

September 30 2014

Implantable Auditory Technologies

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Financial Disclosure

- Ravi Sockalingam is a full-time employee of Oticon Medical LLC

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Agenda

- Middle Ear Implants
 - Semi-implantable
 - Fully implantable
- Implantable Bone Conduction Technologies
 - Percutaneous bone anchored (osseointegrated) hearing devices
 - Transcutaneous bone anchored solutions
 - Active (direct-drive) where the vibrator is implanted
 - Passive (skin-drive) where magnet is implanted but vibrator is still outside
- Cochlear Implants (CI)
- Auditory Brainstem Implants (ABI)

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Middle ear Implants are.....



- Surgically implanted
- Based on direct stimulation of cochlea by vibrating the middle ear ossicles
- Indicated for adults (greater than 18 years of age) with moderate to severe sensorineural hearing loss*
- Requires normal middle ear structure and function*
- Meant for people who do not benefit from traditional hearing aids

* indications that are FDA cleared in USA



Other indications for some of the middle ear implants– particularly outside of the US

- Recurrent otitis externa
- Abnormal pinna
- Abnormal ear canal
- Occlusion
- Feedback
- Mastoid cavity problem
- Insufficient benefit from middle ear surgery

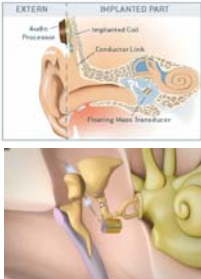
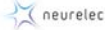

Considerations:

- Surgical risks and complications
- General versus local anesthesia
- Fully-implantable versus semi-implantable
- Reversibility
- MRI compatibility
- Cost (reimbursement)





Med-EL Vibrant Soundbridge

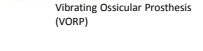
- Originally developed by Symphonix of San Jose, CA
- FDA cleared in 2000, CE marked in 1998
- Became Med-EL Vibrant Soundbridge in 2002
- Over 1000 implantations performed in the US and Europe; most widely used middle ear implant
- Based on electromagnetic stimulation
- FMT is crimped around long process of the incus – Incus Vibroplasty
- Improved patient satisfaction and sound quality, less feedback and occlusion (Snik and Cremers, 1999; Sterkers, 2003)


Middle Ear Implant – Semi Implantable
MED-EL Vibrant Soundbridge



Audio Processor

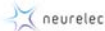



Vibrating Ossicular Prosthesis (VORP)



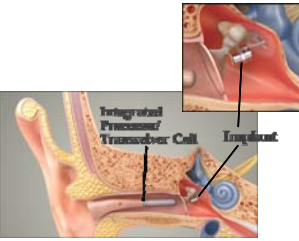
Floating Mass Transducer (FMT) attached to the incudostapedial junction

Bilateral moderate to severe sensorineural hearing loss
Totally reversible and MRI compatible up to 1.5 Tesla
No gain at 125, 250 and 500 Hz






Semi-Implantable Middle Ear Implant- Maxum

- Introduced by Oticon (Houston USA based) in 2009; FDA cleared
- Indication: adults (> 18 years old) with bilateral severe to moderate sensorineural hearing loss
- Based on electromechanical stimulation
- Surgical procedure: minimally invasive transcanal approach under local anesthesia, 30-45 min
- Implant consists of a magnet and is attached to the incudostapedial joint
- Activation: 4 weeks post implantation
- Reversible, MRI compatibility up to 0.3 Tesla
- Least expensive middle ear implant



Integrated Piezoelectric Transducer Coil
Implant

Middle Ear Implants – Fully Implantable Carina




- Developed by Otologics LLC of Boulder Colorado; in its fourth generation
- Indication: >14 years old with post lingual moderate to severe sensorineural hearing loss, mixed conductive hearing loss (not very clear)
- Based on electromagnetic stimulation
- Electromagnetic transducer typically attached to laser drilled hole on body of incus
- 2 hour surgery under general anesthesia
- Internal battery lasts 10 years after which electronic capsule must be replaced; not transducer
- No MRI compatibility; not FDA approved
- Activation: 8 weeks post implantation
- Cost: ~ USD15K








Middle Ear Implant - Fully Implantable The Envoy Esteem Implant

- Developed by Envoy Medical Corporation, Minnesota, USA
- First FDA cleared fully implantable middle ear implant
- Indication: adults with bilateral sensorineural hearing loss; speech discrimination >50%
- Based on piezoelectric stimulation
- No microphones
- Consists of three parts: sensor, speech processor and driver
- Incus and stapes are disarticulated and long process of incus removed
- Activation: 45 days post implantation
- Battery life: 4.5 to 9 years
- No MRI compatibility

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 - Percutaneous bone anchored (osseointegrated) hearing devices
 - Transcutaneous bone anchored solutions
 - Active (direct-drive) where the vibrator is implanted
 - Passive (skin-drive) where the magnet is implanted but vibrator is still outside

Bone Conduction Technologies - Overview



Direct Drive
Features the most direct route when it comes to bone conduction. Since the vibrator is in direct contact with the bone, the energy transmission is more efficient than those devices that are damped by the skin (skin drive). Direct drive devices offers the best fitting range.

