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Advances in Implantable Amplification Devices

Presenter: Brad A. Stach, Ph.D.

Moderator: Carolyn Smaka, AuD, Editor in Chief, AudiologyOnline

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Advances in Implantable Amplification Devices

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Disclosures – Brad A. Stach, Ph.D.

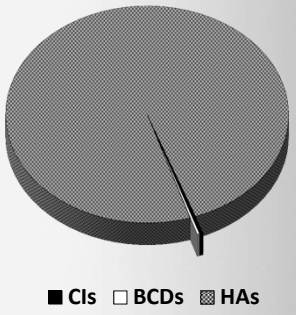
ENVOY medical	**Chair, Audiologist Advisory Panel**
OTOTRONIX	**Member, Medical Advisory Board**

Overview

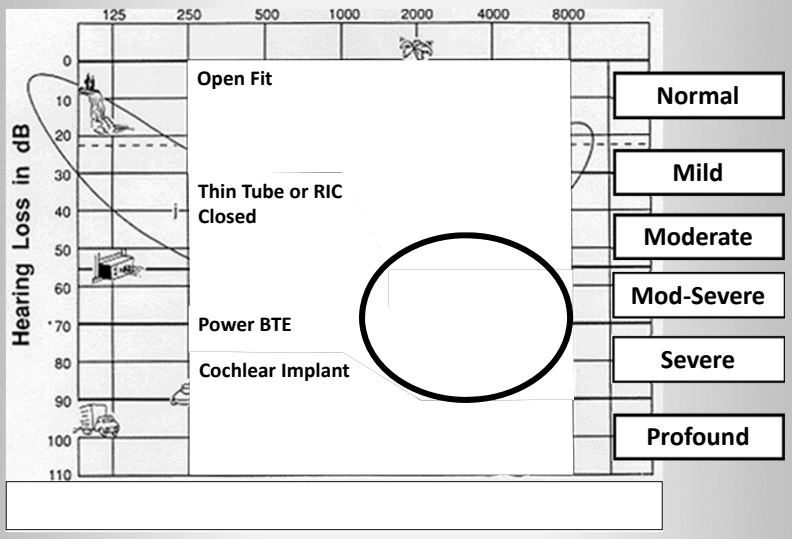
- Why Middle-ear Implants?
- Partially Implanted MEIs
- Fully Implanted MEIs

Implants

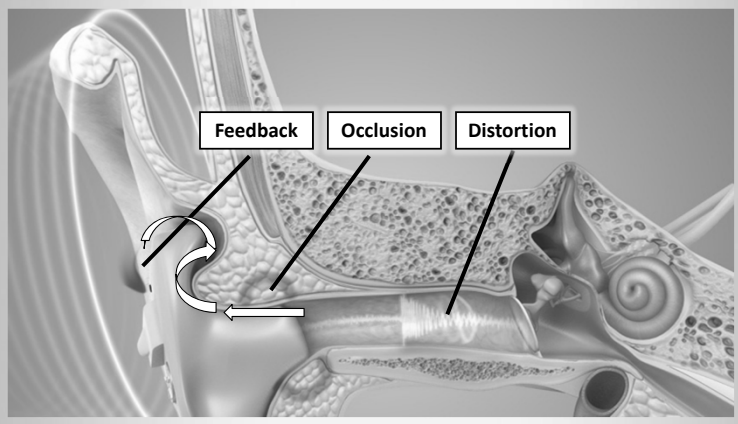
- Bone-conduction devices
  - Conductive loss
  - ~20,000/yr
- CI
  - Profound SNHL
  - ~40,000/yr
- MEI
  - Moderately to severe SNHL



HA Fitting Profiles

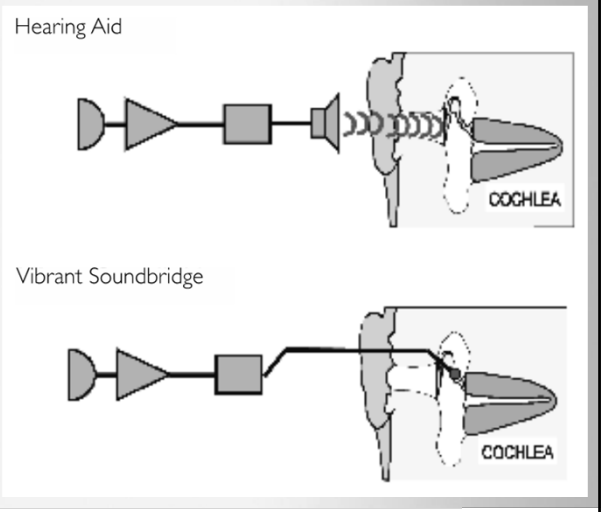


Acoustic Speaker Limitations



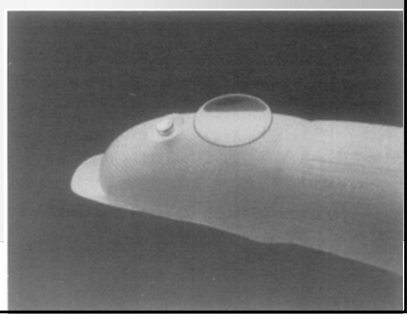
MEIs are "*speakerless*"

MEIs use electromechanical energy to directly vibrate the ossicular chain and cochlear instead of using acoustic energy to vibrate the TM



MEI Benefits

- Improved fidelity and quality of sound
  - Direct stimulation of ossicles
    - Elimination of speaker
    - Elimination of acoustic distortion



MEI Benefits, cont.

