Implantable Auditory Technologies

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Financial Disclosure

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

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 Ototronix (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

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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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 offer 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 traditional 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

- Middle Ear Implant

- Implantable Bone Conduction Technologies
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Bone Conduction Technologies
- Overview

Direct Drive
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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
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: BAHAs until 2009.

Percutaneous Bone Anchored Implant Hearing

Percutaneous Implant-Abutment
**Abutment design**

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

**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

*Hultcrantz (2011)
Ponto Pro Sound Processor – smart, safe and reliable

The New Ponto Plus

The most powerful sound processor
Wireless Connectivity

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

Ponto Streamer buttons/plugs

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.

Transcutaneous solution - Passive

Comparing sound processors........
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

• 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
BCI vs BoneBridge

- **BCI-Bone Conduction Implant**
  - Length: 55.5 mm
  - Depth: 6.4 (7.4 centrally)
  - Size: 12 x 14 mm

- **Bonebridge Med-EI**
  - Length: 69 mm
  - Depth: 8.9 mm
  - Size: 15.8 mm

Not available in the US

Eeg-Olofsson and Håkansson, 2014

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**A rough benchmark trans- vers. percutaneous**

**Percutaneous**

**Trancutaneous**

**Ipsilateral**

**Contralateral**

SSD < 20 dB HL

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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: Indications

- 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
Cochlear 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

Advances in Cochlear Implant Systems

- Compact implant design allowing least invasive surgery
- Easy insertion of electrode array
- Safe fixation system
- Binaural System
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
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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?
THANK YOU FOR LISTENING!

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