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The Ponto System and Benefits of Percutaneous BAHS

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Agenda

- 0 – 5: Introduction
- 5 – 10: Brief BAHS Principles Review
- 10 – 15: History of BAHS
- 15 – 35: Summarizing Percutaneous BAHS research results
- 35 – 45: Counseling Tips
- 45 – 55: Surgical Considerations
- 55 - 60 : Q & A

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Learning Objectives

- After this course learners will be able to identify the different types of bone conduction hearing solutions.
- After this course learners will be able to describe the importance of high frequency amplification on language development.
- After this course learners will be able to describe the detrimental impact of skin drive systems on hearing performance.

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Introduction

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History of Oticon Medical

2004 - Project started by Henrik Holtenstedt

2006 - William Demott acquires the project

2007 - Oticon Medical is established in Gothenburg

2009 - CE and FDA approval

2009 - Launch of Ponto - Bringing Superior Quality to Bone Anchored

2011 - First bone anchored digital power processor

2011 - Freedom of choice with the Ponto System external interface

2012 - Launch of Ponto Plus and Ponto Streamer - superior sound quality and wireless connectivity

2012 - First bone anchored digital power processor

2012 - First implant/external system designed for those preservation

2013 - First implant/external system designed for those preservation

2013 - Entering in to the field of cochlear implants with the acquisition of Neurelec

2013 - The philosophy - a holistic approach towards hearing patient outcomes

2014 - Launch of Signia and collection speech processor

2014 - Entering partnership with the M&M group on the BCI

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Bone Anchored Hearing System
Freedom of choice for superior hearing

- BAHS business division in Gothenburg, Sweden
- First commercial bone anchored launch in 2009
- Fast growing with over 25% of new patients choosing Ponto
- Superior sound quality – 2 out of 3 choose Ponto when given the choice

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Review
BAHS Principles






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Ponto – How does it work?

- External sound processor

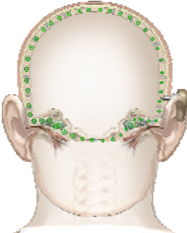


Abutment (6, 9, 12 or 14 mm long)
Implant (3 or 4 mm long)

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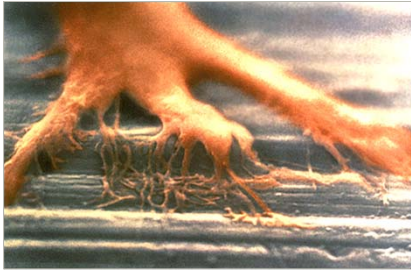
Ponto – How does it work?




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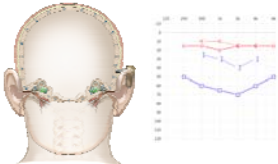


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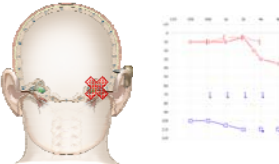
Candidates

Conductive or Mixed Hearing Loss




- Sound processor provides the correct pathway for sound, skipping over issues in the outer and middle ear
- Average BC threshold up to 55 dB HL

Single-sided Deafness (SSD)



- Sound processor helps to lift the head shadow, allowing sounds to be heard in the working cochlea on the opposite side
- Good ear has normal or near-normal hearing

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Perspective

History of BAHS



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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
 - Skin Drive** devices send vibrations through the skin to bone
- Softband and magnet solutions provide similar performance¹

1) Briggs (2015) Clinical Performance of a New Magnetic Bone Conduction Hearing Implant System: Results From a Prospective, Multicenter, Clinical Investigation. *Ear Hear*. 36(4):e1-e11

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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 region²
 - These devices have lower output in the mid to high frequency region.

2) Verstraeten et al (2008) Comparison of the audiologic results obtained with the bone-anchored hearing aid attached to the headband, the softband 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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Percutaneous BAHS Research

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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.⁵

- Sothnud
- Doztul
- Fosnush
- Stomun
- Homtul

Bandwidth	Number of trials
Extended bandwidth	25
Limited bandwidth	75

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. V05: 795-797

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Pediatric case; Maintaining normal language development

Pos.	Age, years/months	Language development
0 (A)	0y 4 m	Fitting on soft band
1	2y	Above normal
2	3y	Below normal
3 (B)	3y 8m	Fitting on abutment
4	3y 9m	Further below normal
5	4y 4m	Well above normal

