

Implantable hearing devices: Where we are

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Implantable hearing devices

Topics

- History of Implantable hearing devices
- Types of Implantable hearing devices
- Indications for Implantable hearing devices
- Surgery
- Our experience
- Future of Implantable hearing devices
- Discussion

Implantable hearing devices

History of Bone Conduction Implants (BCI)

- Bone conduction devices
 - Already during the renaissance period Girolamo Cardano demonstrated amplification of sound when transmitted through the spear hold by the teeth
 - Original BC device: Anders Tjellström in 1977 – BAHA

History of BC implants

Edison museum, Fort Myers, FL













Implantable hearing devices

History of AME

- Alvar Wilska (1911–1987), Finnish scientist in 1935 placed pieces of iron on the ear drum and with electromagnetic coil created magnetic field and vibrations
- Rutschmann in 1959 attached 10mg magnet to the ear drum and created alternating EM field with vibrations
- Goode (1970), Fredrickson (1973) a Nunelly (1976) already placed the source of energy to the ear drum

BC implants

Implanted to the bone							
Percutaneous		Transcutaneous active		Transcutaneous pasive			
Baha Connect 	Ponto 	Sentio 	Bonebridge 	Sophonon 	Baha Attract 	Tlak na kosť Soft Band  	Prilepenie na kožu Adhear  

AMI

Middle ear					
Transcutaneous active or fully implantable					
Semi-implantable (electromagnetic)				Fully impl. (piezoelectric)	
SoundBridge VSB	DACS	MET	Soundtec	Carina	ESTEEM

Original indications (90th)

BAHA ENTIFIC

(BAHA Cochlear)

- Conductive hearing loss
- Mixed hearing loss
- Single sided deafness
(cochlear nad retrocochlear)

- Otitis media chronica
- Congenital aural atresia
- Active radical cavity
- Recurrent cholesteatoma
- Otosclerosis (when other techniques fail)
- Tympanosclerosis
- Posttraumatic conductive or mixed hearing loss

Symphonix

(VSB MEDEL)

- Sensorineural hearing loss

- SNHL

BAHA (BCI) vs. VSB (AMEI) 2004 – 2012 (VIBROPLASTY)

• **Single sided deafness**

- Otitis media chronica
- Congenital aural atresia
- Active radical cavity
- Recurrent cholesteatoma
- Otosclerosis (when other techniques fail)
- Tympanosclerosis
- Posttraumatic conductive or mixed hearing loss

• **Sensori-Neural HL**

- Otitis media chronica
- Congenital aural atresia
- Active radical cavity
- Recurrent cholesteatoma
- Otosclerosis (when other techniques fail)
- Tympanosclerosis
- Posttraumatic conductive or mixed hearing loss

**BAHA remained percutaneous (fixture)
VSB offered transcutaneous solution**

New Bone Conduction devices

BoneBridge
BAHA Attract
Sophono

Changes in indications

Audiologic indications for BCI

- In majority of BCI the BC threshold should not exceed 40dB
- Output of transcutaneous BCI is in average 15dB less the percutaneous

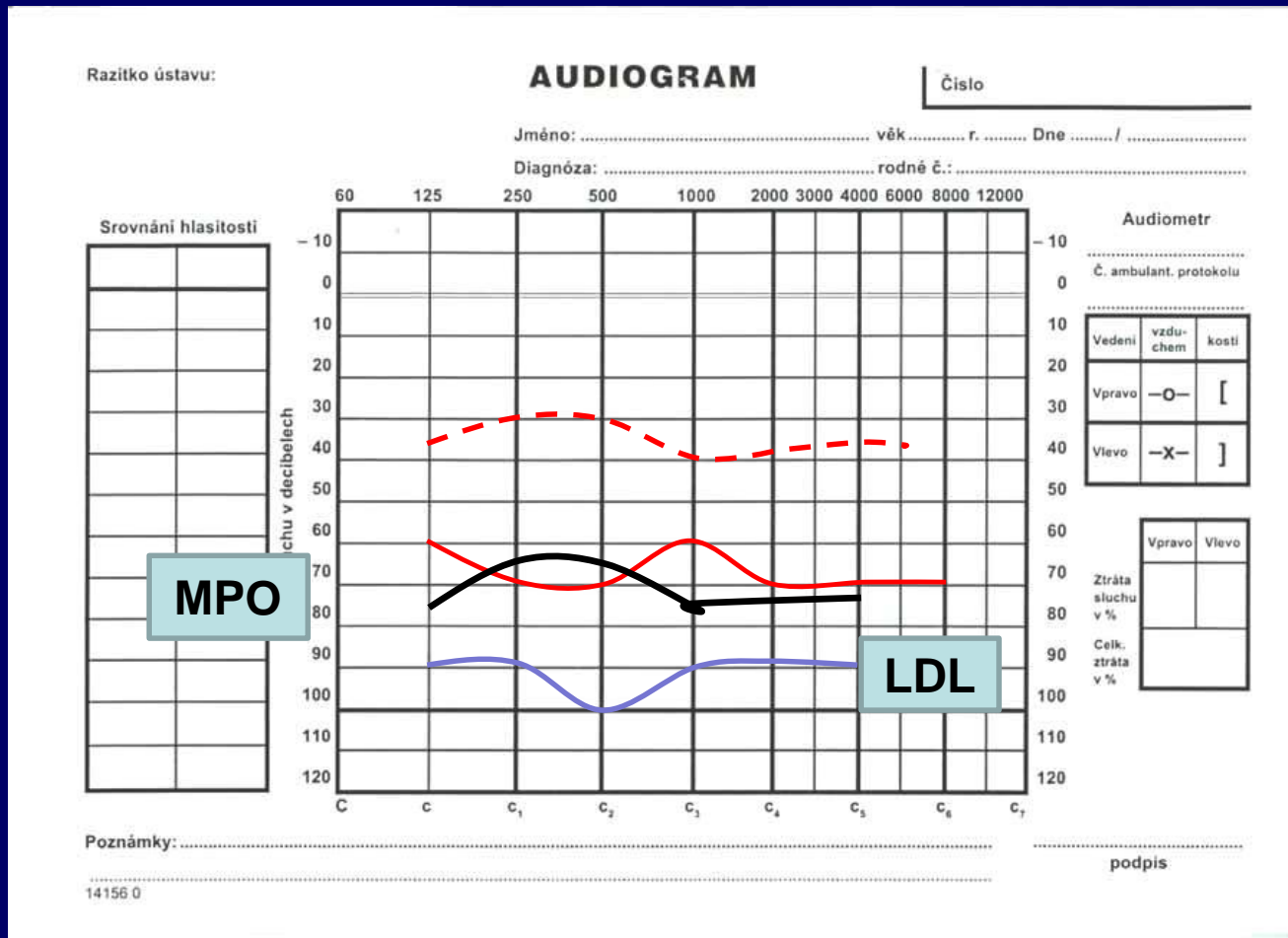
How to define acceptable BC threshold in mixed hearing loss

