Disclosures

Research grant through Advanced Bionics
Learning Objectives

1. Provide an overview of implantable and non-implantable bone conduction technologies

2. Detail candidacy criteria and common surgical procedures for implantable technology

3. Describe challenges to care from an ethical, geographical and limited resource perspective
Overview

1. Role of Audiology in Public Health
2. Evolution of Bone Conduction Technology
3. Fitting Considerations
4. Outcome Measures
5. Future Outlook
PUBLIC HEALTH AUDIOLOGY
649,947 square km

Population: 1.282 million
31 Public Health Audiologists

- 2 Audiologists
- 5 Audiologists
- 2 Audiologists
- 20 Audiologists
- 2 Audiologists

Winnipeg RHA
Northern RHA
Interlake-Eastern RHA
Prairie Mountain Health
Southern Health Santé Sud
Surgical Hearing Implant Program

HSC – Surgical

Central Speech & Hearing - Clinical
Universal Newborn Hearing Screening

12,115 babies born (Winnipeg)

11,746 babies screened for hearing loss (99%)

455 babies referred for full audiologic assessment (3.8%)

274 (60%) – Normal Hearing
97 (21%) – Confirmed Hearing Loss
84 (19%) – Not Yet Diagnosed/ Lost to Follow-Up

97 babies with confirmed hearing loss:

64 (66%) – Temporary Conductive Hearing Loss
3 (3%) – Permanent Conductive Hearing Loss
20 (21%) – Sensorineural Hearing Loss (SNHL)

MB UNHS - 2017
Role of Audiologist in Public Health

Clinician
System analyst
Patient advocate
Lobbyist
Accountant
Educator
Marketer
Quality control
Researcher
Event organizer
HR Specialist
Tech support
Government Investment (Manitoba)

- 2011 Surgical Hearing Implant Program
- 2013 Sound Processor Replacement Program
- 2014 Direct Referral to ENT
- 2016 Universal Newborn Hearing Screening
- 2016 Specialized Services for Children & Youth (SSCY)
- 2017 Jordan’s Principle / NIHB Investment
Public Health Audiology (Manitoba)

Hearing Screening → Diagnosis → Medical Evaluation → Candidacy Assessment → Rehab → Implantation → Early Intervention
BONE CONDUCTION TECHNOLOGY
Bone Conduction Hearing Devices

Amplification device that conducts sound directly to the cochlea via mechanical vibrations through the skull
Bone Conduction Devices

**Direct Drive**
- Percutaneous BAHA
- Cochlear BAHA
- Oton Ponto
- Med-El Bonebridge
- Cochlear “BCI”
- Oticon “BCI”

**Active Transcutaneous**
- Cochlear SoundArc
- Med-El AdHear
- Medtronic Sophono
- Cochlear Attract

**Passive Drive**
- Non-Magnetic
- Softband
- Med-El AdHear
- Medtronic Sophono
- Cochlear Attract

**Passive Transcutaneous**
Percutaneous Implants

Anchoring the hearing aid to the skull involves osseointegration, or the functional merging of living bone with a load bearing implant.

Osseointegration allows for an efficient and consistent delivery of amplified sound to the cochlea.
BAHD Components

External processor – contains the 3 essential hearing aid components: microphone, amplifier and receiver

Abutment – the coupling between the external processor and internal implant (6mm to 14mm)

Titanium implant – a 4mm screw drilled directly into the skull
Mixed/Conductive Hearing Loss

Comprises approximately 83% of our patient population

Hearing sensitivity at the cochlea is normal or near-normal

BCHD bypasses problematic middle ear space to send sound directly to inner ear

**Goal:** to restore hearing audibility for soft and average sounds
Single Sided Deafness

Comprises approximately 17% of our patient population

Better the bone conduction thresholds of contra ear = increased benefit

Reluctance to upgrade processors when needed due to reduced benefit
Surgical Procedure

Biopsy punch or incision makes a hole through the skin and soft tissue.

