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### Bone Anchored Hearing System: Current Developments and Challenges

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### Outline

- Introduction of Bone Anchored Hearing Systems (BAHS)
- Candidacy of BAHS
- Key Design Features of the Ponto BAHS
- Key Technological Features of the Ponto BAHS System
- Current Challenges and Future Directions

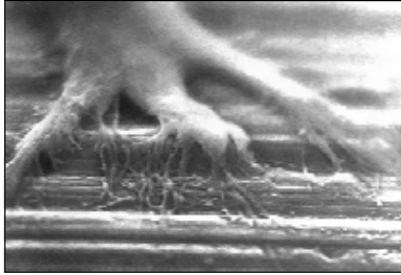


### What is a Bone Anchored Hearing Device


- A well established hearing solution for conductive and mixed hearing losses, and, single sided sensorineural deafness
- It is based on 2 principles: **Osseointegration** and **Direct Bone Conduction**
- It is composed of three parts: a titanium implant, an external abutment and a sound processor





### Osseointegration



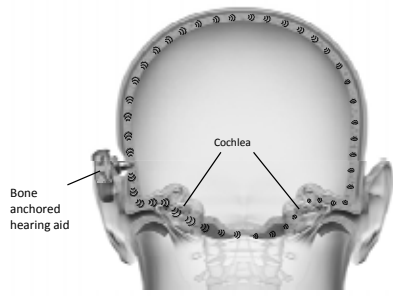
"The direct structural and functional connection between ordered living bone and the surface of a load carrying implant"




### Direct Bone Conduction



### Bone anchored hearing solution




Sounds are converted to vibrations, which the skull transmit to the cochlea (the inner ears).



### Direct Bone Conduction

- Works independently of ear canal and middle ear
- Direct transmission gives clear sound
- Preoperative testing possible
- High wearing comfort
- Safe and simple surgery




In 2009 Oticon Medical Ponto came into being.....




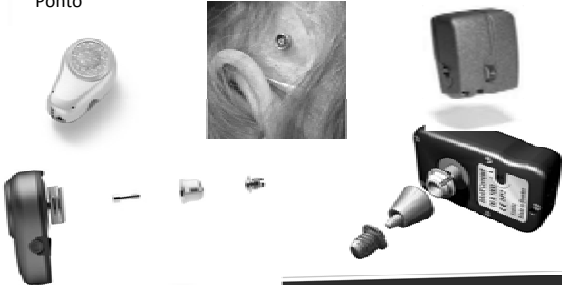


### Two Device Systems Now:

Oticon Medical Ponto

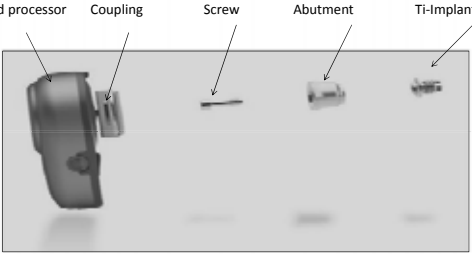



Cochlear BAHA®








### The Ponto System

### Candidates for bone anchored hearing solution


- Conductive & mixed hearing losses
- Single-sided deafness

### FDA Clearances


1996 - 2002

- 1996**
  - cleared to treat mixed and conductive hearing loss.
- 1999**
  - cleared for pediatric use in children age five and older.
- 2001**
  - cleared for bilateral fittings.
- 2002**
  - cleared for use in patients with unilateral sensorineural hearing loss also known as Single Sided Deafness (SSD).




