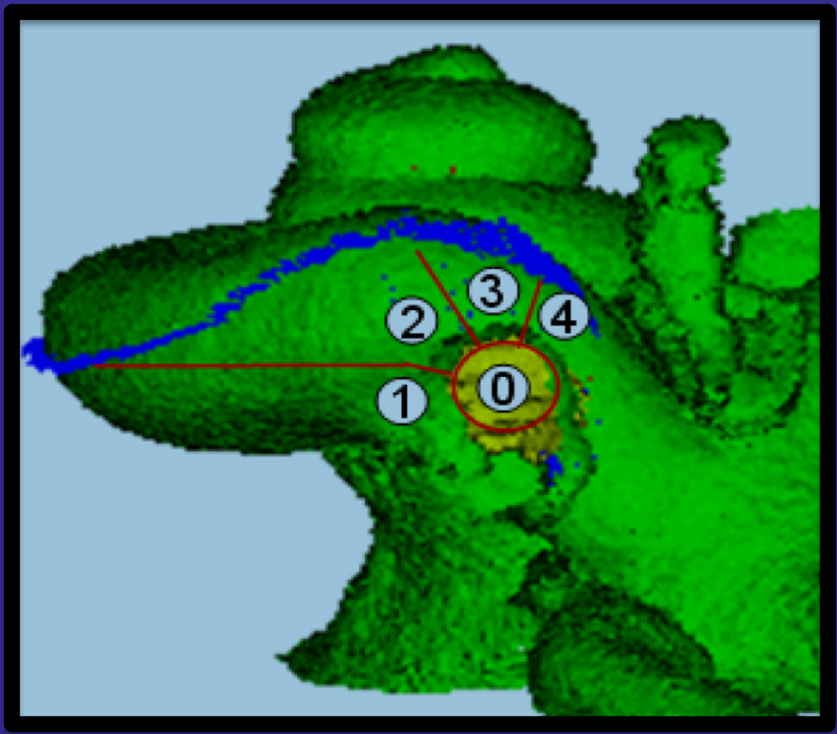
Finley, et al

Resulting change in rate of damage



To be ultimately successful we need to combine the best electrode technology with optimum surgical technique.





How can we ensure this understanding is communicated in a meaningful way to surgeons worldwide?

Temporal bone insertions are excellent preparation for this clinical procedure.

Hospitals in China (n=19) practice with TBs ranged from 1- >40 per resident
13 Hospitals = 5 or less, 6 Hospitals >10 TBs*

*Collaboration with Liu Shuai and Prof. Guan, Tsinghua University

Summary

1. CI devices and subject performance are improving worldwide.

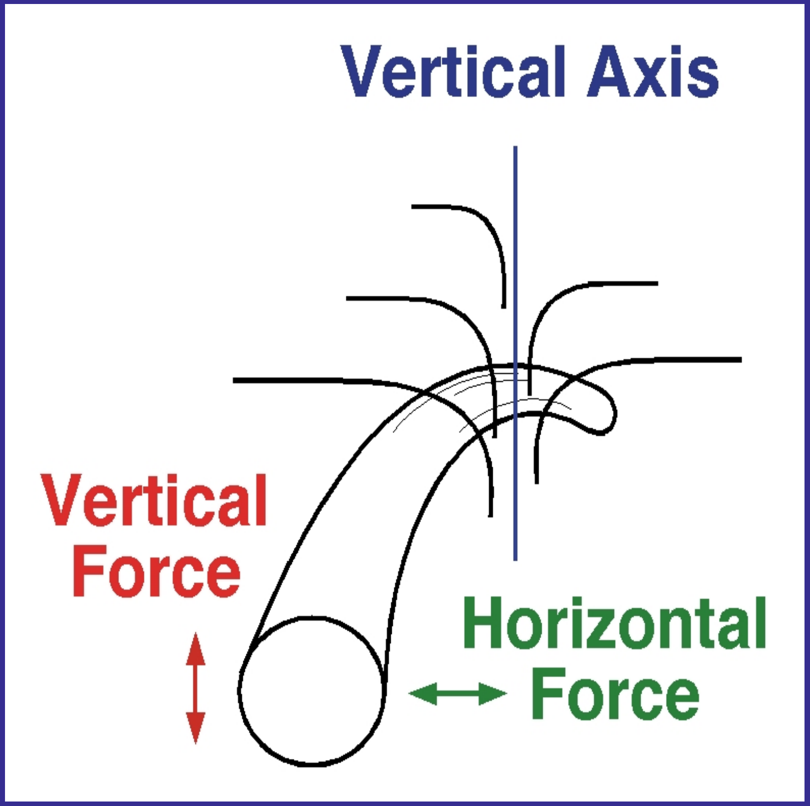
2. Cost of CI devices is declining and government support is increasing throughout the world. Nurotron will be a major part of this effort.

