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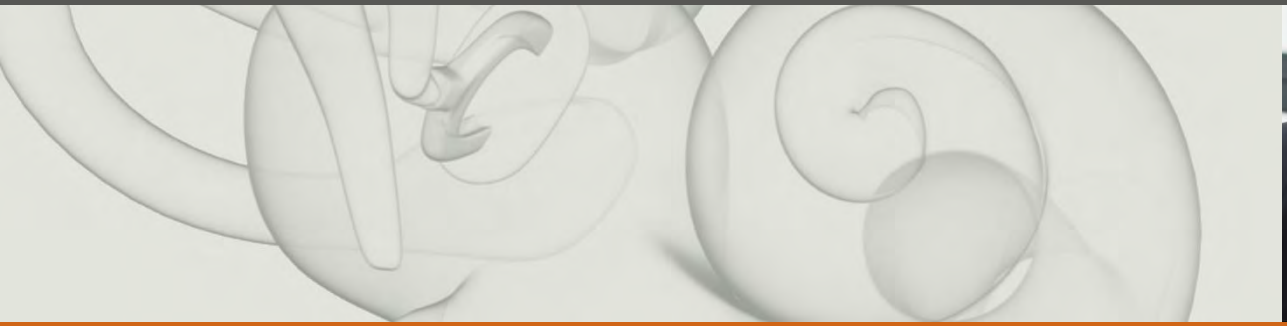
March 24, 2021

Counseling Patients through the Ponto Trial Journey: Benefits of Direct Sound Transmission

Carissa Moeggenberg, MA, CCC-A
Training Manager, Oticon Medical



Learner Outcomes

- Following completion of this course the participants will be able to describe the benefits of direct sound transmission.

- Following completion of this course the participants will be able to list the steps involved in the trial process of a Ponto System.

- Following completion of this course the participants will be able to illustrate effective counseling tips to use during the patient journey process.

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Agenda

- Bone Conduction Hearing
- The Ponto System
- The Trial Process
- Benefits of Direct Sound Transmission
- Transitioning to the Abutment and Implant
- Clinical Evidence Supporting Direct Sound Transmission

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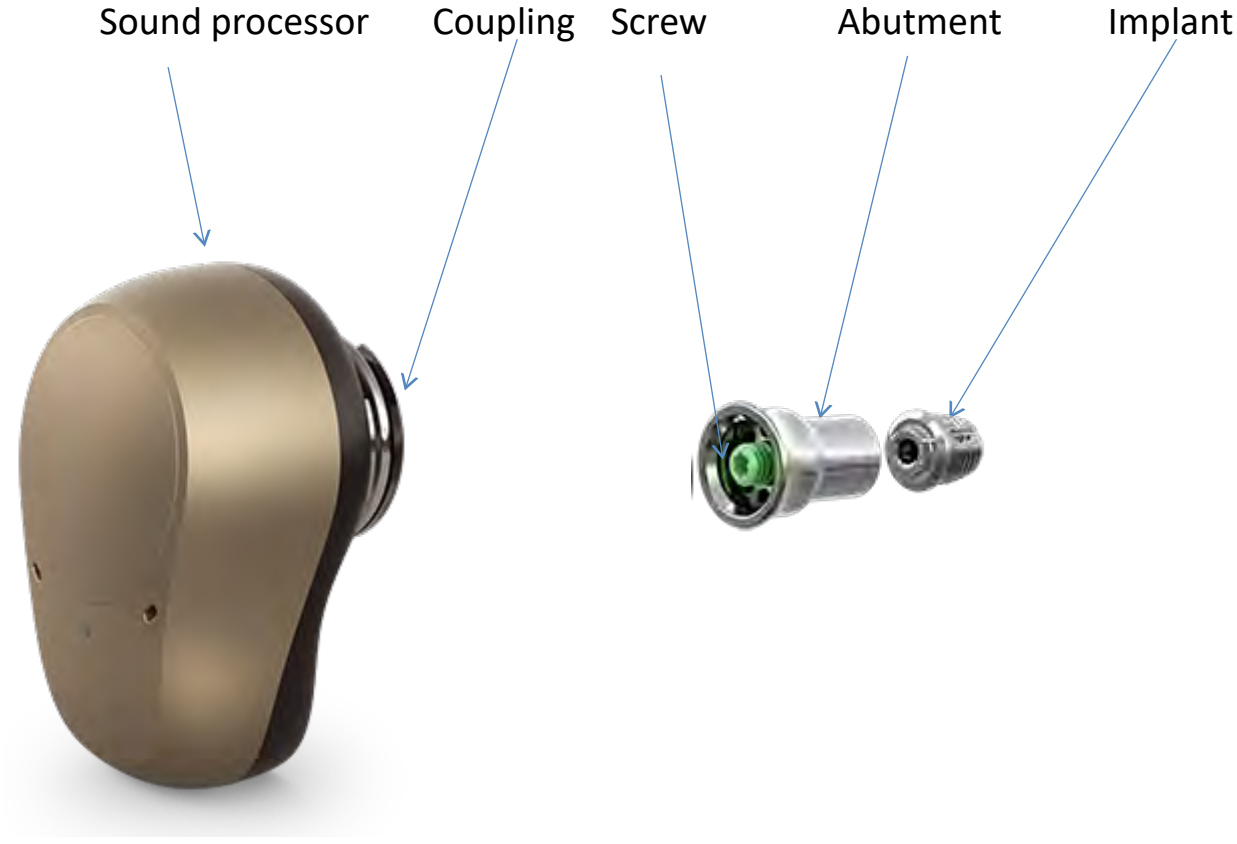
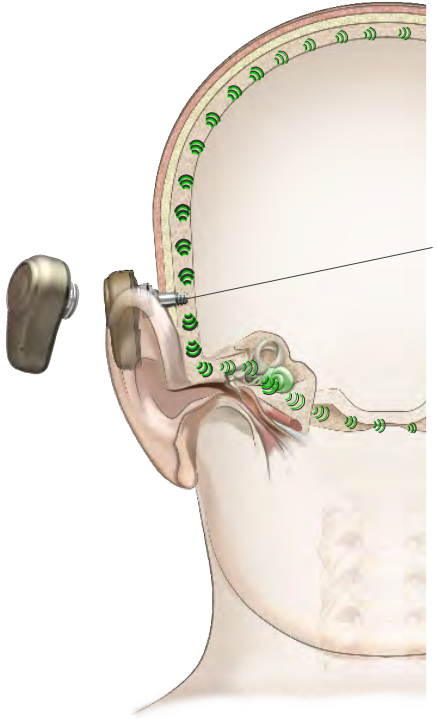
Bone Conduction Hearing and The Ponto System

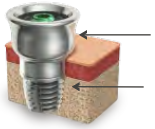
Components of a Bone Anchored Hearing System



Osseointegration and Direct Bone Conduction



Osseointegration



Abutment (6, 9, 12, or 14 mm long)

Implant (3 or 4 mm long)

