



***The Ponto Bone Anchored System:  
The Right Choice for Pediatrics***

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## Financial Disclosure



**Financial:** I am a paid employees of Oticon Medical, LLC

Course content describes the Oticon Medical Ponto Bone Anchored System

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## Learning Objectives



- Participants will be able to describe when the MIPS surgical procedure is appropriate.
- Participants will be able to describe patient indications.
- Participants will be able to discuss the importance of the speech envelope on speech intelligibility.
- Participants will be able to describe the newly FDA cleared abutment extender.

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## The William Demant Family



Offerings	William Demant					
Hearing instruments 	 <small>SONIC FIRST</small>	 <small>hearing solutions</small>	 <small>hearing solutions</small>			
Cochlear implants 	 <small>hearing solutions</small>	 <small>hearing solutions</small>				
Bone anchored hearing solutions 	 <small>hearing solutions</small>					
Diagnostic instruments 	 <small>hearing solutions</small>	 <small>hearing solutions</small>	 <small>hearing solutions</small>	 <small>hearing solutions</small>	 <small>hearing solutions</small>	 <small>hearing solutions</small>
Related areas 	 <small>hearing solutions</small>	 <small>hearing solutions</small>	 <small>hearing solutions</small>			

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## The Ponto Bone Anchored System: The Right Choice for Pediatrics



### Fundamentals of bone anchored technology and osseointegration

#### Ponto Bone Anchored System

- Candidacy
- Surgical Considerations and Soft Bands
  - MIPS, Biohelix™, Soft Healing Cap & soft bands
- Fitting considerations
  - Abutment Extension
- Processor Models & Signal Processing
  - Evidence supporting the use of advanced features for children

#### Conclusion

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## The Fundamentals of Bone Conduction and Osseointegration

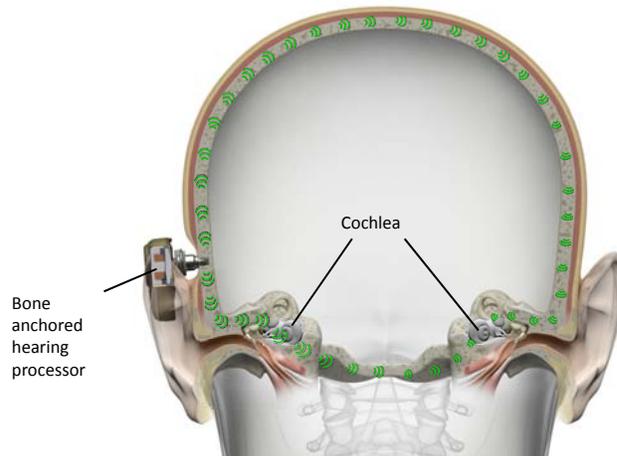


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## Bone Anchored Hearing Systems (BAHS)



Sounds are converted to vibrations, which the skull transmits directly to the inner ears.

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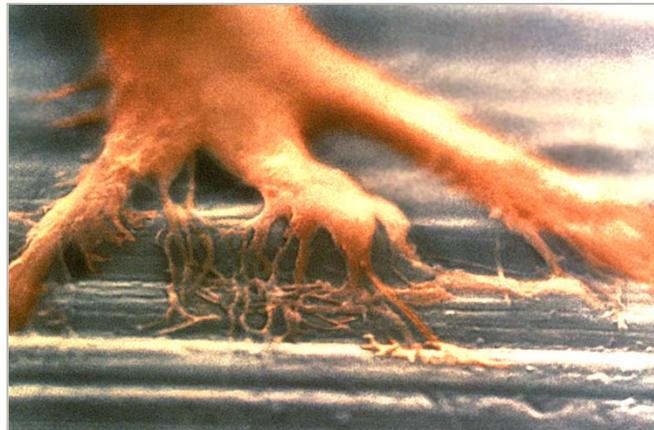
## A Bone Anchored Hearing System Consists of Three Parts:



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## Osseointegration

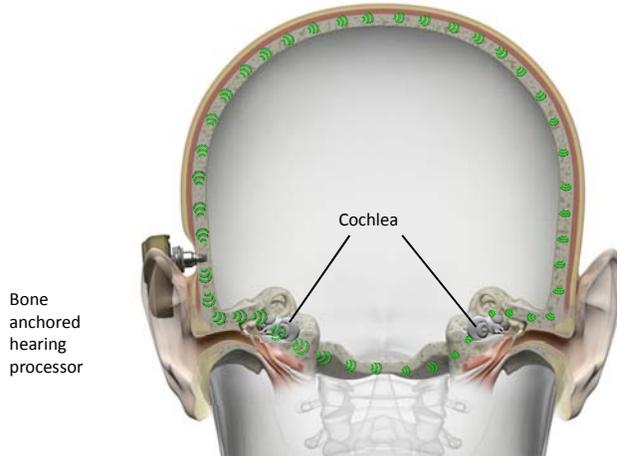


Living Bone Tissue (Osseo) Integrating with Titanium

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# The Ponto is an Osseointegrated Bone Conduction Implant System That Provides Direct Bone Conduction Stimulation



