Implantable hearing devices: Where we are

Milan Profant
Lukáš Varga, Zuzana Kabátová

Univ. Dept. of ORL HNS, Bratislava Slovakia
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

<table>
<thead>
<tr>
<th>Implanted to the bone</th>
<th>Transcutaneous active</th>
<th>Transcutaneous passive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percutaneous</td>
<td>Transcutaneous active</td>
<td>Transcutaneous passive</td>
</tr>
<tr>
<td>Baha Connect</td>
<td>Ponto</td>
<td>Sentio</td>
</tr>
<tr>
<td>Bonebridge</td>
<td>Sophono</td>
<td>Baha Attract</td>
</tr>
<tr>
<td>Tlak na kość</td>
<td>Prilepenie na kožu</td>
<td></td>
</tr>
<tr>
<td>Soft Band</td>
<td>Adhear</td>
<td></td>
</tr>
</tbody>
</table>
## AMI

### Middle ear

<table>
<thead>
<tr>
<th>Transcutaneous active or fully implantable</th>
<th>Semi-implatable (elektromagnetic)</th>
<th>Fully impl. (piezoelectric)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SoundBridge VSB</td>
<td>DACS</td>
<td>MET</td>
</tr>
</tbody>
</table>
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\geq35 \text{ 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

<table>
<thead>
<tr>
<th>Device</th>
<th>Measured MPO</th>
<th>Reference</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sophono Alpha 1</td>
<td>56 dB HL</td>
<td>Hol et al., 2013</td>
<td>Sophono, Boulder, US</td>
</tr>
<tr>
<td>Bonebridge</td>
<td>65 dB HL</td>
<td>Mertens et al, 2014</td>
<td>Med-El, Innsbruck, Austria</td>
</tr>
<tr>
<td>Standard Ponto</td>
<td>Idem</td>
<td>Zwartenkot et al. 2014</td>
<td>Oticon Medical, Askim, Sweden</td>
</tr>
<tr>
<td>Baha Cordelle, Baha 5 SuperPower*; Ponto 3 SuperPower*</td>
<td>80-85 dB HL</td>
<td>Idem</td>
<td>Cochlear BAS, Goteborg, Sweden Oticon Medical, Askim, Sweden</td>
</tr>
<tr>
<td>Vibrant Soundbridge</td>
<td>85 dB HL</td>
<td>Idem</td>
<td>Med-El, Innsbruck, Austria</td>
</tr>
<tr>
<td>Codacs</td>
<td>100 dB HL?</td>
<td>Idem</td>
<td>Cochlear Mechelen, Belgium</td>
</tr>
</tbody>
</table>

* updated spring 2017

http://www.snikimplants.nl
# Maximal BC threshold

<table>
<thead>
<tr>
<th>Device</th>
<th>Measured MPO*</th>
<th>Max SNHLc if the ‘DR 2/3 rule’ is used</th>
<th>Max SNHLc if the “DR&gt;35 dB rule” is used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sophono Alpha 1</td>
<td>56 dB HL</td>
<td>5 dB HL</td>
<td>20 dB HL</td>
</tr>
<tr>
<td>Bonebridge</td>
<td>65 dB HL</td>
<td>20 dB HL</td>
<td>30 dB HL</td>
</tr>
<tr>
<td>Standard Baha Divino/BP100</td>
<td>67-69 dB HL</td>
<td>25-30 dB HL</td>
<td>30-35 dB HL</td>
</tr>
<tr>
<td>Standard Ponto</td>
<td>Idem</td>
<td>25-30 dB HL</td>
<td>30-35 dB HL</td>
</tr>
<tr>
<td>Baha Cordelle</td>
<td>80 dB HL</td>
<td>45 dB HL</td>
<td>45 dB HL</td>
</tr>
<tr>
<td>Vibrant Soundbridge</td>
<td>85 dB HL</td>
<td>50 dB HL</td>
<td>50 dB HL</td>
</tr>
<tr>
<td>Codacs</td>
<td>100 dB HL?</td>
<td>&gt;65 dB HL</td>
<td>&gt;65 dB HL</td>
</tr>
</tbody>
</table>

[http://www.snikimplants.nl](http://www.snikimplants.nl)
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
- D1Incus long process
- Stapes
- Piston

BC threshold 50dB (RW application)
Vibrant Soundbridge with Couplers

- Incus – short process
- Stapes head
- Incus – long process
Implantable hearing devices
Mixed hearing loss: When to implant

- Primary surgery
  - Externall and middle ear atresia uni- and bilateral
- Revision surgery
  - Second revision in unfavorable anatomical and functional confition
  - 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
- 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

<table>
<thead>
<tr>
<th></th>
<th>BAHA</th>
<th>BB</th>
<th>VSB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of patients</td>
<td>13</td>
<td>10</td>
<td>29</td>
</tr>
<tr>
<td>N=52</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of adult patients</td>
<td>10</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>(18+)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>M:F</td>
<td>6M:3F</td>
<td>3M:5F</td>
<td>2M:14F</td>
</tr>
<tr>
<td>Average age</td>
<td>14.2</td>
<td>36.25</td>
<td>48.25</td>
</tr>
<tr>
<td>Nonusers</td>
<td>1</td>
<td>0</td>
<td>4</td>
</tr>
</tbody>
</table>
Material
Indications

<table>
<thead>
<tr>
<th></th>
<th>BAHA (N1=10)</th>
<th>BB (N2=8)</th>
<th>VSB (N3=16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic otitis</td>
<td>6</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Atresia, stenosis of ear canal</td>
<td>3</td>
<td>3</td>
<td>11</td>
</tr>
<tr>
<td>SSD</td>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Tympanosclerosis</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Sensorineural HL</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>
Material to evaluate (N=34)

- Exclusion of paediatric patients
- Exclusion of non-users
- Series of 34 patients implanted with 3 different implants
  - BAHA
  - BoneBridge
  - VibrantSoundbridge
Speech audiometry

Speech Audiometry

- BAHA
- BB
- VSB

without implant vs with implant
Monosyllabic words

![Bar chart showing monosyllabic words with and without implant.](image)
Appreciation of implantable hearing devices by patients

**International outcome inventory for HA**

- Use
- Benefit
- Residual problems
- Satisfact
- Every day life
- Other people impact
- QoL

Evaluation scores range from 0 to 6.
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