- DR: dynamic range: difference between BC threshold and LDLs (Loudness Discomfort Level)
- LDL stimuli intensity (frequency specific, speech), too intensive and discomfort for the patient
- MPO Maximal Power Output – maximal device output
- Lower the MPO is lower the gain, poorer understanding

Recommended BC threshold for BCI

- Goal: to provide at least 35dB of the dynamic range 'DR_≥35 dB' rule (Zwartenkot et al., 2014; Rheinfeldt et al., 2015)
- More strict criterium: at least 2/3 of DR should be heard with intensity 35 dB (rule 'DR 2/3')

Audiogram: mixed hearing loss



Maximal power output

Table 2.1. Objective measurement of the MPO of several hearing devices

Device	Measured MPO	Reference	Manufacturer
Sophono Alpha 1	56 dB HL	Hol et al., 2013	Sophono, Boulder, US
Bonebridge	65 dB HL	Mertens et al, 2014	Med-El, Innsbruck, Austria
Standard Baha Divino/BP100	67-69 dB HL	Carlsson & Hakansson, 1997 Zwartenkot et al. 2014	Cochlear BAS, Goteborg, Sweden
Standard Ponto	Idem	Zwartenkot et al. 2014	Oticon Medical, Askim, Sweden
Baha Cordelle, Baha 5 SuperPower*; Ponto 3 SuperPower*.	80-85 dB HL	Idem	Cochlear BAS, Goteborg, Sweden Oticon Medical, Askim, Sweden
Vibrant Soundbridge	85 dB HL	Idem	Med-El, Innsbruck, Austria
Codacs	100 dB HL?	Idem	Cochlear Mechelen, Belgium

<http://www.snikimplants.nl>

* updated spring 2017

Maximal BC threshold

Device	MeasuredMPO*	Max SNHLc if the 'DR 2/3 rule' is used	Max SNHLc if the "DR _≥ 35 dB rule" is used
Sophono Alpha 1	56 dB HL	5 dB HL	20 dB HL
Bonebridge	65 dB HL	20 dB HL	30 dB HL
Standard Baha Divino/BP100	67-69 dB HL	25-30 dB HL	30-35 dB HL
Standard Ponto	Idem	25-30 dB HL	30-35 dB HL
Baha Cordelle	80 dB HL	45 dB HL	45 dB HL
Vibrant Soundbridge	85 dB HL	50 dB HL	50 dB HL
Codacs	100 dB HL?	>65 dB HL	>65 dB HL

Types of implants

- BAHA (Cochlear)
- BAHA Attract (Cochlear)
- BONEBRIDGE (Medel)
- SOUNDBRIDGE (Medel)
- SOPHONO (Medtronic)
- ADHEAR (Medel)

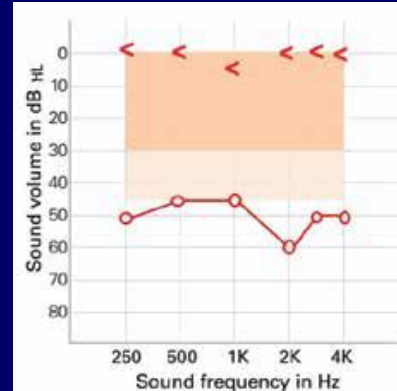
BAHA Connect and BAHA Attract Percutaneous vs. Transcutaneous