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Conductive / Mixed Hearing Loss

Single Sided Deafness

## Patient Indications and Candidacy



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## Children with Conductive / Mixed Indications



Unilateral or bilateral typical diagnosis:

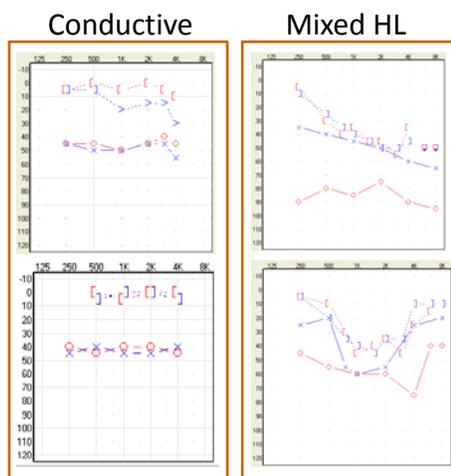
- Atresia / Microtia
- Chronic otitis media
- Cholesteatoma
- Middle ear dysfunction/disease
- External otitis
- Syndromes (e.g. Treacher Collins, Goldenhar, CHARGE...)



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## Conductive / Mixed Indications



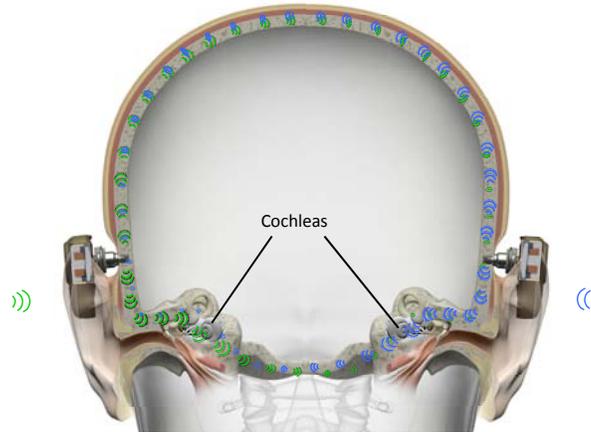
Pure Tone Bone Conduction scores on average @ .5, 1, 2 & 3 kHz

- Ponto Plus - better than or equal to 45 dB HL
- Ponto Plus Power - better than or equal to 55 dB HL
- $\geq 5$  years of age (implanted) otherwise fitted with a softband

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## Children with Bilateral Conductive/ Mixed HL



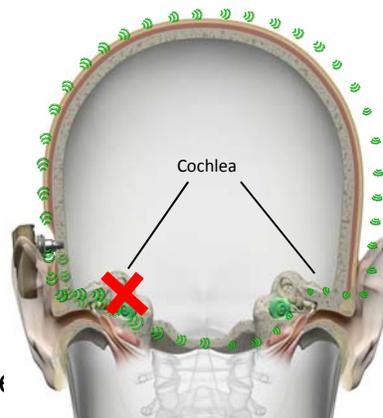
- Audiologic considerations are to have **symmetrical BC thresholds**
- To provide bilateral hearing (localization, improved speech understanding in noise, etc.)

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## Children with Single-Sided Deafness / Unilateral Hearing loss (UHL)

- Acoustic neuroma
- Sudden unilateral deafness
- Ototoxic treatments
- Trauma
- Surgical intervention  
resulting in unilateral deafness
- Neurological degenerative diseases



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## Hearing Loss in Only One Ear, “What’s the big deal?”



### Listening Challenges

- Any time listening is not easy it will be harder for a child with unilateral hearing loss to pick up new words.
- Hearing from a distance is a challenge.
- Children with unilateral hearing loss may be **10 times** more likely to fail a grade in school or need special help to keep up in school.
- **1/3 to 1/2** of children with hearing loss who have not received help to hear better have problems learning in school!
- Also, because most rules of social interaction are learned via subtle auditory cues and visual cues, rather than direct teaching, it isn’t a surprise that about **1/5** of these children will develop behavior or social issues.

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<http://successforkidswithhearingloss.com/resources-for-parents-of-children-with-hearing-loss/unilateral-hearing-loss>



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## Children with Single-Sided Deafness / Unilateral Hearing loss (UHL)



- Studies show that children with unilateral hearing loss may cause\*:
  - Difficulty locating sound
  - May hear sound from a distance but not understand what is being said
  - Some children may experience delays in speech and language development
  - 1/3 of children with UHL needed to repeat one grade



\*Bess F, Tharpe A. Case history data on unilaterally hearing-impaired children. Ear Hear. 1986; 7(1):14-9.

