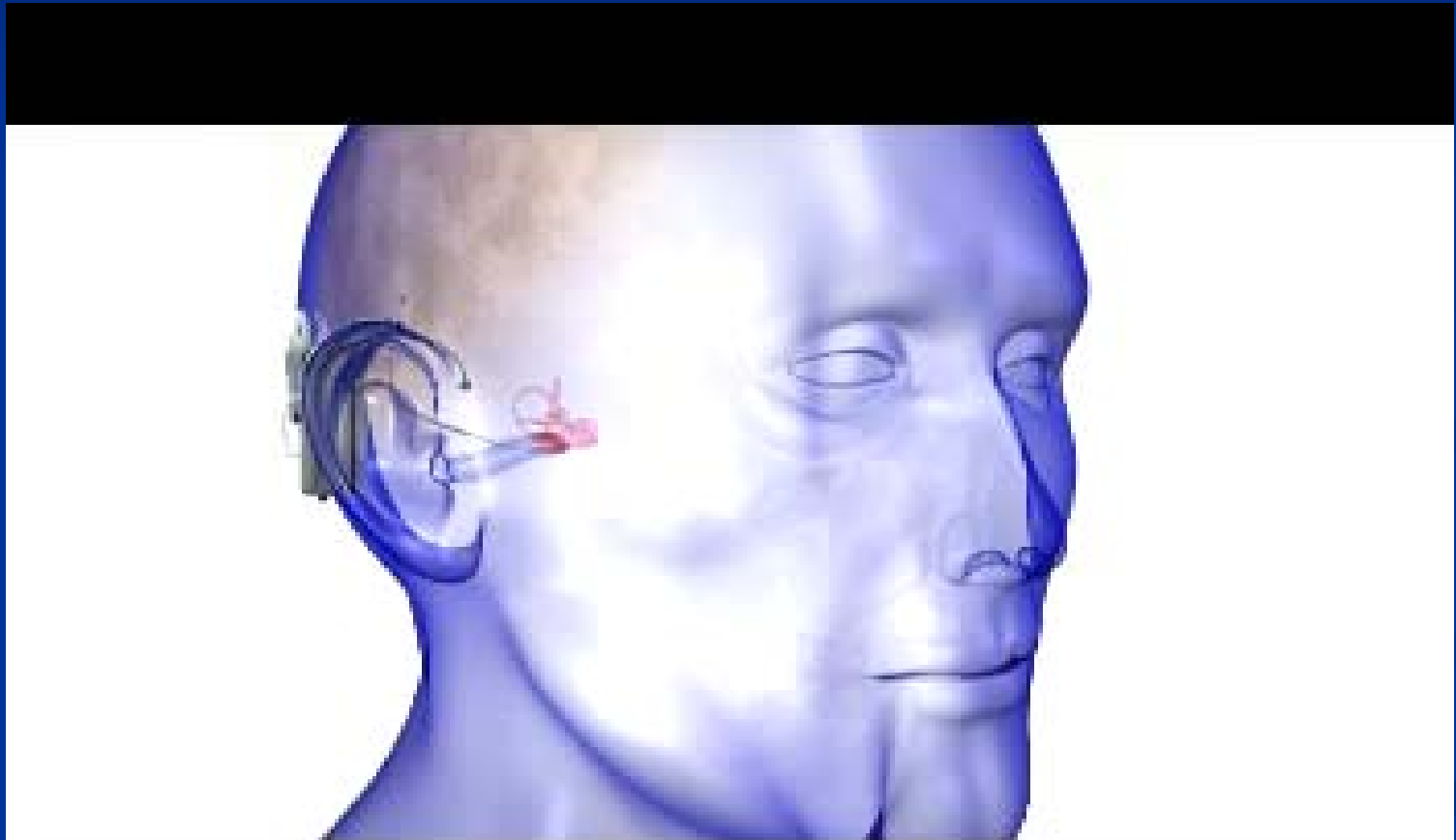


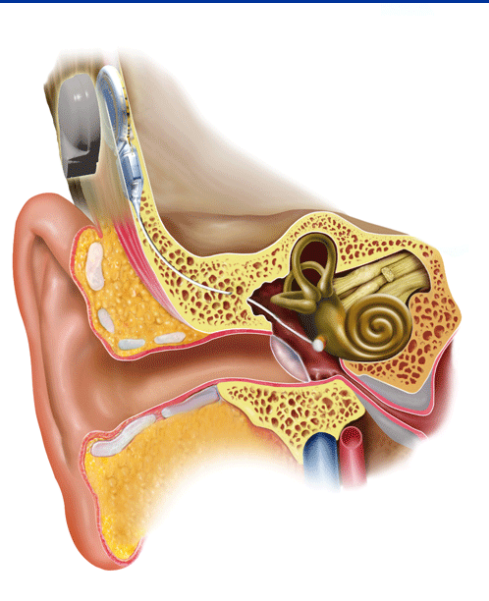
人工電子耳的原理



A cochlear implant helps people

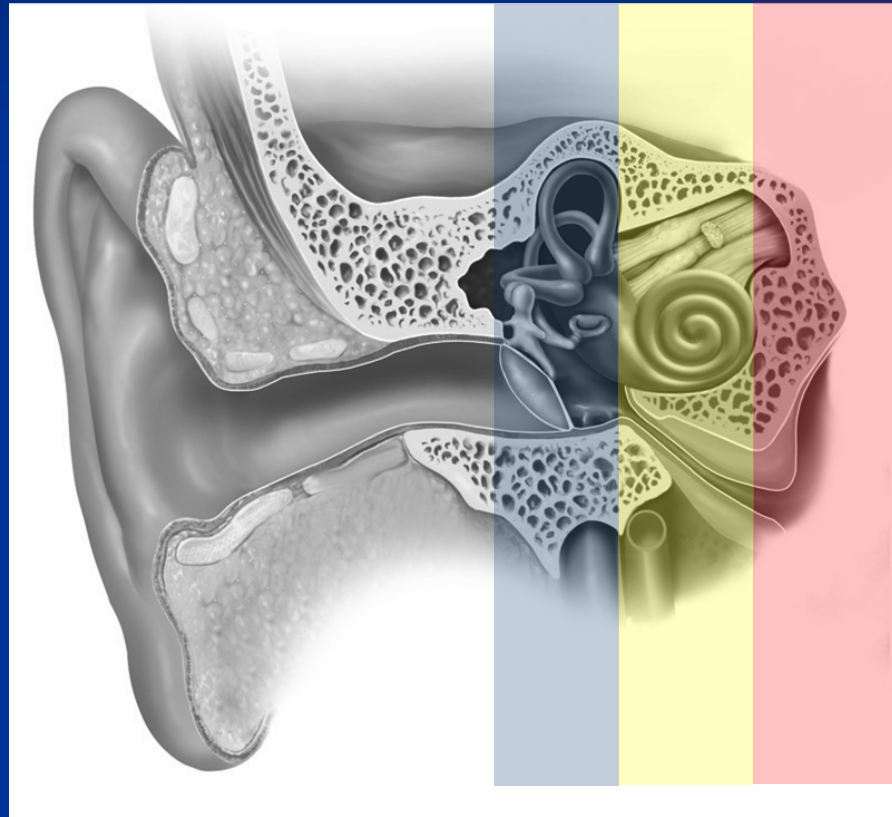
VIBRANT SOUNDBRIDGE®

The Implantable Hearing System



台中慈濟醫院 吳弘斌醫師

Hearing Implants – Level of Intervention



hearing aids

MEIs CIs ABI

VIBRANT SOUND BRIDGE

System Components



- AP (Audio Processor)
 - the external signal processor containing microphone, battery and electronics



- VORP (Vibrating Ossicular Prosthesis)
 - the complete implant device, including internal coil, attachment magnet, electronics and FMT



- FMT (Floating Mass Transducer)
 - the electromagnetic transducer that generates the vibratory motion

Audio Processor (AP)

- Microphone
- Digital signal processing (Siemens)
- Battery

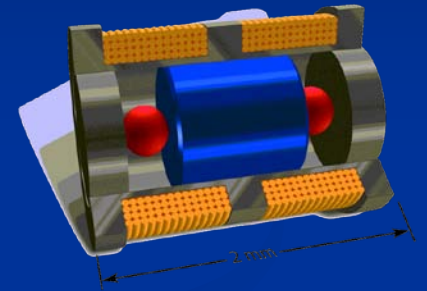


Vibrating Ossicular Prosthesis (VORP)



Floating Mass Transducer (FMT)

