




<h2>Introduction to BONEBRIDGE:</h2> <p>An Active Transcutaneous Device</p>	
<p>Kim Twitchell MS, Reg. CASLPO Clinical Education Manager – Bone Conduction</p>	

AO22
KT7



Disclosures

Financial - employee of MED-EL Canada

Non-financial - member of College of Audiologists and Speech Pathologists of Ontario

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Agenda

History of MED-EL implants

Who benefits from bone conduction (B/C) hearing aids

Types of B/C hearing aids

Difference between passive and active B/C aids

Who is a candidate

BONEBRIDGE components

How to program

Research on efficacy and safety



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MED-EL portfolio of devices

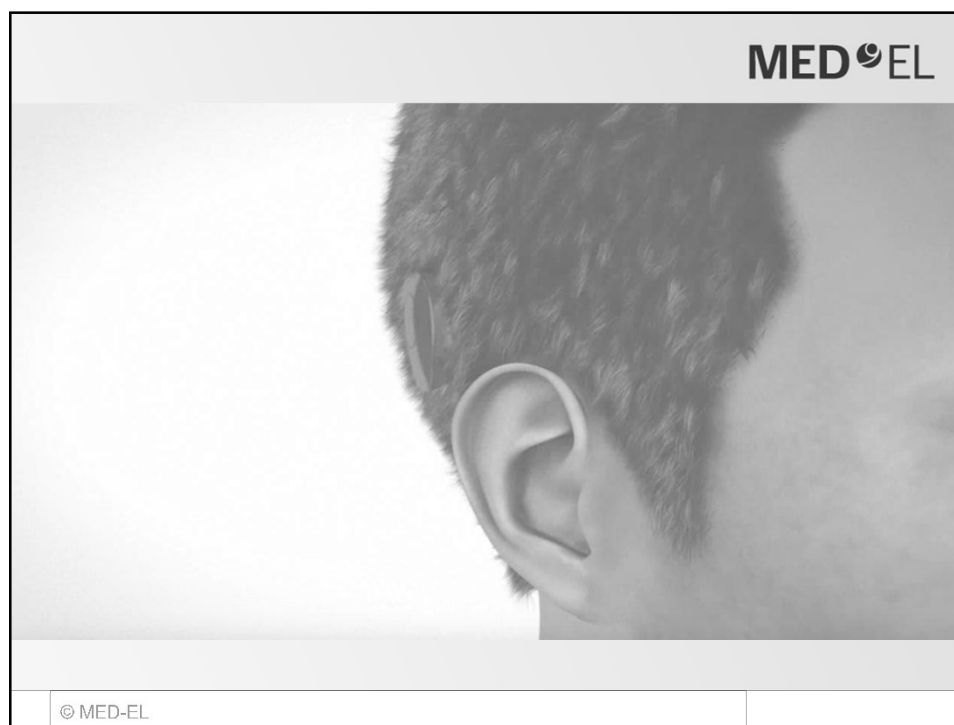
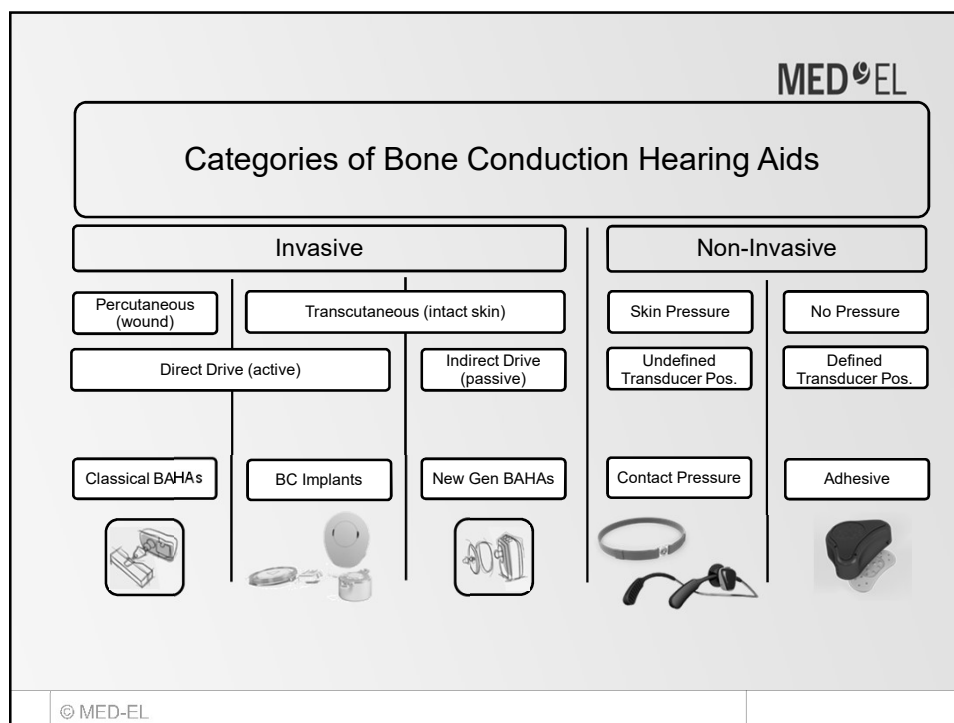