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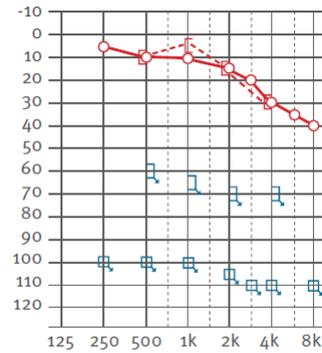
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## Children with Single-Sided deafness / Unilateral Hearing loss (UHL)



The hearing in the better ear should be

- **Better than or equal to 20 dB HL @ .5, 1, 2 & 3k Hz**
- $\geq 5$  years of age (implanted) otherwise fitted on a softband



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## Other Patient Indications for Bone Conduction – Fluctuating Hearing Loss



### Softband

- Non surgical option with children who should eventually grow out of middle ear problems that create the fluctuating hearing loss

### Benefits:

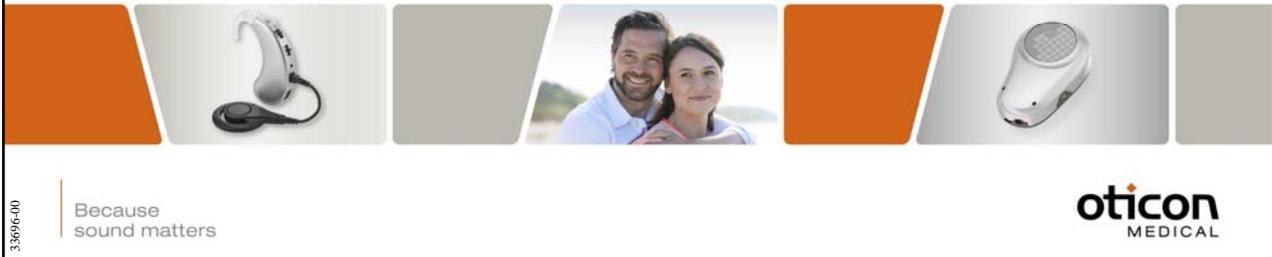
- No risk of over amplification if wearing on days when hearing is normal
- Ear canal remains open – small canal, wax, drainage does not affect function
- Hearing is constant. The amount of fluctuation is all related to the middle ear and Ponto on softband overcomes any middle ear issue



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## Surgical Considerations



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## Cosmetic Expectations

- Surgical technique has evolved over recent years
- Unfortunately, older surgical techniques are still prevalent on internet
- Tissue preservation is commonplace
- With tissue preservation techniques:
  - Scars are barely visible
  - No divots at surgical site from tissue reduction
  - Hair follicles are not taken out



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## The Ponto System for Tissue Preservation

### The Ponto Implant/Abutment

- **An implant design for high initial stability**
  - Wide Ponto Implant –  $\varnothing$  4.5 mm
  - OptiGrip™ geometry – maximized implant surface in contact with bone
  - The highest initial implant stability in the market\*
- **A skin friendly Abutment family concept**
  - OptiFit™ design for tissue preservation surgery
  - The proven surface for tissue preservation. Pure medical grade Titanium (Ti) abutment surface
  - Perfectly matched interface. Full skin support from underlying bone and periosteum



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\*Initial ISQ values measured in pre-clinical tests in artificial bone (Westerkull & Jinton (2012))

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## MIPS - A truly new perspective on tissue preservation



*"Tissue preservation has been a great improvement for patients. With MIPS, the cosmetic outcomes are even better"*

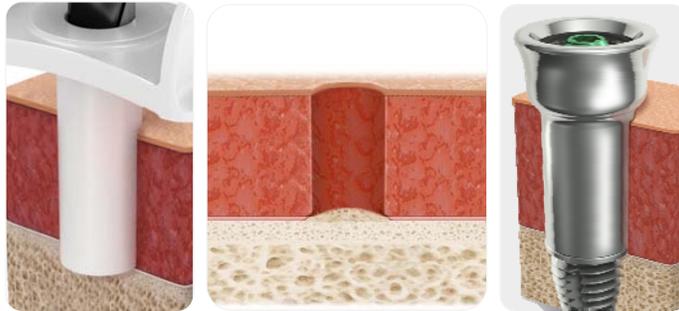
Malou Hultcrantz, Professor, MD, PhD

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## Perfect Fit

- The OptiFit™ shape of the Ponto abutments fits naturally to the circular incision made by MIPS
- No pockets or pathways surrounding the abutment



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## Patient Outcomes 7 Days Post-Op



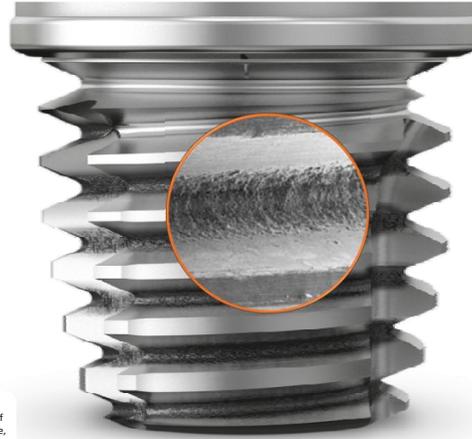
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## Setting New Standards for Implant Technology