- "Language development testing showed an accelerated improvement in speech development after implantation"⁶

Receptive language development


Age (year/month)	Receptive language quotient
0y 4m (A)	~88
2y	~108
3y	~98
3y 8m (B)	~88
3y 9m	~85
4y 4m	~115

6) Verhagen et al (2008) The BaSa Softband a new treatment for young children with bilateral congenital aural atresia. International Journal of Pediatric Otorhinolaryngology 72, 1455-1459

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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.⁷
- Auditory system development, and particularly development of speech perception, is guided by access to relevant acoustic and linguistic information early in life.⁸

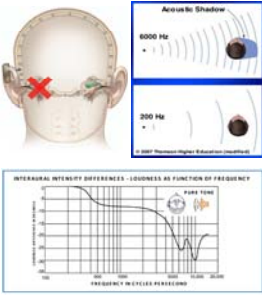


7) Springer et al (2010) Auditory development in early amplified children: Factors influencing Auditory-based communication outcomes in children with hearing loss. Ear and Hearing 31(2), pp166-185
8) Kuhl, P. K. (2005). A new view of language acquisition. Proc Natl Acad Sci, 97, 11850-11857.

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Emphasis on HF amplification for SSD patients

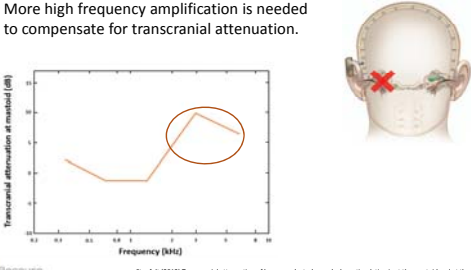
- The goal is to lift the head shadow effect:
 - The head shadow effect exists above 1500Hz, therefore only high frequencies need to be amplified
 - Amplifying the low frequencies might disturb the natural hearing of the contralateral ear, leading to poorer hearing in background noise



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Emphasis on HF amplification for SSD patients

- More high frequency amplification is needed to compensate for transcranial attenuation.



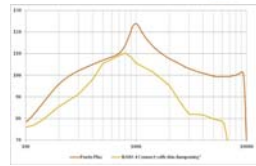
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Storfeldt (2012) Transcranial attenuation of bone-conducted sound when stimulation is at the mastoid and at the bone conduction hearing aid position. Otolary & Neurotology 33, 105-114

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Summary - Avoiding poor results for SSD patients

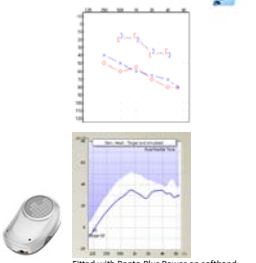
- Only direct drive solutions can amplify the needed frequencies.
- Fitting a skin drive solution to an SSD patient will most likely lead to very poor results.
- Thanks to the Feedback shield, Ponto can provide more high frequency amplification than any other bone conduction device, all without feedback.



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Mixed hearing losses

- The need for amplification is high because:
 - The hearing loss in the cochlea needs to be compensated for
 - Additional amplification is needed in a softband / skin drive solution to compensate for the skin attenuation.
- Only a **Power** bone anchored hearing device can provide the needed amplification.



Fitted with Ponto Plus Power on softband

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Mixed hearing losses

- The Power sound processor needs to have a very effective feedback management system, to ensure that
 - the prescribed gain will not be limited by the feedback limit
 - the patients are not bothered by feedback.
- A Power sound processor is also needed in order to provide the patient with the possibility to turn up the volume.

Fitted with Ponto Plus Power on softband

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Counseling Tips

What patients should know about Skin Drive versus Direct Drive BAHS

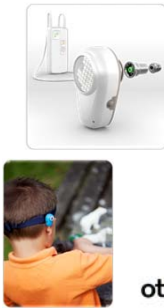


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Support informed decisions!

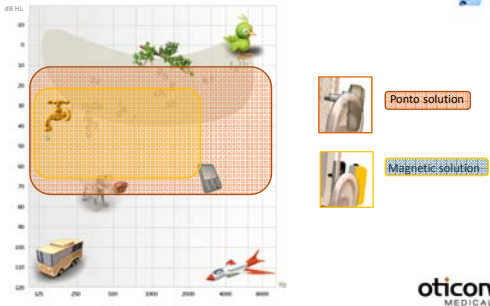
- More options than ever for bone anchored hearing patients
- There are both benefits and limitations in the different solutions for the individual patient
 - Does the solution provide enough amplification / output?
 - Is it comfortable enough to wear for a full day?
 - Cosmetically, how does it compare?