Who can benefit from bone conduction devices?



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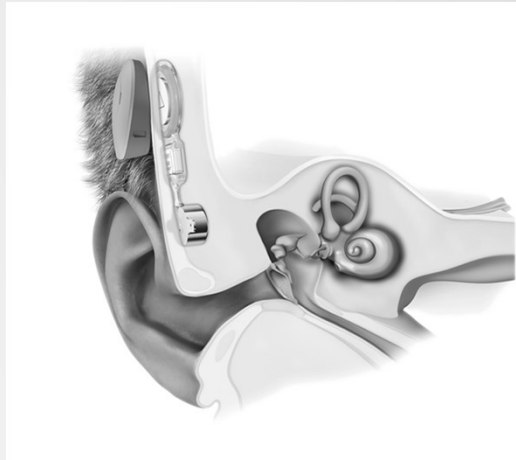
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Advantages of an active transcutaneous bone conduction device

Intact Skin

Stable Output

No Pressure



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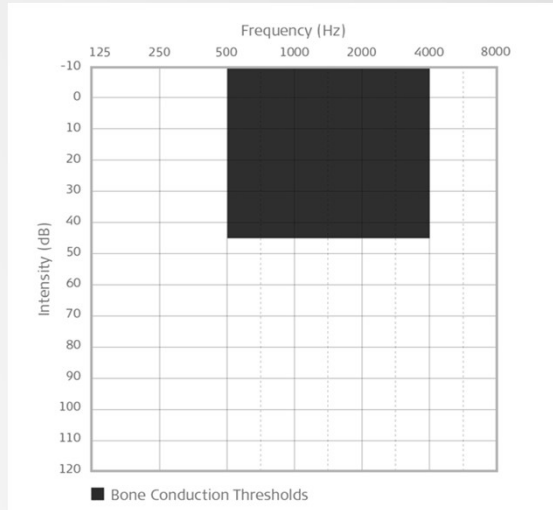
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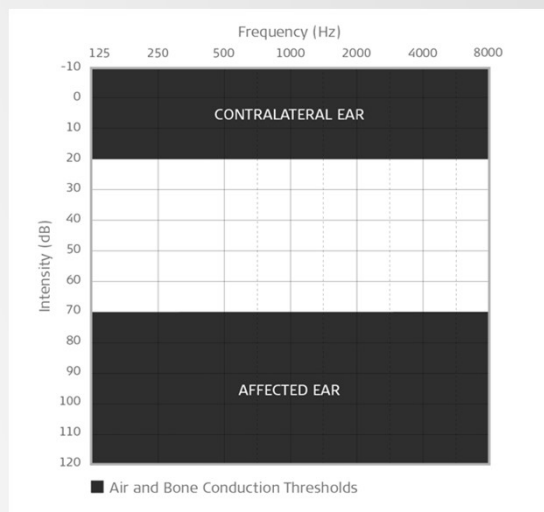
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Who is a candidate?



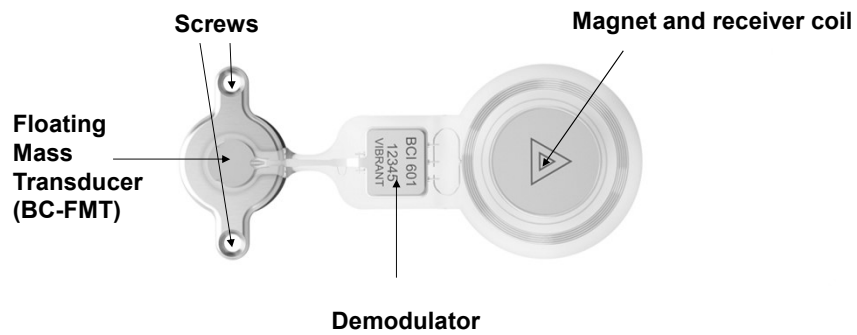
Who is a candidate?