The Ponto BHX Implant is the perfect match between the proven OptiGrip™ geometry and the latest surface technology. With its micro- and nano-sized structures it takes osseointegration to the next level - bone bonding

- First laser-ablated titanium surface
- Stronger than bone<sup>1</sup>
- Highest stability from day one



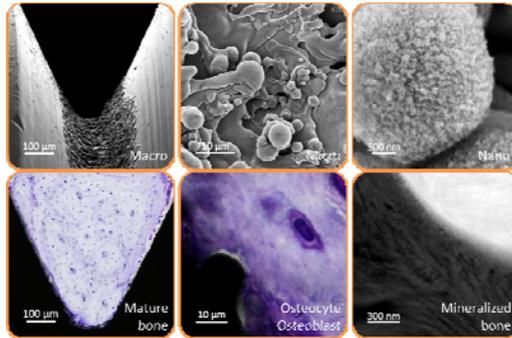
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1. Johansson M L, et. al., "Site-specific laser modification promotes higher osseointegration of titanium implants". Present. at Osseo, Lake Louise, Canada, May 2015

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## First Laser-Ablated Titanium Surface

The surface of Ponto BHX Implant matches the building blocks of bone:



*"Nanometer roughness plays an important role in osseointegration. The improvement in biomechanical capacity is even greater than I imagined."*

**R. Brånemark, Associate Professor MD Msc. PhD**

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## Lifelong Patient Outcome

- Freedom of choice with the Ponto System



Oticon Medical abutment



Cochlear abutment

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## Small Change. Big Difference

- The **Abutment Extension** is connected on the existing abutment without any surgery involved
- It is delivered non-sterile.
- Placement can take place outside the operating room
- The Abutment extension does not work with BAHA processors. It must be removed if a BAHA is fitted



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## Ponto Unilateral and Bilateral Soft Bands



- Easily adjustable soft band enables even young children to wear Ponto Plus.



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## Ponto Plus with Proven Technologies



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## Ponto Plus with Proven Technologies

Year	Product	Key Features
2009	Ponto & Ponto Pro	<ul style="list-style-type: none"> <li>Automatic multichannel directionality</li> <li><b>Split directionality</b></li> <li>Tri-state Noise reduction</li> <li>Fully adaptive operation through automatic listening environment detection</li> <li>Active Wind noise reduction</li> <li>Data logging</li> </ul>
2011	Ponto Pro Power	<ul style="list-style-type: none"> <li>2-stage feedback Management</li> <li><b>Speech guard</b></li> <li>BC in situ</li> <li>Nano coating</li> </ul>
2012	Ponto Pro Power	<ul style="list-style-type: none"> <li>Product design award</li> </ul>
2013	Ponto sound processors	<ul style="list-style-type: none"> <li>Ponto earns IP57 classification</li> </ul>
Today	Ponto Plus & Ponto Plus Power	<ul style="list-style-type: none"> <li><b>The most powerful transducer</b></li> <li><b>Feedback shield</b></li> <li><b>Wireless connectivity</b></li> </ul>

And the development continues...

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## Ponto Plus Processors

- Most **powerful FAMILY** of **wireless** bone anchored sound processors!
- More **High Frequency Gain & Extended Bandwidth** provides access to the full pitch range of speech, especially the important high frequencies
  - Speech perception
  - sound quality
  - understanding speech in noise
- **Inium** Wireless Platform with **Feedback Management** system
  - Developed for power aids and bone anchored device

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## Ponto Plus Sound Processors

- Durable, reliable, and easy to operate



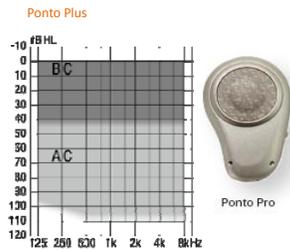
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\* Please note, Ponto Plus is not waterproof. Users should always remove their sound processor while showering or bathing

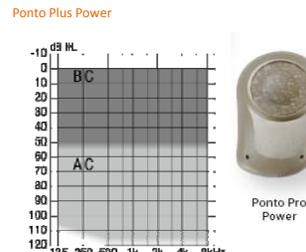
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## Ponto Bone Anchored System

### Fitting range for Ponto Plus and Ponto Plus Power



Avg. BC ≤ 45 dB HL



Avg. BC ≤ 55 dB HL



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## It is Easy to Fit Ponto

### Genie Medical 2013.1 software

1. Select type of fitting
  - Check box to ensure correct fitting rationale
    - Single-sided deafness
    - Softband
2. Measure BC In-situ
3. Measure Feedback limit

### Oticon Medical Streamer

- Ready to use 'out-of-the-box'



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## Children Need Access to Speech to Develop Their Listening, Language and Learning Skills