Specialized drill counter-sinks the 4mm titanium implant into the skull.

Abutment protrudes through skin by 3-4mm for device coupling.
Abutments

1st Generation
- Sharp Edges
- Skinny/Smooth
- Single Length

2nd Generation
- Rounded
- Wider Implant
- Single Length

3rd Generation
- Hydroxyapatite Coating
- Further Smoothing
- Variable Lengths

Recurrent post-operative skin issues have decreased from approximately 12% to 4-5% (but those that remain seem to be chronic and harder to resolve)
Case Study #1

40 year old female with bilateral mixed hearing loss

Chronic OM, previous mastoidectomy (right ear)

Fit on softband for 2-week trial with significant benefit

Allergy testing indicated negative to nickel/titanium

Immediately reported pain and significant swelling around implant site
10 days post-op
Significant pain around site

2 Months Post-op
Inflammation and Pain around Site

4 Month Post-op
Progressive Skin Growth

6 Month Post-op
Topical Treatments/Skin Resection

8 Months Post-op
Inflammation and Pain

12 Months Post-op
Abutment Removal
Case Study #2

7 year old male with bilateral microtia (Grade 2) and associated conductive hearing loss

Duane Syndrome, asthma, ADHD

Fit on softband at age 2

Responded positively with change in behaviour

First implant at age 5 (R) and second at age 6 (L)
3 Months Post-op
Granulation Tissue/Infection

4 Months Post-op
Topical Treatments/Skin Resection

6 Months Post-op
Granulation Tissue

10 Months Post-op
Abutment Extension (12 mm)

12 Months Post-Op
Inflammation/Infection

14 Months Post-op
Healed/No Infection
FITTING CONSIDERATIONS
Candidacy Criteria

BC Thresholds < 65 dBHL

Air-Bone Gap of > 30 dB @ .5, 1 & 2KHz

Minimum of 5 years of age

Subjective benefit from amplification
## Clinical Protocol

**Protocol includes**

- Pre-op assessment & audiogram
- 2-week trial on soft head band
- (Un)aided sub/obj outcome measures
- Implant/device selection
- Initial fitting and fine-tuning
- Aided thresholds in SF
- Aided SIN testing
- Coupler verification of user settings
- Aided subjective outcome measures

### Appointment Details

<table>
<thead>
<tr>
<th>Appointment Type</th>
<th>Description</th>
<th>Time (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Candidacy Assessment</td>
<td>Patients receive complete audiometric exam, including air/bone thresholds, speech audiometry, unaided pure tones in soundfield, unaided SIN testing.</td>
<td>1.0</td>
</tr>
<tr>
<td>2 Initial Consultation</td>
<td>Patients are provided with information on Baha technology, bone anchored implant technology, surgical procedure and risks, trial devices are programmed for use in the field with device orientation conducted. Patients are provided with manufacturer literature and a trial questionnaire for benefit assessment (custom).</td>
<td>1.0</td>
</tr>
<tr>
<td>3 Post-Consult</td>
<td>Patients return the trial device, completed questionnaire and subjective information are reviewed. Patient and provider decide on appropriate clinical course. Device selection performed at this time provided patient wants to proceed.</td>
<td>0.5</td>
</tr>
<tr>
<td>4 Device Activation</td>
<td>Wound and implant placement evaluated. Processor is activated according to software fitting prescription and fine-tuned per subjective comments. Device orientation conducted and practiced with patient. Patients provided with fine-tuning questionnaire (custom).</td>
<td>1.0</td>
</tr>
<tr>
<td>5 Post-Fit (1)</td>
<td>Device is cleaned and checked. Further fine-tuning as necessary. Completed questionnaire is reviewed. Questions/concerns addressed.</td>
<td>0.5</td>
</tr>
<tr>
<td>6 Post-Fit (2)</td>
<td>Device is cleaned and checked. Further fine-tuning as necessary. Questions/concerns addressed.</td>
<td>0.5</td>
</tr>
<tr>
<td>7 Post-Fit (3) - optional</td>
<td>Device is cleaned and checked. Further fine-tuning as necessary. Questions/concerns addressed. Patients provided with QOL/Satisfaction questionnaires.</td>
<td>0.5</td>
</tr>
<tr>
<td>8 Outcome Measures</td>
<td>Device is cleaned and checked. QOL/Satisfaction questionnaires are reviewed. Further fine-tuning as necessary. Electroacoustic measurements to document user settings. Sound field testing in booth. Aided thresholds, speech understanding in quiet/noise. Localization &amp; Quickspin Testing.</td>
<td>1.0</td>
</tr>
<tr>
<td>9 Troubleshooting (multiple)</td>
<td>Issues are assessed per patient. May require return visit.</td>
<td>0.5</td>
</tr>
<tr>
<td>10 Annual Review</td>
<td>Device is cleaned and checked. Further fine-tuning as necessary. Questions/concerns addressed. Repeat audiogram for monitoring purposes.</td>
<td>0.5</td>
</tr>
</tbody>
</table>
Candidacy Assessment