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BONEBRIDGE implant – BCI 601



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BCI

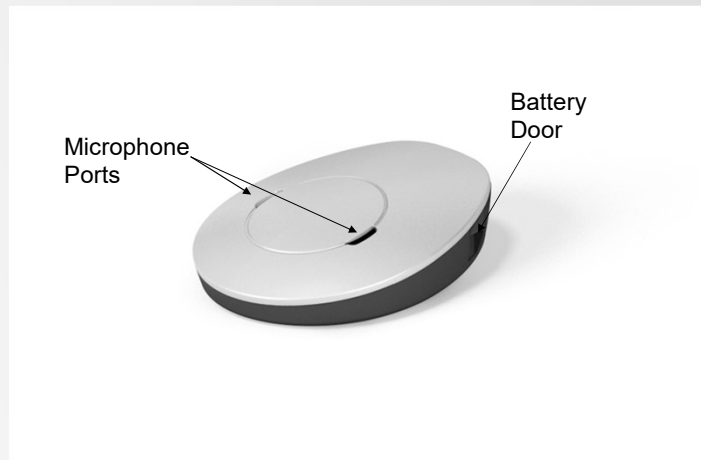


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SAMBA Audio Processor



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SAMBA Audio Processor

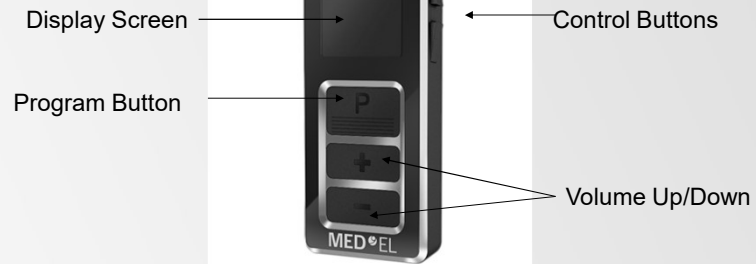


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SAMBA remote control



SAMBA Audio Processor



- ✓ Automatic/Ambient Sound
- ✓ Adaptive Directional Microphone
- ✓ Speech Tracking

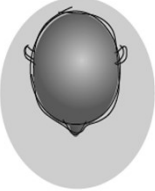

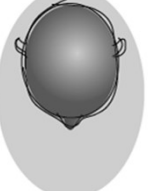
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Automatic/Ambient Sound

SOUND ENVIRONMENT

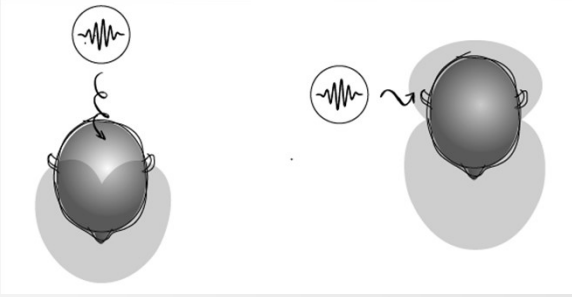
SPEECH	MUSIC	NOISE
		
AMBIENT SOUND	OMNIDIRECTIONAL	ADAPTIVE DIRECTIONAL

MICROPHONE SETTING

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Adaptive Directional Microphone



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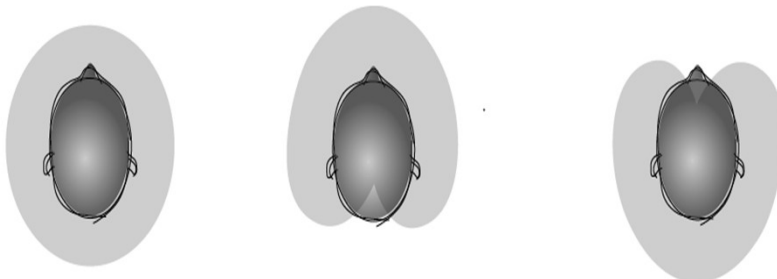
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Speech Tracking

SPEECH IN QUIET

SPEECH IN NOISE FROM FRONT

SPEECH IN NOISE FROM BACK



Directionality patterns of the SAMBA in Speech Tracking Mode

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How do you program the BONEBRIDGE?