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## Factors That Compromise Listening Under Complex Acoustic Conditions



Factor	Challenge	Reference
<b>Brain immaturity</b>	The late development of pre-frontal connections makes it challenging for children to employ attention control to relevant sound sources in distracting environments.	Hwang et al. 2010
<b>Auditory inexperience</b>	Children need a rich “auditory diet” to practice perceiving and processing sound to become good listeners.	Flexer 2011
<b>Language unfamiliarity</b>	Non-native listeners and second/third-language learners are compromised with respect to phoneme recognition and show poorer performance of speech understanding in noise.	Tabri et al. 2011

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## Factors That Compromise Listening Under Complex Acoustic Conditions



Factor	Challenge	Reference
<b>Unilateral or minimal hearing loss</b>	Audibility and binaural hearing is a prerequisite for optimal spatial separation of competing sound sources in complex listening situations.	Rothpletz et al. 2012
<b>Cognitive or perceptual load</b>	Considerable listening effort is required when listening at SNRs that are typical of the school classroom. As proven by a dual-task paradigm, the availability of cognitive resources impacts a child's ability to perform in noise.	Howard et al. 2010

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## Getting the Best Possible Representation of Sound



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## American Academy of Audiology Clinical Practice Guidelines:

### Pediatric Amplification 2013



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## Pediatric Considerations

- “Children are learning language, and do not have the capacity to “fill in the blanks” for sounds that are not audible”
- “Children spend most of their time listening to the speech of other children and women, which has greater high frequency content than that of males”
- “Children who use hearing aids must develop the ability to use information acquired while hearing amplified, processed sound”
- “Children have more demanding listening environments than adults for understanding speech... Enhancement of audibility is required either through increased level, increased SNR, or improvement of the listening environment”

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AAA Pediatric Amplification Guidelines, 2013

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## The Importance of Providing Amplification Early in Life

- Age at fitting of amplification is predictive for speech perception, speech production, and spoken language skills.<sup>7</sup>
- Auditory system development, and particularly development of speech perception, is guided by access to relevant acoustic and linguistic information early in life.<sup>8</sup>



7) Sininger et al (2010) Auditory development in early amplified children: Factors influencing Auditory-based communication outcomes in children with hearing loss. *Ear and Hearing* 2010, 31(2), pp166-185  
8) Kuhl, P. K. (2000). A new view of language acquisition. *Proc Natl Acad Sci*, 97, 11850–11857.

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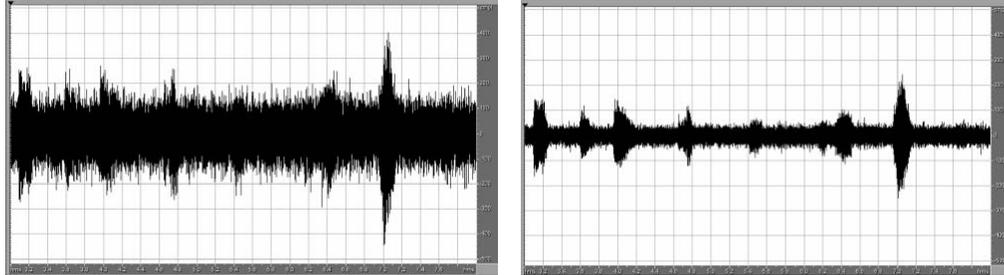
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## Pittman (2011) Children's Performance in Complex Listening Conditions: Effects of Hearing Loss and Digital Noise Reduction



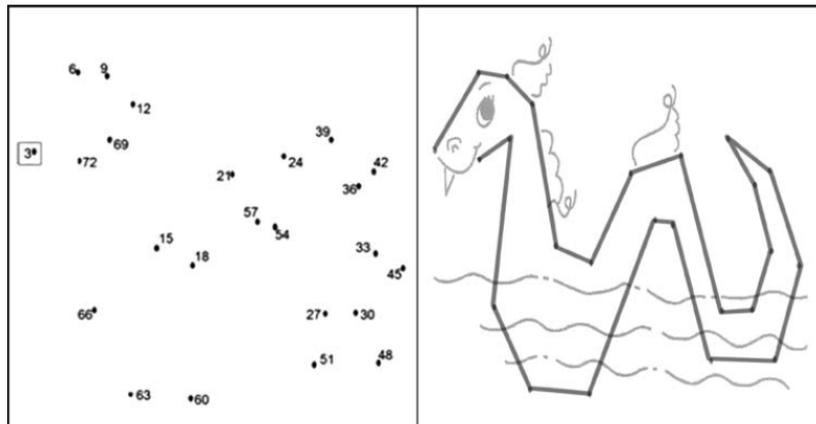
Figure 2. Waveforms showing five words embedded in broadband noise at 0 dB SNR. The upper panel shows the stimuli amplified without DNR, and the lower panel shows the same stimuli amplified with DNR.