**Interview**
- History
- Motivations
- Expectations

**Audiometry**
- AC/BC pure tones
- Speech audiometry
- Speech in Noise Testing
- Unaided questionnaires
Softband Trial

**Cursory fitting**
- Generally 1 program (unless experienced user)
- Compensate for softband
- Conduct general orientation
- Assess subjective benefit (trial questionnaire)

**Common issues**
- Limited loaner bank, may be outdated technology
- Loaner devices are often lost/damaged
- Added gain can lead to excessive feedback
- Device placement not optimized
Subjective Questionnaire – Softband Trial

1. How often were you able to detect sound from your impaired ear?  
   (Circle one)  
   - Never  
   - Rarely  
   - Sometimes  
   - Often  
   - Always  
   Please describe:  

2. How often were you able to locate a sound source while wearing the BAHA?  
   (Circle one)  
   - Never  
   - Rarely  
   - Sometimes  
   - Often  
   - Always  
   Please describe:  

3. How often were you able to understand speech while wearing the BAHA?  
   (Circle one)  
   - Never  
   - Rarely  
   - Sometimes  
   - Often  
   - Always  
   Please describe:  

4. Were SOFT sounds ever too soft?  
   (Circle one)  
   - Y  
   - N  
   Please describe:  

5. Were LOUD sounds ever too loud?  
   (Circle one)  
   - Y  
   - N  
   Please describe:  

6. How would you rate the overall sound quality of the BAHA?  
   (Circle one)  
   - Very Poor  
   - Poor  
   - Okay  
   - Good  
   - Very Good  
   Please describe:  

7. How would you rate the sound quality/performance of the BAHA in these environments?  
   (Circle one)  
   - Quiet room with one other person  
   - Noisy restaurant/party  
   - Family or large group gathering  
   - In the car  
   - Large meeting with many people  
   - Auditorium or large hall  
   - Outside  
   - Watching TV  
   - Listening to Music  
   - Other:  