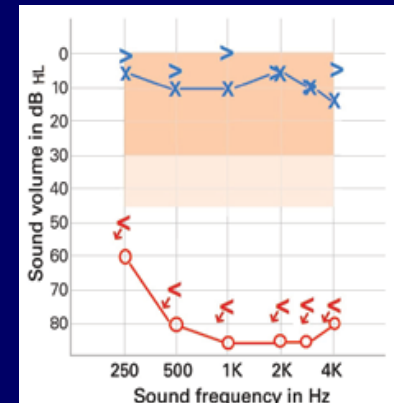
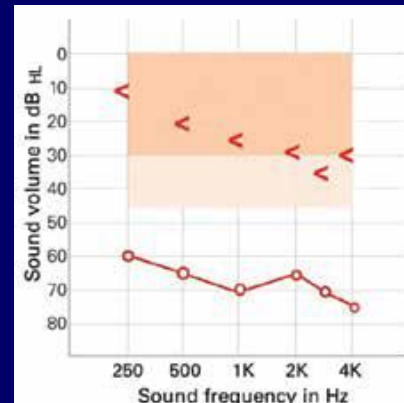
BAHA Candidacy

- Conductive Hearing Loss
 - The conductive component of the hearing loss is greater than 30 dB
- Mixed Hearing Loss
 - BC threshold up to 50/60dB
 - BAHA 5 (45)
 - BAHA 5 Power (55)
 - BAHA 5 Superpower (65)
- Single sided deafness
 - BC threshold in the hearing ear up to 20dB

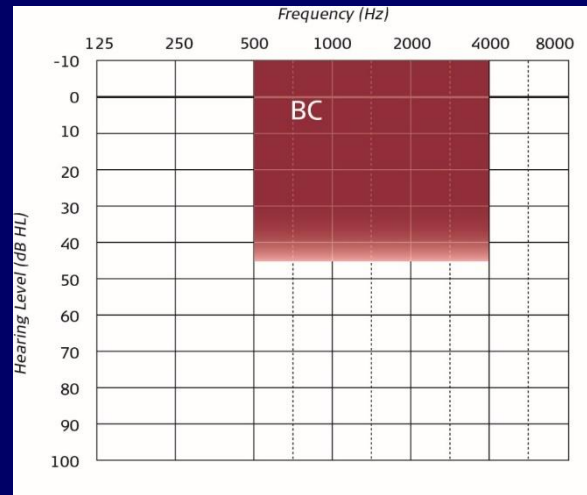
SOPHONO



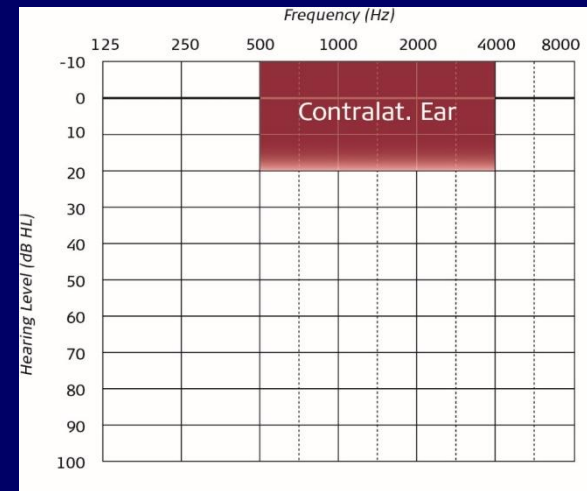
**BC threshold
30-40dB
(20dB)**



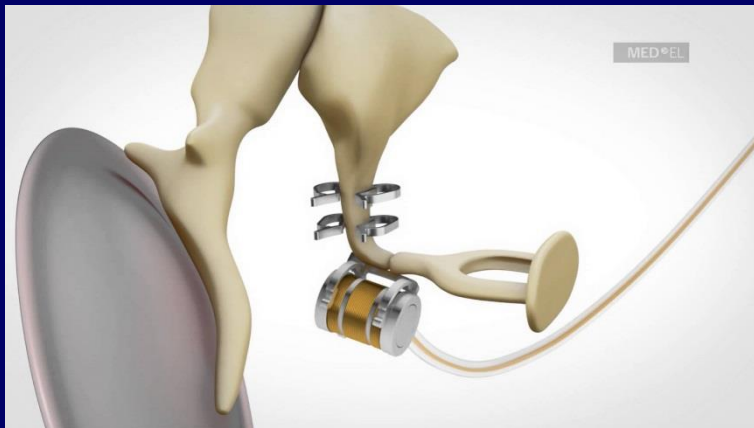
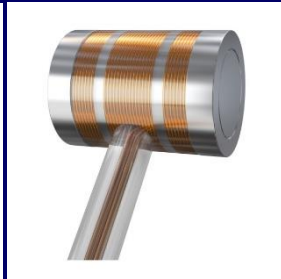
BONEBRIDGE