- Avoidance of feedback
  - No acoustic energy
- Improved gain
  - Gain not hindered by feedback
- Reduced or eliminated occlusion effect
  - Open-fit or totally open canal

Partially Implanted Devices

- Implanted component
- External component
  - Hearing aid like device
  - Similar lifestyle restrictions as a hearing aid

Partially Implanted Devices

- Vibrant Soundbridge by Med-El
- Maxum by Ototronix

Vibrant Soundbridge

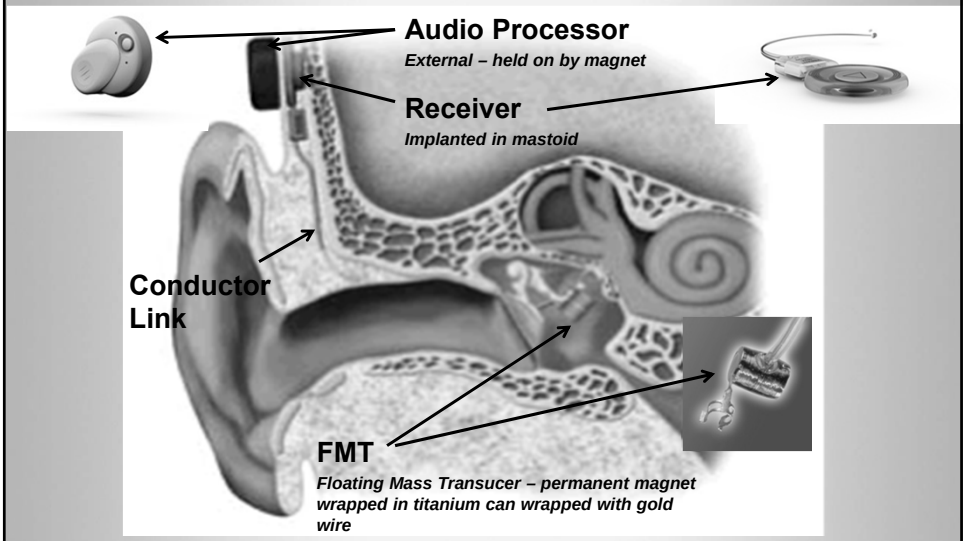
- First introduced in 1996
- Made by Symphonix until 2002
- Re-released by Med-El in 2004
- http://www.medel.com/int/vibrant-soundbridge