<table>
<thead>
<tr>
<th>Environment</th>
<th>Very Poor</th>
<th>Poor</th>
<th>Okay</th>
<th>Good</th>
<th>Very Good</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quiet room with one other person</td>
<td>Very Poor</td>
<td>Poor</td>
<td>Okay</td>
<td>Good</td>
<td>Very Good</td>
</tr>
<tr>
<td>Noisy restaurant/party</td>
<td>Very Poor</td>
<td>Poor</td>
<td>Okay</td>
<td>Good</td>
<td>Very Good</td>
</tr>
<tr>
<td>Family or large group gathering</td>
<td>Very Poor</td>
<td>Poor</td>
<td>Okay</td>
<td>Good</td>
<td>Very Good</td>
</tr>
<tr>
<td>In the car</td>
<td>Very Poor</td>
<td>Poor</td>
<td>Okay</td>
<td>Good</td>
<td>Very Good</td>
</tr>
<tr>
<td>Large meeting with many people</td>
<td>Very Poor</td>
<td>Poor</td>
<td>Okay</td>
<td>Good</td>
<td>Very Good</td>
</tr>
<tr>
<td>Auditorium or large hall</td>
<td>Very Poor</td>
<td>Poor</td>
<td>Okay</td>
<td>Good</td>
<td>Very Good</td>
</tr>
<tr>
<td>Outside</td>
<td>Very Poor</td>
<td>Poor</td>
<td>Okay</td>
<td>Good</td>
<td>Very Good</td>
</tr>
<tr>
<td>Watching TV</td>
<td>Very Poor</td>
<td>Poor</td>
<td>Okay</td>
<td>Good</td>
<td>Very Good</td>
</tr>
<tr>
<td>Listening to Music</td>
<td>Very Poor</td>
<td>Poor</td>
<td>Okay</td>
<td>Good</td>
<td>Very Good</td>
</tr>
<tr>
<td>Other:</td>
<td>Very Poor</td>
<td>Poor</td>
<td>Okay</td>
<td>Good</td>
<td>Very Good</td>
</tr>
</tbody>
</table>
Physical Fit

- Implant Placement: Angle, Length
- Feedback: Hats, Glasses, Helmets
- Performance: Height, Proximity
Device Activation

- Coupler target match
- In-situ audiometry
- Feedback Manager
- Gain adjustments
- Subjective impressions
- Soundfield validation

*Repeat as necessary*
Verification

Skull Simulator available from Audioscan and Interacoustics

Converts force output from BAHD to an electrical signal
Verification
Verification
Verification
Verification

<table>
<thead>
<tr>
<th>All</th>
<th>250</th>
<th>500</th>
<th>750</th>
<th>1k</th>
<th>1.5k</th>
<th>2k</th>
<th>3k</th>
<th>4k</th>
<th>6k</th>
<th>8k</th>
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</thead>
<tbody>
<tr>
<td>Loud</td>
<td>-33</td>
<td>-17</td>
<td>0</td>
<td>4</td>
<td>10</td>
<td>12</td>
<td>9</td>
<td>7</td>
<td>8</td>
<td>8</td>
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<tr>
<td>Moderate</td>
<td>-32</td>
<td>-14</td>
<td>3</td>
<td>4</td>
<td>10</td>
<td>12</td>
<td>9</td>
<td>7</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Soft</td>
<td>-17</td>
<td>-3</td>
<td>14</td>
<td>4</td>
<td>10</td>
<td>12</td>
<td>9</td>
<td>7</td>
<td>8</td>
<td>8</td>
</tr>
</tbody>
</table>
Verification
OUTCOME MEASURES
Validation

Aided thresholds in SF
Count the Dots Audiogram
SRT in SF
WRS in SF
SIN testing
Ling sounds
Frequency specific LDL’s
Subjective Questionnaire – Unaided vs. Aided

DOSO - Form C

1. Making loud speech clear?
   A. Not at all
   B. A little
   C. Somewhat
   D. Medium
   E. Considerably
   F. Greatly
   G. Tremendously

2. Eliminating the need to have someone else explain what was said?
   A. Not at all
   B. A little
   C. Somewhat
   D. Medium
   E. Considerably
   F. Greatly
   G. Tremendously

3. Making other people’s voices sound clear in a moving car?
   A. Not at all
   B. A little
   C. Somewhat
   D. Medium
   E. Considerably
   F. Greatly
   G. Tremendously

4. Making children’s voices understandable?
   A. Not at all
   B. A little
   C. Somewhat
   D. Medium
   E. Considerably
   F. Greatly
   G. Tremendously

5. Catching the beginning of sentences?
   A. Not at all
   B. A little
   C. Somewhat
   D. Medium
   E. Considerably
   F. Greatly
   G. Tremendously

6. Picking up overhead announcements in stores?
   A. Not at all
   B. A little
   C. Somewhat
   D. Medium
   E. Considerably
   F. Greatly
   G. Tremendously