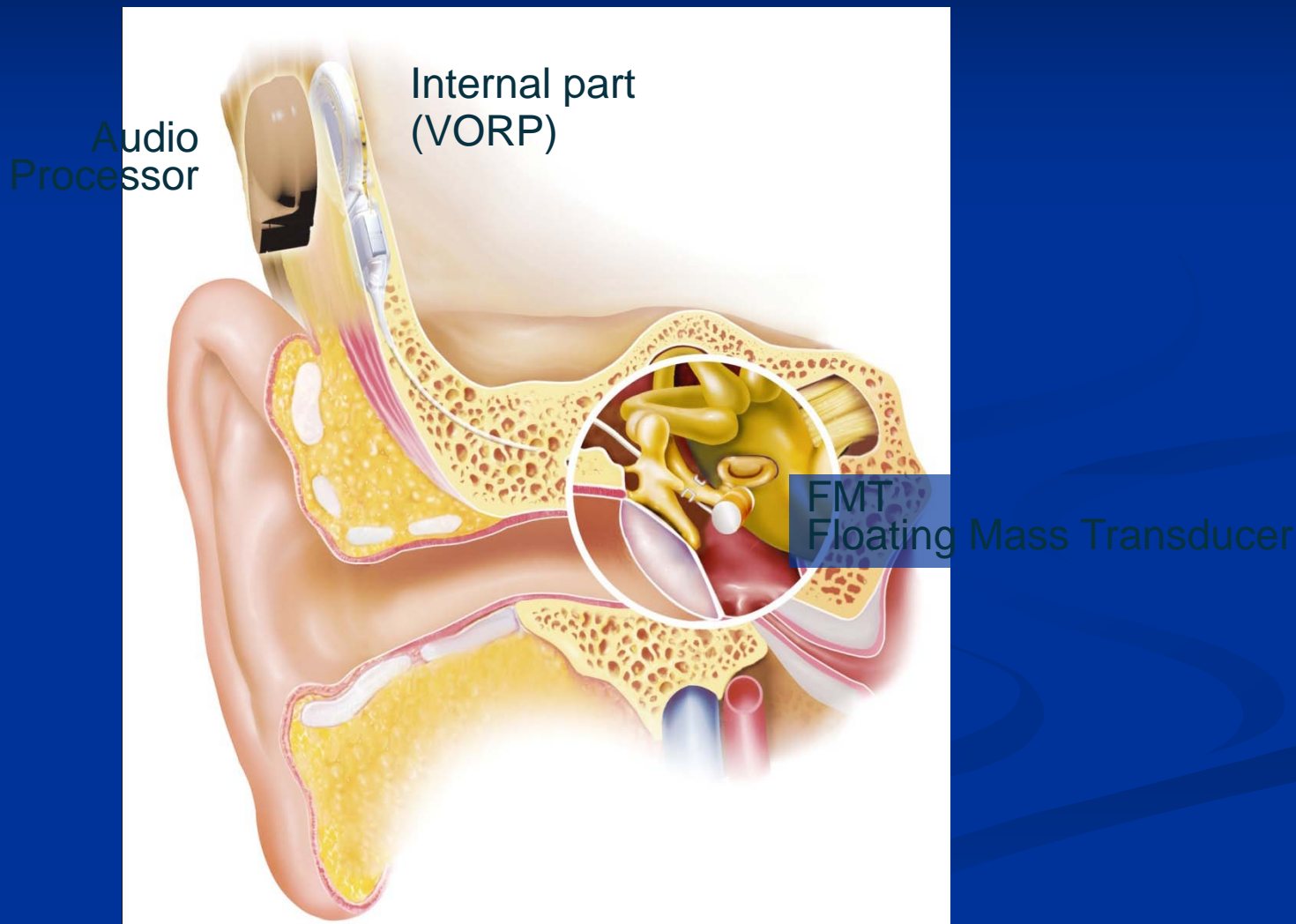
- Electro-magnetic transducer



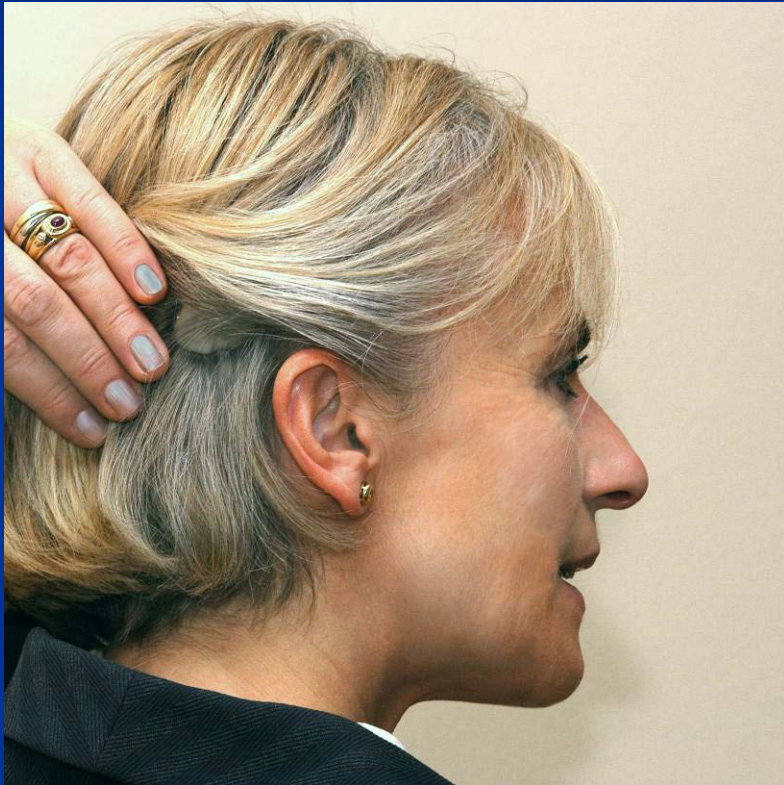
- Requires only one point of fixation (e.g. ossicles)
- Reproduces and augments the natural movement of the ossicular chain



VIBRANT SOUND BRIDGE



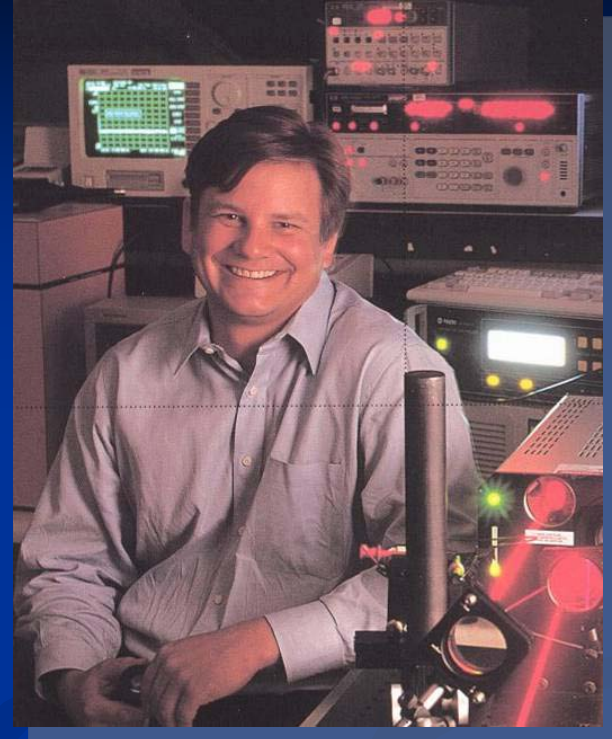
Wearing the VIBRANT SOUNDBRIDGE



- AP held by magnetic attraction
- Comfortable to wear
- No parts on the ear or in the ear canal – leaves ear canal completely open
- Easily hidden (covered by hair)
- Easy handling

History

- Inventor: Geoffrey Ball
(bilateral SOUNDBRIDGE user)
- 1996: 1st patient implanted
by U. Fisch
- 1998: CE-mark (Europe)
- 2000: FDA approval (USA)
- 2003: Foundation of VIBRANT MED-
EL Hearing Technology GmbH
- 2007: Approval for treatment of
conductive & mixed HL



Symphonix

VIBRANT
MED-EL 

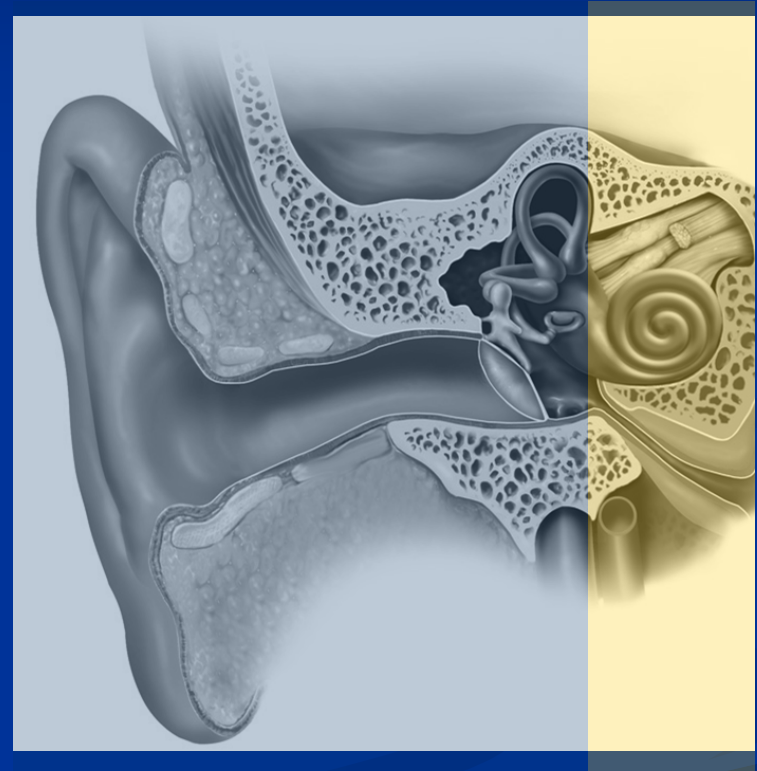
Today

- More than 11 years experience with the Vibrant Soundbridge
- Thousands of patients worldwide
- The VSB is the only MEI that is both approved in Europe and the US



Indications for the VIBRANT SOUNDBRIDGE

- Sensorineural hearing loss
(inner ear)
- Conductive hearing loss
(outer and/or middle ear)
- Mixed hearing loss



Vibroplasty

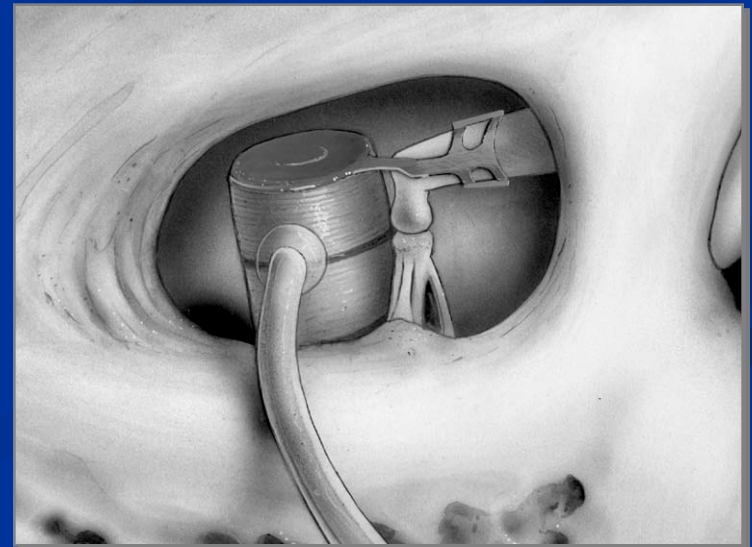
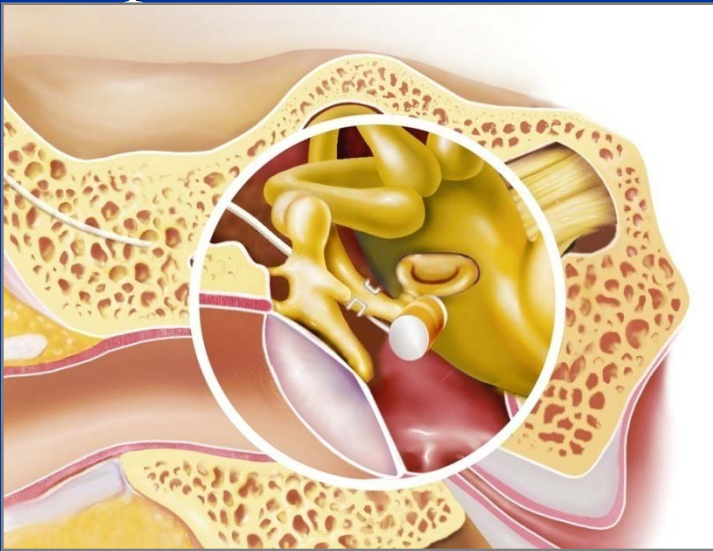
Treatment of hearing loss via vibratory stimulation in the middle ear.

