Are We Restoring Binaural Hearing With Other Implantable Devices?

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www.implantsaustria.com

ENT Univ. Department Vienna
CI Department Karolinska University Stockholm
YES !!
Why bilateral hearing?
Why bilateral implantation?

for the surgeon?
for the manufacturer?
bilateral hearing aids - cochlear implants
speed of speech production!
speech understanding (noise)!
directional hearing!
• earth is a disc  (15th century)
• electrical light will never replace gas light  (W Siemens 1878)
• prospective world market of PC is 5  (IBM 1948)
• from the physiological point of view CI will not work  (Nelson Kiang 1961 & Rainer Klinke 1978)
• 640 kb are enough for everybody  (Bill Gates 1990)

Single sided deafness with one healthy ear doesn´t need therapy (ENT textbook 1990)

there is no need, no benefit of BILATERAL cochlear implantation, no cost-benefit
(CI „experts“ Hongkong bilat CI Roundtable 2004)
Minimum audible angle in healthy bilateral human listeners is in mean 3 degrees (7-15 degrees)

On the minimum audible angle—A decision theory approach

William Morris Hartmann
Department of Physics, Michigan State University, East Lansing, Michigan 48824

Brad Rakerd
Department of Audiology and Speech Sciences, Michigan State University, East Lansing, Michigan 48824

(Received 15 March 1988; accepted for publication 13 January 1989)
Passive sound-localization ability of the big brown bat (Eptesicus fuscus).

Koay G1, Kearns D, Heffner HE, Heffner RS.
BILATERAL COCHLEAR IMPLANTATION is THE superior treatment in hearing loss in children & adults
Cochlear Implantation Patients
University Vienna ENT n > 1450

70's: William House first bilateral

1995: 1st adult bilateral CI Vienna

1996: 1st pediatric bilateral CI Vienna

> 260 bilateral CI ~ 18 % sequentiel & simultan

> 60 adults (8%) > 200 children (28%)
bilateral cochlear implantation does not necessarily mean bilateral cochlear implant user

How to become a bilateral cochlear implant user!!

( The bilateral CI child is the big one )
Med El 32 mm insertion

WD Baumgartner - classic approach

insertion angle: 860°
A deeply inserted array allows matching the output filters with the natural tonotopic map.

Full, deep insertion: Good match

Shallow insertion: Regression
Bill had NO fast Coding Strategies

- The cochlea codes a signal in place (tonotopicity) and in time/rate ("Phase Locking").
  - Low frequencies: Place and Time
  - High frequencies: Place only

FS4 and FS4-p are not approved in the US
Bilateral Implantation: adults & children

- Speech perception
  - Significant improvement due to benefits from all binaural effects
- Sound localization
  - Performance changes from guessing to knowing.
- Quality of life
- Psychoacoustics
- Objective measures
- Technology

* Significant difference
Speech reception

(Müller J, Baumgartner WD et al., 2002)
Sound localisation

Deviation vs. age of onset of deafness and bilateral implantation

clinical data Vienna & Würzburg
Fig. 2. Individual trajectories for P1 latency changes for the early- and late-implanted groups. In all subjects (except those indicated by asterisks) the initial data point was obtained at the time of implant activation. The solid lines represent the 95% confidence intervals for normal development of P1 latencies.
Monosyllable-Trochee-Polsysyllable-12
1 CI baby group vs. Bilateral baby group  n=49

NOT significant

Pattern 1 CI
Word 1 CI

Pattern bilateral CI
Word bilateral CI

Months after fitting

Pre-op 1 3 6 12 18 24 36
Open Set  monaural vs. bilateral baby group

N=49

SIGNIFICANT !!