**BC threshold
40-45dB
(30dB)**



SOUNDBRIDGE



- Round window
- Incus short process
- Incus long process
- Stapes
- Piston

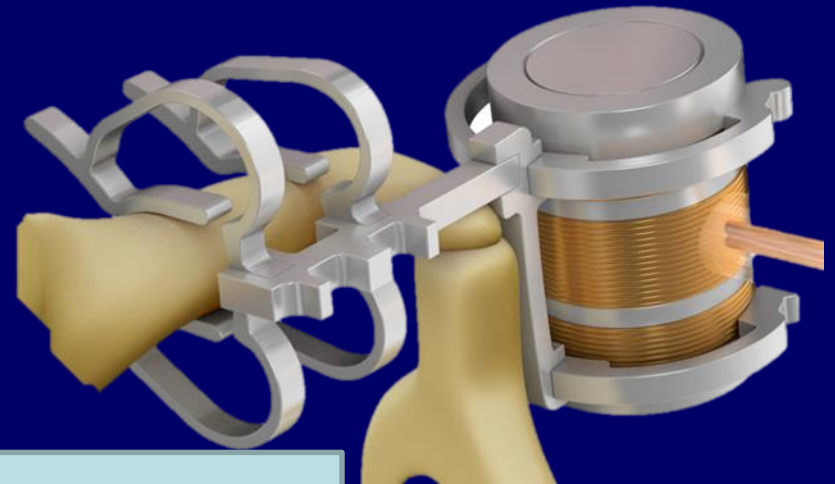
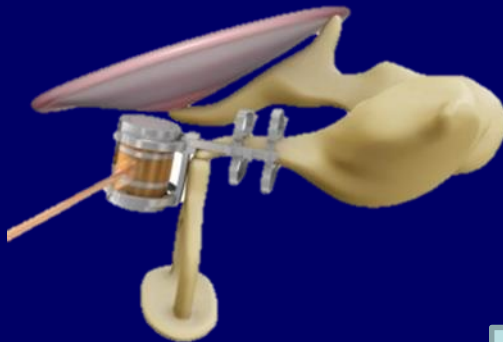
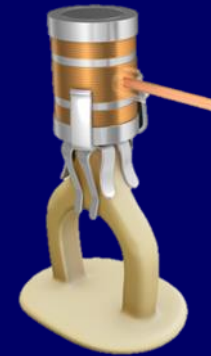
BC threshold 50dB (RW application)

VibrantSoundbridge with Couplers

Incus – short process



Stapes head



Incus – long process

Implantable hearing devices

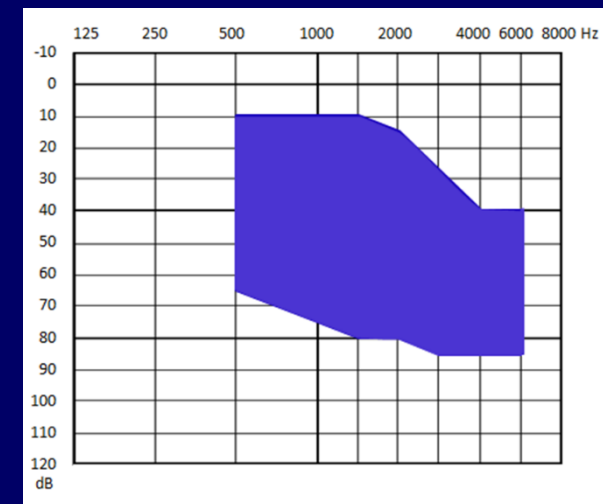
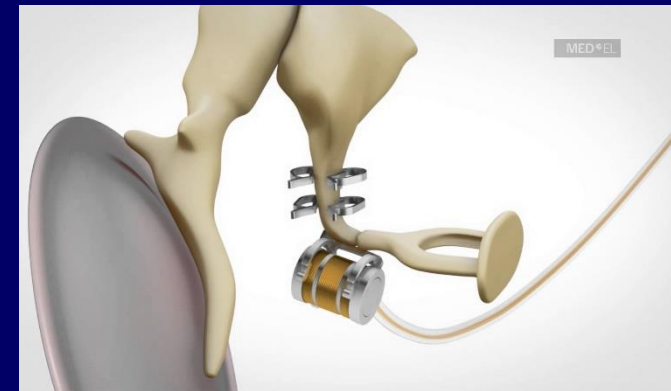
Mixed hearing loss: When to implant

- Primary surgery
 - External and middle ear atresia uni- and bilateral
- Revision surgery
 - Second revision in unfavorable anatomical and functional condition
 - Need of the 3rd revision is indication for implantation
- Salvage surgery
 - Unilateral deafness after schwannoma removal