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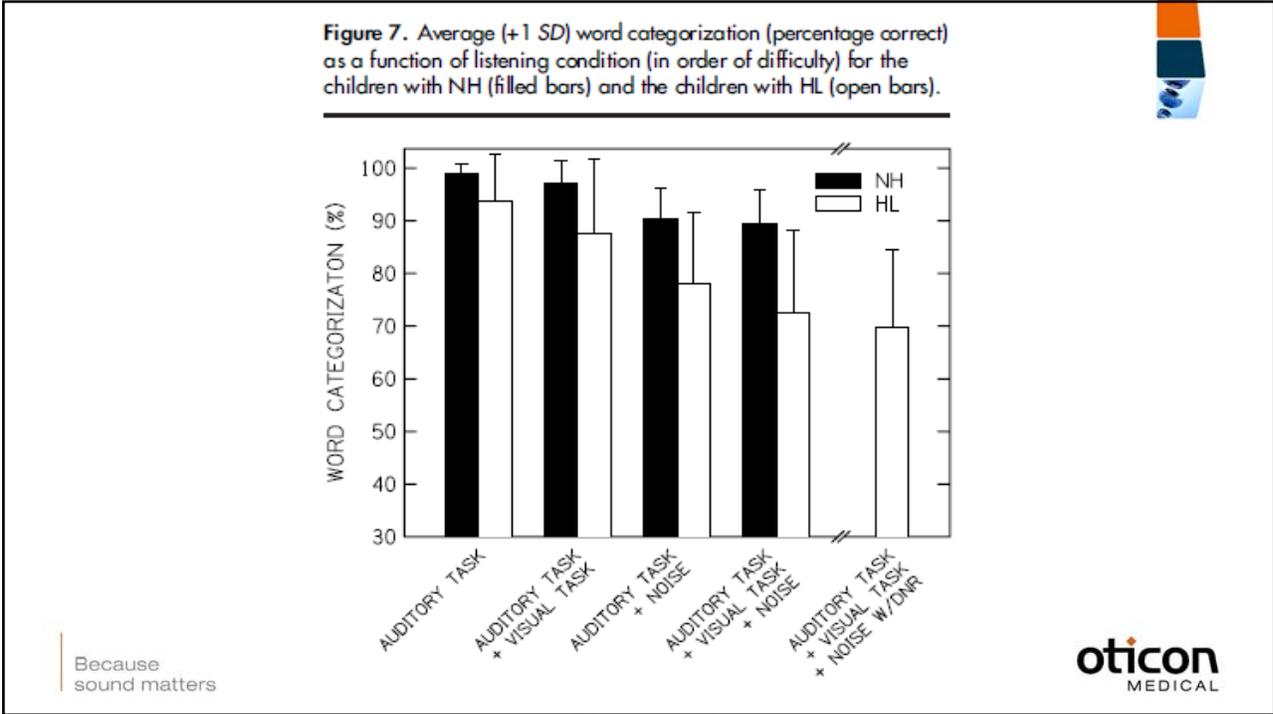
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Figure 3. Example of a dot-to-dot game. The left panel shows the game as it was presented to the child with only the dots and their numbers. The right panel shows the finished game with additional art but no numbers. The completed picture was displayed on the back of the page of the corresponding dot-to-dot game.



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## Age-Related Benefits of Digital Noise Reduction for Short-Term Word Learning in Children with Hearing Loss (Pittman, 2011)

Figure 5. Visual stimuli used as referents for the nonsense words.

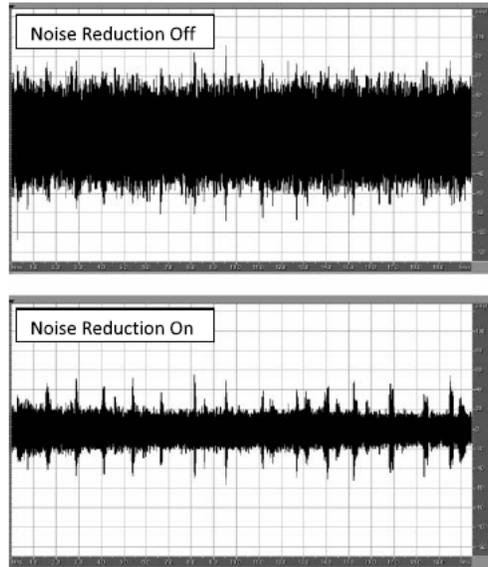
You are going to hear some silly names. Your job is to choose the picture on the screen that has that name by touching it with your finger or clicking on it with a mouse. If you choose the right picture, the game on the screen will play. If not, nothing will happen, and you will hear the next silly name. Don't be surprised if it takes a little while to figure out the name that goes with each picture.