7. Catching your name being called in a waiting room?
   A. Not at all
   B. A little
   C. Somewhat
   D. Medium
   E. Considerably
   F. Greatly
   G. Tremendously

8. Picking up speech when the talker’s lips are not visible?
   A. Not at all
   B. A little
   C. Somewhat
   D. Medium
   E. Considerably
   F. Greatly
   G. Tremendously

9. Catching what waiters say in a busy restaurant?
   A. Not at all
   B. A little
   C. Somewhat
   D. Medium
   E. Considerably
   F. Greatly
   G. Tremendously

10. Catching what someone says on the first try?
    A. Not at all
    B. A little
    C. Somewhat
    D. Medium
    E. Considerably
    F. Greatly
    G. Tremendously

11. Picking up soft sounds that follow loud ones?
    A. Not at all
    B. A little
    C. Somewhat
    D. Medium
    E. Considerably
    F. Greatly
    G. Tremendously

12. Making speech clear in a face-to-face conversation?
    A. Not at all
    B. A little
    C. Somewhat
    D. Medium
    E. Considerably
    F. Greatly
    G. Tremendously

13. Picking up what strangers say the first time?
    A. Not at all
    B. A little
    C. Somewhat
    D. Medium
    E. Considerably
    F. Greatly
    G. Tremendously

14. Improving enjoyment of everyday activities?
    A. Not at all
    B. A little
    C. Somewhat
    D. Medium
    E. Considerably
    F. Greatly
    G. Tremendously

15. Catching the words when someone speaks from another room?
    A. Not at all
    B. A little
    C. Somewhat
    D. Medium
    E. Considerably
    F. Greatly
    G. Tremendously

16. Picking up what someone says across a large room?
    A. Not at all
    B. A little
    C. Somewhat
    D. Medium
    E. Considerably
    F. Greatly
    G. Tremendously

17. Picking up sounds that are mixed without them?
    A. Not at all
    B. A little
    C. Somewhat
    D. Medium
    E. Considerably
    F. Greatly
    G. Tremendously

18. Catching a person’s name when they are introduced?
    A. Not at all
    B. A little
    C. Somewhat
    D. Medium
    E. Considerably
    F. Greatly
    G. Tremendously

(continued over page)
Results

BAHD Subjective Benefit: Mixed/CHL (12 months), n=40

Subjective Benefit (1=Minimum, 7=Maximum)

DOSO Question

Unaided
Aided
### Subjective Questionnaire (HHIE) – Unaided vs. Aided

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes (4 pts)</th>
<th>Sometimes (2 pts)</th>
<th>No (0 pts)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does a hearing problem cause you to feel embarrassed when meeting new people?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does a hearing problem cause you to feel frustrated when talking to members of your family?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have difficulty hearing when someone speaks in a whisper?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you feel handicapped by a hearing problem?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does a hearing problem cause you difficulty when visiting friends, relatives, or neighbors?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does a hearing problem cause you to attend religious services less often than you would like?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does a hearing problem cause you to have arguments with family members?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does a hearing problem cause you difficulty when listening to TV or radio?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you feel that any difficulty with your hearing limits or hampers your personal or social life?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does a hearing problem cause you difficulty when in a restaurant with relatives or friends?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TOTAL SCORE = _______ (sum of the points assigned to each of the items)**

Results

**BAHD Subjective Benefit: Mixed/CHL (12 months), n=40**

- **No Hearing Handicap**
- **Mild-Mod Hearing Handicap**
- **Significant Hearing Handicap**

Pre-Implant vs. Post-Implant comparison.
FUTURE OUTLOOK
Future Outlook

Active transcutaneous implants

On-ear verification
Future Outlook

Clinician
System analyst
Patient advocate
Lobbyist
Accountant
Educator
Marketer
Quality control
Researcher
Event organizer
HR Specialist
Tech support
References


References


References


Thank You