Implantable hearing devices

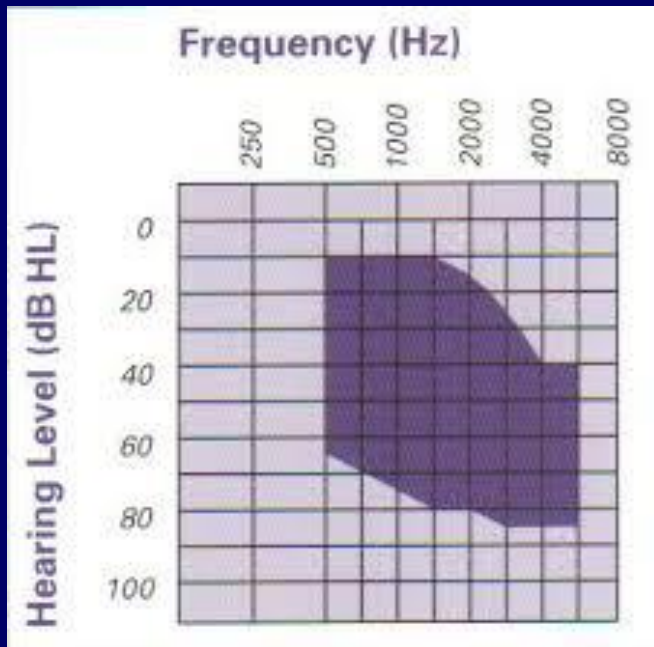
Sensorineural Hearing Loss When to implant?

- Audiologic criteria
- HA intolerance
- Recurrent external otitis
- Patient asks for implantable device
- After unilateral implantation patient asks for the second implant