### Candidacy: Mixed and Conductive Hearing Loss

- $\geq 5$  years of age
- $\leq 45$  dB HL BC PTA
- $\geq$  or equal to 60% speech discrimination scores
- Symmetric bone conduction thresholds are defined as less than 10 dB difference in average or less than 15 dB at individual frequencies (0.5, 1, 2, and 4Khz)




## Conductive & Mixed Hearing Loss

- This group benefits most from a bone anchored hearing device

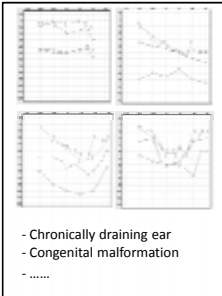


### Candidates with Mixed and Conductive hearing loss

- Due to examples such as:
  - Chronic otitis media
  - Congenital atresia
  - Syndroms (e.g. Treacher Collins, Goldenhar, ...)
  - Cholesteatoma
  - Middle ear dysfunction/disease
  - ...
- The hearing losses can be monaural or bilateral

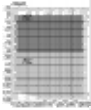


### Candidates with Mixed and Conductive hearing loss




- Chronically draining ear  
- Congenital malformation  
- .....

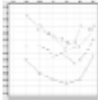

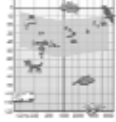
- If air-bone gap  $>30$  dB, speech recognition is likely to be better with a bone anchored sound processor than with a traditional hearing aid.<sup>1,2</sup>
- Bone Conduction (BC) threshold up to av. 55 dB HL




1) Mylonsus et al. Intra-individual comparison of the bone-anchored hearing aid and air-conduction hearing aids. Otolaryngology - Head & Neck surgery. 1998; 124(3): 271-6  
2) Mester et al. Better performance with bone-anchored hearing aid than acoustic devices in patients with severe air-bone gaps. The Laryngoscope 121:613-616, 2011.



### Candidates with mixed & Conductive HL, how do they hear unaided?






- Often bilateral hearing losses; unaided: They can not follow a conversation
- Very dependent on their bone anchored sound processor





### Candidates with chronic otitis media

- Chronic otitis media
- Chronically draining ear
- External otitis



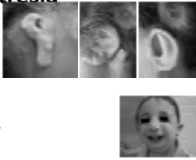


Cronic otitis media

- Conductive or mixed hearing loss
- Long history of ear diseases
- A long track of visits to Ear-, Nose- & Throat professionals (ENT)

### Candidates with Microtia / Atresia



- Congenital atresia (born with malformation or no outer ear)
- Syndroms (e.g. Treacher Collins, Goldenhar, ...)
- Most often conductive hearing loss (normal inner ear)

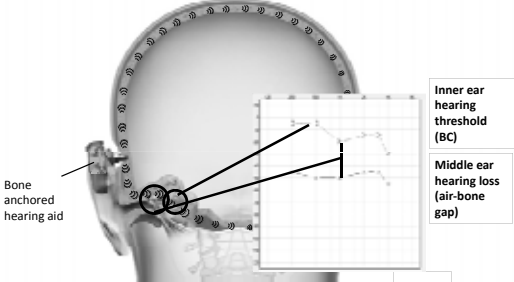
### Microtia / atresia




### How does a bone anchored hearing system work for mixed and conductive hearing loss?

### Bone anchored sound processor




Inner ear hearing threshold (BC)

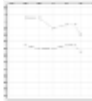

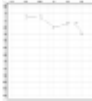

Middle ear hearing loss (air-bone gap)


Bone anchored hearing aid

- Vibrations bypass the hearing loss in the middle ear.



### Traditional HA versus bone anchored HA



<ul style="list-style-type: none"> <li>■ Traditional HA</li> </ul>   <ul style="list-style-type: none"> <li>■ Need <u>high</u> gain.</li> </ul> <p>[gain(BC) + gain(ABG)]</p>	<ul style="list-style-type: none"> <li>■ Bone anchored HA</li> </ul>   <ul style="list-style-type: none"> <li>■ Need <u>little</u> gain.</li> </ul> <p>[gain(BC)]</p>
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### Advantages with bone anchored sound processor for people with conductive and mixed HL

... compared to traditional hearing aid



- Little amplification
- Better sound quality
- Ear canal remains open

### Advantages with bone anchored sound processor for people with conductive and mixed HL

... compared to traditional bone-conduction hearing aid



- No pressure against the skin and skull
- Better sound quality as no damping via skin
- More discreet
- Advanced technology in Ponto