TOYS	FLOWERS	ALIENS

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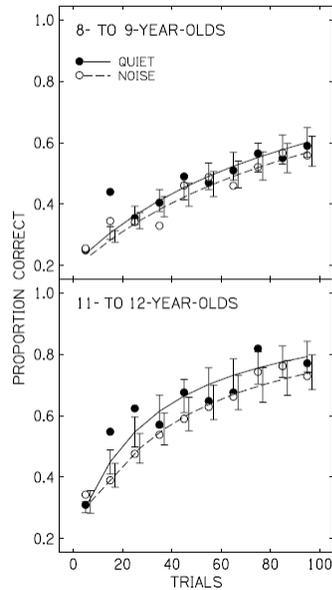
**Figure 3.** Waveforms showing the 15 novel words embedded in broadband noise at 0 dB SPL. The upper panel shows the stimuli amplified without digital noise reduction (DNR), and the lower panel shows the same stimuli amplified with DNR.



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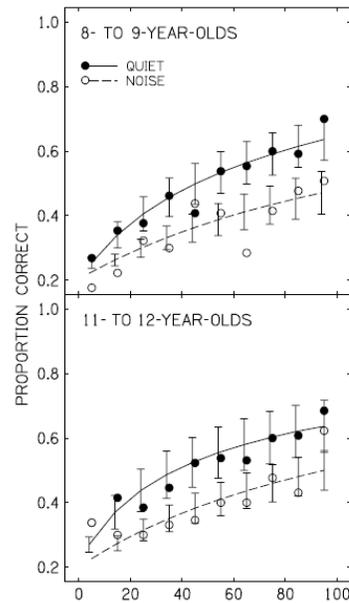
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**Figure 7.** Averaged learning functions ( $\pm 1$  SE) for the two groups of children with NH—the 8- to 9-year-olds (upper panel) and the 11- to 12-year-olds (lower panel). Solid and dashed lines represent quiet and noise listening conditions, respectively. Data points are the averaged performance for each trial block.



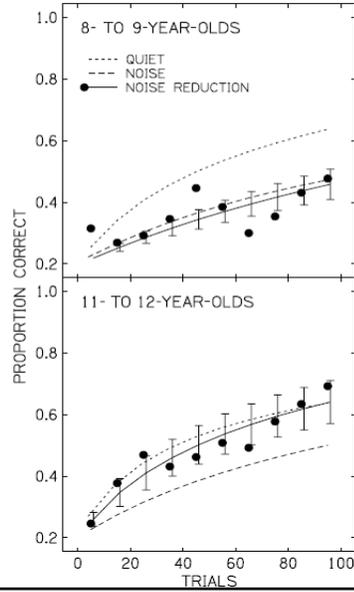
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**Figure 8.** Averaged learning functions ( $\pm 1$  SE) for the two groups of children with HL—the 8- to 9-year-olds (upper panel) and the 11- to 12-year-olds (lower panel). Solid and dashed lines represent quiet and noise listening conditions, respectively. Data points are the averaged performance for each trial block.



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Figure 9. Averaged learning functions ( $\pm 1$  SE) for the two groups of children with HL—the 8- to 9-year-olds (upper panel) and the 11- to 12-year-olds (lower panel). Solid lines represent the learning function for the noise listening condition with DNR. Short and long dashed lines represent the quiet and noise listening conditions, respectively. Data points are the averaged performance for each trial block.



Pittman, 2011

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## Directionality and Noise Management



Directionality will clean up the S/N whenever possible

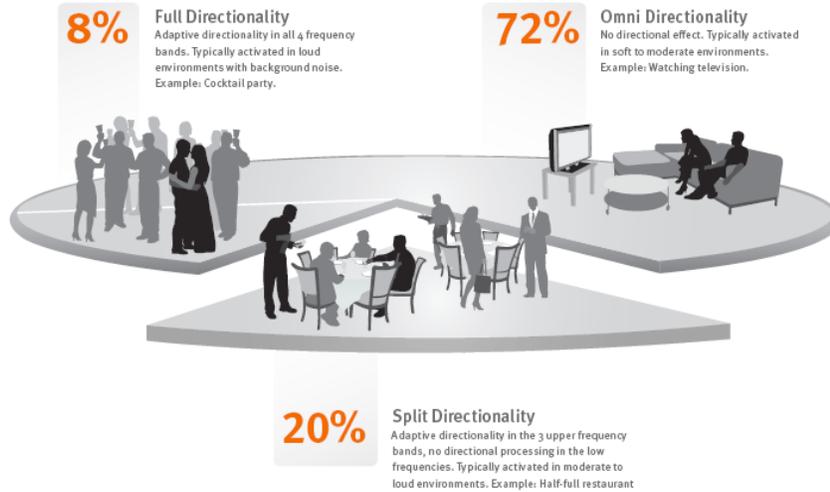
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## Unique Split Directionality Mode