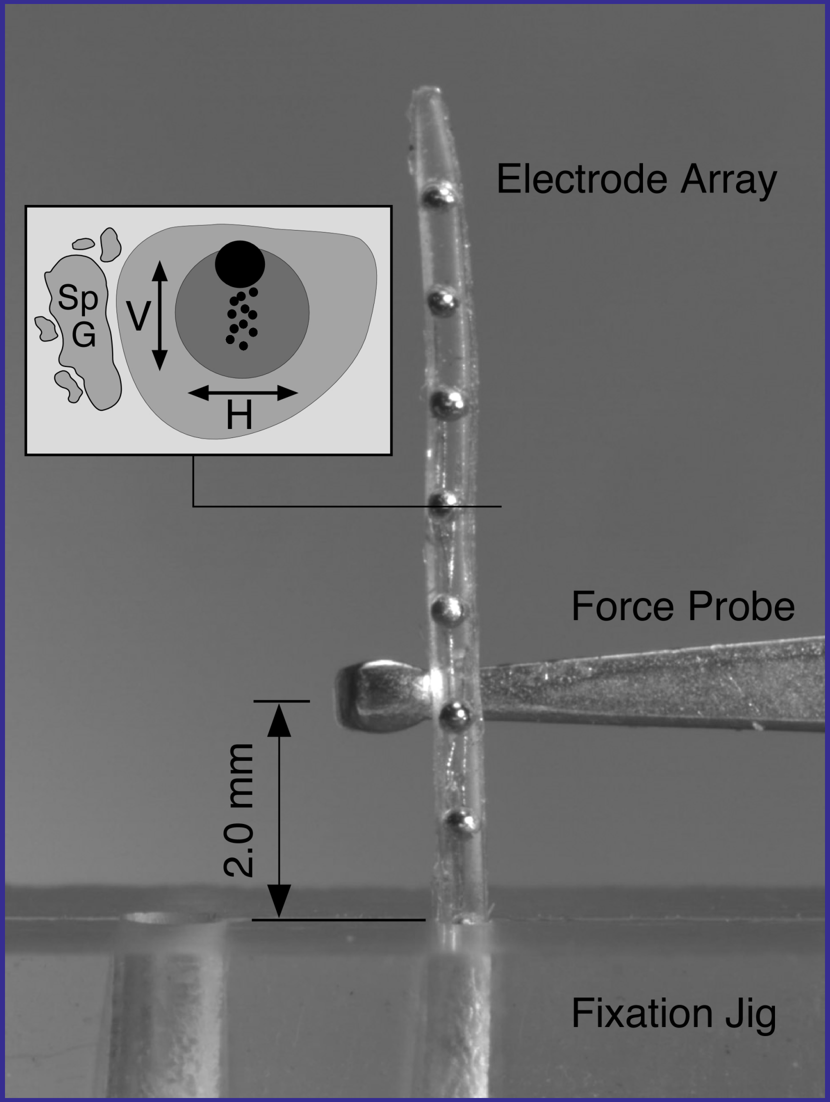
3. Supporting infrastructure, funding and training are key to broad access and quality of CI.