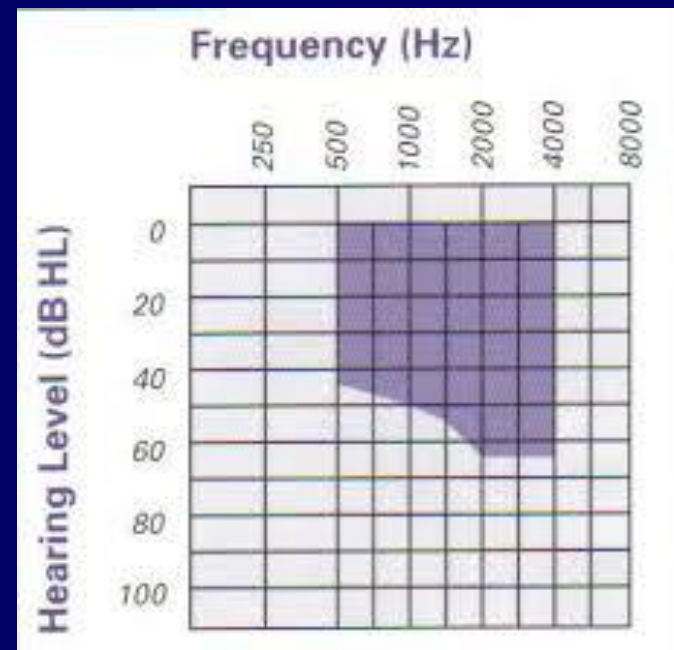


Audiological indications

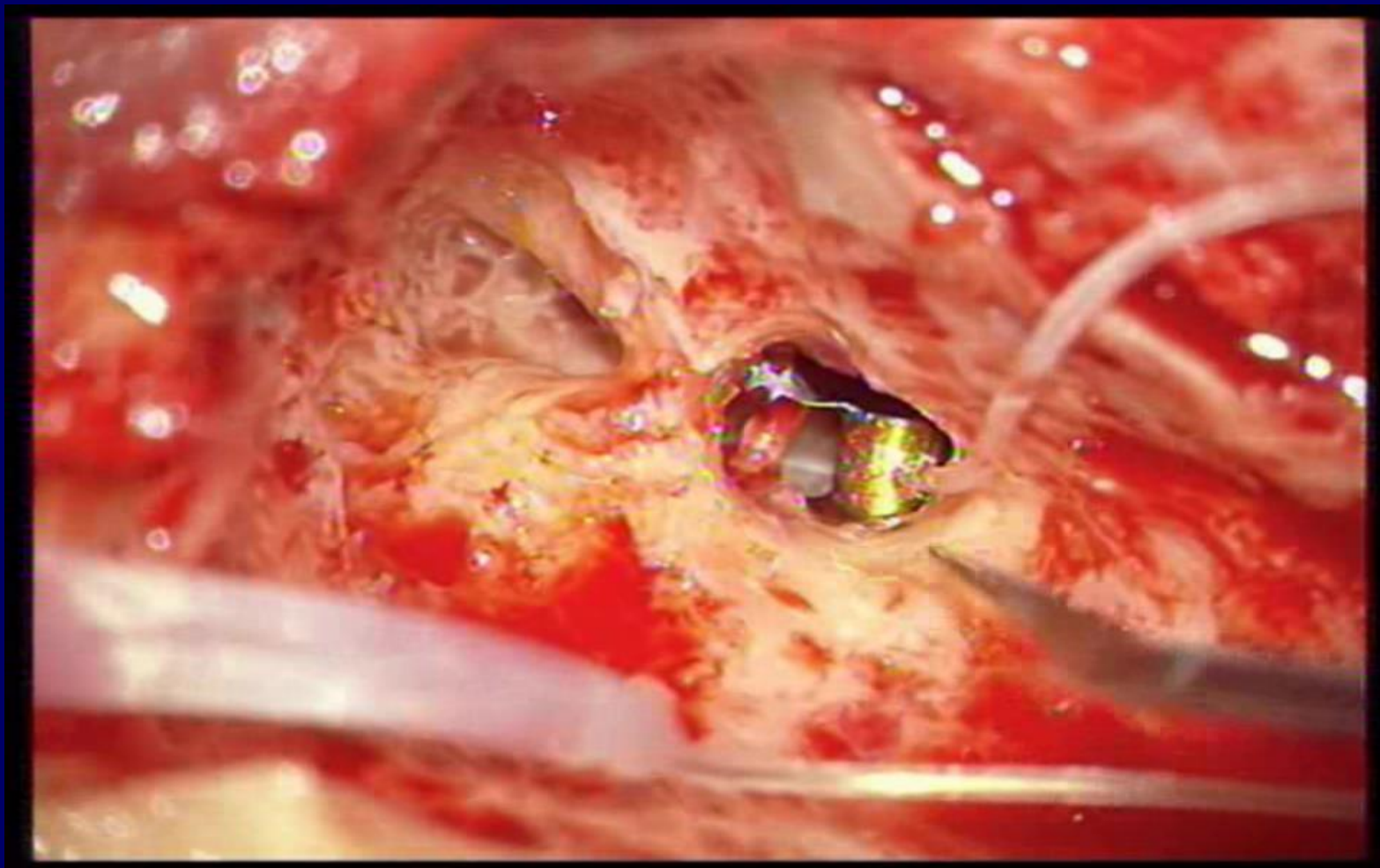
SNHL



Mixed HL



VSB pri SNHL



Material to evaluate (N=34)

- Exclusion of paediatric patients
- Exclusion of nonusers a
- Series of 34 patients implanted with 3 different implants
 - BAHA
 - BoneBridge
 - VibrantSoundbridge

Methods – Audiologic tests

- Free field with warble tone without hearing device 6 frequencies 250 – 6000 Hz
- Free field with warble tone with hearing device 6 frequencies 250 – 6000 Hz
- Speech audiometry without/with HD (SNR 60/50 dB HL)
- Monosyllabic test without/with HD (SNR 60/50 dB HL)

Methods - Questionnaire

- International questionnaire (International Outcome Inventory IOI-HA)
 - with 7 questions to evaluate implanted device have been completed by all patients
- Data were collected in the period April - May 2015
- The questionnaires were completed by patients at home without any time limit
- The material was processed by statistical software SSS

How patients appreciate implants

Material

	BAHA	BB	VSB
Total number of patients N=52	13	10	29
Number of adult patients (18+)	10	8	16
M:F	6M:3F	3M:5F	2M:14F
Average age	14.2	36,25	48,25
Nonusers	1	0	4