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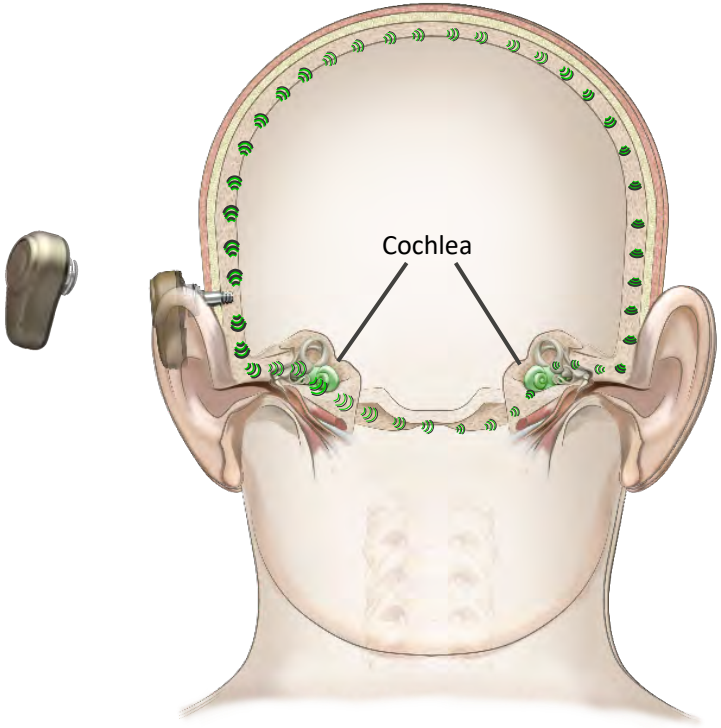
Direct Bone Conduction



Sounds are converted to vibrations, which are transmitted directly to both inner ears.

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The Ponto System Today

- Ponto 4 and Ponto 3 Superpower share the same basic foundation built on *BrainHearing*™ oticon MEDICAL UNIQUE

  a. Offer the widest frequency bandwidth in the market oticon MEDICAL UNIQUE

  b. Durable design and coupling

  c. Incorporate Oticon, Inc. sound processing and feedback management

World's most powerful abutment-level sound processor

World's smallest & advanced sound processing

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The Trial Process

The Trial Process

Different for Adults and Children

Adults

- Acute simulation completed in one appointment
- Patient fitting on test band
- Verification of benefit using a test protocol
- Subjective questionnaire administered to patient
- Counseling

Pediatrics

- Not an acute trial but a non-surgical process until child meets minimum age requirements
- Softband fitting
- Counseling
- Parent report measure
- Baseline testing
- Follow-up testing and monitoring

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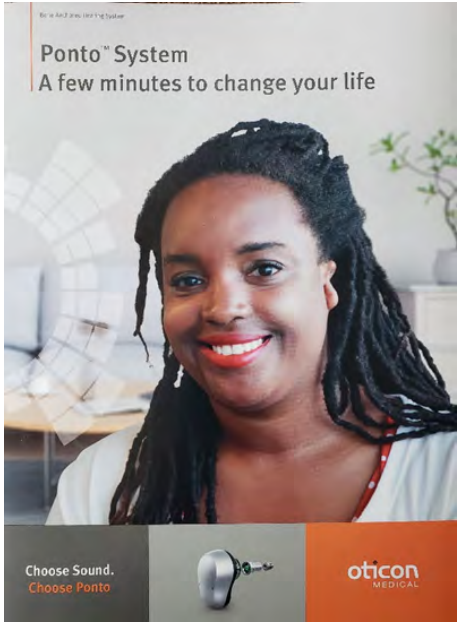
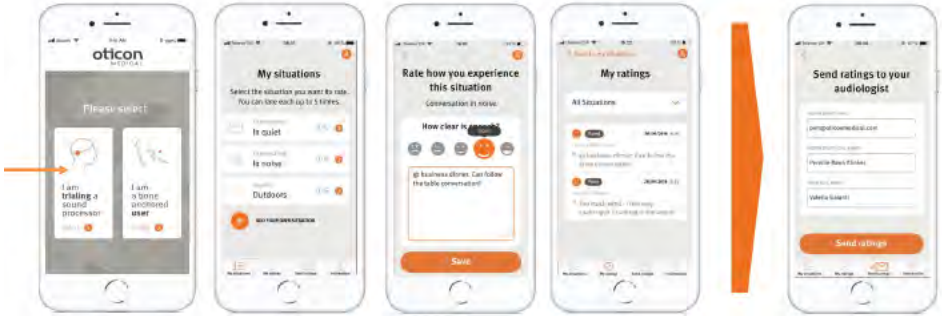
Clinical Tools and Resources

To have available for Patient Simulation

- Ponto Sound Processor (i.e. Ponto 3 SP)
- Verification/Test Protocol
- Subjective Questionnaire/Parent Report Measure
- Test band (preferred), Head band, or Soft band
- Ponto Counseling Kit
- Ponto Care APP – Trial Companion
- Ponto Candidate Materials





Why the Non-Surgical Process is Important

Opportunity to hear with the device

Verification of benefit

Comparison of different solutions

Assessment of subjective impressions

Assist with counseling

Provides best practices

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Direct Sound Transmission

Counseling Patients

Making an informed decision

- More options than ever for bone anchored patients

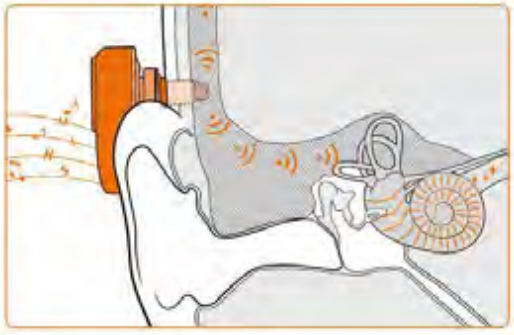
- There are both benefits and limitations in the different solutions for the individual patient
  - Does the solution provide enough amplification / output?
  - Is it comfortable enough to wear for a full day?
  - Cosmetically, how does it compare?
  - **Are there any benefits available beyond better hearing?**

- As professionals we must ensure that the patients make informed decisions before any surgical intervention

Direct Sound Transmission vs. Skin Transmission Systems

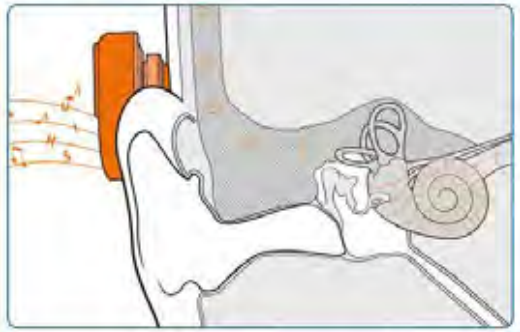
There are two types of bone conduction devices:

1. Direct Sound Transmission



Devices send vibrations via direct route to bone

2. Skin Transmission



Devices send vibrations through the skin to bone

Reinfeldt et al., 2015

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Bone Conduction Devices

Direct Sound Transmission
Vibrations directly to the bone

- **Active transcutaneous**
  Transducer in implant
- **Percutaneous**
  Transducer in external sound processor

Skin Transmission
Vibrations through the skin

- **Non-surgical solutions**
- **Passive transcutaneous**
  Implanted magnet

Reinfeldt et al., 2015

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Bone Conduction Devices

Direct Sound Transmission
Vibrations directly to the bone

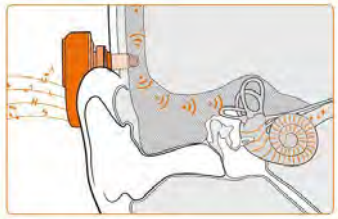
Skin Transmission
Vibrations through the skin