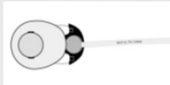





Siemens ConnexLink™



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Equipment needed		MED [®] EL
Software	Siemens Connexx 6.5.5 software MED-EL SYMFIT 7.0 software	<div> SYMFIT 7.0 Article number: 51529</div> <div> CONNEXX 6.5.5 Article number: 51590</div>
Cables	Programming cable CS64 Samba Battery pill	<div></div> <div></div>
Device	Samba Processor	
Programmer	Hi-Pro Noahlink Siemens ConnexxLink	<div></div> <div></div> <div></div>
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How to program the BONEBRIDGE system

Detect hearing instruments

Instruments to be read

Right Hearing Instrument

VIBRANT MED-EL
Samba BB audio processor

Serial Number:
001533

Left Hearing Instrument

No Instrument detected.

What would you like to do as a next step?

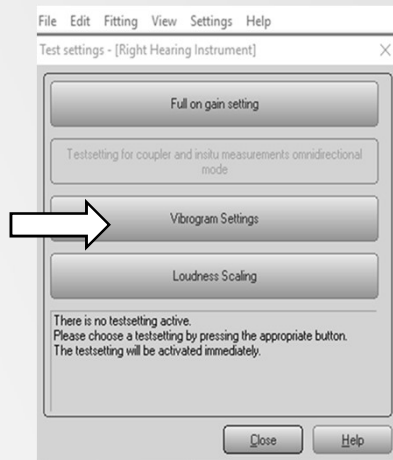
☐ New fitting (go to FirstFit Navigator)
☒ Follow-Up fitting (go to Fine Tuning)
☐ AutoFit (go to real ear measurement)

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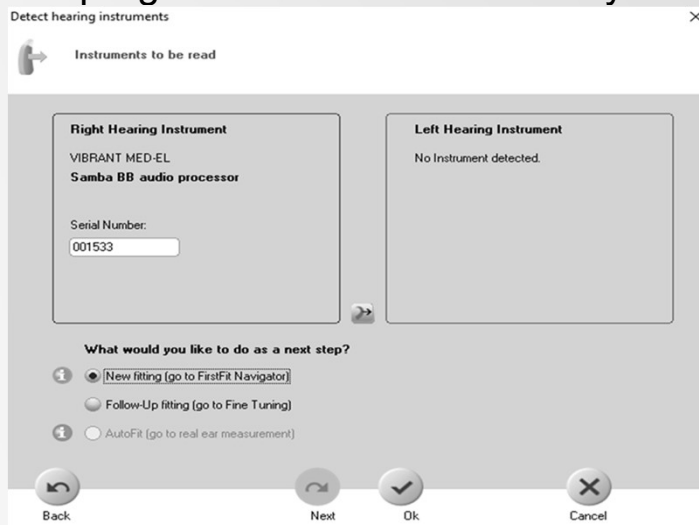
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How to program the BONEBRIDGE system



How to program the BONEBRIDGE system



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How to program the BONEBRIDGE system

First Fit Navigator

Fitting Method

Acclimatization level:

1 2 3 4

Familiar

Fitting formula

DSL I/O*

Reserve

4 dB

Volume Control Range

8dB

Number of Programs

3

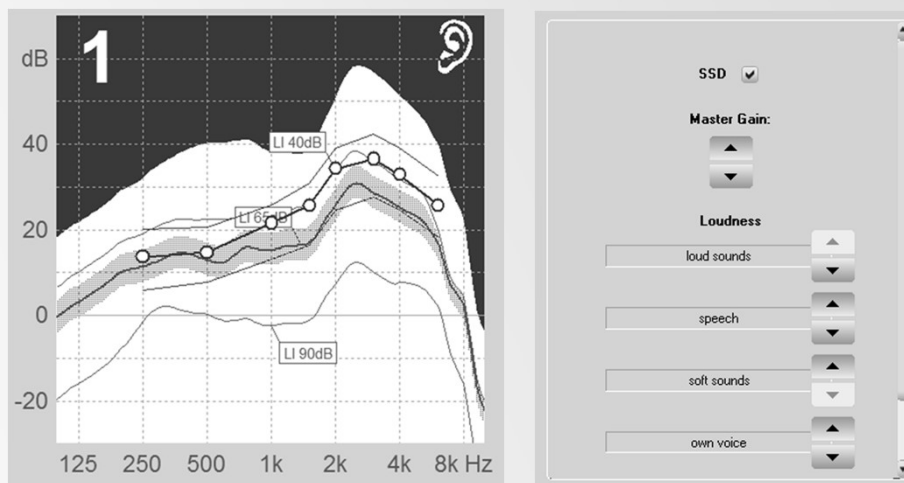
In situ Corrections

☐ Use client's measurement curves

Back Next Apply First Fit Cancel

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How to program the BONEBRIDGE system