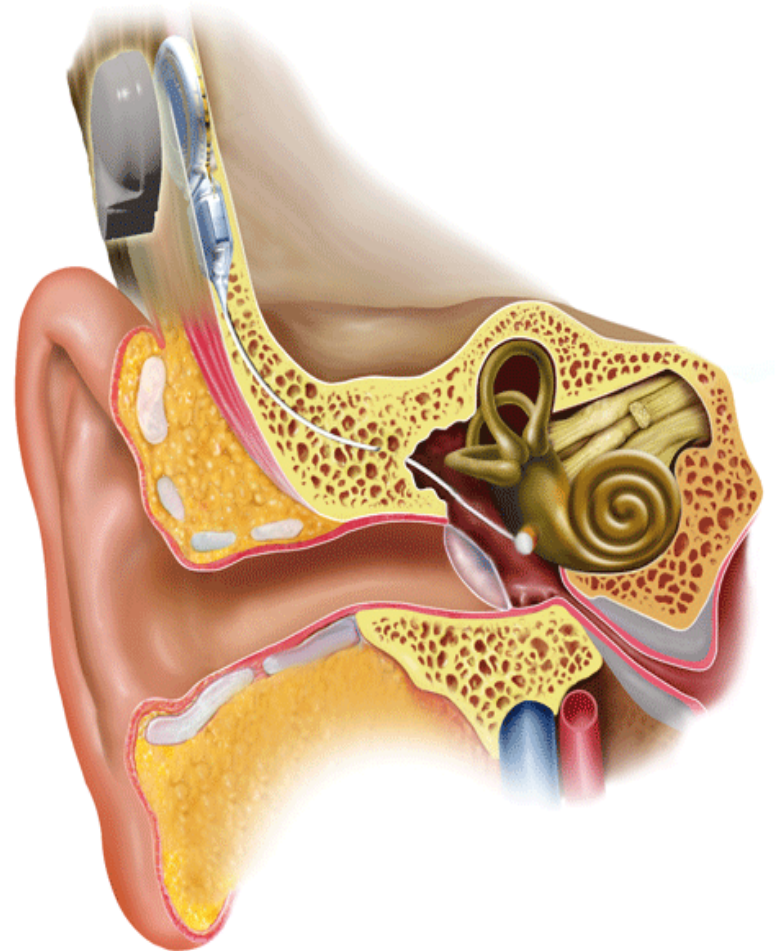
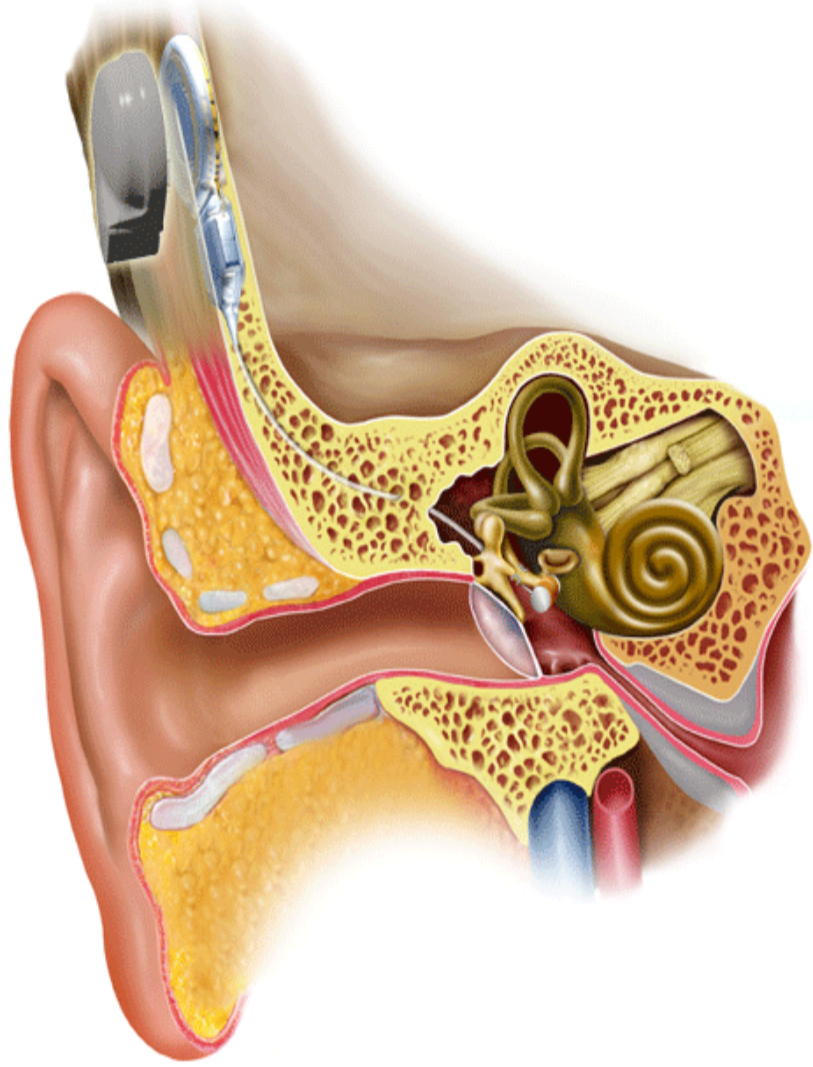
SNHL	Conductive & Mixed HL
Incus Vibroplasty	Round Window Vibroplasty PORP / TORP Vibroplasty Oval Window / Stapes Vibroplasty

The VIBRANT SOUNDBRIDGE
in Sensorineural Hearing Loss

Incus Vibroplasty

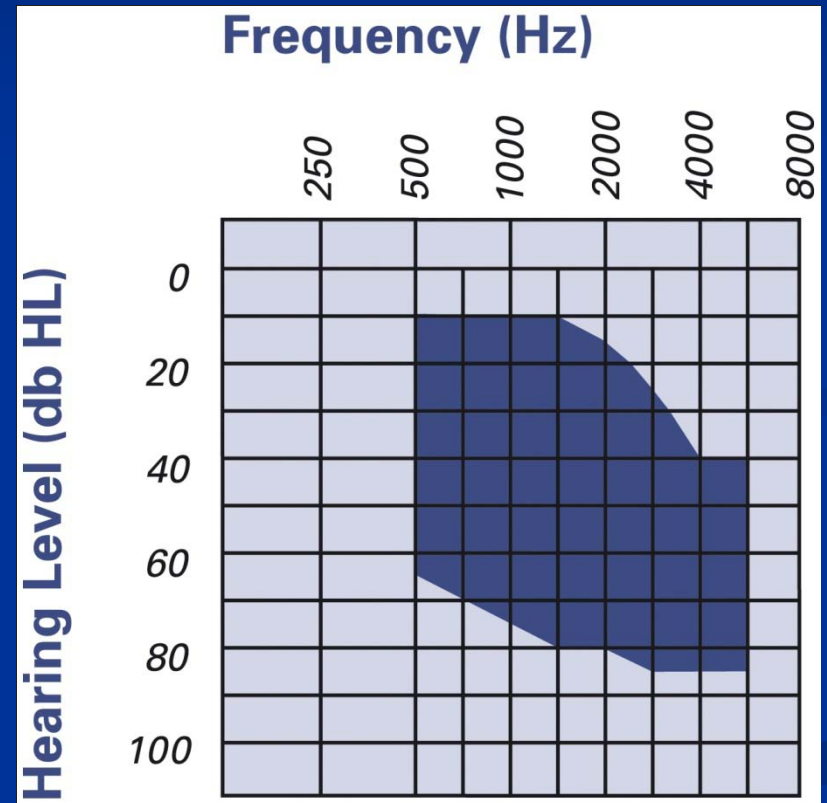
- The FMT is attached to the long process of the incus with help of its titanium clip
- It should be in close contact and parallel to the stapes





Indications

- Mild to severe sensorineural hearing loss
- Patient dissatisfied with or unable to wear hearing aids
- Normal tympanometry
- Normal anatomy of the middle ear
- Speech understanding >50% (at 65 dB) for word lists with amplification or at most comfortable level under earphones.



air conduction ~ bone conduction

Indications

■ Medical indications

- otitis externa
- psoriasis
- exostosis
- excessive cerumen

■ Audiological indications

- HF hearing loss
- occlusion problems
- distortion problems

■ Professional indications

- heat and steam
- enhanced frequency range (e.g. musicians)
- free ear (e.g. pilots)

