Bone Anchored Hearing Solutions: Past, Present, and Future

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Agenda

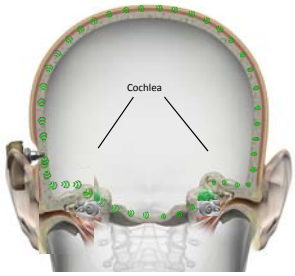
- The Concept
  - Branemark
- The beginning
  - The implants
- Now
  - The processors and accessories
- The future
  - Implants and other options

Who Was This For?

- Hearing loss
  - Cochlear reserve serviceable
- No ear canal
- Chronic ear drainage
- Otitis externa

Bone Conduction

Bone Conduction



Initial Instruments

Osseointegration (Branemark)

"The direct structural and functional connection between ordered living bone and the surface of a load carrying implant"

OSSEOINTEGRATION

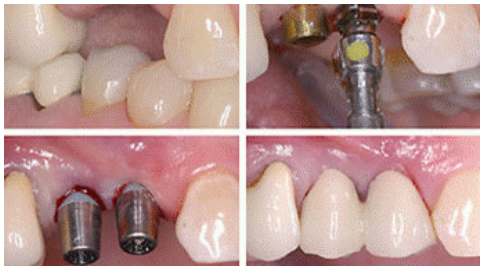
- Term coined by Professor Per-Ingvar Branemark
- Discovered the ability of living tissue to integrate with titanium
- An active bond between tissue and implant is created at the molecular level
- The titanium fixture/implant is not only accepted but also incorporated within the bone

Applications of Osseointegration

1965-Dental Implants

1977-Bone anchored implants for hearing

Dental Implant



Percutaneous Auditory Implant

Percutaneous Bone Anchored Hearing Device In Place

Percutaneous Implant

Benefit of Percutaneous Devices

- Sharper Sound Quality
- Greater Auditory gain
  - 10-25 dB as compared to bone conduction hearing aids.

Coming to Market

- Europe-1987
- United States-1997
- Single Sided Deafness-2002

Single Sided Deafness

- Criteria
  - Profound hearing loss in 1 ear.
  - Pure tone average of 20 dB or better in the better hearing side.

Single Sided Deafness

- Bone anchored hearing devices (BAHD) vs. CROS systems
  - Hol et al.-3 in 4 preferred BAHD
  - Lin et al.-BAHD produced better:
    - Subjective benefit
    - Sound localization
    - Speech discrimination in quiet and noise

FDA Indications for Bone Anchored Auditory Devices

- Unilateral profound SNHL with normal functioning contralateral ear.
- 2 of the following:
  - Conductive and mixed hearing loss
  - Recurrent otorrhea preventing the use of air conduction hearing aids
  - Surgically altered or malformed ear canals precluding use of air conduction hearing aids

Concerns

- Torque on implant
- Depth of Skull

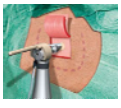
Result of These Concerns

- Shorter length of abutment
- Delayed loading of processors

In The Beginning

- 2 Stage Procedure
- Soft Tissue Reduction
- Exclude use in children aged under 5 years

Soft Tissue Reduction



Experience

- Staging unnecessary-1995
- Dermatome produced soft tissue problems
  - Up to 36% had abnormal healing-Van Rampaey
  - Delayed skin healing
  - Skin necrosis
  - Skin overgrowth over abutment

Single Stage

- FDA Recommendation-Processor loading in 3 months
- Studies—3-5 week loading is adequate

Surgical Innovations

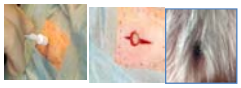
- The Wide Fixture

Multiple Sized Abutments

Surgical Innovations

- Linear Incision

- Biopsy Punch



Surgical Innovations

- Less soft tissue complications
- Shorter duration of surgery
- Better cosmesis

Soft Tissue Reduction

No Soft Tissue Reduction

Continued Challenges

- Continued delayed soft tissue complications
- Device extrusion/failure to osseointegrate
- Continued contraindications in children under 5 years of age

Contraindications to Percutaneous Bone Anchored Hearing Devices

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

MRI Compatibility?

- Yes to 1.5 Tesla machines

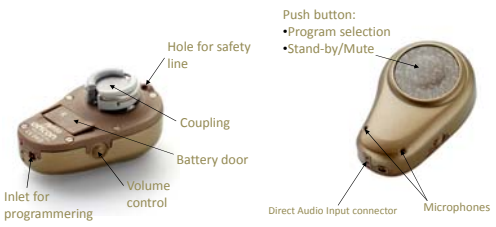
Processor Innovations

Was

Analog

Directional microphones
- Fixed and manual

Contemporary Processor



Processors With Greater Gain

Processors with Greater Gain

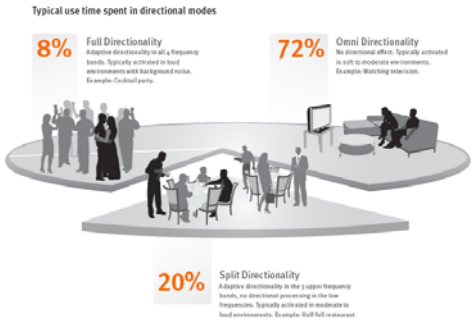
- Useful for patients with some sensorineural component to their hearing loss
- Bone conduction threshold < 55 dB