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Connectivity with BONEBRIDGE

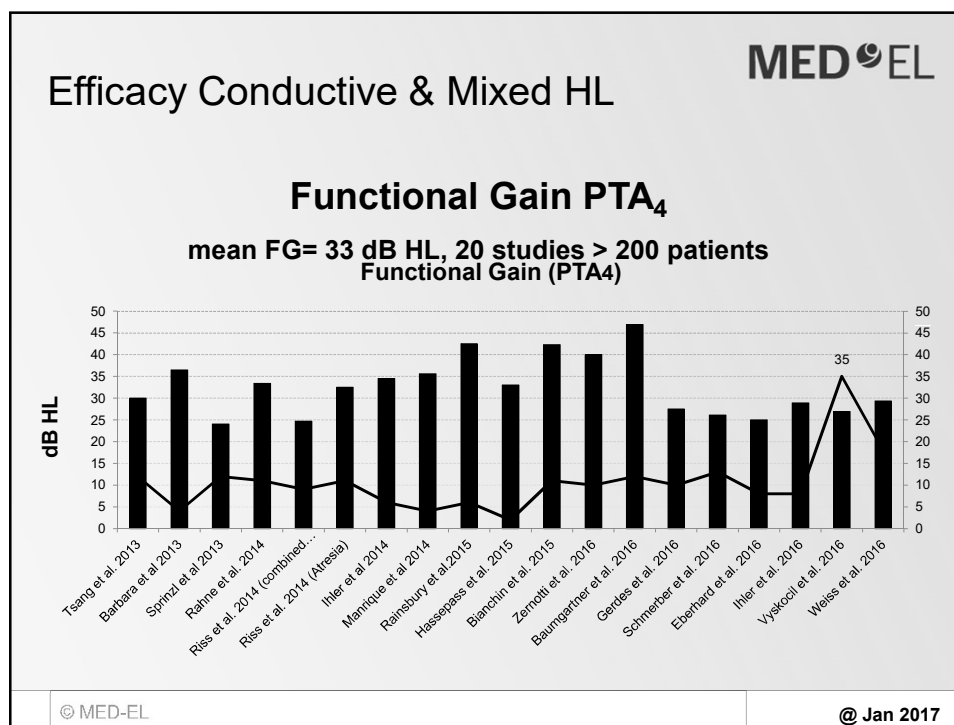
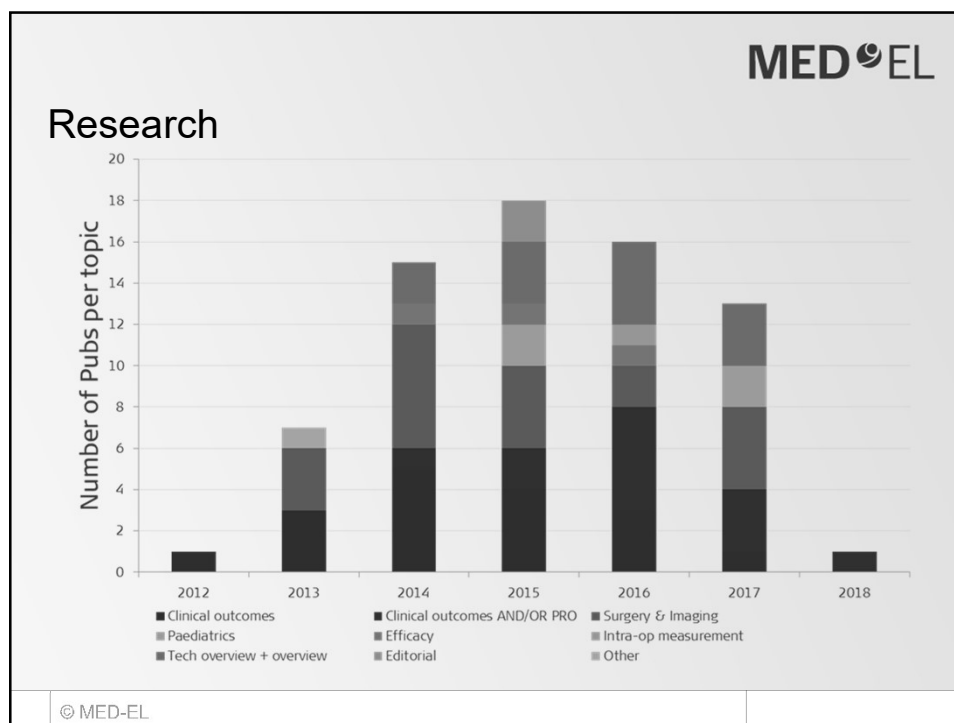