■ Improvement of quality of life

- comfort
- sound quality



Limits of Conventional Hearing Aids



Wearing & Handling

- Discomfort
- Visibility
- Wax problems

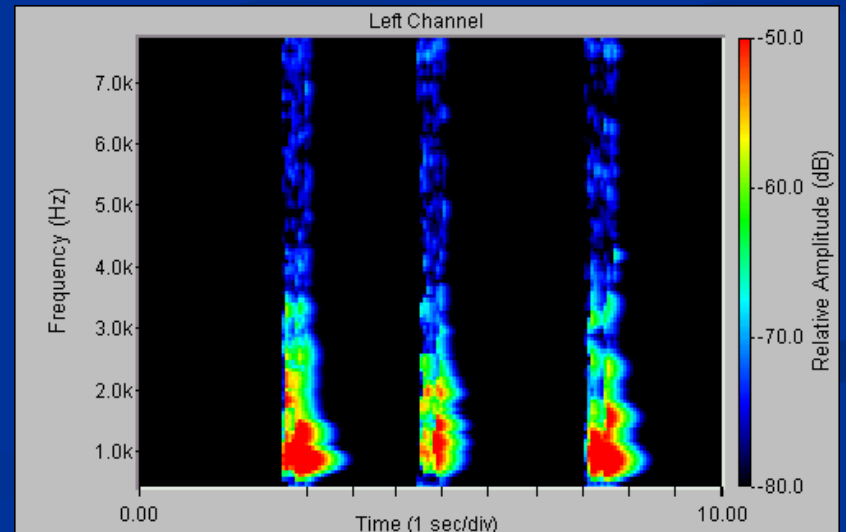
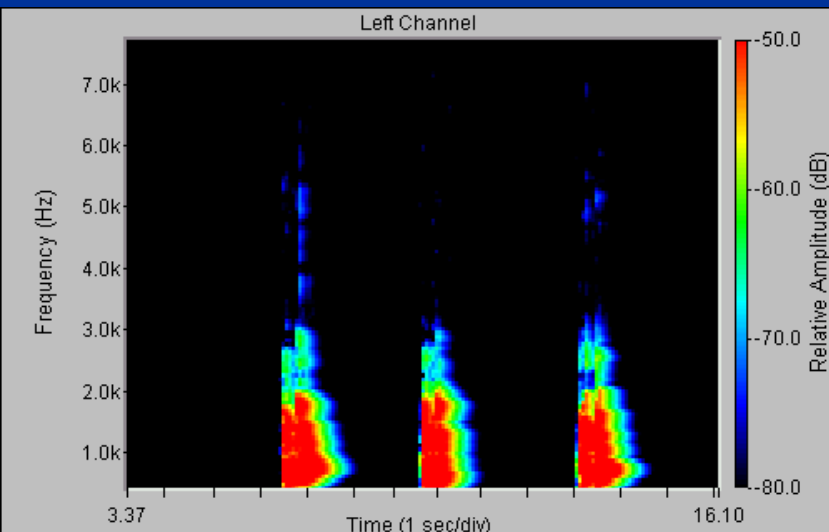
Sound Quality & Speech Perception

- Occlusion
- Feedback (whistling)
- Poor sound quality
 - Distortion
 - Limited frequency range
- Limited amplification
 - Open ear HAs
 - ITE HAs

High Frequency Amplification Spectral Analysis

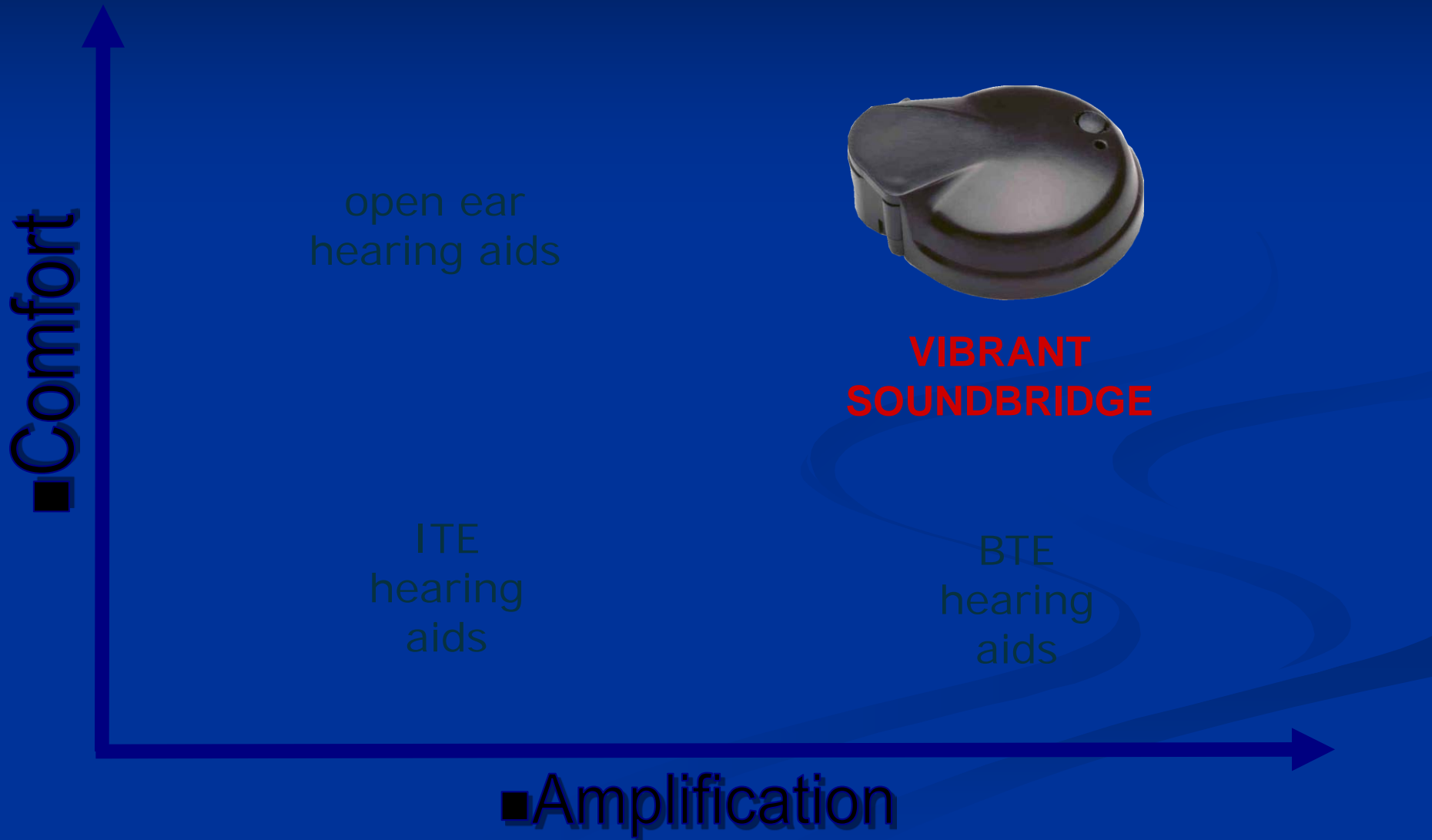
HA Loudspeaker
Response: Measured At
Stapes Footplate

FMT : designed for
better response in high
frequency range



"Playground" "Daybreak" "Northwest"

Positioning

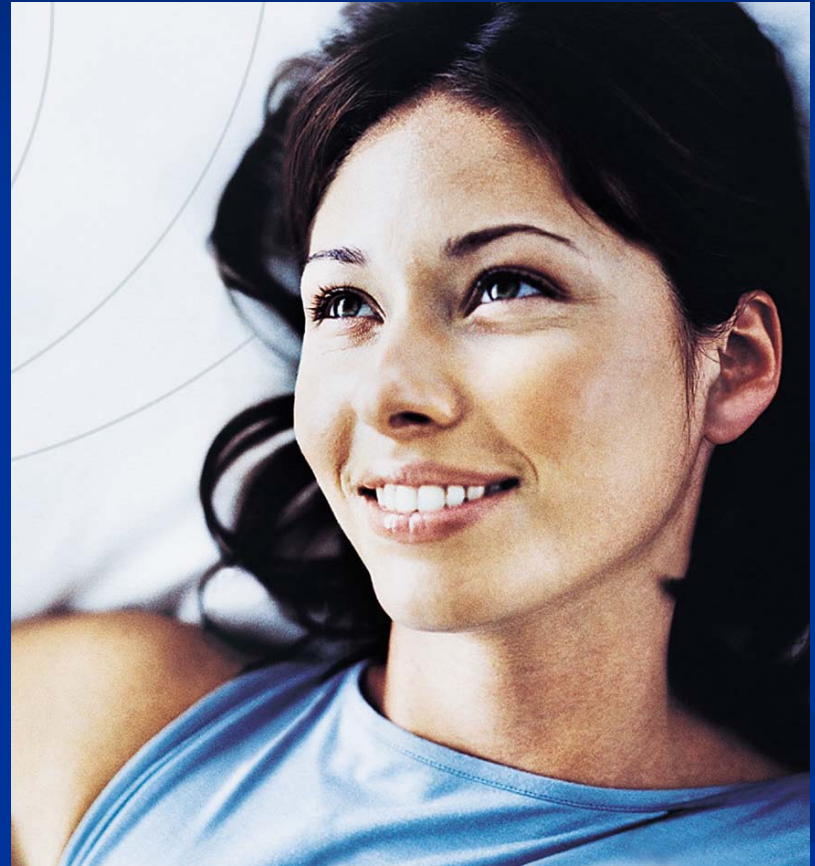


The Sound Quality Features of the VIBRANT SOUNDBRIDGE

- Open ear
- Elimination of feedback
- Superior, high frequencies amplification without distortion
- Large frequency range (up to 8 kHz)