Split Directionality applies directionality only above 1000 Hz

Typical use time spent in directional modes

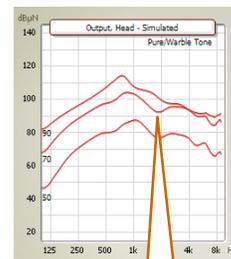


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## Speech Guard

- MFO of bone anchored devices is more limited compared to air conduction hearing aids
  - Ponto Systems uses linear gain approach
  - Sudden, loud sounds can put device in saturation more quickly
  - Compression has been used in bone-anchored processors to tackle signal distortion
  - Compression also distorts signal
- **Speech Guard** is an amplification system to *preserve signal integrity and minimize distortion*



Saturation for input of 70 dB SPL

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## Speech Guard

- The adaptive amplification system in Ponto



## Inium Feedback Shield

Addressing the feedback issue within bone anchored hearing systems

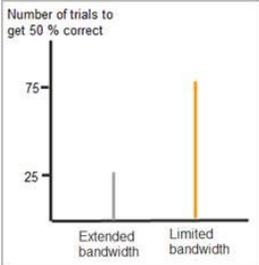
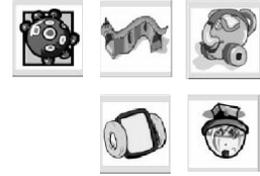


## The Importance of High Frequencies for Children Language Development

### Clinical study

- Purpose: Determine learning rate for words presented with 4 kHz and 9 kHz bandwidths
- Method: Five nonsense words, paired with 5 novel pictures
- Outcome: Children need **3 times as many trials with limited bandwidth** to learn new words as compared to the children who listen to extended bandwidth.<sup>5</sup>

- Sothnud
- Doztul
- Fosnush
- Stomun
- Homtul



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5) Pittman (2008) Short-term word-learning rate in children with normal hearing and children with hearing loss in limited and extended high-frequency bandwidths. *Journal of Speech, Language and Hearing Research*. Vol5; 785-797



## Differences Between Direct Drive and Skin Drive Bone Conduction



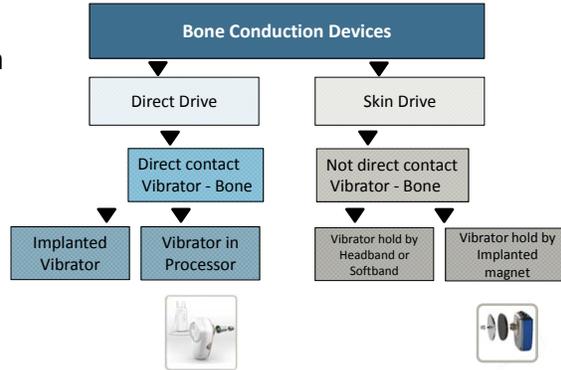
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## Bone Conduction Direct Drive vs Skin Drive Systems

- There are two types of bone conduction devices:
  - **Direct Drive** devices send vibrations via direct route to bone (percutaneous)
  - **Skin Drive** devices send vibrations through the skin to bone
    - Transcutaneous
    - Softband and magnet solutions provide similar performance<sup>1</sup>



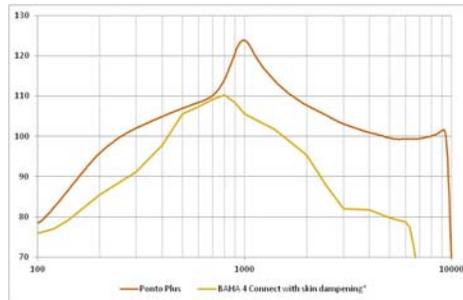
<sup>1</sup> Briggs (2015) Clinical Performance of a New Magnetic Bone Conduction Hearing Implant System: Results from a Prospective, Multicenter, Clinical Investigation. *Otol Neurotol*, 2015 Jun;36(5):834-41.

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## Sounds are Attenuated in Skin Drive Solutions

- Physical facts with skin drive solutions:
  - There is 10-20 dB sound attenuation in mid to high frequency region<sup>2</sup>
  - These devices have lower perceived output in the mid to high frequency region
  - Similar to using a softband or test headband



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Magnetic

<sup>2</sup> Verstraeten et al (2008) Comparison of the audiologic results obtained with the bone-anchored hearing aid attached to the headband, the testband and to the 'snap' abutment. *Otology & Neurotology* 30: 70-75

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## Consequence of Skin Attenuation on Speech Phonemes



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## Please Contact us

Please contact us at 1-888-277-8014

- [www.oticonmedical.com/us](http://www.oticonmedical.com/us)

Mary Humitz, AuD

[mhum@oticonmedical.com](mailto:mhum@oticonmedical.com)



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## Other AO Ponto Courses for your Reference



- Parents' Perspective: The Decision Making Process for Bone Anchored Hearing Systems for Children
- Overcoming Distance and Noise: Strategies for Successfully Utilizing FM with the Ponto System
- Minimally Invasive Ponto Surgery – A New Perspective on Bone Anchored Surgery
- Wireless Connectivity in our Daily Lives: Enhancing the Ponto Plus Experience

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