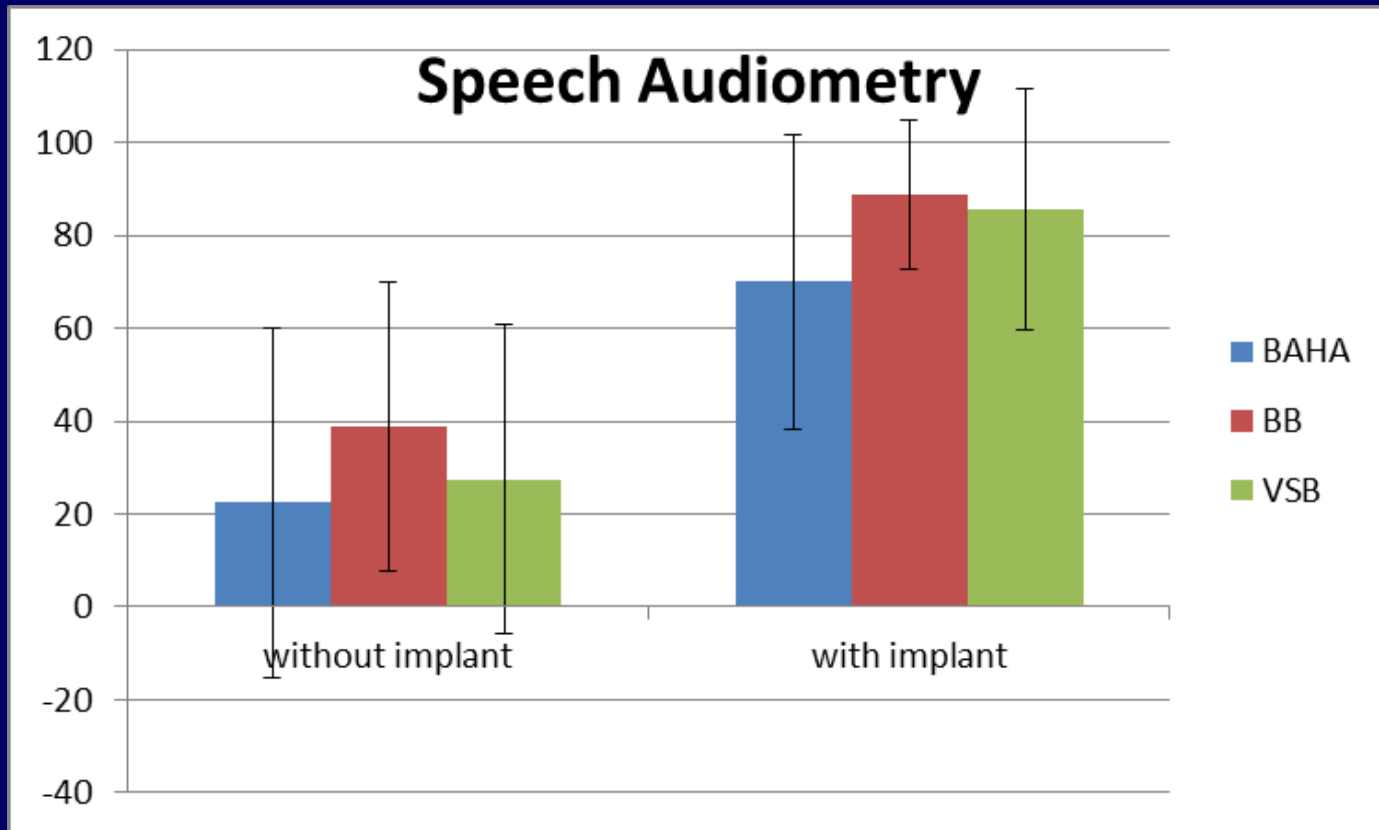
Material Indications

	BAHA (N1=10)	BB (N2=8)	VSB (N3=16)
Chronic otitis	6	3	1
Atresia, stenosis of ear canal	3	3	11
SSD	1	2	0
Tympanoscler osis	0	0	1
Sensorineural HL	0	0	2