### Advantages with bone anchored sound processor for people with conductive and mixed HL



... compared to middle ear implant

- Preoperative testing possible
- Simple surgery for bone anchored sound processor


### Candidates for bone anchored hearing solution

- Conductive & mixed hearing losses
- Single-sided deafness

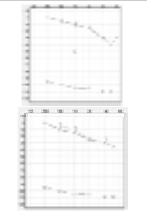
### Etiologies of Single Sided Deafness

- Acoustic neuroma tumors
- Sudden deafness
- Neurological degenerative disease
- Genetics
- Ototoxic treatments
- Inner ear malformation
- Trauma




### Candidates

Single-sided deafness





- A patient with Single-sided deafness (SSD) has
  - a profound sensorineural hearing loss in one ear (aka unilateral sensorineural hearing loss)
- Average hearing threshold in better ear better  $\leq 20$  dB HL

- Sudden deafness  
- Acoustic neuroma  
.....




### Candidates with Single sided deafness, how do they hear unaided?

- What is relatively easy?
  - Following conversation in quiet,
  - Listening to radio and TV
  - Concerts and theatre shows
- What is challenging?
  - Difficulties understanding speech in group conversations and in noise.
  - Difficulties hearing sounds directed to the deaf side
  - Difficulties localizing sounds

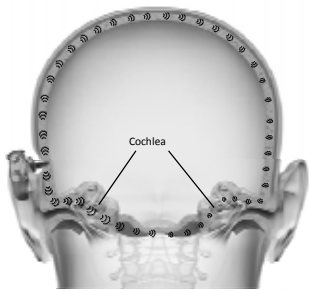



### Bone Anchored Hearing Device for Single Sided Deafness


- Benefit first reported by Vaneecloo in 2000 in 2 patients. In 2001 Vaneecloo reported on 29 patients
- Reports of greater benefits with BAHS compared to conventional CROS solutions (Niparko, 2003) – head shadow effect appears compensated but no localization reported
- Better speech discrimination in noise with BAHS compared to conventional CROS (Wazen et al, 2003)



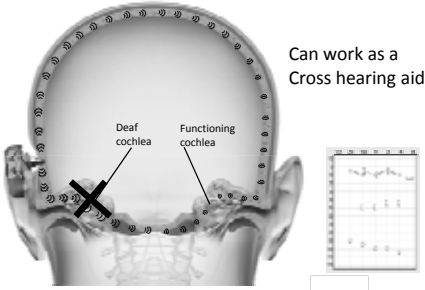
### Bone anchored sound processor



Vibrations are transmitted to both cochlea




### Bone anchored sound processor



Can work as a Cross hearing aid

The normal cochlea is picking up sound from both sides.

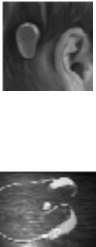



### Advantages with bone anchored sound processor for people with Single Sided Deafness

- Reduces the head shadow effect
- Increases speech understanding in noise

... compared to AC Cross HA

- The ear canal remains open
- There is no cord





### Bone Anchored Hearing Device in Single Sided Deafness

**Average Soundfield Testing - CNC**

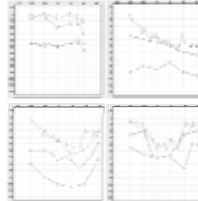
**Average Soundfield Testing - HINT**

Ortega et al 2011, Silverstein Institute



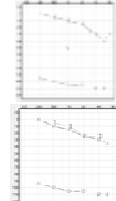
### Candidates

**Conductive and mixed HL**




- BC up to av. 55 dB HL
- if ABG >30 dB, speech recognition is likely to be better with a bone anchored sound processor

**Single-sided deafness**




Normal hearing in best ear (av. AC ≤ 20 dB HL)