MRI

- MR imaging up to 1.5 Tesla
- Force-free, patented magnet technology
- No magnet removal necessary

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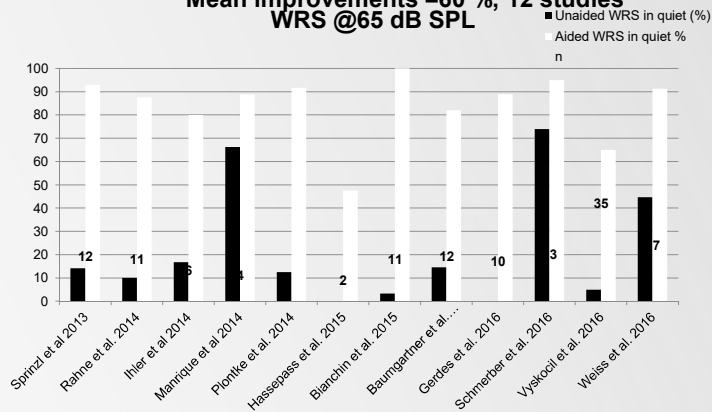
Efficacy Conductive & Mixed HL

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Word Recognition Scores @ 65dB

SPL

Mean improvements =60 %, 12 studies
WRS @65 dB SPL



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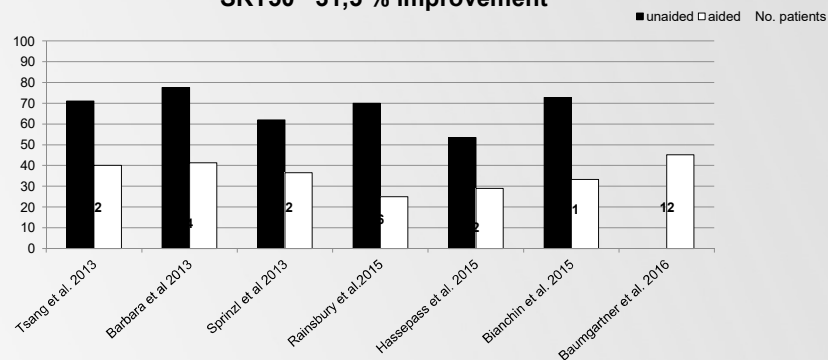
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Efficacy Conductive & Mixed HL

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Speech Reception Threshold SRT₅₀

SRT50 ~31,5 % improvement



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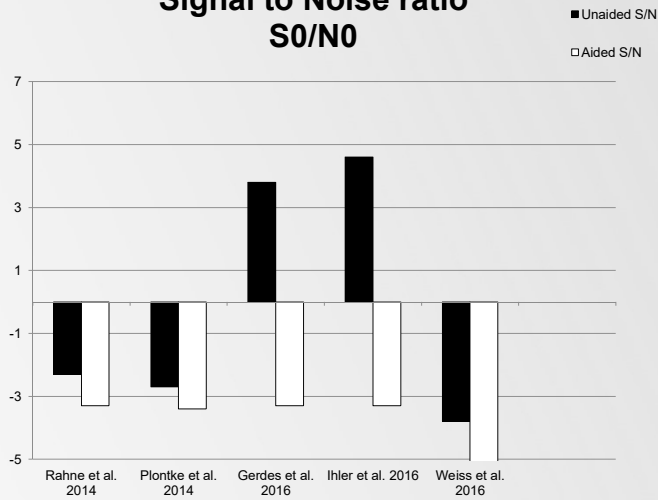
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Efficacy Conductive & Mixed HL

