Implantable Hearing Devices
Indications, Surgery, Outcome

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# Devices and Indications

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<th>Indications</th>
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<td><strong>Active Middle Ear Implants</strong></td>
<td>SNHL, CHL, mixed in selected cases</td>
</tr>
<tr>
<td><strong>Cochlear Implants and ABI</strong></td>
<td>Severe to Profound SNHL</td>
</tr>
<tr>
<td><strong>Hybrid electrodes (EAS)</strong></td>
<td>Hi-frequency SNHL</td>
</tr>
<tr>
<td><strong>Bone Anchored Hearing Device (BAHA)</strong></td>
<td>CHL, Mixed HL SSD</td>
</tr>
</tbody>
</table>
Active Middle Ear Implants

- Ossicular chain drivers
- Simplify a 3 steps process to a 2 steps process
- Direct drivers of the ossicular chain
  - Transduction of amplified electrical to acoustic, then to vibrational
  - Transduction from electrical directly to vibrational
<table>
<thead>
<tr>
<th>Population</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 M</td>
<td>Million with hearing loss</td>
</tr>
<tr>
<td>16 M</td>
<td>Moderate to moderate-severe hearing loss</td>
</tr>
<tr>
<td>6 M</td>
<td>Own HA</td>
</tr>
<tr>
<td>5 M</td>
<td>Use HA</td>
</tr>
<tr>
<td>2.4 M</td>
<td>Unhappy with HA</td>
</tr>
<tr>
<td>25%</td>
<td>Of people &gt;55 need amplification</td>
</tr>
</tbody>
</table>
Problems with Hearing Aids

Reasons for complaints:

Occlusion effects
Distortion
Feedback
Discomfort
Stigma of wearing a hearing aid
# Active Middle Ear Implants

- **Partially implantable**
  - Vibrant Med-EL
  - Otologics MET
  - Ototronix Maxum
  - Transducer type
  - Electromagnetic

- **Totally implantable**
  - Envoy Esteem
  - Otologics MET
  - Piezoelectric
  - Electromagnetic
Envoy Medical Corporation
Esteem® — The Hearing Implant

Only FDA fully implantable prosthetic hearing restoration device for SNHL
Esteem uses the ear drum as a microphone
Maintenance free battery lasting from 4.5 to 9 years
Esteem® – The Hearing Implant

- FDA approved
- Surgical training courses are being conducted in the US
- CE Mark obtained
- Being implanted in Europe, and Middle East
Esteem® - The Hearing Implant™

Components

SENSOR  SOUND PROCESSOR  DRIVER

Sensor at the malleus/incus  Holds the battery  Driver at the stapes

The sound Processor is programmed by a health care professional to customize Esteem settings to the particular hearing needs of the patient
The *Esteem®* Hearing Implant

**Programming**

- **Esteem Programmer**
  - Health care professional

- **Personal Programmer**
  - Remote control turns the device on and off
  - Volume Selection
  - Selection of one of 3 programs
Esteem® Sound Processor/Battery

- Sound Processor/Battery life is 4.5 to 9 years
- Battery never needs recharging
- Sound Processor/Battery change is done under local anesthesia
- Patient hears dual tone beeps approximately 1 to 1.5 months prior to Sound Processor/Battery change
The *Esteem®* Hearing Implant

- Mastoid surgery
- Extended facial recess to access the ossicular chain
- Ossicular chain disarticulation (long process of incus lasered and removed)
- Sensor and driver connected to incus and stapes respectively
The *Esteem®* Hearing Implant Indications

- 18 years of age or older
- Stable bilateral SNHL
- Moderate to severe SNHL
- Unaided speech discrimination test score greater than or equal to 40%
- Normal TM and middle ear
- Adequate mastoid size (CT)
- Minimum 30 days experience with appropriately fit hearing aids
The *Esteem®* Hearing Implant
Adverse Events

- 5% revision rate
- 2% explant rate
- Taste disturbance 42% (14% at one year)
- Facial paralysis /paresis 7% (1% at one year)
- Tinnitus 18% (5% at one year)
The *Esteem®* Hearing Implant Results

- Mean SRT improvement compared to pre-implant hearing aid use is 10.6 dB

- 93% scored on Word Recognition *equal (37%)* to or *better (56%)* than their pre-implant hearing aid

- 80% rated Esteem *equal (21%)* to or *better (60%)* than their pre-implant hearing aid

- On Quality of life measures the majority of patients consider the Esteem somewhat or much better than their hearing aid
VIBRANT MED EL

• Semi Implantable device

• FDA approved for the SNHL indication

• Undergoing clinical trials for the Round Window application in patients with conductive or mixed hearing loss
  – Feasibility study 25 subjects done with robust results
  – Pivotal study adding another 25 subjects
VIBRANT MED EL Components