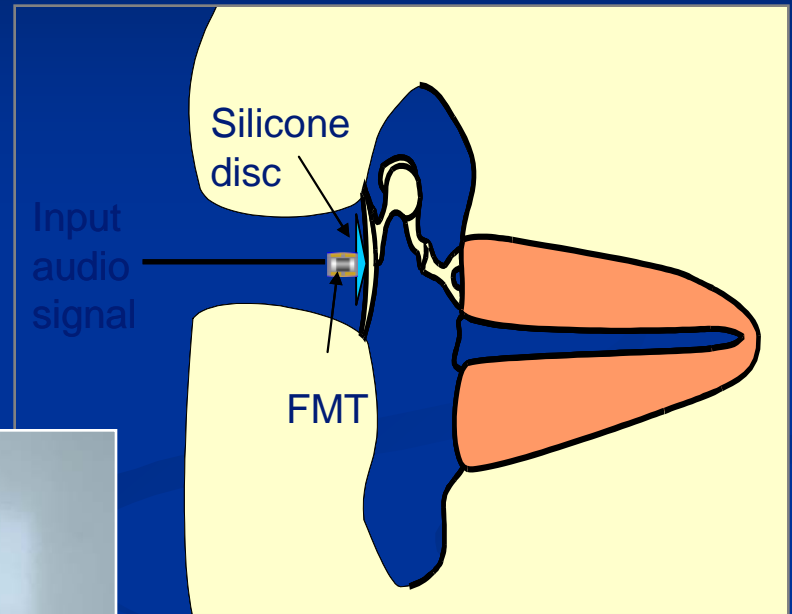
This leads to

- Elimination of the occlusion effect
- Increased naturalness of sound quality
- Improved sound quality of own voice
- Efficient high frequency amplifications
- Better speech perception in background noise



Direct Drive Simulator - DDS

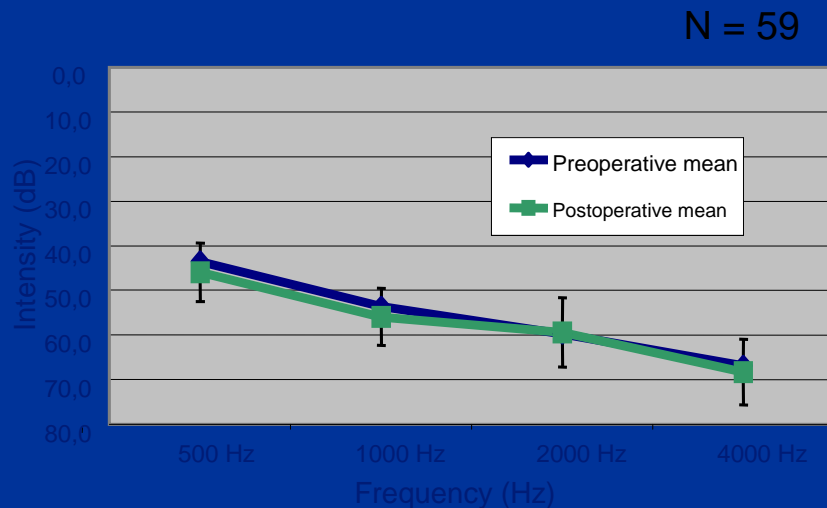
- Educational tool that provides a unique experience with direct drive hearing devices before implantation
- Candidates can listen to the high fidelity of the FMT
- Family members and professionals can experience the high fidelity of the device as well



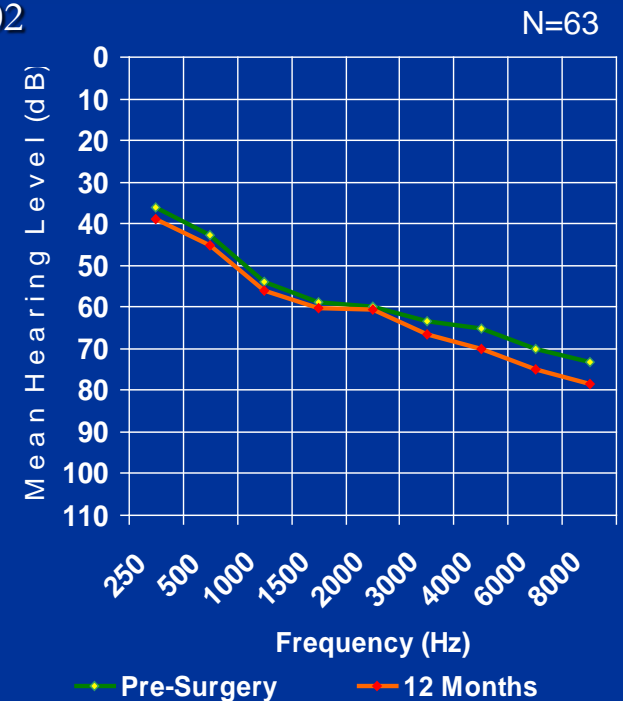
**Results with the VIBRANT
SOUNDBRIDGE in
Sensorineural Hearing Loss**

No Damage to Hearing due to Implantation

- Sterkers et al., Retrospective Study of the First 125 Patients Implanted in France, *Otology and Neurotology*, 2003

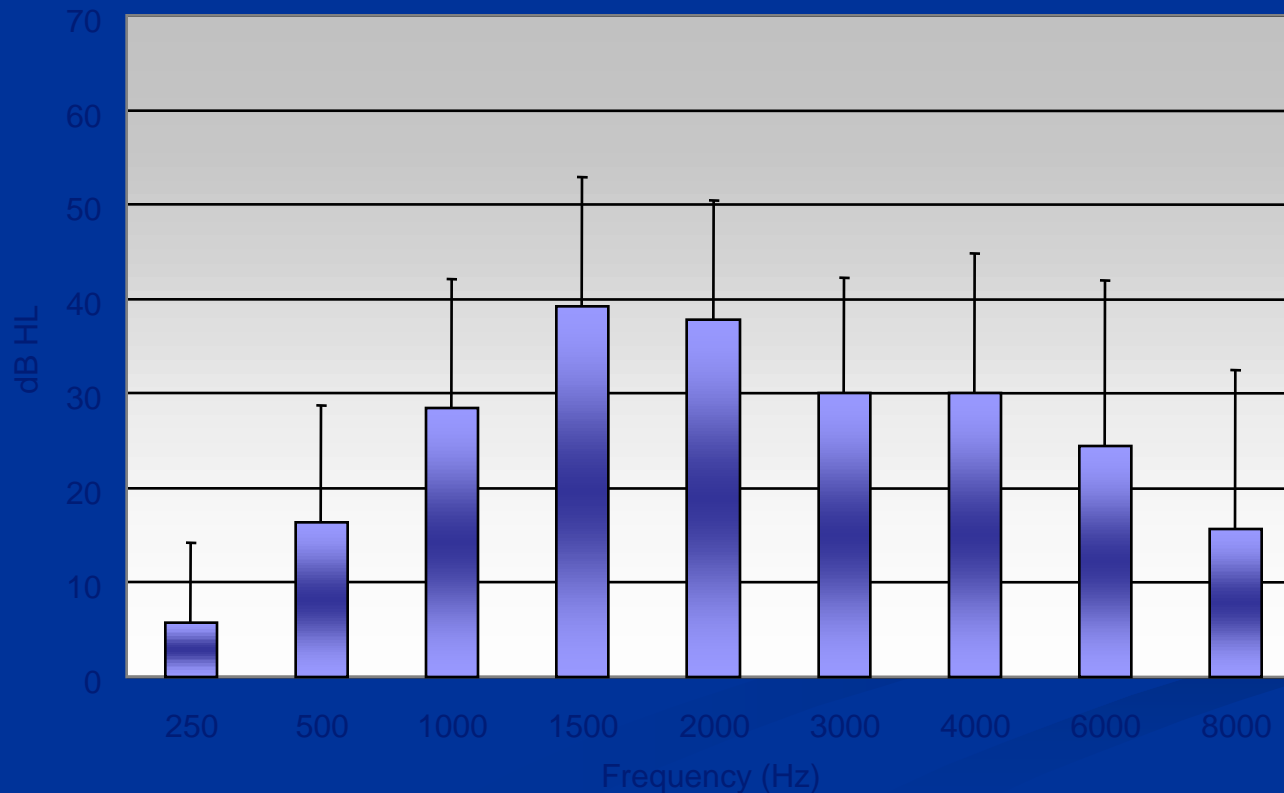


- Luetje et al., Phase III Clinical Trial Results with the Vibrant Soundbridge: A Prospective Controlled Multicenter Study; 2002



Functional Gain

- Sterkers et al., Retrospective Study of the First 125 Patients Implanted in France, *Otology and Neurotology*, 2003
- Mean gain 0.5, 1, 2 & 4 kHz: **28.5 dB**



N = 121

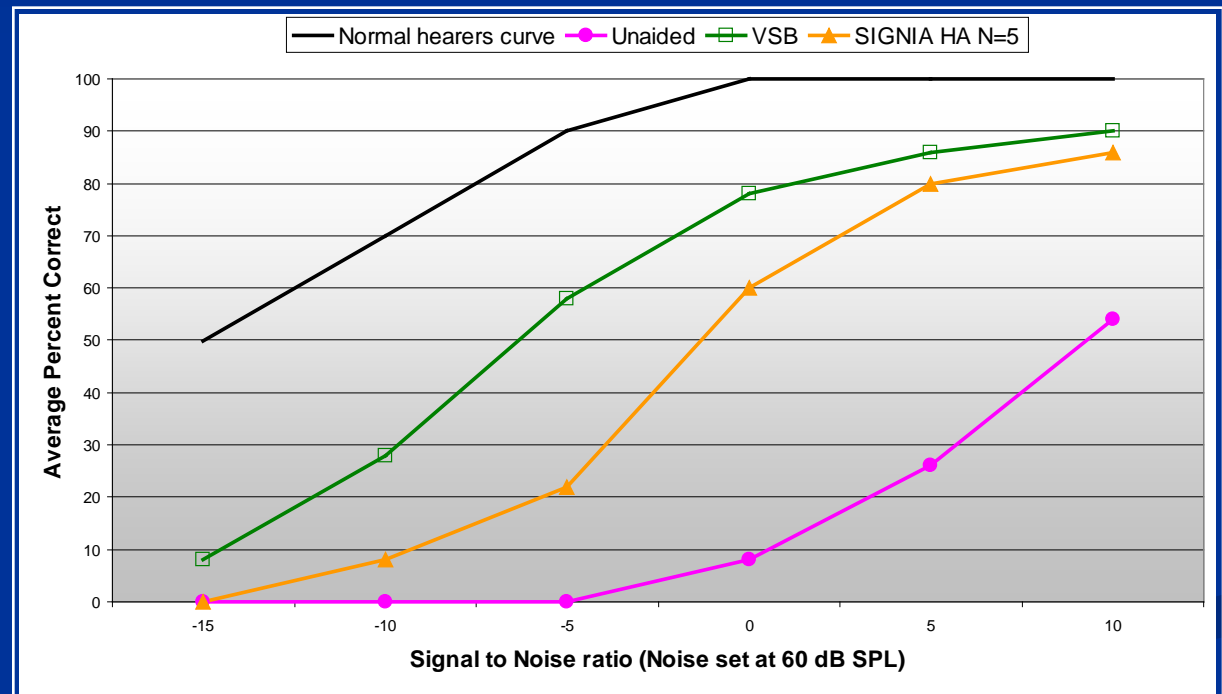
Direct Drive Superior to Amplification

- Comparison of the VSB with a hearing aid using identical signal processing.