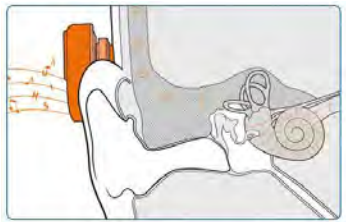
Active transcutaneous
Transducer in implant

Percutaneous
Transducer in external sound processor

Non-surgical solutions

Passive transcutaneous
Implanted magnet





Reinfeldt et al., 2015; Briggs et al., 2015

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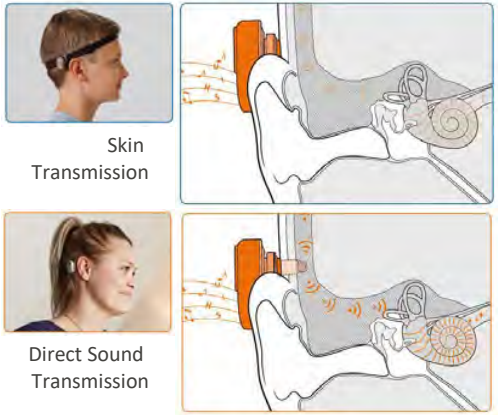
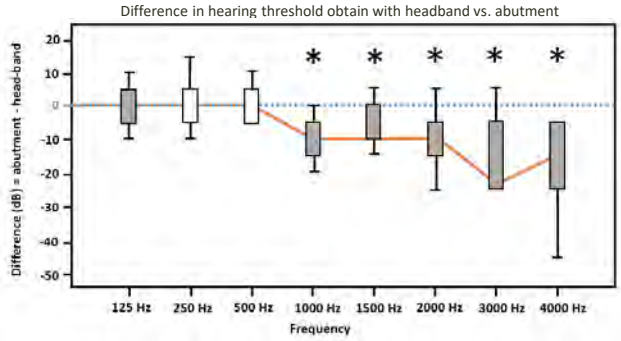
Benefits of Direct Sound Transmission

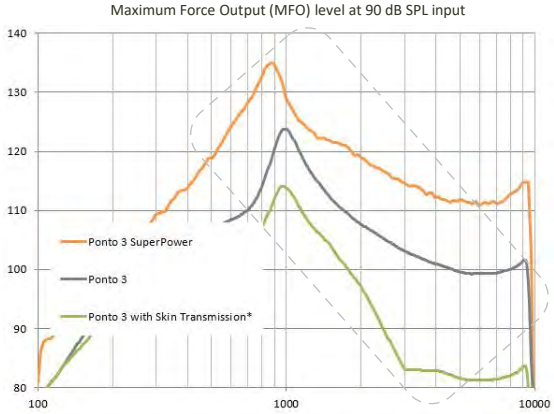
- Sounds are attenuated in Skin Transmission solutions – even with Softband correction.



- Direct Sound Transmission systems can provide an extra 10-20 dB of output in the mid to high frequency range.*



- The mid to high frequency range contains the most important sound information for speech understanding.



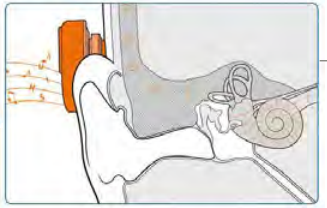
** MFO of Ponto 3 corrected by Skin Transmission dampening as measured in ref 5.*

** 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*

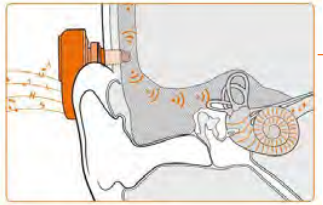
Benefits of Direct Sound Transmission

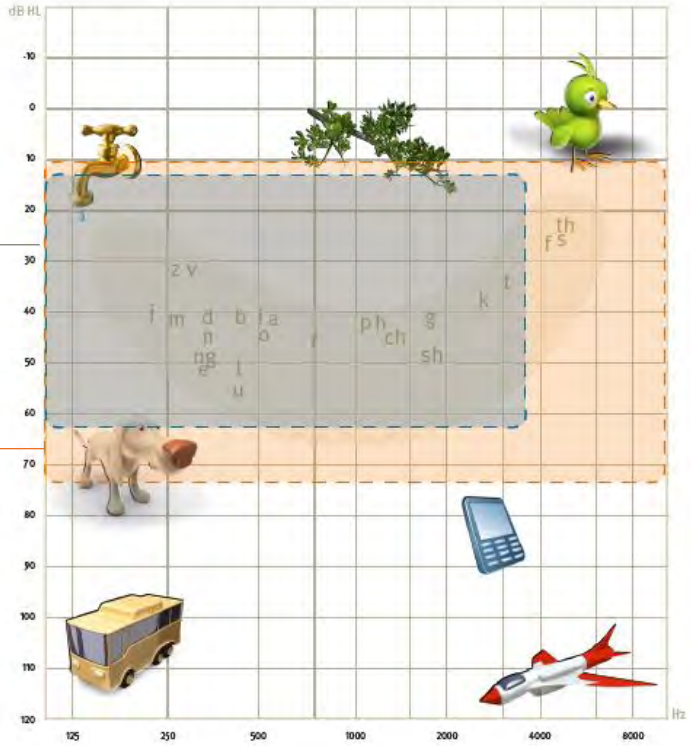
- Consequence of skin attenuation of speech phonemes

Skin Transmission

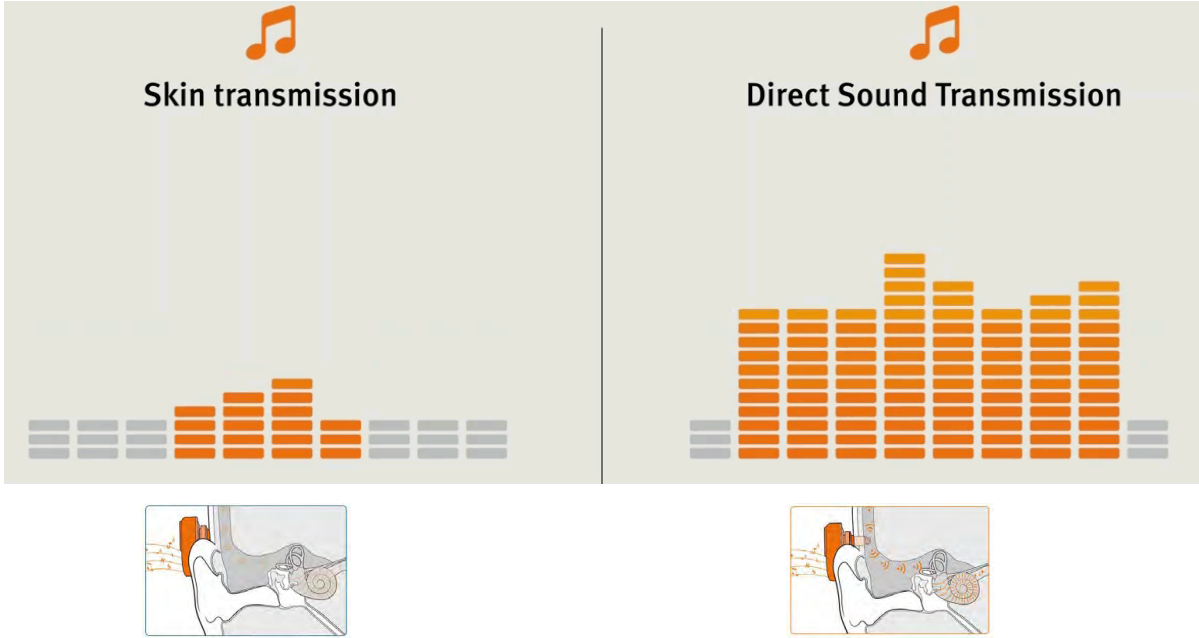


Direct Sound Transmission





Another Way to Look at it !