- External audio processor
  - Held in place with a permanent magnet
  - Battery

- Implanted receiver

- FMT “floating mass transducer”
  (permanent magnet suspended in a titanium can wrapped with gold wire)
VIBRANT MED EL Surgery

• Mastoidectomy and facial recess approach

• Magnet placed against the incudo stapedial joint for the SNHL application

• Magnet placed against the Round window in conductive hearing loss and mixed hearing loss cases

The FMT™ should be in contact with the incudostapedial joint and parallel to the axis of motion of the stapes
Patient Selection Criteria

- Adults 18+
- Word recognition score 50% or better
- Normal middle ear function
- Realistic expectations
Better Sound Quality

Overall Sound Quality
- Vibrant Soundbridge: 89%
- Hearing Aid: 18%

Clearness of Sound Tone
- Vibrant Soundbridge: 86%
- Hearing Aid: 31%

Naturalness of Speech
- Vibrant Soundbridge: 90%
- Hearing Aid: 27%

Satisfaction
- Vibrant Soundbridge
- Hearing Aid
FMT on round window membrane

• Magnet placed against the Round Window in conductive hearing loss and mixed hearing loss cases

• Failed revision tympanoplasties with Porps and Torps

Dry stable mastoid cavities
Implantation of a round window stimulator in a radical mastoidectomy cavity
Implantation of a round window stimulator in a radical mastoidectomy cavity
• Semi Implantable device for SNHL nearly 1000 patients in Europe.
• Fully implantable system (Europe):
  • 700+ SNHL Patients
  • 70+ Conductive and Mixed Loss Patients
• In the US, 86 clinical trial patients for the SNHL study implanted. Not FDA approved yet.
• Plan to start the Conductive/Mixed loss trial with the fully implantable device.
Implant

- Microphone
- Digital Signal Processor
- Battery
- Lead
- IS-1 Connector
- Receiver Coil
- Magnet
- Transducer
Surgical Procedure

Incision/Atticotomy
Surgical Procedure

Loading the MET Ossicular Stimulator

Transducer Placement
Otologics totally implantable
Attachment to Anatomy

Incus

Stapes

Oval Window

Round Window
Attachment to Anatomy

• Classic SNHL

• Conductive Loss
Placement
Adverse events

- Microphone issues
- Transducers issues and failures
Charging

- **Implant Charger**
  - Recharges battery of implant
  - Daily recharge takes less than 1 hour
  - Patient can use implant during re-charge

- **Base Station**
  - Charges implant charger

- **Implant Battery**
  - Warranted for 5 years
  - Life > 12 years
Remote

- Volume control
- On/Off
Candidacy
APHAB

N=25
Planned Clinical Trials

• Sensorineural Hearing Loss
  • Completed Phase II B trial

• Conductive and Mixed Hearing Loss

• Atresia
Beyond hearing aids...before cochlear implants.
MAXUM BTE Design

IPC Design (ITE or CIC)

Implant
MAXUM Keys

- Minimally invasive
- Simple, safe procedure
  - Transcanal approach
  - No cutting of I-S joint
- Surgery performed under local anesthetic
  - Can be done in a procedure room
  - Surgical center not required
- Surgical time: ~30 min.
Adverse Events

- No serious device related events
- No implant failures, extrusion or dislodgements
- No revisions
- No severe loss of hearing
- No incus necrosis or I-S joint separation
- All adverse events were unrelated, transitory or patient recovered without sequelae
- Residual hearing change: -4.2 dB
  - Due to mass loading of implant
FDA Approved

- **Indications**
  - Adults – 18 years of age and older
  - Moderate to severe sensorineural hearing loss

- **Contraindications**
  - Conductive hearing loss
  - Retrocochlear or central auditory disorder
  - Active middle ear infections
  - Tympanic membrane perforations associated with recurrent middle ear infections
  - Disabling tinnitus
Functional Gain

- Average MAXUM Gain: 7.0-7.9 dB PTA Gain over HA
- 9.2-10.8 dB HF Gain over HA

The chart shows the mean functional gain dB across different frequencies (0.25K, 1K, 3K, 6K) for Hearing Aid and MAXUM. The graph highlights the gains at various frequencies, with the "Average MAXUM" box indicating the range of gain values.
Device Preference

- Occlusion
- Sound Quality
- Less Feedback
- Satisfaction

MAXUM

Hearing Aid

OTOTRONIX
Active Middle Ear Implants

• Rationale:
  – Better cosmesis
  – Precludes occlusion effect
  – Improves sound fidelity (eliminates receiver and drives middle ear directly)
  – Avoidance of feedback
  – Increases high frequency emphasis and gain
Implantable Middle Ear Devices