Word Phoneme
GASP
Sentence

monoaural
bilateral

Months post fitting

Pre-op 1 3 6 12 18 24 36
To compare monaural vs. bilateral: CORRECT AGE GROUP
Kids implanted 6 - 12 months old

Open Set testing:

<table>
<thead>
<tr>
<th>Age</th>
<th>Test Type</th>
<th>Monaural %</th>
<th>Bilateral %</th>
</tr>
</thead>
<tbody>
<tr>
<td>12m</td>
<td>Word-phoneme</td>
<td>55%</td>
<td>95%</td>
</tr>
<tr>
<td>12m</td>
<td>GASP</td>
<td>20%</td>
<td>40%</td>
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<tr>
<td>24m</td>
<td>Word-phoneme</td>
<td>81%</td>
<td>99%</td>
</tr>
<tr>
<td>24m</td>
<td>GASP</td>
<td>50%</td>
<td>100%</td>
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<tr>
<td>24m</td>
<td>Sentence</td>
<td>0%</td>
<td>45%</td>
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<td>Word-phoneme</td>
<td>81%</td>
<td>99%</td>
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<tr>
<td>36m</td>
<td>GASP</td>
<td>60%</td>
<td>100%</td>
</tr>
<tr>
<td>36m</td>
<td>Sentence</td>
<td>78%</td>
<td>100%</td>
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</tbody>
</table>

**BILATERAL BABIES are 24m post fitting as MONAURAL BABIES 36m post fitting !!**
Results LittlEARS Questionnaire

Expected values
normal hearing kids
Spatial hearing - bilat. children vs. bilat. adults

(Kühn-Innacker et al., 2004)
in > 200 children:
> 800 (!) bilateral observation years

- no negative effects of bilateral stimulation
- excellent feed back (patients, parents, teachers)
  - children: no refusers, love both CI
  - 100% of the bilateral schoolage children attend mainstream schools !!
  - second ear doesn´t start at zero !!
  - directional hearing !!
- speech understanding in noise improves !!
Cochlear Implants in Single Sided Deafness

adults since 2008 , children since 2011

- 55 adults , 5 children (age 4 -10 years)
- Deafness < 10 years (postlingual)
- excellent results

- Pitfall: anamnesis, prelingual, deafness > 30 years in elderly patients
VIBROPLASTY Overview
not licensed in the US!

> 240 VSB OP´s, 175 long process + 65 Vibroplasty

- Incus Vibroplasty
- TORP Vibroplasty
- PORP Vibroplasty
- Piston Vibroplasty
- RW Vibroplasty
- OW Vibroplasty

ENT Vienna data only
Vibrant since 2010 approved in children (not in USA !)


INTERNATIONAL CONSENSUS ON VIBRANT SOUNDBRIDGE IMPLANTATION IN CHILDREN AND ADOLESCENTS

Internat. Journal of Pediatric Otorhinolaryngology 2010
10 pediatric VSB, 7 kids – 3 bilateral sequentiel
3 Typ I, 1 RW, 3 Fen, 3 Stapes (1 clip coupler)

4 – 17 years old

<table>
<thead>
<tr>
<th>Alter bei OP</th>
<th>Seite</th>
<th>OP Datum</th>
<th>Name</th>
<th>Geboren</th>
<th>Implant Nr</th>
<th>Adresse</th>
<th>Kasse</th>
<th>OP</th>
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<td>4 dext</td>
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<td>14.04.11</td>
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<td>39728 1150</td>
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<td>38354 3400</td>
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<tr>
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<td>NÖGKK</td>
<td>Typ I</td>
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<td>09.01.07</td>
<td>RO ch</td>
<td>15.04.90</td>
<td>35029</td>
<td>2294 Marchegg</td>
<td>WGKK</td>
<td>Radikalhöhle bds., Stapesremnant</td>
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<tr>
<td>11 dext</td>
<td></td>
<td>08.11.11</td>
<td>LI</td>
<td></td>
<td>1100</td>
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<tr>
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<td>02.02.12</td>
<td>KA ju</td>
<td>26.04.06</td>
<td>1150</td>
<td>Wien</td>
<td>WGKK</td>
<td>Fenestration bei Franceschetti Syndrom</td>
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</table>
VSB surpasses the conductive block
Aided thresholds 5 -10 dB(A), special Audioprocessor
Spatial hearing down to 20 degrees!
Oval Window

In between
Stapescrura
First Fitting, Round Window, Franceschetti – years old
BCI 601 – Active Bone Conduction Implant

Electromagnetic Floating Mass Transducer (FMT)

Implant Coil

1.5 Tesla compatible Magnet

Implanthousing with Siliconecoating

Electronic Housing

Feed through: flexibel to bend in all directions

NOT FOR USE IN THE US!
MRI licenced up to 1,5 Tesla

Patented MRI safe and licenced Magnet

Implant is screwed into cortical bone, forces tested up to 1,5 Tesla, without any problem!