Counseling Considerations

Benefits of Direct Sound Transmission

- Hearing thresholds obtained are 5-20 dB lower (better) between 600 – 6000 Hz
- Speech reception thresholds are 4-7 dB lower (better) than conventional devices

Benefit to your patients:

- Access to more sounds
- Access to softer sounds

} Clearer, more natural sound with fewer distortion and less feedback

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Other Important Considerations

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Wearing Comfort

Ponto	Magnetic Solution
Minimal physical sensation of the device	One-third of patients experienced pain
Device stays attached to abutment	High risk of retention issues
Nothing prevents the user from wearing it all waking hours	Tissue reduction if skin over 6 mm
90% of users wear 8 hours or more	22% of users wear 8 hours or more

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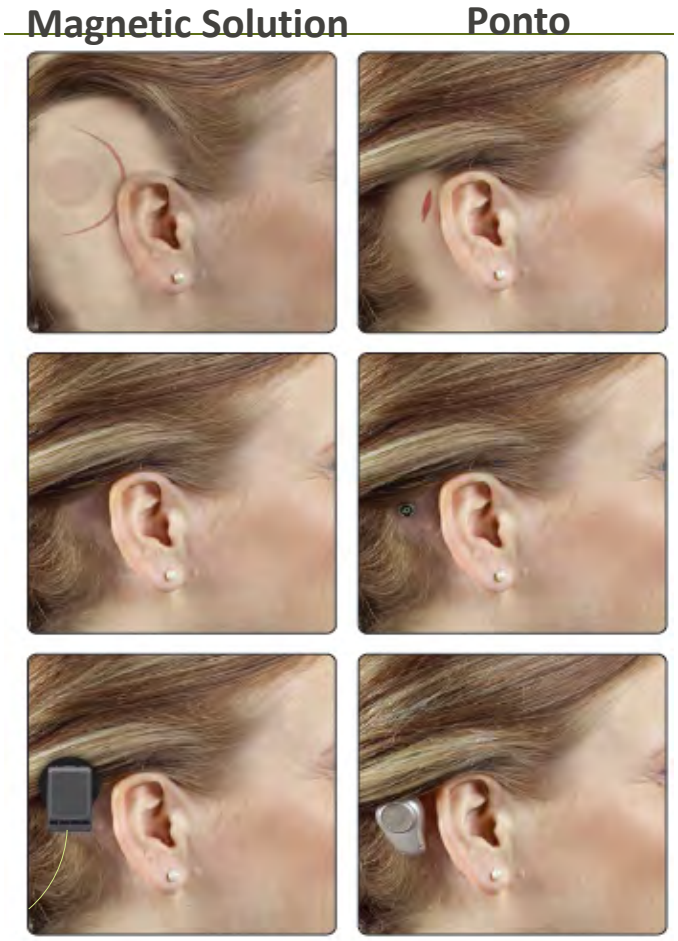
Cosmetic Considerations

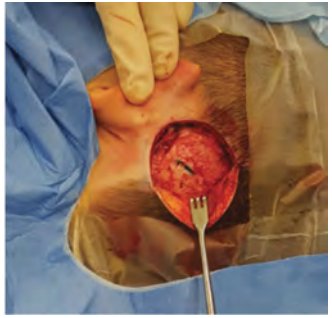


Surgical Considerations

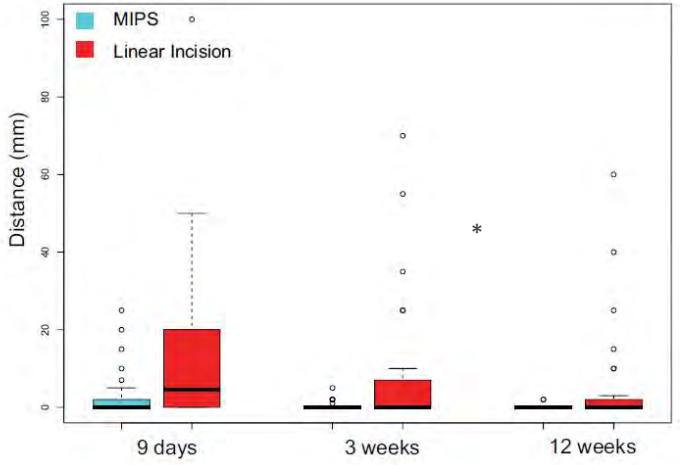
- A surgery should be as minimally invasive as possible for less numbness and pain
- Numbness is virtually gone as complication after MIPS surgery[3]
- With Attract, tissue reduction needed if skin thickness over 6mm
- Tissue preservation with MIPS is therefore reversible without side effects
- Average 45 minute Attract surgery[4] vs. 7 min for MIPS[4]

MIPS

Attract



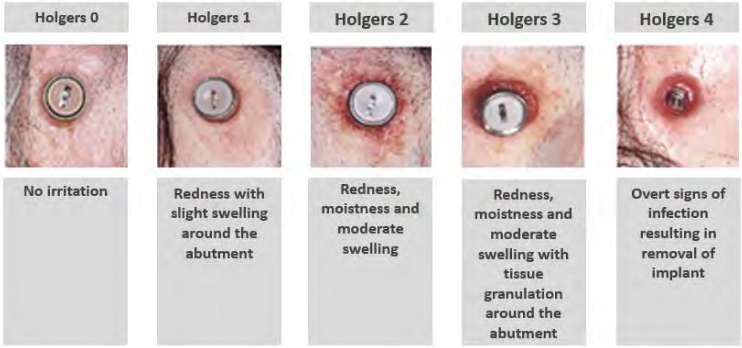
Area of Numbness (mm) MIPS vs. Linear



Post-Surgical Complications

Percutaneous Devices

- Accepted classification system
  - Holgers Score



Passive Transcutaneous

- No accepted classification system
- Systematic review (Cooper et al.)
  - 26 articles covering 482 implantations
    - Major complications was reported in 25 cases
    - Minor complications mostly consisting of pain or erythema due to magnet strength

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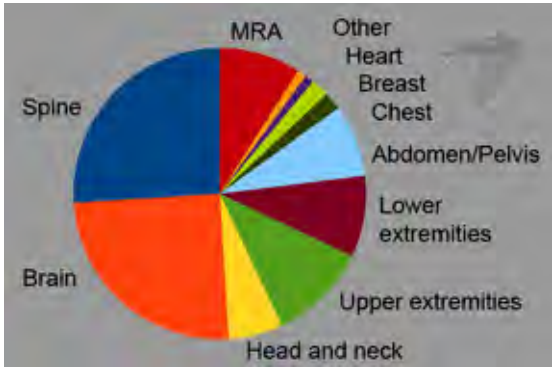
MRI Considerations