Other medical background:  
-Skin allergies in ear canal

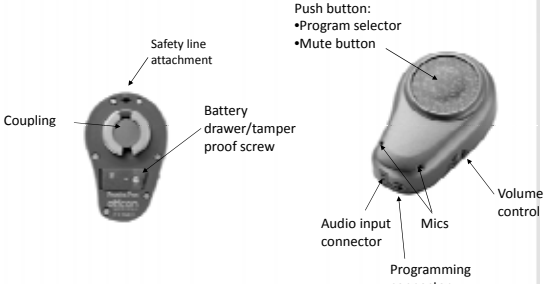



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### Design is not just how it looks – it is how it works



### Designed for users

- Shaped to blend in
- Left and right versions
- Easy to use






### Ease of use

- Big and easy to find program and mute button
- Fully automatic advanced features
- Self learning volume control
- Low battery warning system









### Nano coating

- Protects the Ponto processors from moisture and dirt
- More importantly it seals all the narrow slits between plastic parts in the product
- It therefore protects the outside and inside of the sound processor to create a more durable and reliable product.



### Reliability – Nano Coating

	Non-coated Reference	nanocoating
Manual application on surfaces (cylinder area excluded)	 Liquid inside	 Some traces of liquid on the edges
	 Traces of liquid all over the edges	 No liquid inside





### No interference from cell phones

- Designed to the stringest of hearing aid standards. All Ponto Processors are fully compatible with cell phones and other wireless phones
- Now users can enjoy modern wireless communication within being disturbed by noise or distortion

### Tamper resistant battery door

- Available on all Ponto
- Tested and used by Oticon



### Transducer impact protection

- Protects the vibrator from the strong forces applied when connecting the device to the abutment

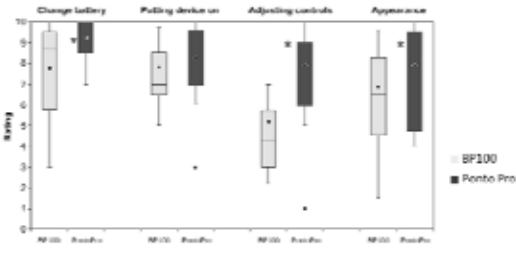



### Ponto for children


- Dedicated Soft band fitting mode in Genie Medical
- Adapt Ponto to the children's needs – for example special programs and deactivate controls
- Extra support in school – fully compatible with Oticon Amigo FM system
- Higher safety in handling – equipped with tamper resistant battery door and safety line
- Stickers to make Ponto more personal

### Ease of device handling



International Journal of Audiology, 2011, 50: 920-928




### Design & Technology of the Sound Processor




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### A complete sound processor family

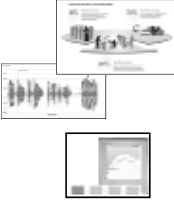

- All based on the same advanced RISE platform
- All fitted via the easy-to-use Genie Medical fitting software

If you can fit one you can fit all!


### Ponto a powerful family

- Designed to offer increased speech intelligibility and less feedback through a combination of:
  - Advanced automatic directionality
  - Speech Guard amplification system
  - 2-stage Feedback Management



### Automatic Multiband Adaptive directionality in 3 Modes

Improving Speech Understanding in Noise



### Automatic Multiband Adaptive Directionality

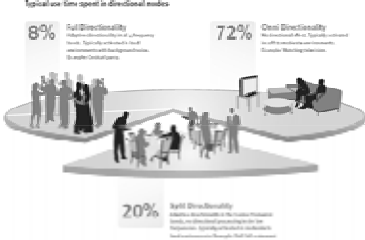

- Multiband:** 4 frequency channels
  - Low
  - Mid
  - Mid
  - High freq.
- 3 modes**
  - No directionality (omni / surround)
  - Split (High Frequency) directionality**
  - Full directionality
- Automatic selection between the 3 modes** based on sound level and best SNR

### Directionality in more situations with Multiple Directionality Modes

Typical use time spent in directional modes


- 8%** Full Directionality: Used in most situations where the user is in a noisy environment and needs to hear a specific speaker.
- 72%** Omni Directionality: Used in most situations where the user is in a noisy environment and needs to hear multiple speakers.
- 20%** Split Directionality: Used in most situations where the user is in a noisy environment and needs to hear a specific speaker while also hearing other speakers.