Vibrant Soundbridge

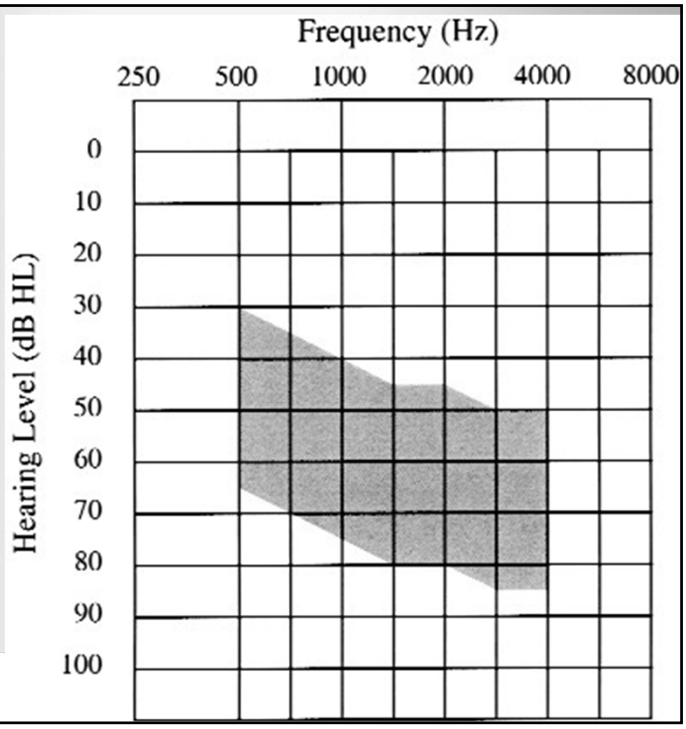
External Processor

Implanted Receiver

Vibrant Soundbridge

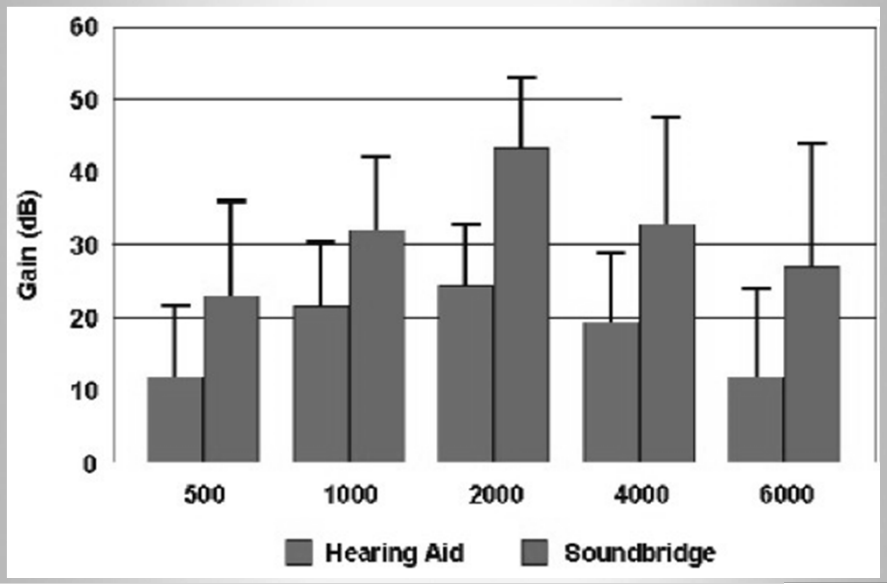


Vibrant Soundbridge



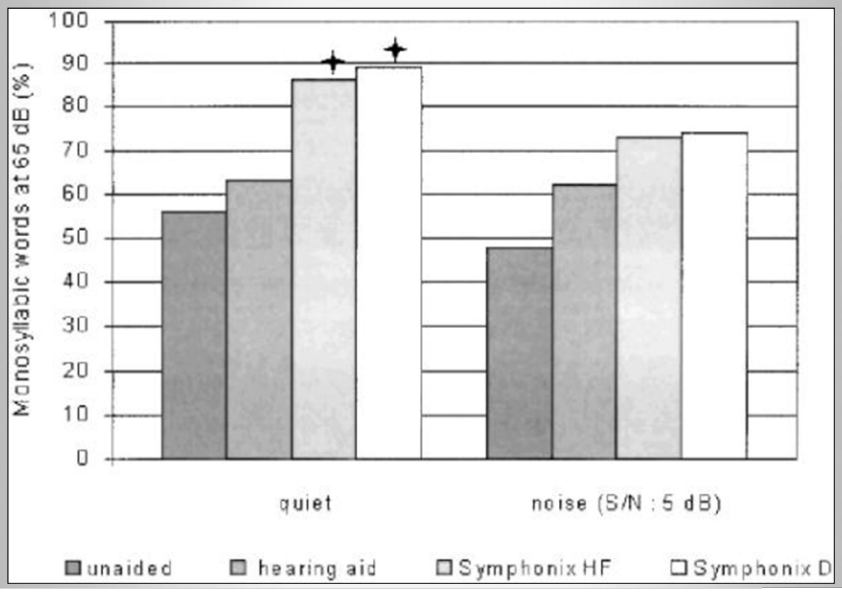
From Todt et al., 2002

Vibrant Soundbridge



From Luetje et al., 2002

Vibrant Soundbridge



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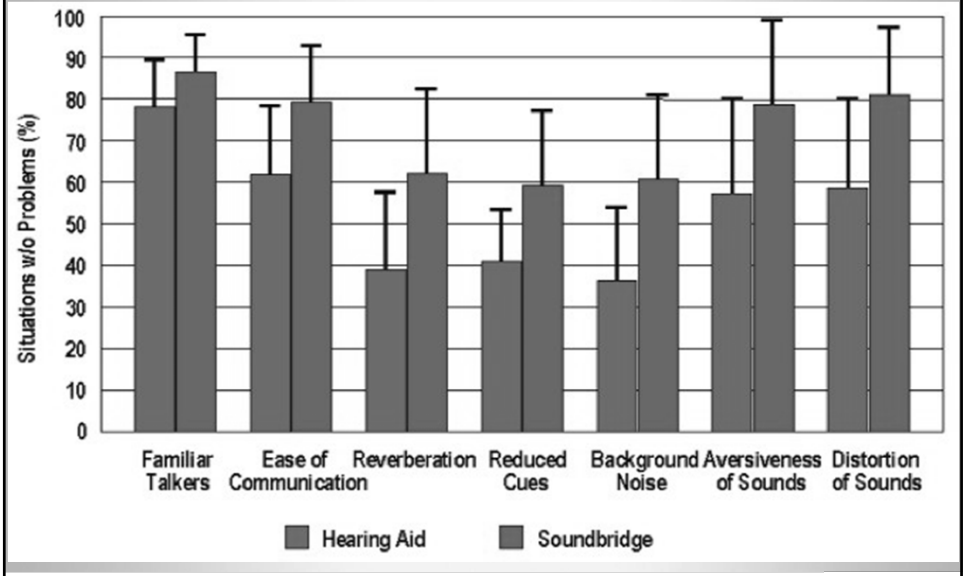
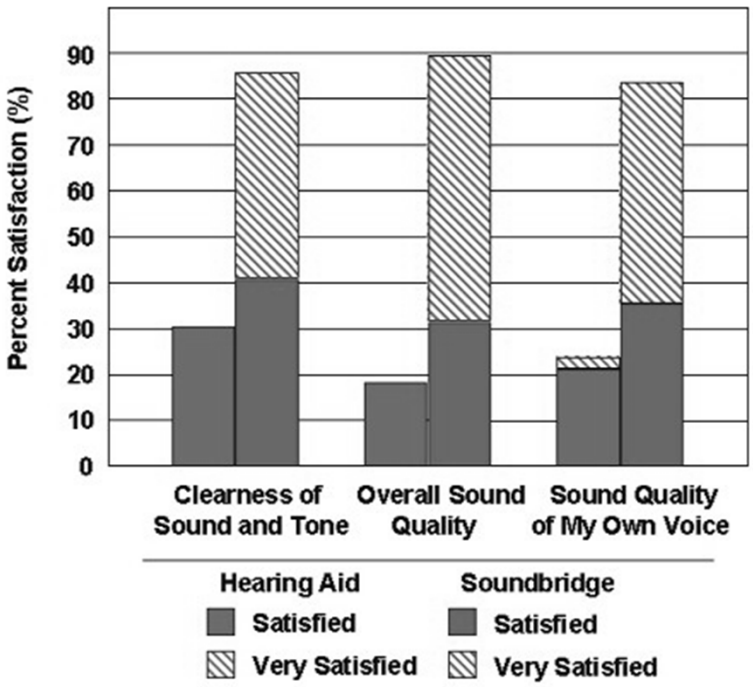
Vibrant Soundbridge



From Luetje et al., 2002

Vibrant Soundbridge



From Luetje et al., 2002

Vibrant Soundbridge

- Current status:

  ~ 3,000 implants worldwide this past decade

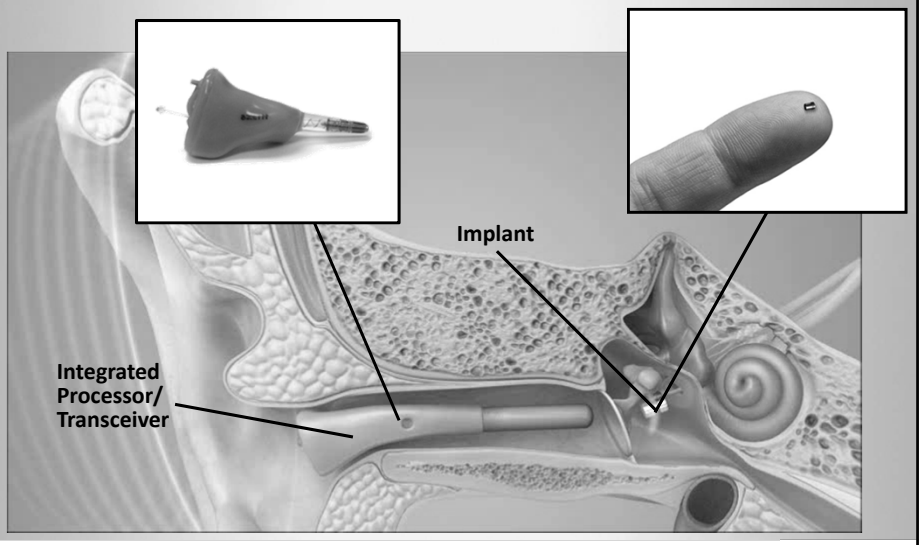
Ototronix Maxum

- Based on the early work of Dr. Jack Hough
- Later refined by Ototronix
- http://www.mymaxum.com

Ototronix Maxum

- FDA Approved
  - Adults 18 years and older
  - Moderate to severe sensorineural hearing loss

Ototronix Maxum



Maxum Procedure

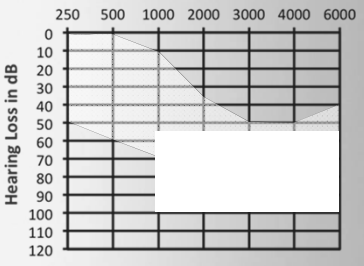
- Minimally invasive
- Transcanal approach
- Local anesthetic
  - In-office procedure room or surgical center
- ~30 min.