- MRI is widely used procedure with the likelihood that a patient will need on in their lifetime
- The implant may cause an artifact
  - Artifact shadowing will obstruct the scan
- Acoustic neuroma patients undergo several MRI´s post surgery



http://www.magnetic-resonance.org/ch/21-01.html

Ponto
- 3 Tesla
- 10 mm artifact

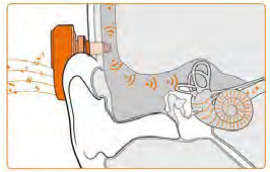
Magnetic system
- 1.5 Tesla
- 115 mm artifact

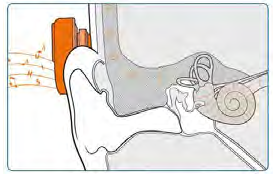
Oticon Medical MRI Security card
Surgery guide, Cochlear Baha 4 Attract System, Surgical procedure

Note! The illustrations are not exact. Just a schematic view of the artifact effect

Who are the Candidates if Sound Matters?

Direct drive	Ponto	• Pediatrics* and adults • Conductive and mixed • Single sided deafness
Skin drive	Transcutaneous, Magnet	• Pediatrics* and adults • Conductive and mixed • Single sided deafness
	Head band or soft band	• Pediatrics before eligible for surgery • Adults: testing or before surgery





* Above the age of 5 years

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Transitioning to the Abutment and Implant

Transitioning to the Implant

Minimally Invasive Ponto Surgery

80% of all Ponto operations in the US are done with MIPS!

- Minimizing post-op complications
  - Less tissue disturbance, numbness and irritation
- Suture free operation
  - No scarring = Better cosmetic outcomes
  - Less surgical time
- Tailor-made operational components
  - Allows for minimal and safe procedure
  - Long-term goal is to further reduce the need for post-surgical treatment

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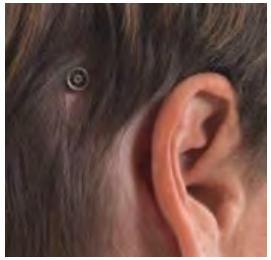
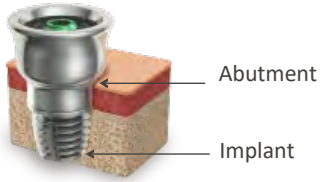
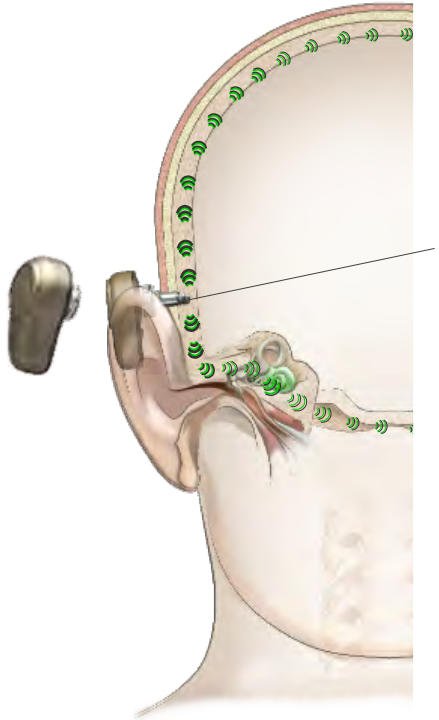
Transitioning to the Implant

Osseointegration and Direct Transmission



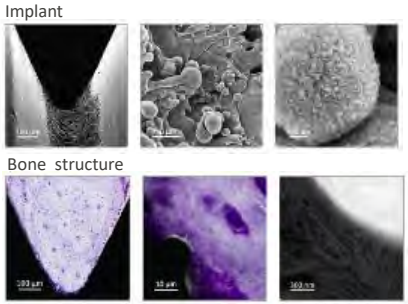




Ponto is an auditory osseointegrated bone conduction implant system.

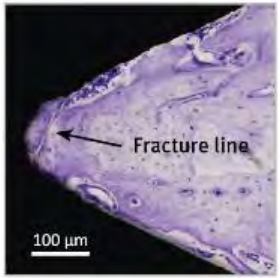
Transitioning to the Implant

Bone bonding – fast and strong osseointegration



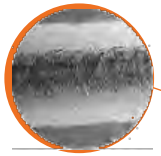
First laser-ablated titanium surface
Site-specific modification at the root of the threads

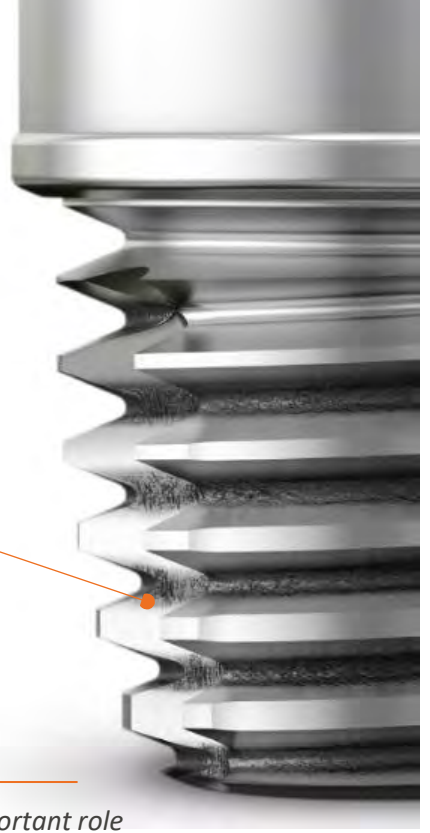
Matching the natural bone structure at macro-, micro-, and nano-scale.



Stronger than bone
The bone bonding to the BHX implant is stronger than the bone itself.[5]

Ponto BHX implant





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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Ponto Abutments

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A unique design for tissue preservation

10 Years of sound that matters

Titanium
22
Ti
47.867

The proven surface

- Ponto abutments feature the proven surface for tissue preservation surgery.[6]

Perfect fit

- Even supportive surface and perfectly matched interface is ideal for MIPS/tissue preservation

OptiFit™ - Perfect fit with no pockets or pathways

> *I would highly recommend it. It has had a huge impact on my life… I don't know it's there. Once it's healed, you don't really need to do anything different."*
>
> Louise