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Signal to Noise ratio S0/N0

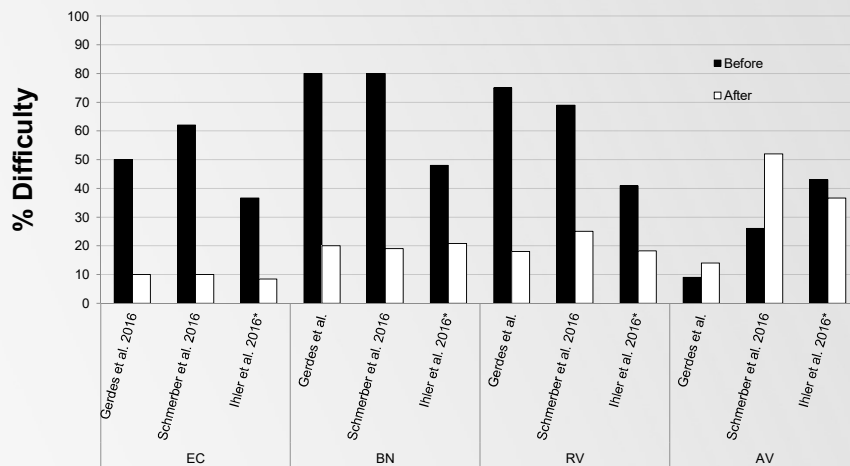


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Assessment of Quality of Life APHAB questionnaire

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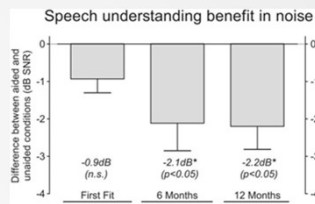
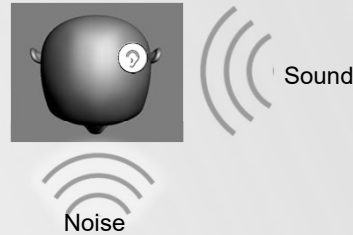
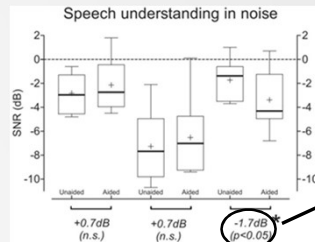
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Efficacy Single Sided Deafness (Laske et al., 2015)

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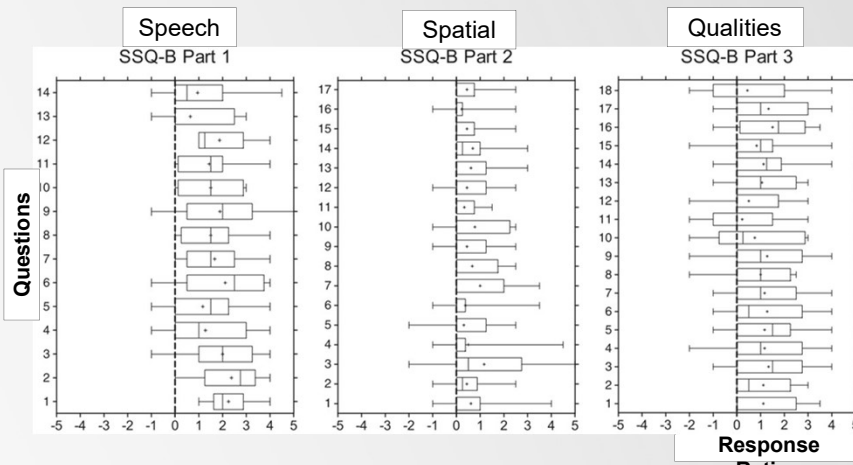


Further decrease of SNR levels after several months due to accustomisation.

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Quality of Life: Single Sided Deafness (Laske et al., 2015)

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Satisfaction rate of 89% with a statistically significant association ($R=0.72$, $p=0.03$, Spearman test) between subjective benefit and objective speech in noise scores.

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Safety BONEBRIDGE

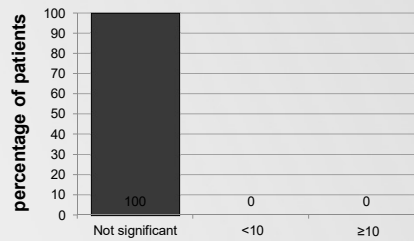
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Pre vs. Post - op BC Thresholds Shift 6 studies, 56 patients: 2012-2016

BC hearing thresholds?

Thresholds shift BB, 6 studies
56 patients

Study	n	BC threshold shift
Baumgartner et al 2016	12	no change
Gerdes et al 2016	10	no change
Sprinzl et al. 2013	12	change < 5 dB
Ihler et al. 2014	6	no change
Manrique et al. 2014	5	no change
Rahne et al. 2014	11	change < 5 dB



Residual hearing remained unchanged post-op.