Maxum Processor

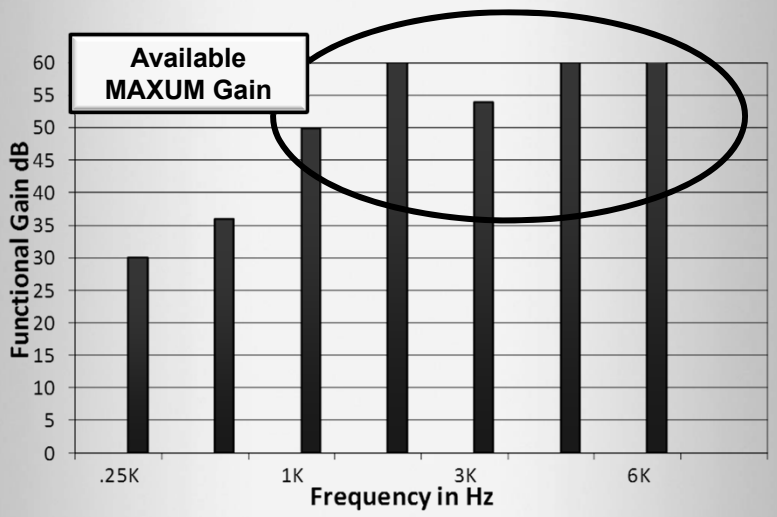
- Digital processing technology
  - Noise reduction – 8 bands
  - Gain adjustment - 8 bands
  - Adaptive directional microphones
  - Advanced compression algorithms - 8 channel WDRC
  - Multiple listening environments – 4 programs
- IPC/CIC or micro-BTE configurations
- Fitting program similar to hearing aids
- Easily upgradable

Fitting Criteria

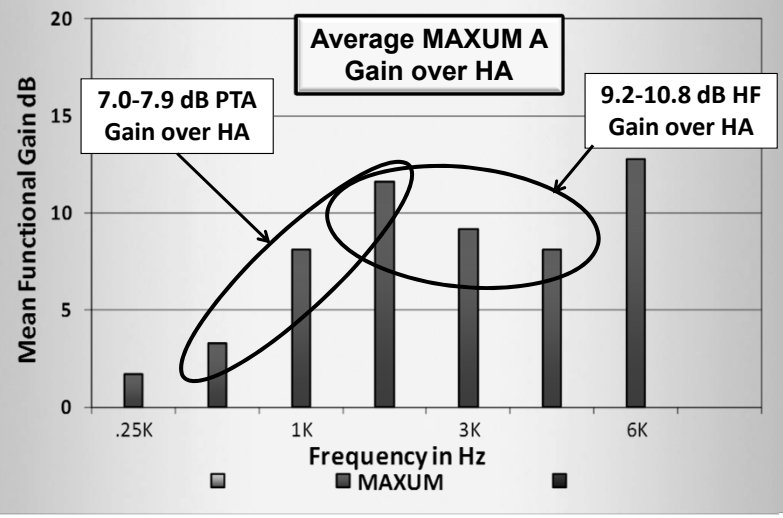
- Hearing aid users
- Custom molds
  - Desire open-fit experience
- Mod-severe to Severe SNHL
  - HF Ave (2K, 3K & 4K) > 55 dB