Speech in noise, N=5

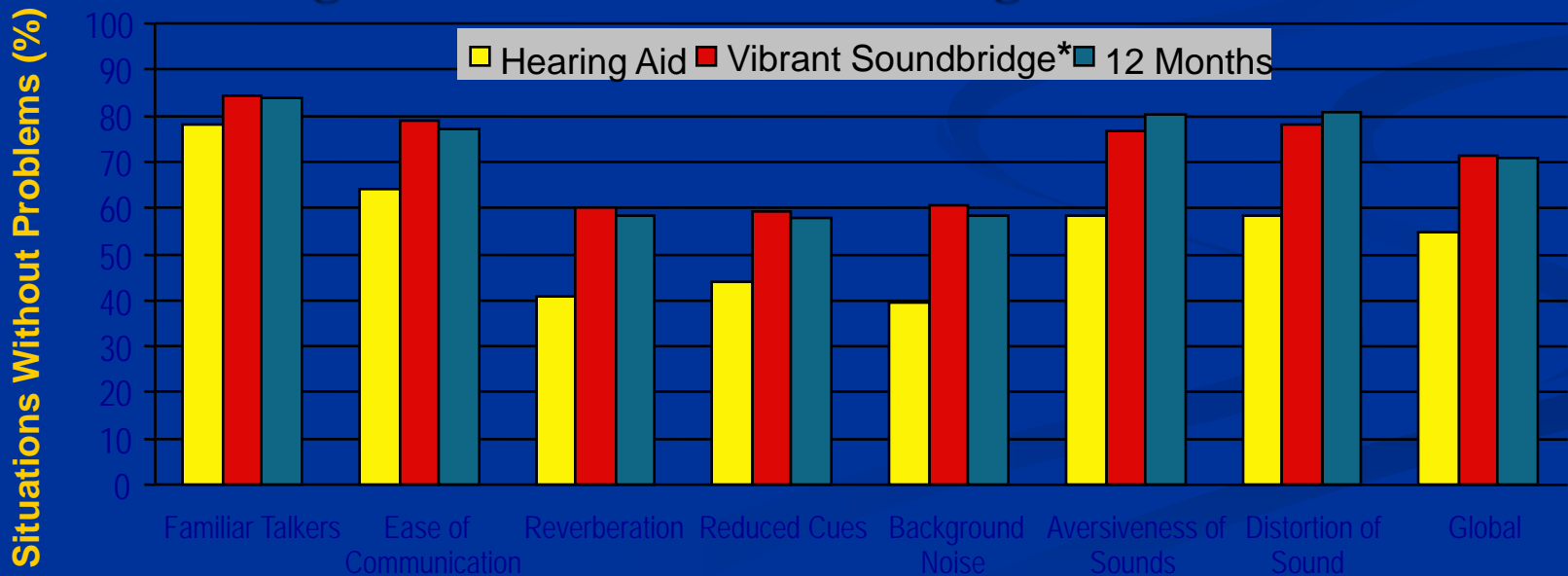
Uziel et al., *Otology and Neurotology*, 2003

“Rehabilitation of Patients with High Frequency Sensorineural Hearing Loss using the Symphonix Vibrant Soundbridge”



Subjective Results

- Luetje et al., 2002
- Hearing Aid vs. Soundbridge at 3 Months and 12 Months (n = 94)
- PHAB: Profile of Hearing Aid Performance
Hearing Aid vs. Vibrant Soundbridge



*statistically significant

PHAB Subscales

Long-Term Results

Benefit of the Vibrant Soundbridge Device in Patients Implanted For 5 to 8 Years

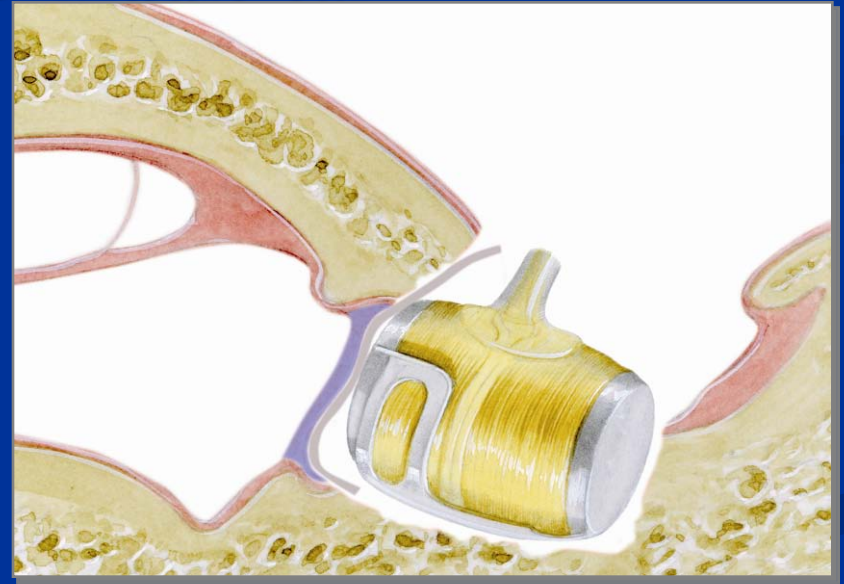
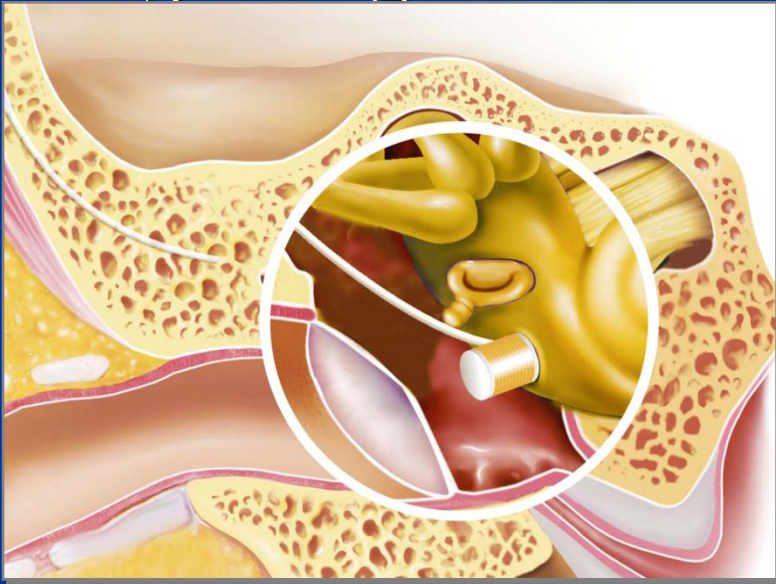
Isabelle Mosnier,^{1,2,3,4} Olivier Sterkers,^{1,2,3,4,5} Didier Bouccara,^{1,3,4} Samia Labassi,⁶
Jean-Pierre Bebear,⁷ Philippe Bordure,⁸ Christian Dubreuil,⁹ Thibaud Dumon,¹⁰
Bruno Frenchet,¹¹ Bernard Frenzel,¹² Jean Pierre Lavoie,^{13,14} Jacques Macqen,¹⁴

- Mosnier et al., 2008, Ear & Hearing
- N=77, VSB use 5-8 years
- Comparison versus 3-18 months postop results
- “This study demonstrates that the performance of the VSB does not deteriorate for more than 5 yr, without adverse effect. These results confirm the safety and the effectiveness of the VSB with a long-term follow-up.”

**The VIBRANT SOUNDBRIDGE
in Conductive & Mixed Hearing
Loss**

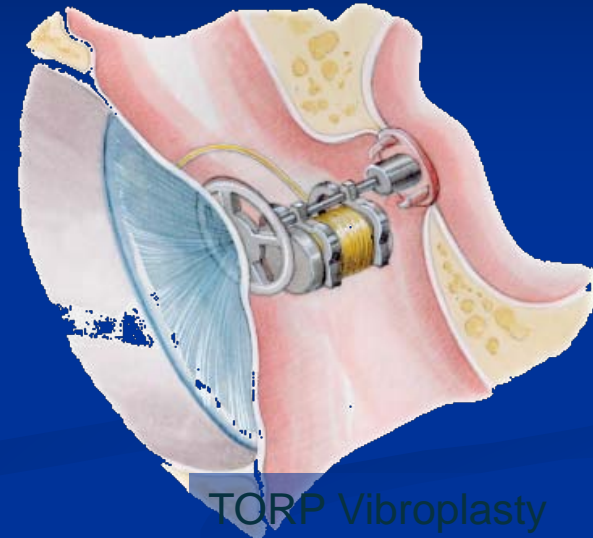
Round Window Vibroplasty

- The FMT sits perpendicular to the RW membrane and is encapsulated in fascia.
- Bypassing the outer and middle ear