• Challenges and risks
  – Long-term injury to the ossicular chain
  – Risks to the facial nerve
  – General anesthesia
  – Total loss of hearing
  – Multiple surgeries to replace battery
  – MRI compatibility
  – Costs
Implantable Hearing Devices
The BAHA system

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The BAHA System
Bone - Titanium Interface
Osseointegration
Limitations in using bone-conduction hearing aids

- Discomfort caused by pressure on mastoid
- Difficulty in maintaining sufficient tension on headband
- Frequent readjustment due to tension failures
- Pressure sores
- Headaches
BAHA BP 100
BAHA Intenso
The Oticon Ponto Product System

- Advanced processing
- Easy to use
- Easy to configure
Oticon Medical Ponto Processor Mechanics

- Housing and Vibrator
  - High performance transducer
  - Transducer impact protection
Two models: Ponto Pro and Ponto

<table>
<thead>
<tr>
<th>Features</th>
<th>Ponto Pro</th>
<th>Ponto</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 channel frequency response shaping</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Multiband Adaptive Directionality</td>
<td>Automatic</td>
<td>Manual</td>
</tr>
<tr>
<td>Tri-state Noise Reduction</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Data Logging</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Learning Volume Control</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Wind Noise Reduction</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Output AGC</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Up to 4 programs</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Volume Control</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Start-up delay</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Mute function</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Low battery warning</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Telecoil/DAI/FM input</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Fitting software, Genie Medical</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Styles available</td>
<td>Left and right</td>
<td>Left and right</td>
</tr>
<tr>
<td>Color palette</td>
<td>Chroma Beige, Mocca Brown, Diamond Black</td>
<td>Chroma Beige, Mocca Brown, Diamond Black</td>
</tr>
</tbody>
</table>
Selection Criteria: Audiologic

- Bone-conduction thresholds cannot exceed 45-50 dB HL for BAHA BP 100, Intenso
- Bone-conduction thresholds cannot exceed 65 dB HL for Cordelle II
Medical / Surgical indications

- Mixed and conductive hearing loss
  unilateral or bilateral fitting
- Chronic otitis media
- Congenital atresia
- Cholesteatoma
- Middle ear dysfunction/disease
- Mastoid cavities
- Recurrent otitis externa
- Post Surgical conditions, such as following cancer resections
Bilateral conductive hearing loss with normal inner ear function.

Diagnosis example: Bilateral microtia
Bilateral Mixed Hearing Loss

Bilateral mixed hearing loss

Diagnosis example: right ear – cholesteatoma operation,
left ear – chronically draining
Severe mixed or sensorineural hearing loss

Diagnosis example: Chronic draining ears for 25 years with 5 – 8 surgeries per ear, one still draining.

* This would be a BAHA Cordelle candidate but still might not receive the required gain.
Medical / Surgical indications

- Unilateral sensorineural hearing loss, or Single Sided Deafness (SSD)

Possible causes include:
- Acoustic neuroma tumor removal
- Sudden sensorineural hearing loss
- Neurological degenerative disease
- Trauma
- Ototoxic treatments (e.g. gentamycin)
- Inner ear malformation
- Genetic
Single Sided Deafness

Diagnosis example: acoustic neuroma removal, left ear.
Selection Criteria: Practical

- Adequate manual dexterity
- Assistance with visual inspection of the abutment and surrounding skin interface
- Realistic expectations
Advantages of the BAHA System over other treatments
Mixed and Conductive Hearing Loss

<table>
<thead>
<tr>
<th>Over bone conduction devices</th>
<th>Over air conduction devices</th>
<th>Over reconstructive surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>• More comfortable</td>
<td>• No occlusion of the ear canal</td>
<td>• Predictable results</td>
</tr>
<tr>
<td>• Better sound quality</td>
<td>• No feedback problems</td>
<td>• Low risk for the patient</td>
</tr>
<tr>
<td>• Aesthetic appearance</td>
<td>• Sound bypasses the middle ear</td>
<td>• Reversible surgery</td>
</tr>
</tbody>
</table>
Implantation phase
1. 2-Stage
2. 1-Stage
Flap design

- Full thickness skin graft
- Split thickness skin graft
- Split thickness skin flap
- BAHA dermatome
- Single incision
  - Originated by Prof Cor Cremers (Nijmegen, Netherlands)
  - Gaining popularity
  - Different but results and complications are not better than the dermatome.
Keys to success
Single line incision
Simply clean around the abutment with a soft Entific cleaning brush and gentle soap. This type of cleaning should take place at a minimum 2 to 3 times weekly after the area is healed from surgery.
Successes and Complications of the BAHA System

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Matthew C. Farrugia, D.O.
Sujana S. Chandrasekhar, M.D.
Soha N. Ghossaini, M.D.
Jaclyn B. Spitzer, Ph.D.
**Outcome Measures**

- **Incidence of complications:**
  - **Major complications:** requiring inpatient hospital care or associated significant morbidity.
    - meningitis,
    - brain abscess
    - Osteitis
    - acute mastoiditis.
  - **Minor complications:** Requiring minimal office treatment or revision ambulatory surgery.