Skin Drive
A Skin drive device is limited in the fitting range due to the dampening by the skin, leading to transmission loss of about 10-20 dB. This is the old bone conduction solution. The Direct drive, like the percutaneous system, was developed to overcome the audiological drawbacks. A passive transcutaneous device will never be better than a softband.

Outline

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Bone Conduction Technologies - Overview

Bone Conduction Devices
Bo Håkansson (2013)

- Direct Drive**
 - Transcutaneous Implanted Transducer
 - BCI, Bonebridge
 - Percutaneous
 - Ponto Family BAHN
- Skin Drive**
 - Implanted Magnet
 - Sophono BAHN Attract
 - Headband Softband Glasses

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Indications for bone anchored hearing systems

- Unilateral profound SNHL
- Conductive and mixed hearing
- Recurrent otorrhea preventing conduction hearing aids

Contraindications for bone anchored hearing systems

- Bone conduction threshold > 55 dB HL
- Speech discrimination < 60%
- Age less than 5 years
- Poor hygiene

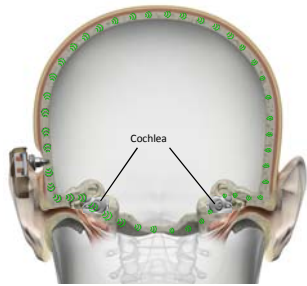
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Why a bone anchored hearing system?

- Most efficient transfer of vibrations to the skull and hence to the cochlea
- Delivers the best audiological outcomes for conductive, mixed hearing loss and single sided deafness
- Surgery is simple, straightforward and quick, and is typically performed under local anesthesia
- Reimbursable



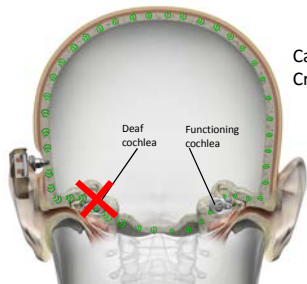
Bone anchored hearing



Vibrations are transmitted to both cochlear



Bone anchored hearing – Single Sided Deafness



Can work as a Cross hearing aid

One cochlea is picking up sound from both sides.







For a long time there was just one system:
BAHA
.....until 2009



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Percutaneous Bone Anchored Implant Hearing



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Percutaneous Implant-Abutment



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Abutment design

- different abutment lengths
- longer abutment lengths
- a design concept that supports the skin optimally

neel Wide Porto implant with 6 mm abutment Wide Porto implant with 9 mm abutment Wide Porto implant with 12 mm abutment oticon MEDICAL

Evolution in surgical techniques

- Dermatome**
 - Used since 2003
 - Hairless Skin flap
- Linear Incision**
 - Less invasive
 - Minimal tissue removal
- Biopsy Punch Technique**
 - Quick Surgery
 - No or Very Minimal tissue removal
 - Catching on and patients prefer

Tissue Preservation Surgery

A huge improvement for the patients*

- Better cosmetics
- Less numbness and pain
- Quicker healing
- Minimal scar tissue
- Quicker surgery
- Fully reversible

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Ponto Pro Sound Processor – smart, safe and reliable

Hole for safety line

Coupling

Battery door

Inlet for programming

Volume control

Direct Audio Input connector

Microphones

Push button:
• Program selection
• Stand-by/Mute

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Advances in Bone Anchored Hearing and the Ponto System

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The New Ponto Plus

User friendly push button for easy operating

Water resistant nano coating

Hole for safety line

IP 57 classification

Easy to access volume control

Metal spring coupling for durability and ease of use

Tamper resistant battery door & Low battery warning system

• With IP57 classification against moisture and dirt – the highest in its class*

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The most powerful sound processor

MFO curves (reproduced from official datasheets)

Frequency [Hz]	Baha 4 Connect [dB µN]	Ponto Plus [dB µN]	Ponto Plus Power [dB µN]
100	~75	~75	~75
1000	~105	~115	~125
10000	~85	~95	~105

Force Output [dB µN]

Frequency [Hz]