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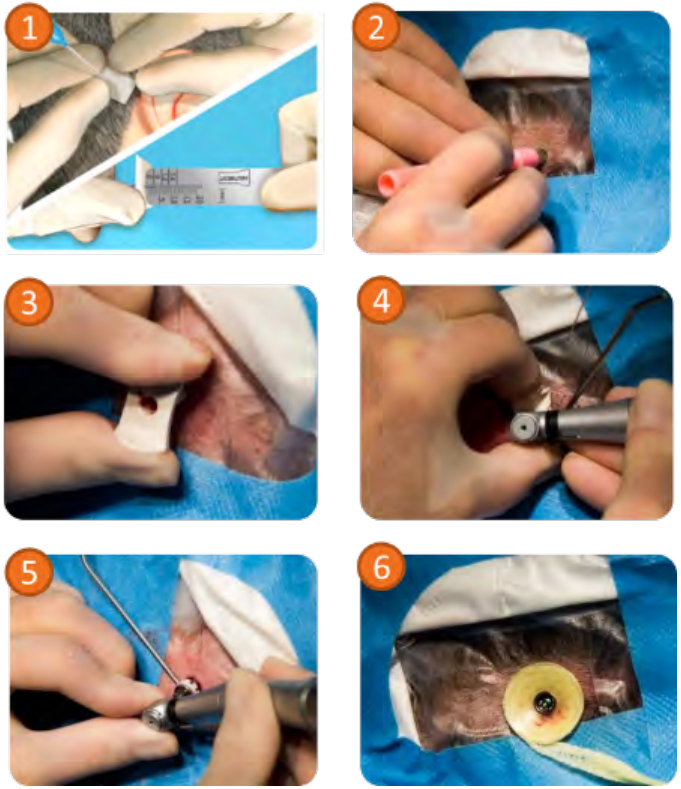
Transitioning to the Implant

The MIPS Procedure

1. Preparing the Site
2. Punching and Inserting the Cannula
3. Initial Drilling with Cannula Guid Drill
4. Drilling with the Cannula Widening Drill
5. Implant Installation
6. Attach the Healing Cap and Dressing



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Safe Outcomes

Safe Outcomes

Safe Outcomes: Technology and Procedure go hand and hand

Longer abutments

More stable implants

Patient Benefit
Safer Outcomes

Less invasive techniques

Earlier activation

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Safe Outcomes

Quality of Life

- Five studies evaluating 176 patients with conductive or mixed hearing loss or single-sided deafness.

- Conditions:
  Change in quality of life measured after Ponto surgery.

- Task:
  The Glasgow Benefit Inventory (GBI) health-related quality of life questionnaire.

98% of users reported improved quality of life after Ponto surgery[1]

1. *Lagerkvist, H, et al. (2020). Ten years' experience with the Ponto bone anchored hearing system – a systematic literature review. Clinical Otolaryngology (under review).*

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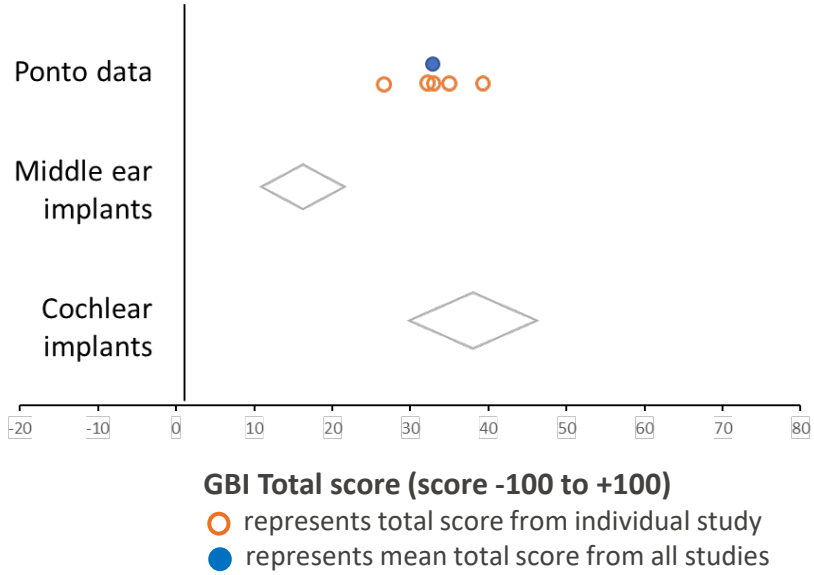
Safe Outcomes

Quality of Life

- Published Ponto data
  - 176 patients (5 studies)
  - 98% of patients reported improvement in quality of life
  - Average improvement 33 points
- Improvement after Ponto surgery larger than for middle ear implants, and almost as large as for cochlear implants[1]



1. Hendry, Chin, Swan, Akeroyd and Browning. The Glasgow Benefit Inventory: a systematic review of the use and value of an otorhinolaryngological generic patient-recorded outcome measure. Clin Otolaryngol. 2016; 41(3): 259–275.

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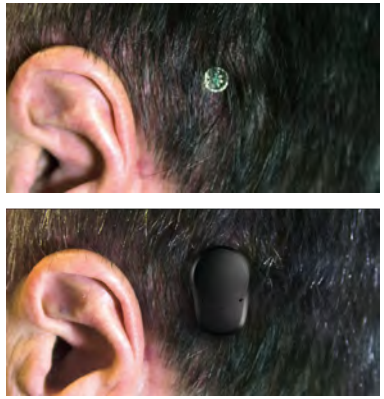
Safe Outcomes
Surgical

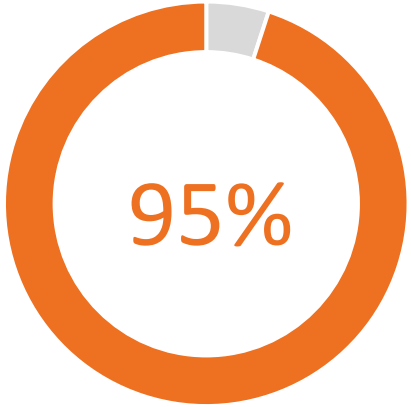
- Participants:
  Twenty-seven studies evaluating more than 1,100 patients with conductive or mixed hearing loss and single-sided deafness.

- Conditions:
  Adverse skin reactions according to *Holgers (across visits) up to five years follow-up (mean follow-up time 16 months).

- Task:
  *Holgers score ≥2 indicates need for skin-related aftercare treatment.

In 95% of follow-up visits no skin-related aftercare treatment* is required[1]





1. *Lagerkvist, H, et al. (2020). Ten years' experience with the Ponto bone anchored hearing system – a systematic literature review. Clinical Otolaryngology (under review).*

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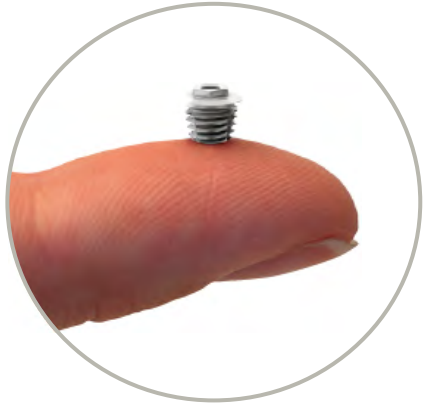
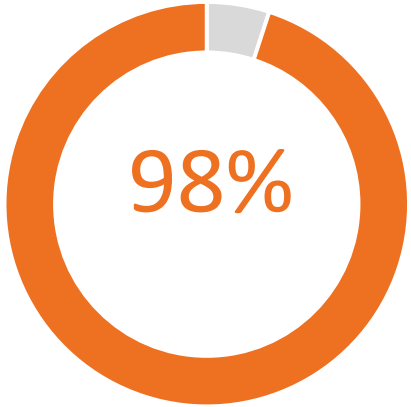
Safe Outcomes

Surgical

A systematic literature review reporting on 10 years' experience with the Ponto™ System demonstrated **an overall implant survival rate of 98%.**[1]





1. *Lagerkvist, H, et al. (2020). Ten years' experience with the Ponto bone anchored hearing system – a systematic literature review. Clinical Otolaryngology (under review).*