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Consequence of skin attenuation on speech phonemes



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Daily usage and comfort

Ponto

- Minimal physical sensation of the device
- Device stays attached to abutment
- Nothing prevents the user from wearing it during all waking hours

Magnetic solution

- A full third of patients experienced pain wearing the device ³⁾
- High risk of retention issues ⁴⁾
- Not comfortable to be worn during all waking hours

Wearing a processor

Usage/day	BAHS ³⁾	Magnetic solution ⁴⁾
< 4 h	2 %	14 %
4 - 8 h	7 %	64 %
> 8 h	90 %	22 %


3) Dutt et al. Day-to-day use and service related issues with bone anchored hearing aids. The ENTIC medical systems questionnaire. Journal of Laryngology and Otology 2002; 116: 20-28
4) Ray (2014) Outcomes and audiological perspective of transcutaneous (Atract magnetic) implants. Presentation at BAHA meeting, Norwich, Oct 2014

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Cosmetic aspects


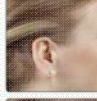
- A surgery should be as minimally invasive as possible for less numbness and pain
- The tissue preservation BAHS surgery leaves just a small post as the only evidence of the procedure.
- Tissue preservation BAHS surgery is reversible.
- Cosmetic outcome matters the most when the processor is in use.

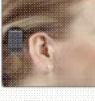

Magnetic solution



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Pediatric patients

- Softband solution is the best and only choice before age of surgery to provide BAHS patients with amplification








It is important to secure the best access to high frequency input - via abutment - as soon as the child is old enough. Children also need to wear their device all day...

Development doesn't stop!

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Who are the candidates if sound matters?

Direct drive	Ponto	<ul style="list-style-type: none"> • Pediatrics* and adults • Conductive and mixed • Single sided deafness 	
Skin drive	Transcutaneous Magnet	<ul style="list-style-type: none"> • Pediatrics* and adults • Conductive and mixed • Single sided deafness 	
	Head band or soft band	<ul style="list-style-type: none"> • Pediatrics before eligible for surgery • Adults: testing or before surgery 	


* Above the age of 5 years

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Percutaneous BAHS


Surgical Overview



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The Ponto Implant System



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Wide Ponto Implant OptiGrip™ Geometry

Improved stability enables longer abutments

OptiGrip geometry
Designed for improved stability
Largest initial bone contact surface in the industry

Wide (∅4.5mm)
Ponto implant

Ponto (∅3.75 mm)
implant

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Ponto supports Tissue Preservation Surgery

OptiFit™ – Designed for Tissue preservation

- OptiFit's Ti surface is the best documented solution for tissue preservation*
- A smooth tissue interface without pockets and pathways for bacteria
- FDA-cleared for tissue preservation surgery

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*Johansson, Holmberg & Hultcrantz (2014)

Abutment

• The Ponto Abutment family

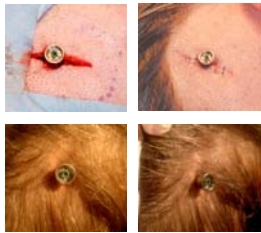
Abutment size	Ponto 6 mm	Ponto 9 mm	Ponto 12 mm	Ponto 14 mm
Natural skin thickness	< 3 mm	3 – 6 mm	> 6 mm	> 9mm

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Tissue Preservation Surgery

- Local anesthesia
- 10-20 min surgery*
- Wound healing within 10 days*
- Start using sound processor 3 weeks after surgery*

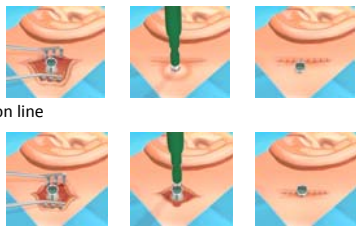


*e.g. Hultcrantz (2011), Hultcrantz & Lank (in press)
*e.g. Faber et al (2014), McLarnon et al. (2012), Nelissen et al. (2013)

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Tissue Preservation Surgery Methods

- Abutment placed beside the incision line
 • (published by M. Hultcrantz)
- Abutment placed in the incision line




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Tissue Preservation Surgery Outcomes


The surgery that makes a difference!

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



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Thank you for your time today!



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