— Baha 4 Connect
— Ponto Plus
— Ponto Plus Power

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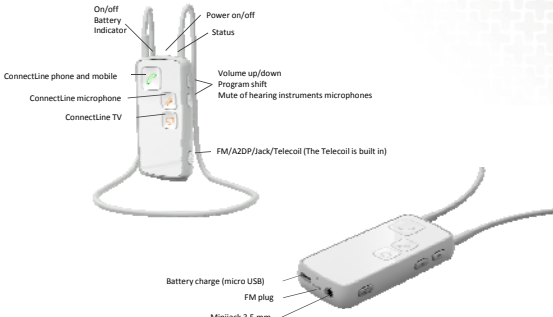
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Wireless Connectivity


- Connectivity to a broad range of bluetooth-enabled devices via a streamer



Ponto Streamer buttons/plugs



- On/off Battery Indicator
- Power on/off Status
- ConnectLine phone and mobile
- ConnectLine microphone
- ConnectLine TV
- Volume up/down
- Program shifts
- Mute of hearing instruments microphones
- FM/A2DP/jack/Telecoil (The Telecoil is built in)
- Battery charge (micro USB)
- FM plug
- Minijack 3.5 mm



ConnectLine and accessories

Extending the communication possibilities



The ConnectLine products are the same as for Oticon Streamer and hearing aids.



Measuring output of bone anchored processor via a skull simulator



- The Skull Simulator is used for the same purpose a 2cc coupler is used for hearing aids
- Using the Interacoustics Affinity hearing aid analyzer and the skull simulator, clinicians can measure the output of the sound processor



Why a bone anchored hearing system?



- Most efficient transfer of vibrations to the skull and hence to the cochlea via direct bone conduction
- Delivers the best audiological outcomes for conductive, mixed hearing loss and single sided deafness
- Surgery is simple, straightforward and quick, and is typically performed under local anesthesia
- Reimbursable
- MRI compatibility up to 3 Tesla



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Passive Transcutaneous – Skin Drive

- Never be better than softband
- Vibrations lost in transmission across skin 10-20 dB
- Critical holding force of the sound processor
- Price same as percutaneous.

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Transcutaneous solution - Passive

transcutaneous vs. percutaneous (skin dampening)

Working point of vibrator

Skin dampening

In-situ audiometry difference including change in vibrator working points

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Comparing sound processors.....

BP100

Baha 4 Connect

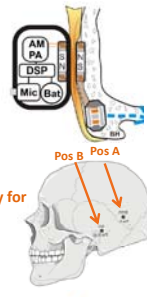
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Transcutaneous solutions -Active





Not available in the US


- Compared to percutaneous solutions:
- Inductive link will lose quite a bit of energy transmitted
- Moving from Pos A to Pos B will give increased sensitivity for ipsilateral cochlea in MF/HF (will be weak in LF)



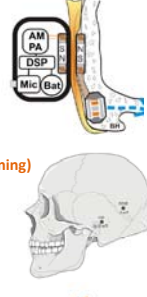
Note: Images from Bo Håkansson/Chalmers and www.medel.com





Transcutaneous solutions - Active



- Price is 2-3 times percutaneous. But less skin issues?
- Size of transducer could be limiting (careful surgical planning)
- MRI could be an issue



Note: Images from Bo Håkansson/Chalmers and www.medel.com






Wim Eeg-Dijffers MD


Prof. Bo Håkansson



BCI vs BoneBridge

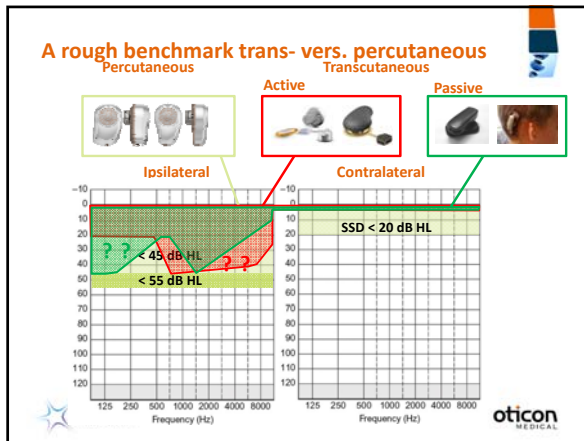


Not available in the US





<ul style="list-style-type: none"> • BCI-Bone Conduction Implant <ul style="list-style-type: none"> – Length: 55,5 mm – Depth 6,4 (7,4 centrally) – Size: 12 x 14 mm 	<ul style="list-style-type: none"> • Bonebridge Med-EI <ul style="list-style-type: none"> – Length: 69 mm – Depth: 8,9 mm – Size: 15,8 mm
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Eeg-Olofsson and Håkansson, 2014