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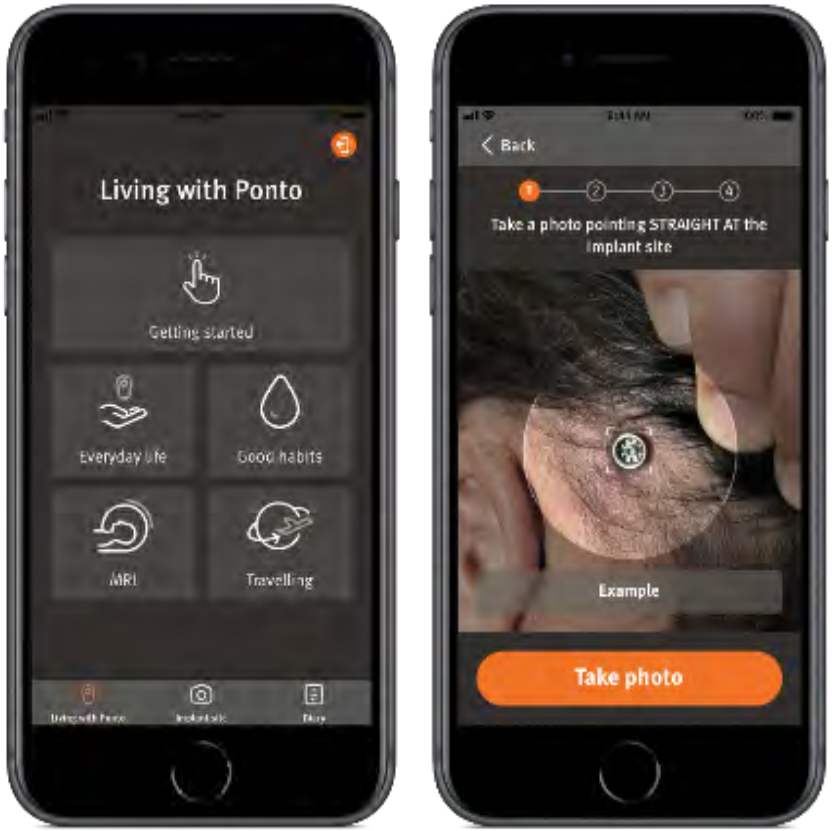


Ponto Care App

Safe Outcomes
Ponto Care App

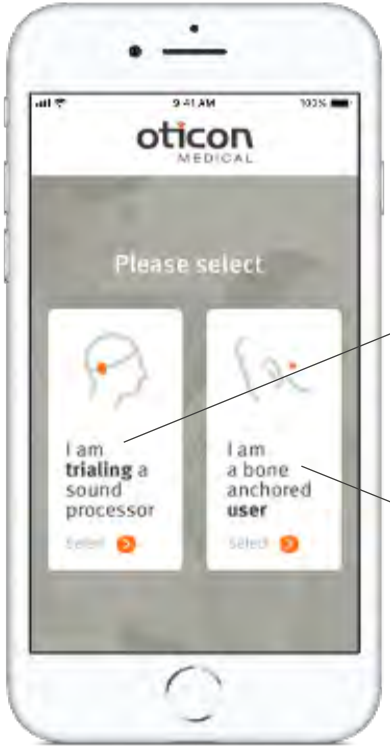
A tool for you and your patients during social distancing times

- ✓ Developed with usability across all age groups in

- ✓ Adhering to the highest privacy standards- photos are saved on patient's phone, never on the app

- ✓ Free for everyone

- ✓ Does not require log in / account



Trial Section

1. Flow
2. Benefits & service evaluation
3. Best practices

Aftercare section

1. Flow
2. Benefits
3. Best practices

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Ponto Care App

What are the benefits?

Patient

- Guidance and engagement during the trial process
- Aftercare information and ability to self-monitor their implant site and their hearing

Professional

- Provides the ability to better engage with patients
- Offers information that can assist with patient management and counseling

- Can have a structured approach to the post trial visit, assist with counseling and overall management
- Patients and HCPs have a better understanding of the evolution of the implant site and their hearing; they can refer to precise and concrete data

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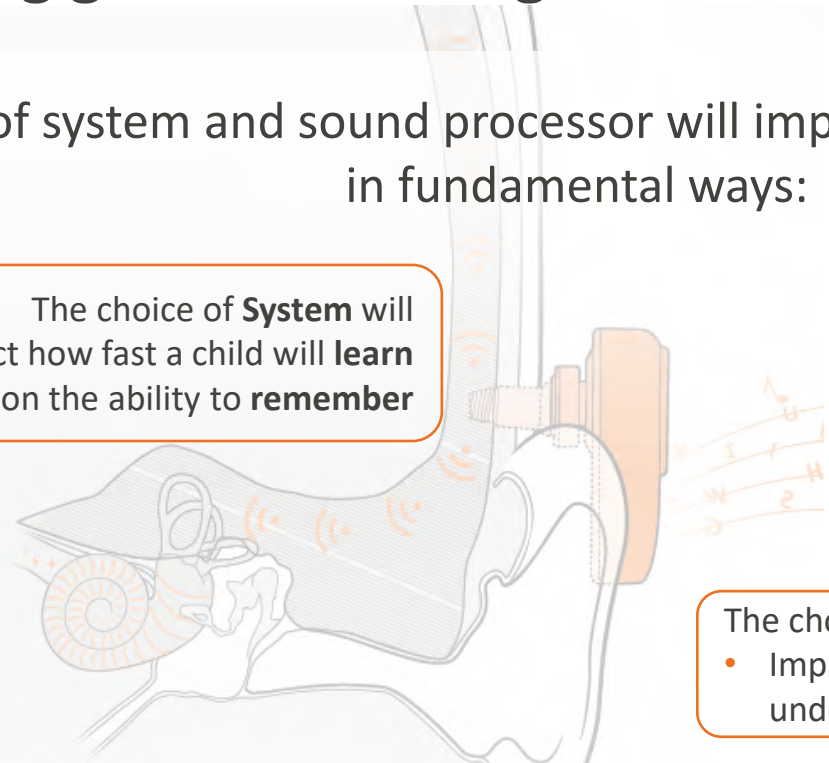
Clinical Evidence

Introducing ground-breaking evidence

The choice of system and sound processor will impact the user's everyday life in fundamental ways:

The choice of **System** will
- Affect how fast a child will **learn**
- Have an impact on the ability to **remember**



The choice of **sound processor** will
- Impact the **level of effort** needed for understanding speech

1. Pittman, A. L. Bone conduction amplification in children: Stimulation via a percutaneous abutment vs. a transcutaneous softband. Ear Hear (under review).
2. Lunner, T., Rudner, M., Rosenbom, T., Ågren, J., and Ng, E.H.N. (2016) Using Speech Recall in Hearing Aid Fitting and Outcome Evaluation Under Ecological Test Conditions. Ear Hear 37 Suppl 1: 145S-154S.
3. Bianchi, F., Wendt, D., Wassard, C., Maas, P., Lunner, T., Rosenbom, T., and Holmberg, M. Benefit of higher maximum force output on listening effort in bone-anchored hearing system users: a pupillometry study. Ear Hear (in press).