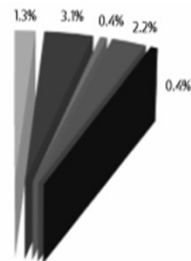
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Safety BONEBRIDGE

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device related
patient related
skin related
surgery related
revision surgery
non-user



13

13 studies 175 subjects 17 incidents



Summary of adverse event ratios

	Minor	Major	Overall
device related	0	0	0
patient related	1.3	0	1.3
skin related	3.1	0	3.1
surgery related	0.4	0	0.4
revision surgery	-	2.2	2.2
non-user	0.4	-	0.4
Sum of complications	5.2	2.2	7.4

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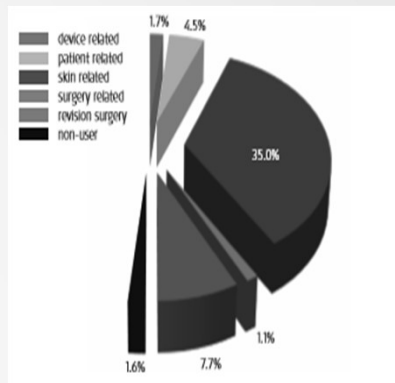
Data search end of march 2016 (Pubmed and Dimdi)

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Safety Baha Connect series

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Summary of adverse event ratios

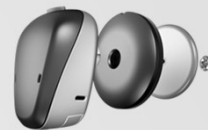
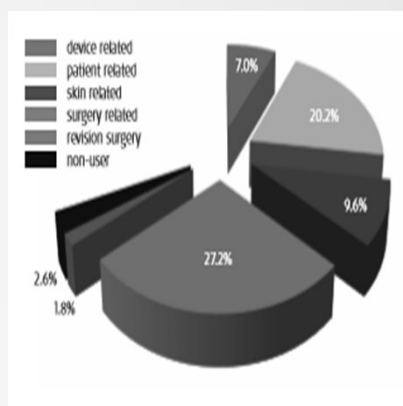
	Minor	Major	Overall
device related	0.7	1.0	1.7
patient related	1.8	2.7	4.5
skin related	25.3	9.7	35.0
surgery related	1.1	0	1.1
revision surgery	-	7.7	7.7
non-user	1.6	-	1.6
Sum of complications	30.5	21.1	51.7

117 studies – 6965 subjects– 3619 incidents

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Safety Baha Attract

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Summary of adverse event ratios

	Minor	Major	Overall
device related	7.0	0	7.0
patient related	20.2	0	20.2
skin related	9.6	0	9.6
surgery related	27.2	0	27.2
revision surgery	-	1.8	1.8
non-user	2.6	-	2.6
Sum of complications	66.7	1.8	68.4

7 studies – 114 subjects– 78 incidents

7 studies – 114 subjects– 2 major incidents

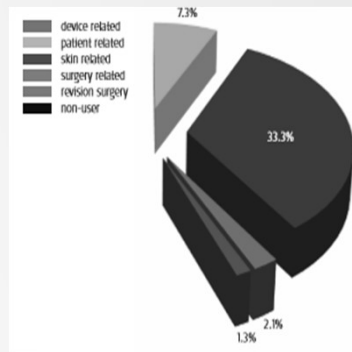
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Summary of adverse event ratios

	Minor	Major	Overall
device related	0	0	0
patient related	7.3	0	7.3
skin related	29.5	3.8	33.3
surgery related	2.1	0	2.1
revision surgery	-	1.3	1.3
non-user	0	-	0
Sum of complications	38.9	5.1	44.0

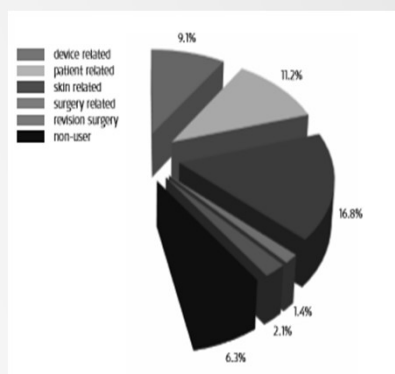
7 studies – 234 subjects– 103 incidents

7 studies – 234 subjects– 12 major incidents

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Safety Sophono

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Summary of adverse event ratios

	Minor	Major	Overall
device related	7.7	1.4	9.1
patient related	11.2	0	11.2
skin related	16.1	0.7	16.8
surgery related	1.4	0	1.4
revision surgery	-	2.1	2.1
non-user	6.3	-	6.3
Sum of complications	42.7	4.2	46.9

12 studies – 143 subjects– 67 incidents

12 studies – 143 subjects– 6 major incidents

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BONEBRIDGE system

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Resources

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