Automatic Multiband Adaptive Directionality

- **Multiband**: 4 frequency channels

- **3 modes**
  - No directionality (omni / surround)
  - **Split (High Frequency) directionality**
  - Full directionality
- **Automatic selection** between the **3 modes** based on sound level and best SNR

Directionality in more situations with Multiple Directionality Modes



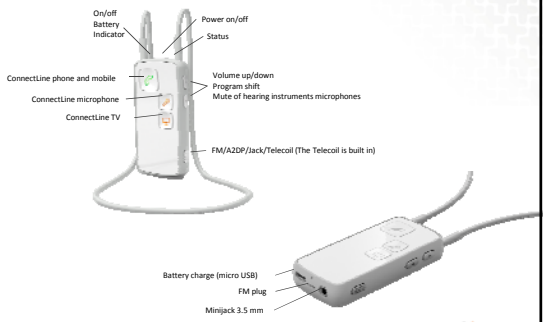
Benefit from Processor Itself

- Loss of head shadow effect
- Improved hearing in noise
- No need for additional hardware for single sided deafness

Continued Challenges with Processors

- Sound localization still poor
- Tinnitus is not alleviated

Ponto Streamer buttons/plugs



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Wireless Connectivity

- Connectivity to a broad range of blue tooth enabled devices via a streamer

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ConnectLine and accessories

Extending the communication possibilities

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

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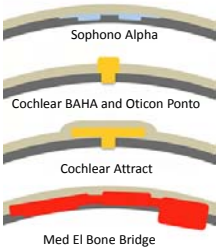
Transcutaneous Options

Transcutaneous Options



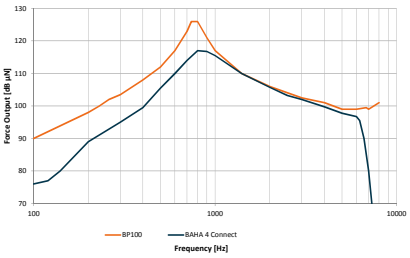
Benefit of Transcutaneous Options

- No visible components when not in use
- Less likelihood of delayed skin reactions
- Failure of osseointegration with extrusion not a risk
- Feedback not an issue

Cochlear Attract

Can Convert to Percutaneous device

Are They Equivalent?



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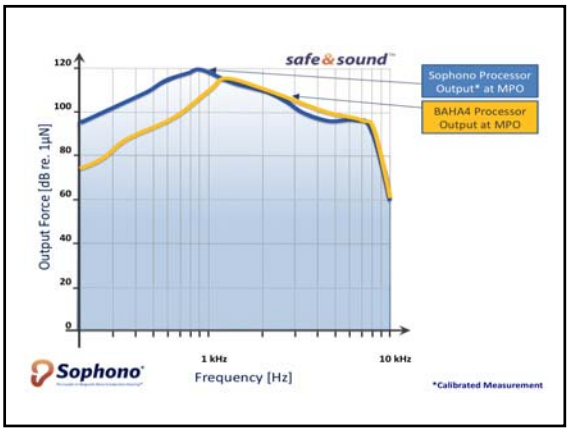
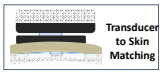
Transcutaneous Energy Transfer Processor

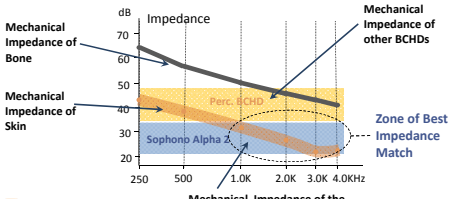


Sophono's TET™ Technology

safe&sound



In a system, where two parts are in **MECHANICAL CONTACT** and **FORCE** or **ENERGY** shall be **TRANSMITTED** from one to the other, then mechanical **IMPEDANCE MATCHING** is most important for **MAXIMUM TRANSFER** of **FORCE** or **ENERGY**



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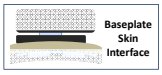
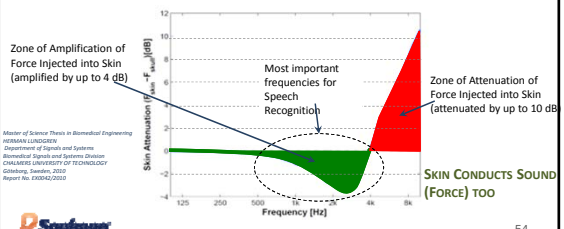


IF a given **FORCE** is **INJECTED** into the skin *(i.e. the portion that is not reflected)* – **THEN** a certain proportion of that **FORCE WILL ENTER THE BONE**. In certain frequencies (500Hz to 4kHz) the skin will actually **AMPLIFY** the **INJECTED FORCE**.



SKIN CONDUCTS SOUND (FORCE) TOO

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Personal Anecdotal Feedback

- Patients generally happy regardless of device
- Consistent usage rate is over 95%
- Patient satisfaction rate between percutaneous vs. transcutaneous device

Transcutaneous Devices: Challenges

- Adequate gain for elevated bone conduction thresholds.
- Sound localization
- Hearing in noise
- Tinnitus

The Frontiers for Single Sided Deafness (SSD)

- Cochlear Implants

CI's for SSD

- Confusion regarding sound input?
- Latency in sound processing?

Realized Benefits of CI for SSD

- Eliminates head shadow effect
- Spatial hearing is improved
- Speech perception in noise improved
- Tinnitus suppression

Caveats

- Follows auditory training
- Requires significant auditory rehabilitation

Obstacles to CI's for SSD

- Cost
- FDA approval
- Cost
- Cost

Any Questions?