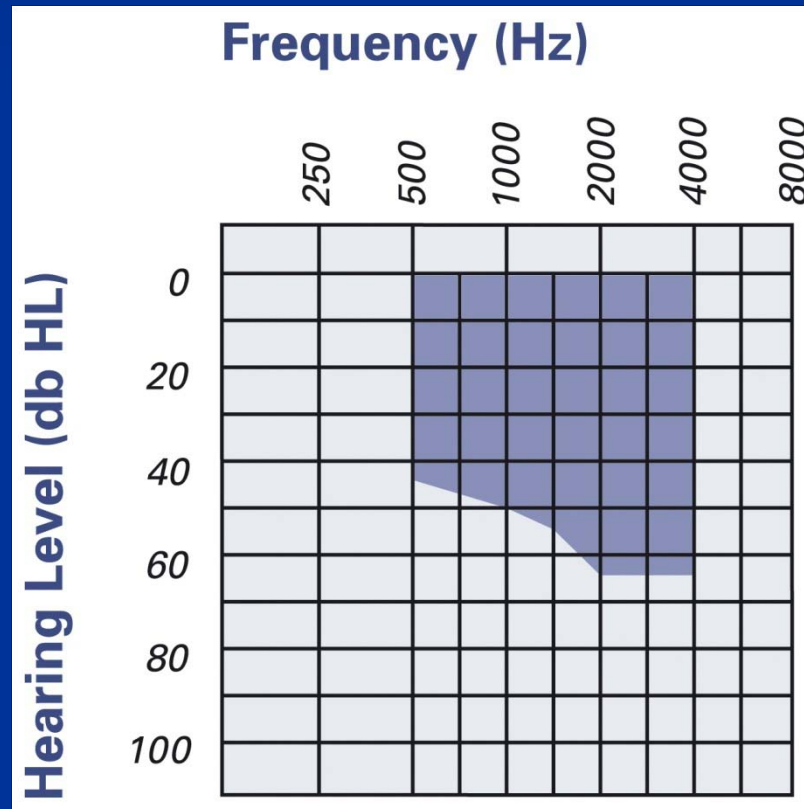
Other Types of Vibroplasty

- PORP/TORP Vibroplasty:
FMT together with passive
ossicular prosthesis
- Oval Window Vibroplasty



Indication Range for Conductive and Mixed Hearing Loss

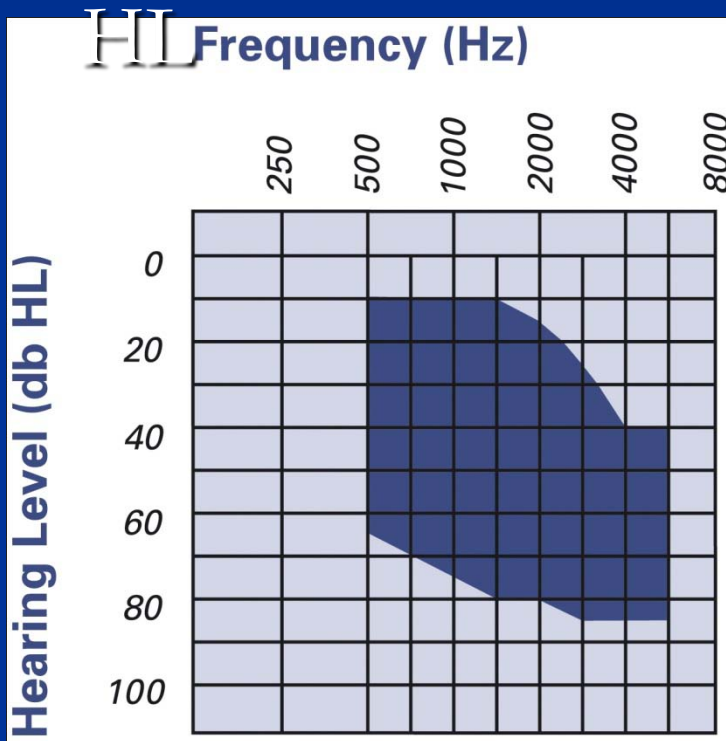
- Bone conduction thresholds



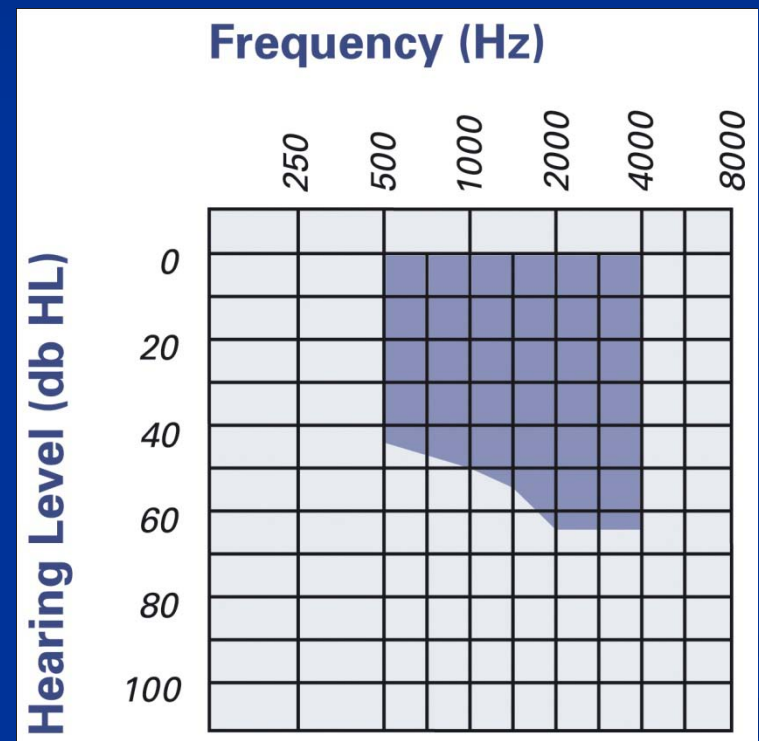
VIBRANT SOUND BRIDGE - Indication Ranges

SNHL

Conductive/Mixed



air conduction ~ bone conduction



bone conduction

Indication

- Insufficient benefit after multiple tympanoplasties
 - reduced risk of further reconstruction surgeries
- Mixed hearing losses with limited benefit from conventional hearing aids

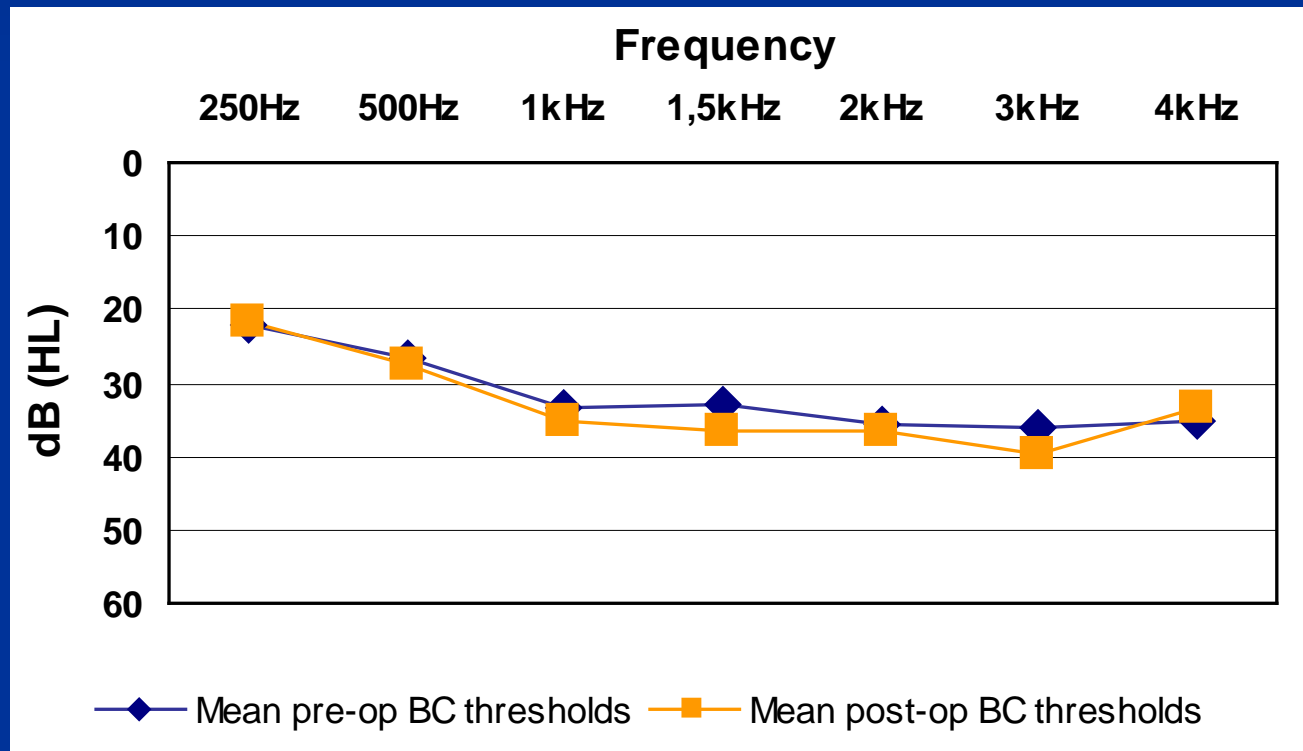


Results with the VIBRANT SOUNDBRIDGE in Conductive & Mixed Hearing Loss

Results from the European multi-center
clinical investigation.