Functional Gain

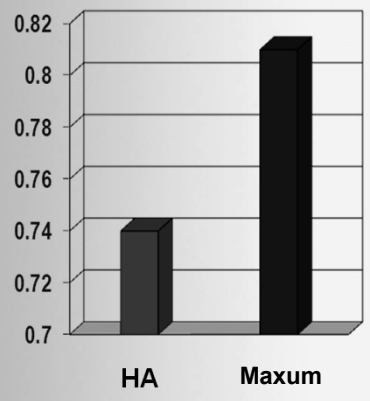


Functional Gain



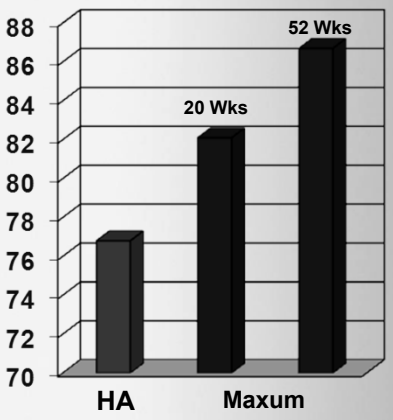
*FDA PMA Phase II Clinical Study

Articulation Index



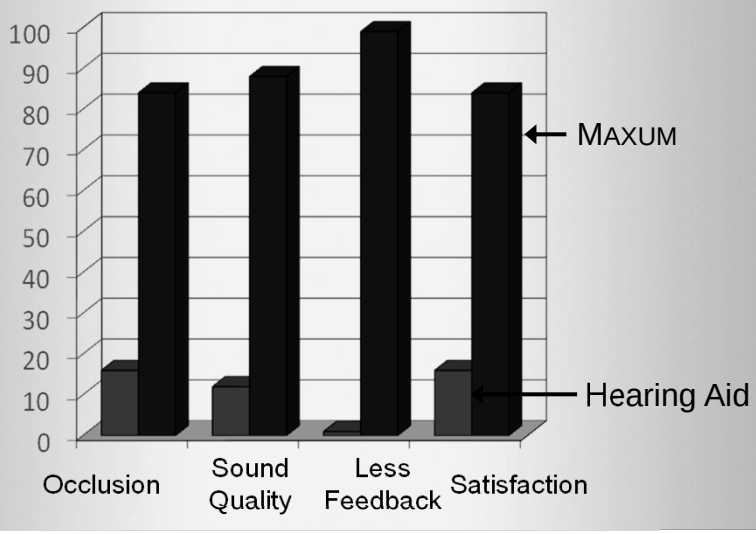
Word Recognition

NU-6 Words at 50 dB presentation level



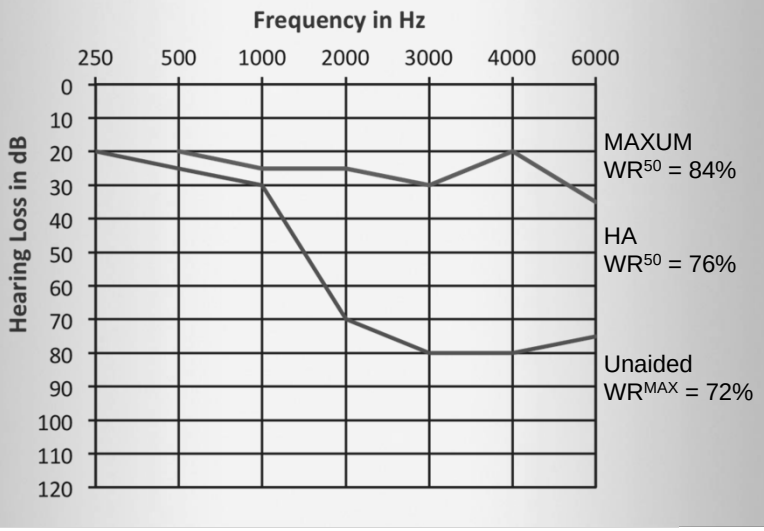
*FDA PMA Phase II Clinical Study

Device Preference

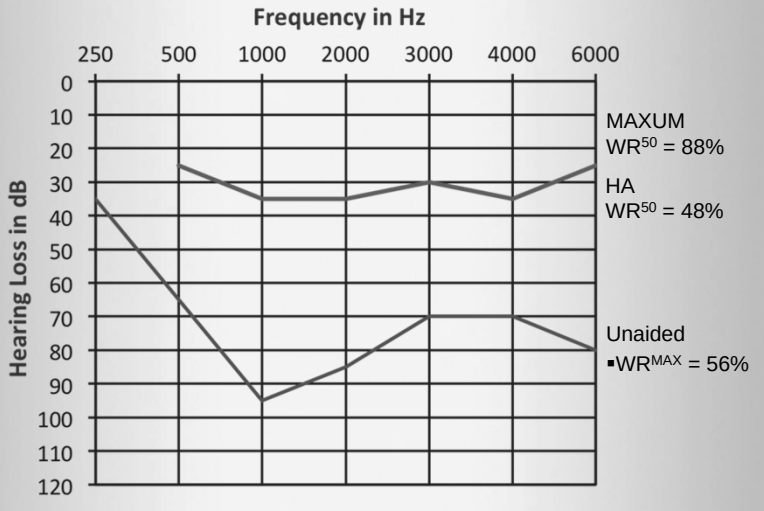


*FDA PMA Phase II Clinical Study

Case Study



Case Study



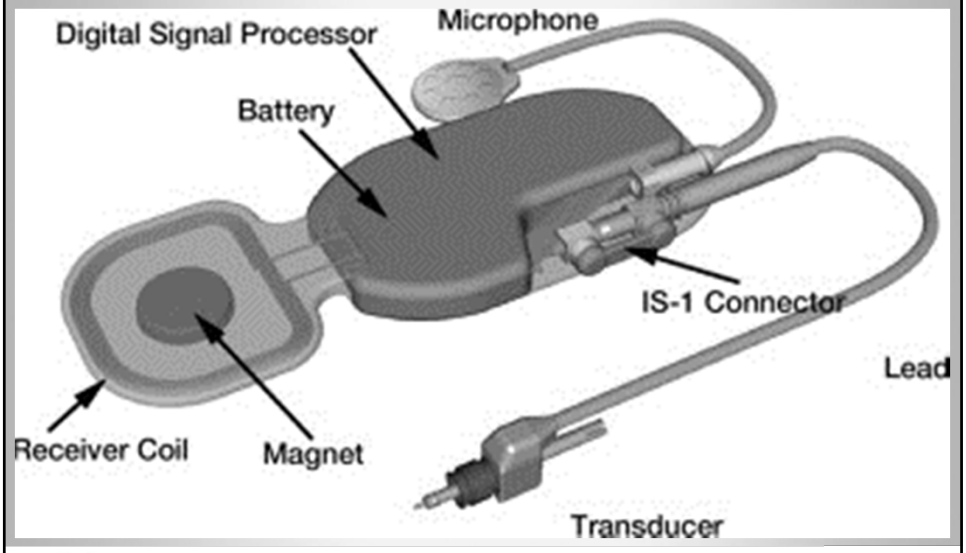
Fully Implanted Devices

- Carina by Otologics
- Esteem by Envoy

Otologics Carina

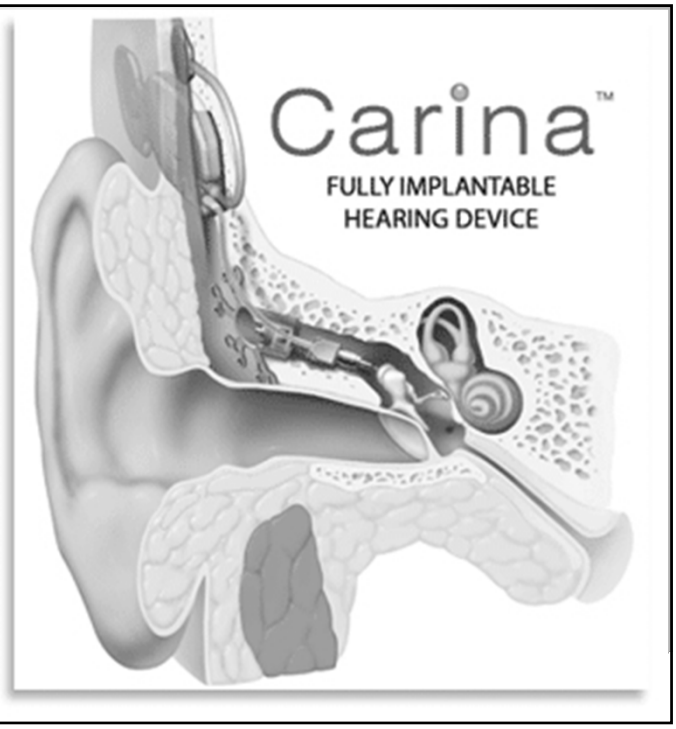
- Developed by John Frederickson at Washington University in St. Louis
- Originally a partially implantable device
- Now fully implantable
- No longer in FDA clinical trials
- Currently distributed in Europe by Cochlear