Thank You

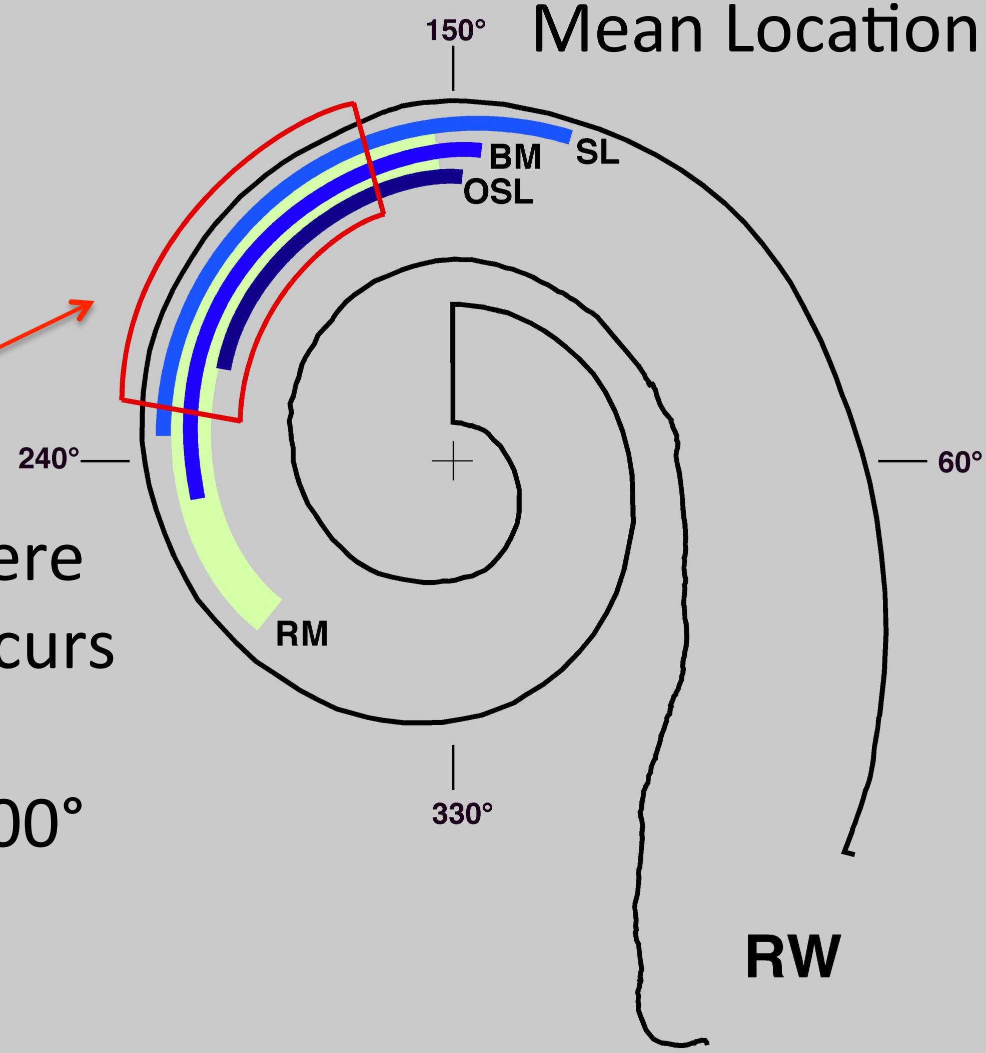
How does electrode stiffness effect trauma?