RW Vibroplasty has no Negative Effect on Hearing

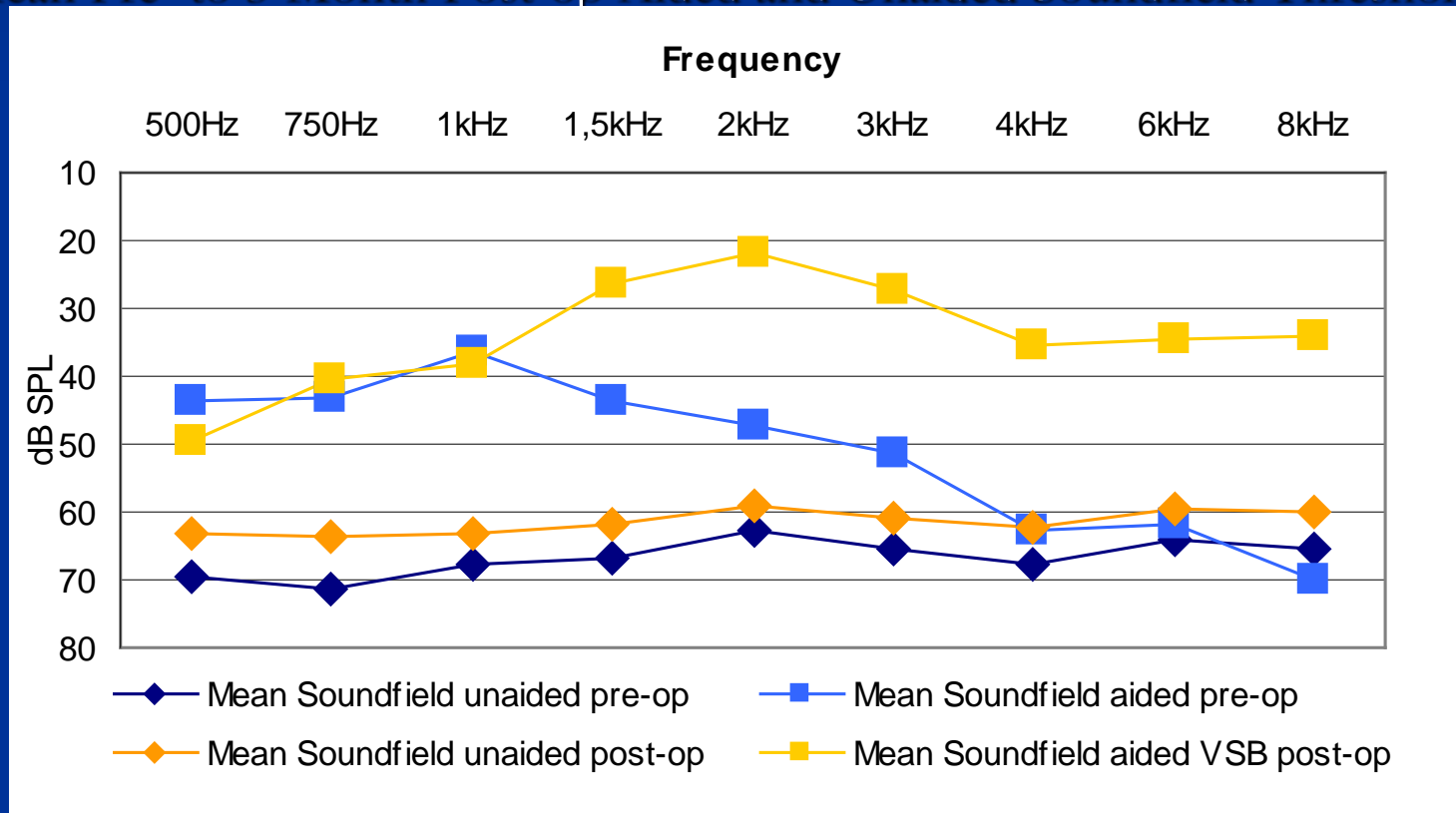
- Conductive and Mixed Hearing Loss Cases (n=12)
Mean Pre- to 3-Month Post- Op Bone Conduction Thresholds



Audiometric Results

■ Conductive and Mixed Hearing Loss Cases (n=12*)

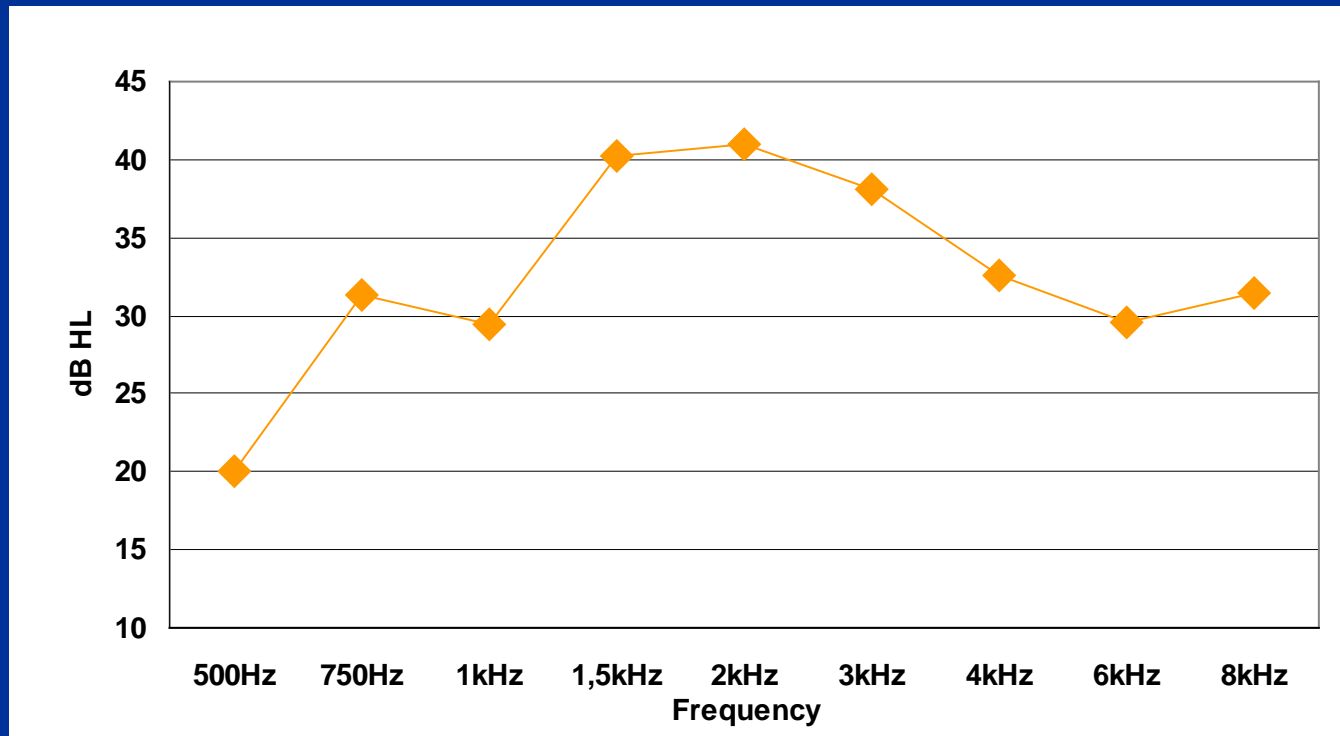
Mean Pre- to 3-Month Post-op Aided and Unaided Soundfield Thresholds



*Pre-op aided (HA): n=6

Functional Gain

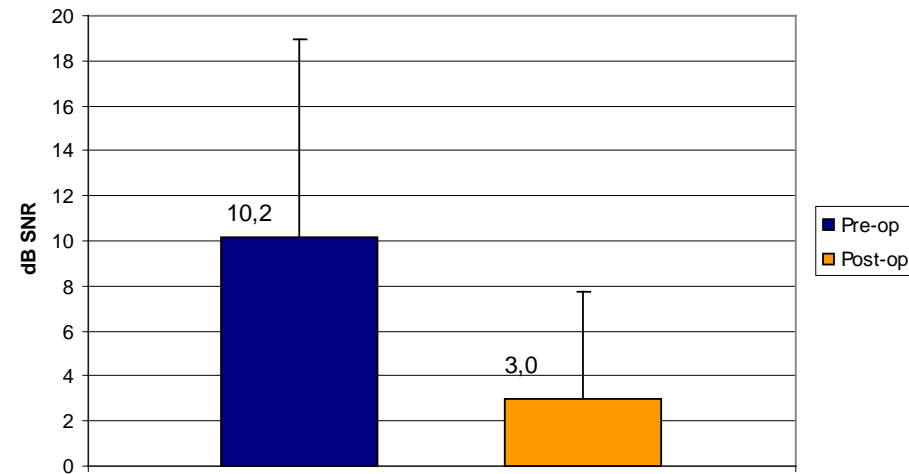
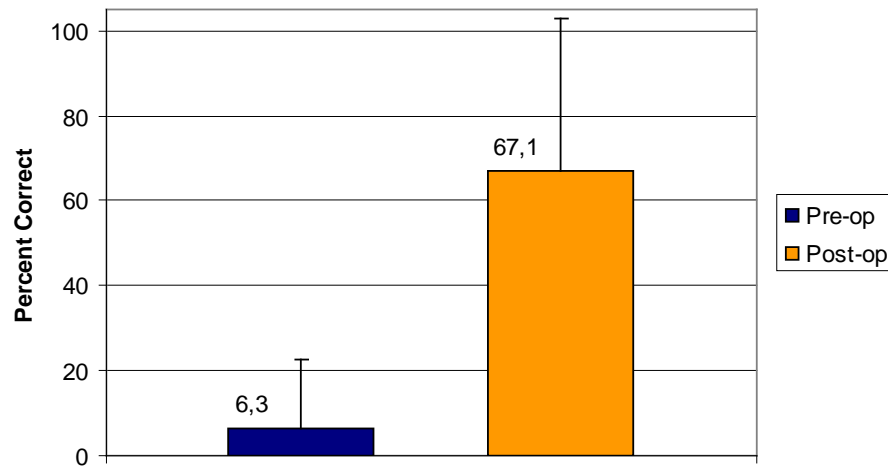
- Conductive and Mixed Hearing Loss Cases (n=12)
Mean Functional Gain at 3 Months



Speech Perception

- Word Recognition in the Soundfield at 65 dB SPL
Pre-Op to 3 Months Post-Op (n=12)

- Sentences in Noise: SNR for 50% Speech Perception
Pre-Op to 3 Months Post-Op (n=12)



Summary

- Thousands of implants world wide
- Approved for SNHL and conductive & mixed HL
- Excellent results in high frequency hearing losses
- Safe and effective
- Highest wearing comfort
- Proven long term experience
- High level of patient satisfaction