- **Patient satisfaction:** A questionnaire was administered on site, or by telephone.
Results

- **Total patients**: 218 (June 1998 and December 2007).
- **Bilateral implantation**: 5
- **Implanted ears**: 223
- **Single-Sided Deafness**: 114 patients
- **Conductive/ Mixed hearing loss**: 104 patients (109 ears)
Results

- **Men**: 96 (44%)
- **Women**: 122 (56%)
- **Age**: 6 to 92 years
  - **Average**: 56.5 years.
- **Follow up period**: 4 months to 114 months (9.5 years)
  - **Average**: 44 months (3.67 years)
Single Sided Deafness Diagnoses

- SSNHL: 42%
- Meniere's Disease: 20%
- Acoustic Neuroma: 24%
- Trauma: 3%
- Other: 6%
- Congenital: 5%
Conductive Hearing Loss Diagnoses

- Chronic Otitis: 62%
- Congenital Aural Atresia: 29%
- Otosclerosis: 5%
- Tumor: 4%
Device Usage

Days/ Week

Hours/ Day

SSD
CHL
Overall
Life Improved By the Device?

- Yes: 77%, 75%, 80%
- No: 23%, 25%, 20%
Complications

- Bone
  - Infection
  - Failure of osseointegration
    - Immediate
    - delayed

- Soft tissue
Minor Complications Requiring Local Care in 223 Implanted Ears

- Cellulitis: 10 cases
- Dermatitis: 3 cases
- Neuralgia: 3 cases
- Immed. Post-Op Comp: 2 cases
Minor Complications Requiring In-Office Procedures in 223 Implanted Ears

- Keloid Needing Kenalog Injection: 4
- Skin overgrowth/granulation requiring excision: 4
- I&D of Abscess/ Hematoma: 2
- Need for longer abutment: 1
Complications Requiring Revision Surgery in 223 Implanted Ears

- Hypertrophic Scar requiring flap revision: 10
- Fixture Extrusion: 3
# Proposed Soft Tissue Reaction Grading Scale

<table>
<thead>
<tr>
<th>Grade</th>
<th>Clinical Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No irritation: Epithelial debris removed if present.</td>
</tr>
<tr>
<td>2</td>
<td>Slight redness: Temporary local treatment indicated.</td>
</tr>
<tr>
<td>3</td>
<td>Red and slightly moist; No granulation tissue present.</td>
</tr>
<tr>
<td>4</td>
<td>Red and moist with granulation tissue, skin overgrowth, or scar formation: Local treatment indicated.</td>
</tr>
<tr>
<td>5</td>
<td>Extensive granulation, skin overgrowth, or scar formation requiring revision surgery.</td>
</tr>
<tr>
<td>6</td>
<td>Removal of skin-penetrating abutment necessary to control infection.</td>
</tr>
</tbody>
</table>
Peri-abutment inflammation (Grade III)
Peri-abutment inflammation (Grade V)
Hypertrophic scar / keloid formation (grade V)
Advantages of grading

- Allows comparative reporting of results between clinics or techniques (dermatome, free hand flaps, linear incision...)

- Allows for meta-analysis and other statistical analyses.
- Successful BAHA implantation is dependent on well-established bone and soft tissue techniques.
- While surgical techniques continuously evolve, it is imperative that surgeons not disregard the basic principles that led us to where we are now.
Conclusion

- The BAHA System is safe and well-received by patients.

- Key features in maximizing success and minimizing complications are:
  - Proper patient selection
  - Accurate location of the implant
  - Strict handling of the implant
  - Creating a thin, hairless, immobile flap
  - Generous wide subcutaneous tissue thinning.
  - Learning the technique through hands-on courses and live surgical observations.
Single sided deafness

- A Behind The Ear (BTE) wireless microphone unit is placed on the deaf ear
- Sound is captured, processed and wirelessly transmitted by the BTE to the ITM

- Behind The Ear (BTE) Microphone Unit
- Microphone is in ear canal
- In The Mouth (ITM) Hearing Device as worn
Our Core Technology Platform: ITM Hearing & Communication Device

“Earless” Sound Delivery that’s invisible, removable, and non-invasive
How it Works: Bone Conduction

Our Technology is New Use of this Well-Established Method of Sound Transmission

- The ITM wirelessly receives sound signals from an external transmitter (such as a behind the ear microphone, cell phone, or radio)
- Signals are processed into imperceptible sound vibrations which travel via bone to the cochleae
System Charger for BTE & ITM
Rechargeable Components
Introducing
TransEAR
380-HF