Otologics MET Fully-Implantable Device

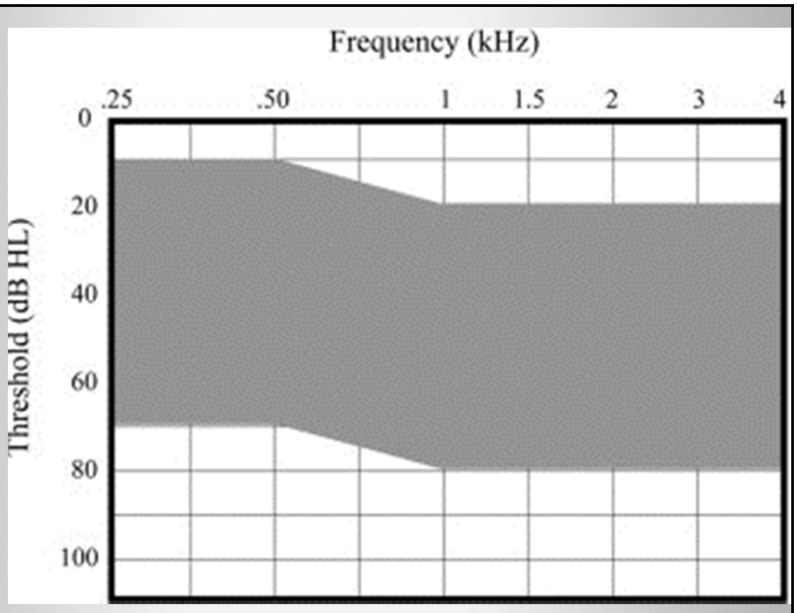


From Jenkins et al., 2007

Otologics Carina



Otologics Carina



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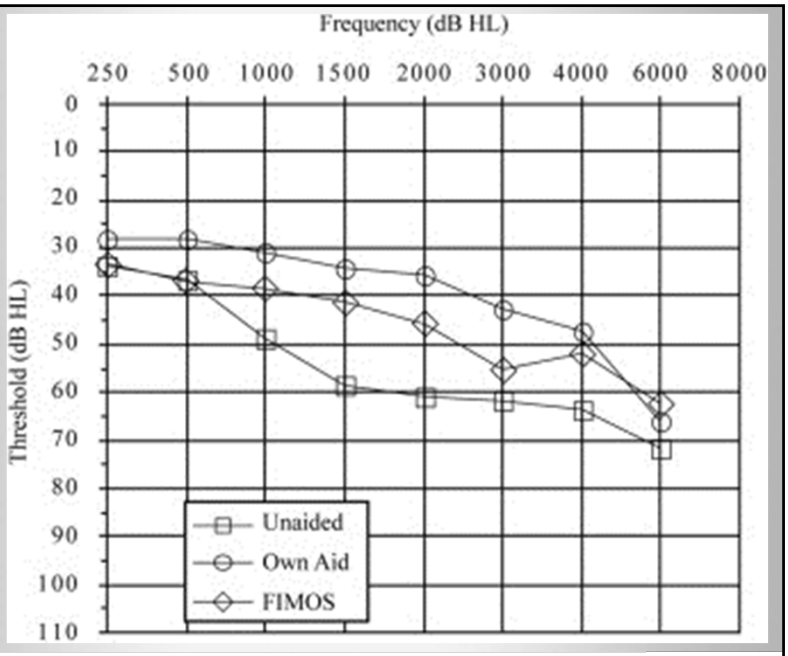
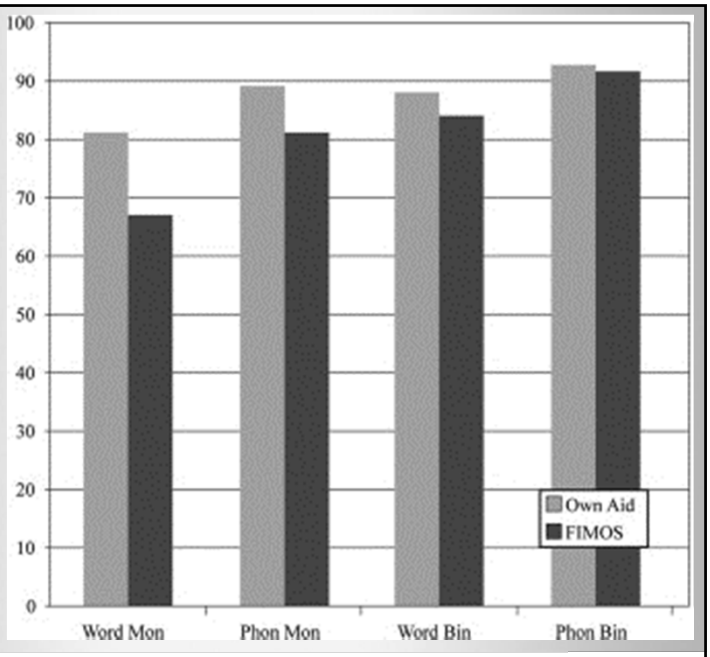
Otologics Carina