NOT FOR USE IN THE US!
Cortical Screws

- Standard screws like in Maxillo- Facial Surgery, delivered together with the implant

- Selftapping screws, drill hole neccessary!
  - total length 6mm, drill depth 4mm!

NOT FOR USE IN THE US!
Pediatric Study finished March 2014, licensed !!!!
Publication SUBMITTED

Since May 2012 available for adults,
Publication Adult Study
in Otology & Neurootology Sept 2013
49 Bonebridge Implantations

39 Bonebridge in Vienna
36 Adults - 28 in Vienna
(12 Atresia, 3 SSD, 19 RC, 2 bilat)
11 children (Atresia, 2 youngest 5 a)
2 Stockholm (Atresia) 1 Bukarest (RC)
1 Linz (RC) 1 Kuwait (RC)
2 Heidelberg (RC, SSD)
1 child bilat (Vie-Lüb) 2 Brno (Atresia - RC)
1st pediatric BONEBRIDGE – boy 11 years
girl 5 years old
7 YEAR GIRL
TREACHER COLLINS
BB LEFT EAR
Bonebridge - KS 12 years old, bilateral Atresia
Limits ??
Solved with BCI Lifts !

• anatomical size of patient
• we need 8 x 15,8 mm
• preoperative Analysis of CT scans
  Osirix Software, Slicer 3D,
  Navigation-system (Brainlab)
• children >= 5 years old (size + screws)
Output Force Levels

BoneBridge versus BAHA

Bonebridge System, Force Output

Output characteristics for Baha® Classic 300
Transcutaneous BC Devices
The Difference between Active and Passive

ACTIVE

- Implant generates stim.
- **Higher output**
- CHL, MHL, SSD
- Lighter AP (8g)
- Lower profile (9mm)
- Low skin pressure (hold AP)

PASSIVE

- SP generates stimulation
- Attenuation through skin
- Mainly CHL
- SP incl. transducer + plate (15/23 g)
- Higher Profile (16/20 mm)
- **Skin pressure** needed for stim.
BB Aided thresholds – Bonebridge in 11 Vienna Atresia children

Green =
with Bone Bridge

Yellow =
Bone Conduction Headband

Blue =
unaided
III. Results - Effectiveness (II)

Word Recognition Score

Mean / median percent correct word recognition scores in quiet (Freiburger/ Göttinger monosyllables) for the implanted ear: pre-operative testing compared to 3-month testing. Mean values are depicted as black squares, median values are depicted as horizontal line, n=12, p≤0.05

Word Recognition increased by 67.6 % over time
III. Results – Effectiveness (III)

Speech Reception Threshold

Speech Reception improved by 27.5 dB HL over time
1. Pediatric fitting April 2012

Clinical pediatric study finished 2014 March

Worldwide 1st BoneBride child
Clinical Experience since 2.5 years

- BONEBRIDGE replaces BAHA in Malformation and Atresia
- BONEBRIDGE replaces BAHA in single sided deafness (SSD)
- BONEBRIDGE is optimal for ears, contraindicated for VSB surgery
- BB works in children age 5!
- MRI compatibility of BB /also VSB!
5 bilateral BB adults (20-40 years old)
2 bilateral BB children 5 & 16 years old

• In adults we see a difference in congenital Atresia vs. Radical Cavity patients !!
• So far to measure 1 year post OP, children have spatial hearing at about 25 degrees
• In adults with retrosigmoid placement of BB we see better performance - new issues for physiology of bone conduction!
YES, WE RESTORE BINAURAL HEARING WITH CI, SOUNDBRIDGE, BONEBRIDGE IN KIDS & ADULTS