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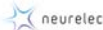

Cochlear Implant System



The featured implant system is not available in the US





Cochlear Implants – Principle



Cochlear Implant – Indications*

- Adults and children suffering from a bilateral severe to profound sensorineural hearing loss
- **No benefit using a conventional hearing aid**
- Pure Tone Audiometry exceed 70 dB (severe) to 90 dB (profound)
- Intelligibility usually between 30% and 60% at 65dB with H.A

**Indications depend on individual countries*



Cochlear Implants: Indictaions



- No medical contra-indications (malformation of the ear, psychologic disorders, etc.)
- Patient highly motivated and has realistic expectations
- Patient who can is able to attend the fitting and speech therapy sessions



Cochlear Implants: Indications in Children



- In children with prelingual deafness, cochlear implant candidacy is established when auditory skills fail to develop after amplification and aural rehab over a 3-month time period
- Implantation usually after 9-12 months

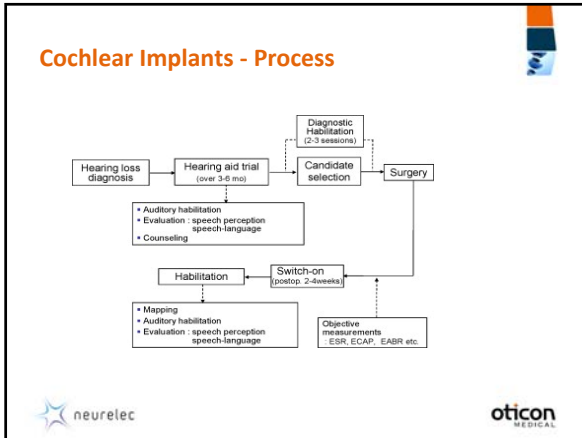


Bilateral Implantation



- In adults: possible in few developed countries (simultaneous after meningitis or trauma to sequential)
- In children: proposed now in most of developed countries:
 - post-meningitis/usher syndrome; congenital/prelingual deaf children (UK, France, Belgium..)
 - Simultaneous or sequential
- Advantage: localization, speech understanding in noise, better balance in children





- ### Cohlear Implants: Outcomes
- Low complication rates (3%): failures, infection, migration,
 - Wide variability of results but:
 - Adults with the shortest duration of deafness tend to experience better outcomes
 - The younger a child who was born deaf is implanted, the greater the benefit achieved in the areas of speech perception, and in speech and language development (< 2 years old)
 - Up to 70% of implanted children are integrated in normal school
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Advances in Cochlear Implant Systems

- Compact implant design allowing least invasive surgery
- Easy insertion of electrode array
- Safe fixation system
- Binaural System

The featured implant system is not available in the US

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Binaural Cochlear Implant System*


- The cost-effective alternative to bilateral implantation (2 implants + 2 processors) in adults
- Similar clinical outcomes compared to bilateral implantation

External part:



- Two microphones: 1 left and 1 right
- Only one speech processor

Internal part:

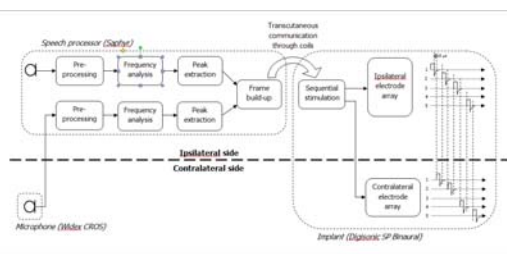
- Only one receiver/stimulator
- Two electrode arrays





*Not available in the US

Binaural Cochlear Implantation

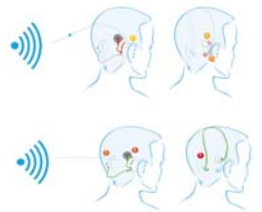







Binaural Cochlear Implant System

Each microphone corresponds to one electrode array



→ Sound routed to corresponding electrode array to restore stereophonic perception



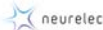

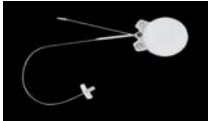
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Auditory Brainstem Implant System

- Indications: NF2, total ossification of cochlea, congenital aplasia
- Electrode-array with 15 flat stimulation electrodes that are attached directly to the brainstem.
- Each electrode stimulates a different region, enabling recipients to perceive a wide range of sounds.

How about the future?



Cochlear Implants → **Profound Sensorineural SSD**

Middle Ear Implants → **Moderate to severe sensorineural**

Percutaneous and Transcutaneous Solution → **SSD Mixed**

Cosmetics → **Audibility Sound quality**

THANK YOU FOR LISTENING!



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