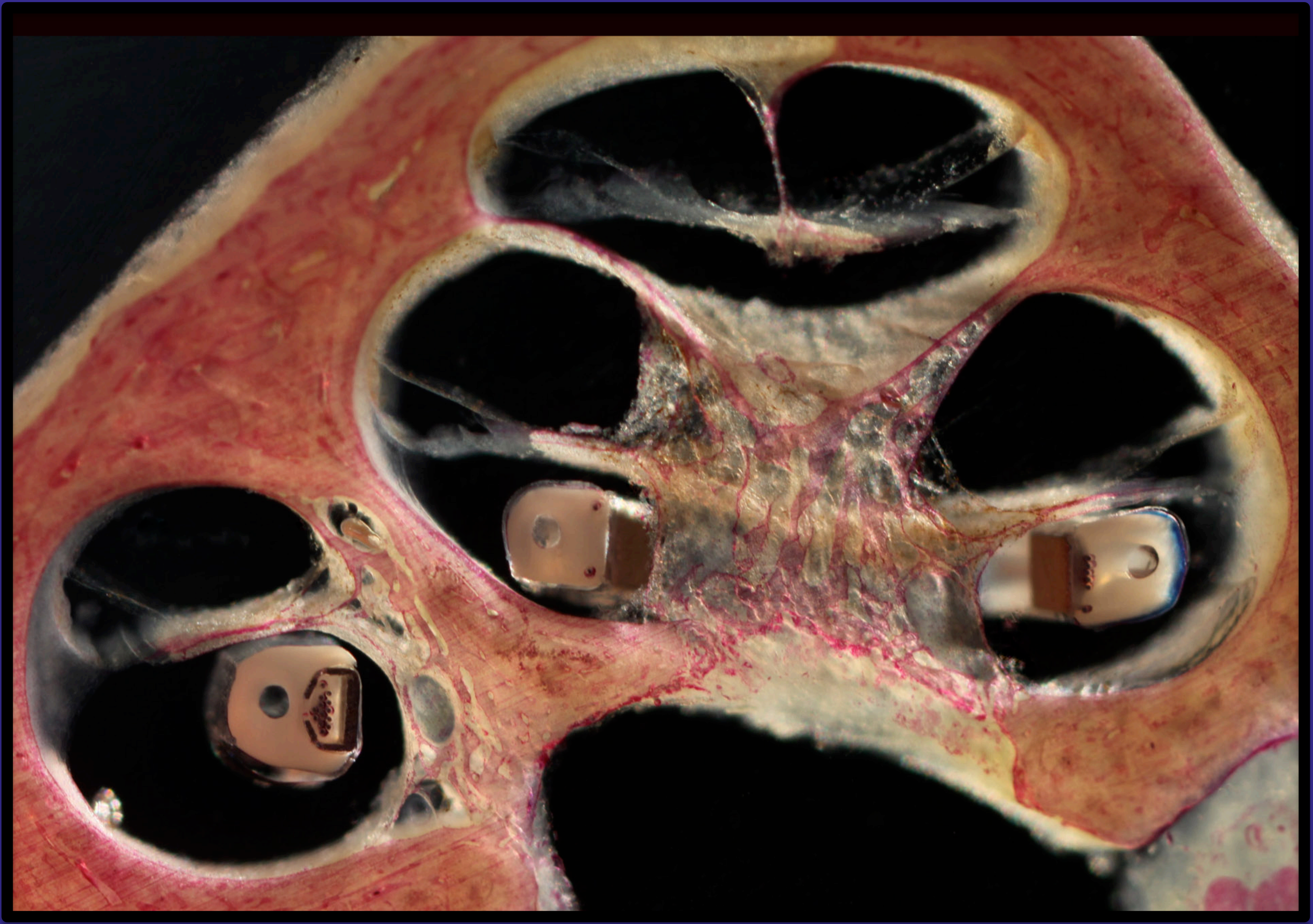


Where, and how, does damage most often occur?

Mean Location 181° from RW



75% of severe damage occurs between 160° and 200°



HiFocus Mid-Scala

Spread of excitation across the tonotopic gradient of the IC

Future electrodes should have the capacity for greater numbers of channels.