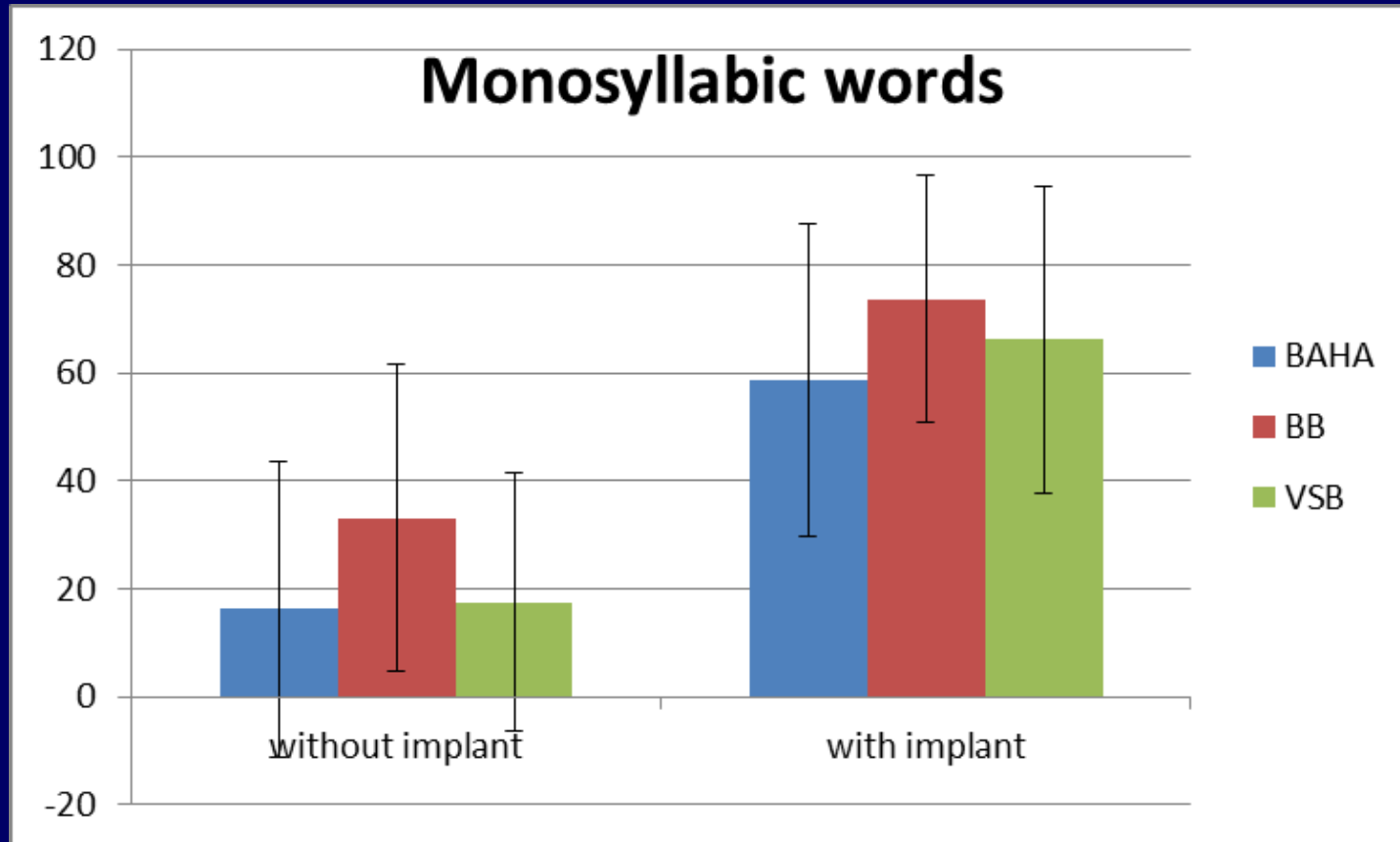
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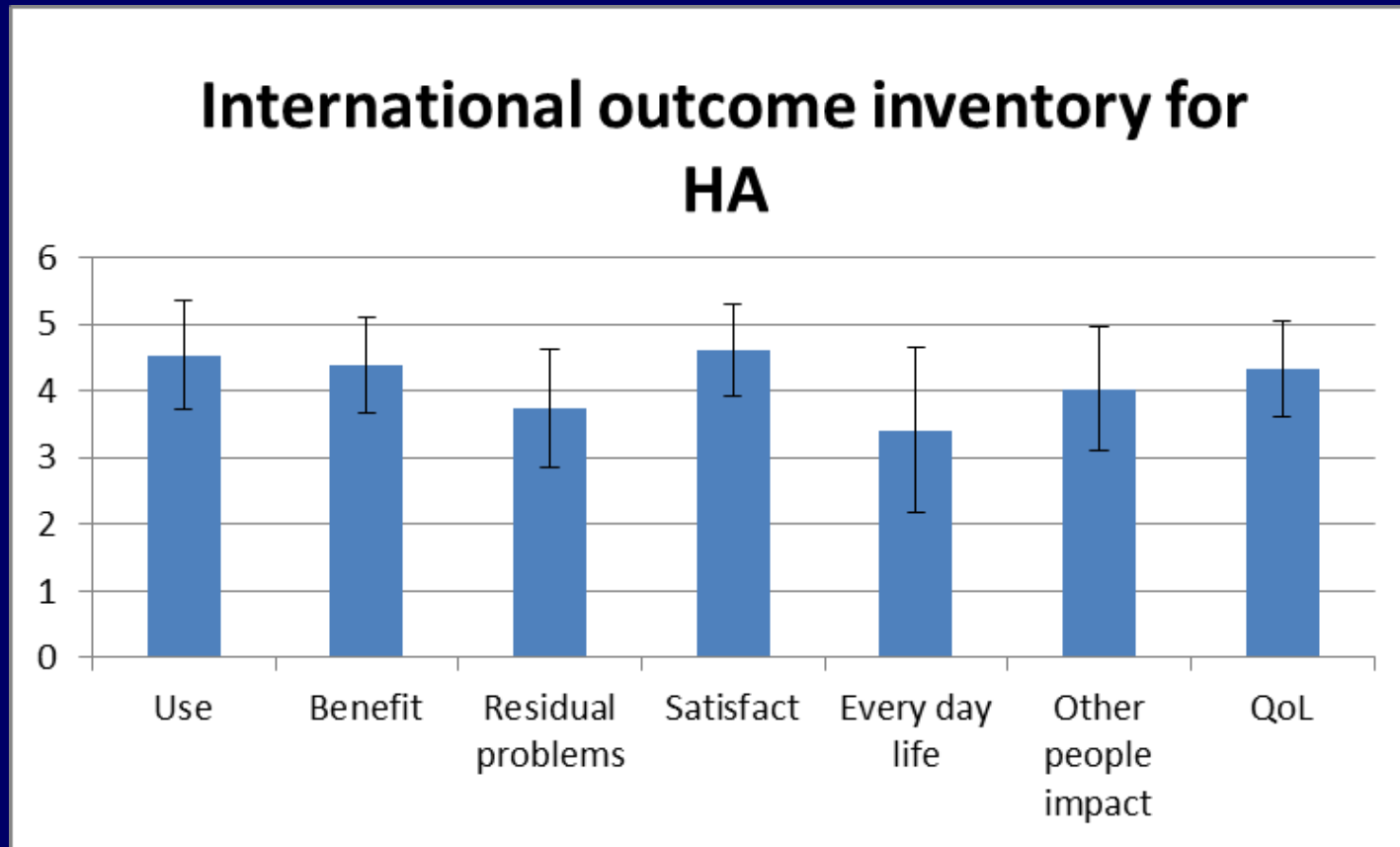
Speech audiometry



Monosyllabic words



Appreciation of implantable hearing devices by patients



Appreciation of implantable hearing devices by patients

- There were no significant differences between the 3 devices

CONCLUSIONS

After the arch of development we slowly return to early indications

BONE CONDUCTION IMPLANTS

- Conductive hearing loss
- Mixed HL (40dB)
- Mixed HL (60dB BAHA Superpower)
- Single sided deafness

ACTIVE MIDDLE EAR IMPLANTS

- Sensorineural hearing loss
- Mixed HL (BC 40-60dB)

Implantable hearing aids

Conclusions

- Powerful instruments to manage sensorineural, conductive and mixed hearing loss
- Functional results and acceptance by patients confirm qualification for clinical use
- Individual selection of device changing with time, new studies and new technology

Implantable hearing aids

Conclusions

Do not forget:

We still have a tympanoplasty to
improve hearing