From Jenkins et al., 2007

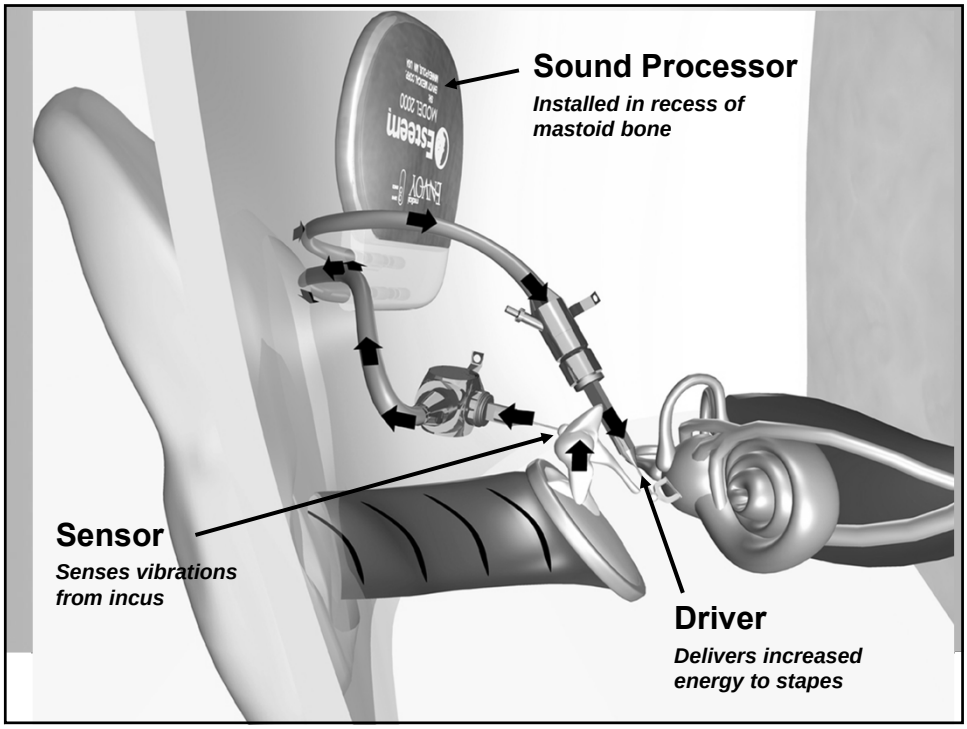
Otologics
Carina



From Jenkins et al., 2007

Envoy Esteem

- 1985 – Original development began
- 1995 – Envoy Medical founded (St. Croix Medical)
- 1997 – 1st animal studies
- 1998 – 1st acute human trial
- 2000 – 1st totally implanted devices for humans
- 2000-2002 – Feasibility trials in Germany and US
- 2004-2007 – FDA Clinical Study
- 2008-2009 – FDA Pivotal Study
- 2010 – FDA approval
- http://envoymedical.com



Esteem Sensor & Driver

PIEZOELECTRIC TRANSDUCERS

Each transducer moves in only one direction:

- **Sensor** – displacement of the incus deflects the piezoelectric portion of the device, which produces an electrical signal that then travels to the sound processor
- **Driver** – electrical signal from the sound processor travels to the driver and causes the piezoelectric portion of the driver to deflect

Key Benefits

- Ultra-low power
- Low distortion even at max output levels
- Low noise

Additional Esteem Benefits

- Uses the TM as the microphone
  - Natural head shadow, pinna, and ear-canal effects
  - Open ear canal
- Totally implanted
  - Invisible
  - Long battery life
- Lifestyle Considerations
  - 24/7 hearing
  - Waterproof (underwater depth rating to 33 ft.)
  - No daily maintenance

Battery Life

Sound Processor battery life estimates for typical acoustic exposure determined through laboratory testing

Hours/day (7 days/week)	Battery life
24 hours	4.5 years
15 hours	6.5 years
8 hours	9 years

Median battery life = 5 – 5.5 years

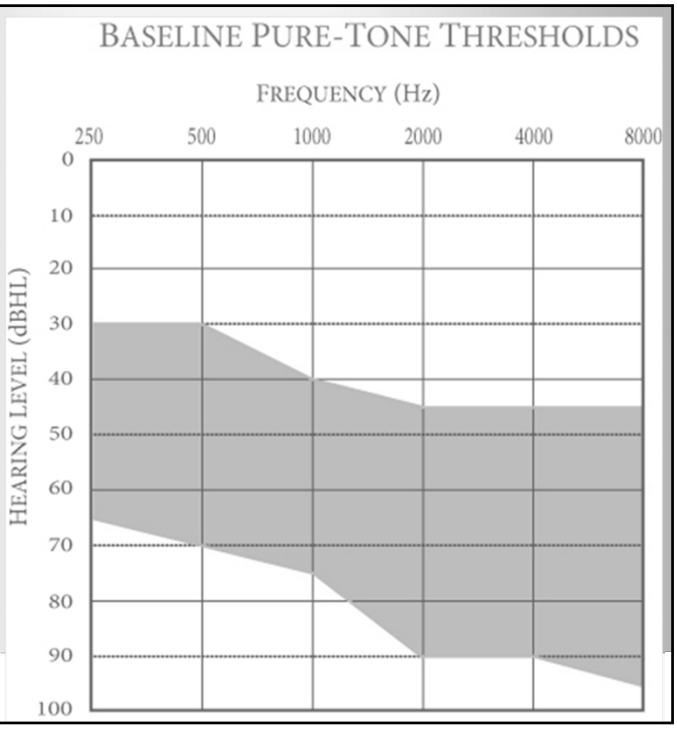
- Note: continuous exposure to excessively loud sound levels (90 dB SPL, 24 hours per day) with the highest gain settings can result in significant reduction of battery life.

Indications for Use

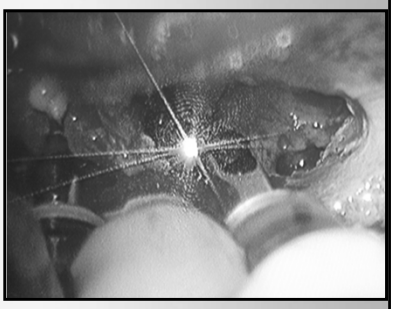
The Esteem is indicated for patients with hearing loss who meet the following criteria:

- 18 years of age or older
- Stable bilateral sensorineural hearing loss of moderate to severe degree (**PTA= 40-90 dB HL**)
- Unaided word recognition test score **≥ 40%**
- Normally functioning Eustachian tube
- Normal tympanic membrane and middle ear anatomy
- Adequate space for Esteem implant determined via a high resolution CT scan
- Minimum of 30 days of experience with appropriately fit hearing aids

Esteem Fitting Range



Esteem Surgery



- Similar to a cochlear implant
- Surgical steps:
  - Postauricular incision
  - Mastoidectomy, facial recess, and ossicular testing
  - Incus resection and stapes cleaning
  - Sensor and driver placement with cements
  - Intraoperative system testing and closure

Sound Processor

The Sound Processor receives the electrical signal from the sensor transducer, processes the analog signal, and sends the modified signal to the driver

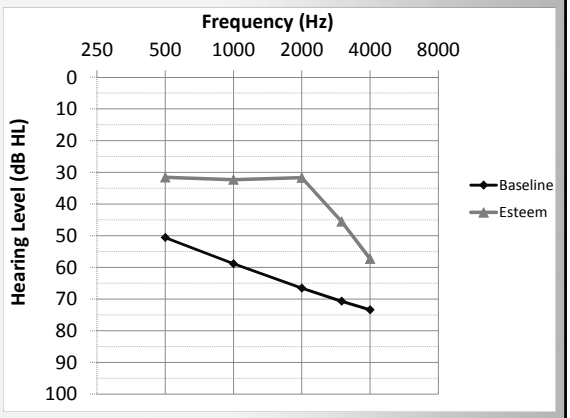
Processor Characteristics:

- Two channel
- Three programmable listening profiles
- Output-controlled compression

Audiogram Results

FOR ALL CLINICAL TRIAL PATIENTS AT 10 MONTHS*

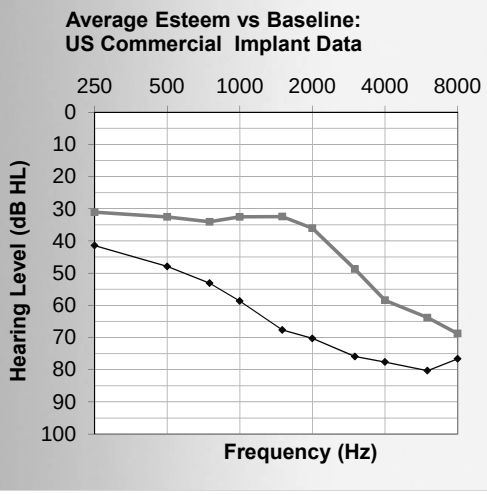
Average Esteem-aided thresholds are about 15-35 dB improved over average baseline unaided thresholds between 500 and 4000 Hz



*Data for 52 patients, last data point for IDE clinical trial patients before FDA submission

Audiogram Results

FOR ALL PATIENTS*



	PTA Gain
0204 Clinical Trial	27.7 dB
US (4/2010-6/2012)	24.9 dB

*Total of 418 patients, including available data for commercial paying patients since FDA approval (4/2010 – 6/2012)

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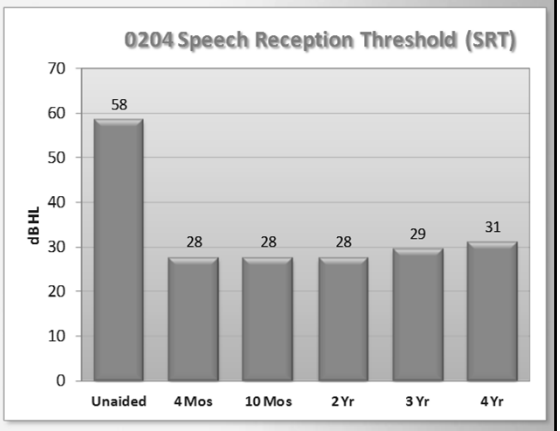
Clinical Study Results: SRT

RESULTS CONSTANT OVER LONG TERM

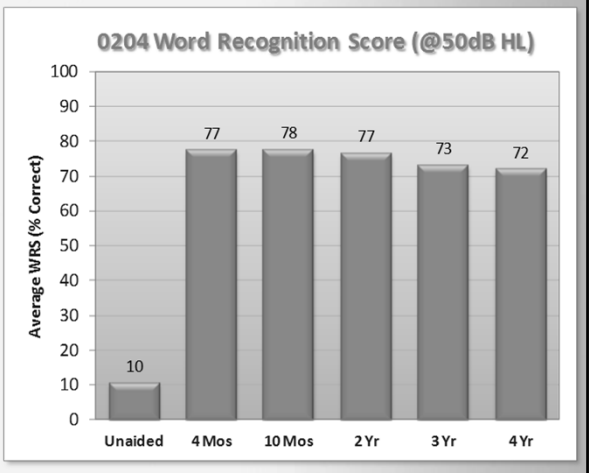
- Esteem 30 dB better than baseline unaided
- Esteem results stable over 4 years and counting



Clinical Study Results: WRS@50 dB HL

RESULTS CONSTANT OVER LONG TERM

- WRS improved by 67% over unaided baseline
- Esteem results stable over 4 years and counting



Clinical Study Results

Thornton Raffin Analysis on WRS@50dB HL

	Baseline-Unaided		Baseline-Aided	
	Percent	N	Percent	N
Better	84 %	42	62%	32
Same	14 %	7	27%	14
Worse	2 %	1	12%	6

WRS with Esteem was compared to baseline scores obtained unaided and with a hearing aid, using Thornton and Raffin (1978) critical difference criteria. Because these criteria take into account WRS test variability, it is a stronger comparison than simply looking at WRS scores.

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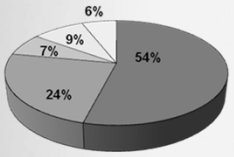
Patient Questionnaire Results

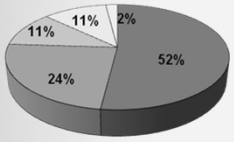
QUALITY OF LIFE: HEARING

Sound Clarity



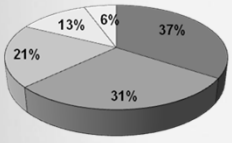
78% rated clarity of sound as somewhat or much better with Esteem®

Sound Natural



76% reported voices sounding natural as somewhat or much better with the Esteem®

Speech in Background Noise



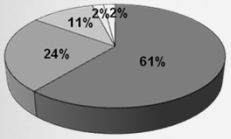
68% rated the ability to understand speech in background noise as somewhat or much better with the Esteem®

Much Better
Somewhat Better
About The Same
Somewhat Worse
Much Worse

Patient Questionnaire Results

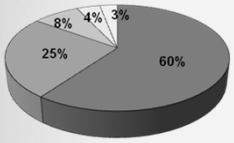
QUALITY OF LIFE: LIFESTYLE

Activity



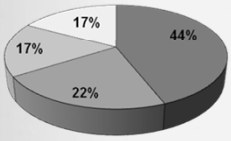
85%
said their activity level was somewhat or much better with the Esteem®

Confidence

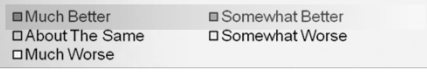


85%
said their feeling of confidence was somewhat or much better with the Esteem®

Invisible



66%
rated the benefit of the entire system being invisible to the onlooker as somewhat or much better with the Esteem®



Reality of an Impaired Cochlea

- We are still delivering sound to an impaired cochlea that is likely to have disordered
  - Frequency resolution
  - Temporal resolution
  - Dynamic range
- Nothing about the nature of MEIs changes those fundamental challenges
- As in conventional hearing aid, success comes with managing expectations