### Automatic Multiband Adaptive Directionality

**Advantages**  
 No need to manually change program to get the benefits of directionality  
 More directionality more often because of spilt directionality mode

**Benefits**  
 Better speech understanding in difficult listening situations and in more situations.




## Speech Guard Amplification System in Ponto

### Preserving Signal Integrity




### Speech Guard in Ponto

- Preserves the natural details and structure of speech
- Preserves speech integrity even when speech is suddenly interrupted by a sudden loud signal
- It's effectiveness has been well established in in Oticon's latest and most advanced hearing systems
  - Benefits have been well documented and published in refereed journals





## 2 stage Feedback Management

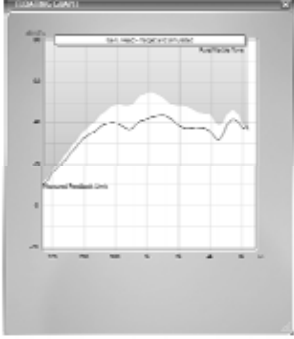



### Managing feedback in bone-anchored sound processors

- Feedback due to Static Conditions
  - Vibrations radiating back from the skull
  - Angle of the abutment
- Feedback due to Dynamic Conditions
  - When the patient moves his/her head, places hand near processor






### Individual feedback limit with Ponto Pro Power, examples

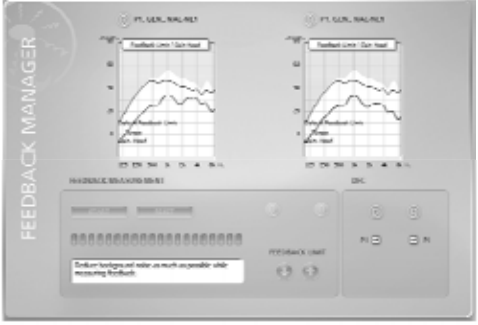




### 2-stage Feedback Management

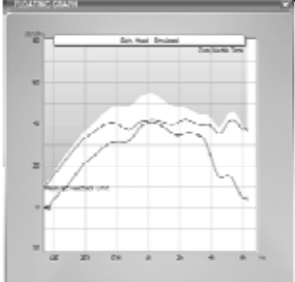
- Measuring the individual feedback limit maximizes the capacity of the Dynamic Feedback Cancellation (DFC) system
- Dynamic Feedback Cancellation cancels out feedback even before feedback occurs


### Feedback Management


### Optimized Volume Control Functionality



Volume control can be increased all the way up to the individual feedback limit.



### WIND NOISE REDUCTION





### Wind Noise Reduction

Active detection of wind noise and reduction of its impact


Forces the instrument into omni mode when wind is detected

Reduces gain, the more wind the greater the reduction

### Outline

- Introduction to the Ponto Family
- Key Audiological Features in the Ponto Family
- Evidence of Effectiveness of these Features
- Current Challenges and Future Directions



### Current Challenges

- Lack of understanding of single sided deafness
- Lack of standardized appropriate evaluation tools
- Lack of objective methods to demonstrate clinical effectiveness and to verify output
- Lack of good quality research data

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### What can we do.....

- Need to establish best practice guidelines for fitting of bone anchored processors. These guidelines will address counseling, pre-surgical evaluation, and post-surgical audiological and non-audiological outcomes
- Such an initiative would have to be driven by the professional association and the audiological community

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### Future Directions

We need.....

- Tools that will allow us to evaluate the patients and to predict post surgical outcomes pre-operatively
- Data on **non audiological** benefits
- **QoL** data using disease specific measures such as GBI and HDHS
- Better controlled systematic studies to demonstrate clinical and cost effectiveness

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Thank you

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