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Clinical Evidence

- We use BrainHearing™ as our guiding star and strive to develop products that make it as easy as possible for the brain to make sense of sound.
- With the Ponto™ System more cognitive resources can be used for understanding, remembering and enjoying life.

LEARN FASTER

REMEMBER MORE

LESS EFFORT

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Clinical Evidence

Learn Faster

- Principal investigator:
  Prof. Andrea Pittman

- Participants:
  17 children (mean age: 11 years old);
  16 with conductive hearing loss,
  1 SSD.

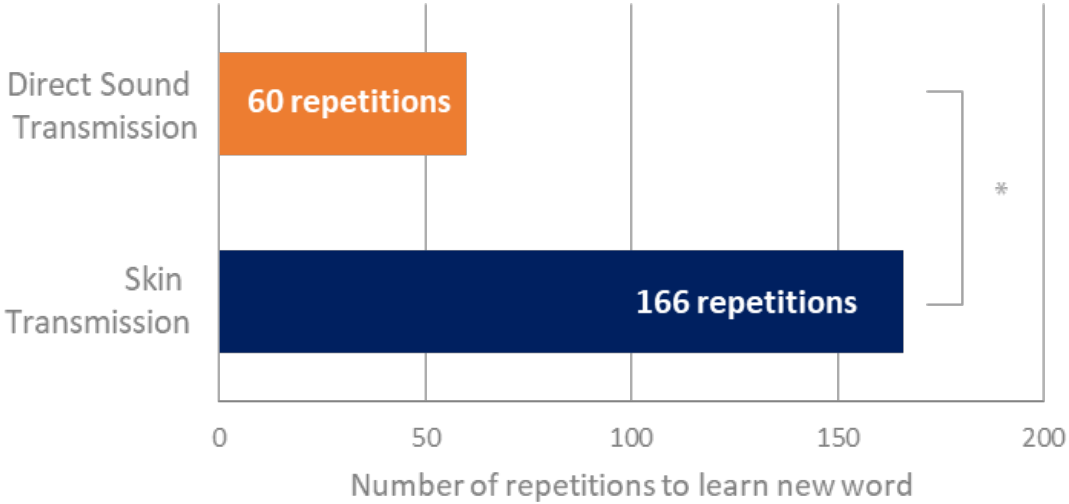
- Conditions:
  Power version of Ponto optimally fitted on abutment and softband.

- Task:
  Listen to and learn six new words.

Pittman, A 2019

Clinical Evidence

Learn faster



Children learn new words
2.5 x faster
using a system with
Direct Sound Transmission
compared to a solution
with Skin Transmission.
(Pittman AL, 2019)

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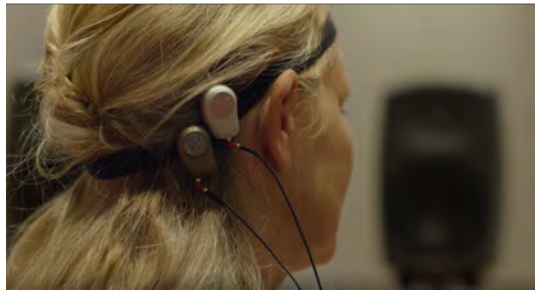
Clinical Evidence
Remember more

- Principal investigators:
  Prof. Thomas Lunner & Oticon Medical

- Participants:
  16 adults (mean age: 58 years old) with conductive or mixed hearing loss



- Conditions:
  Power version of Ponto optimally fitted on abutment and softband

1. Everybody wears **sunglasses**.
2. He is still lying on the **sofa**.
3. The student will write a long **report**.
4. The whole town came to the **wedding**.
5. His daughter wants to go to **college**.
6. Yesterday was the film's **premiere**.
7. The factory port was not **closed**.

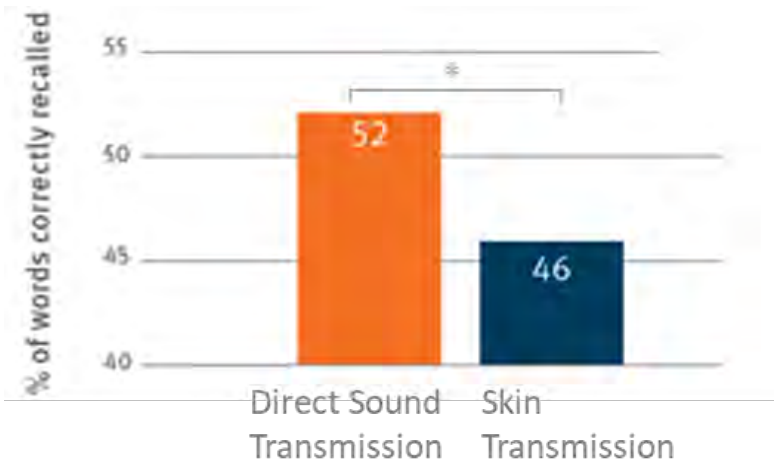
Translated from Danish.

- Task:
  Recall words after listening to 7 sentences (SWIR test[4])

Lunner T, et al 2016

Clinical Evidence

Remember More



13% relative improvement in recall performance with **Direct Sound Transmission.** Fewer resources are needed to process the signal, and more resources can be used for remembering.

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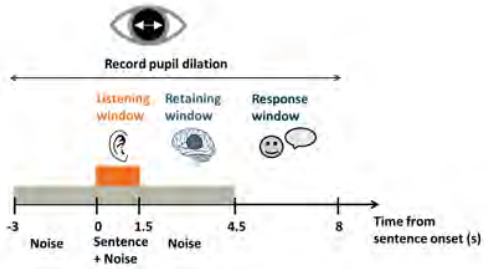
Clinical Evidence
Less Effort

- Principal investigator:
  Oticon Medical

- Participants:
  21 adults (mean age: 59 years old) with conductive or mixed hearing loss.

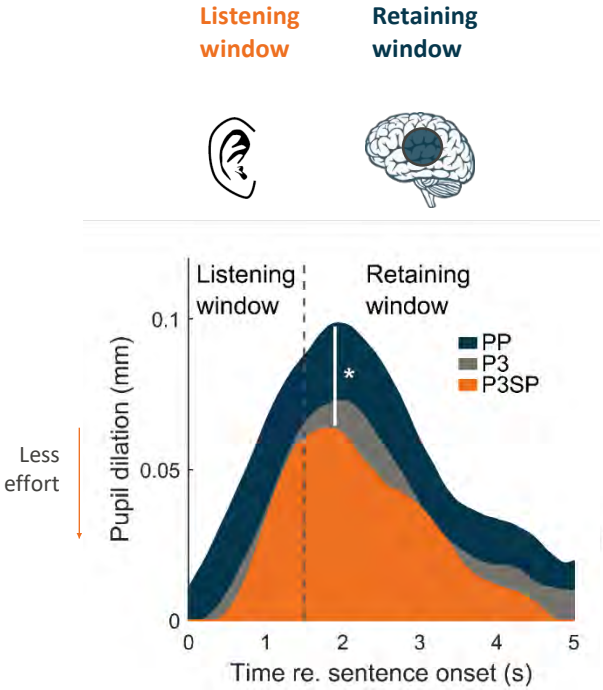
- Conditions:
  Sound processors with different maximum output: Ponto Pro, Ponto 3, Ponto 3 SuperPower.

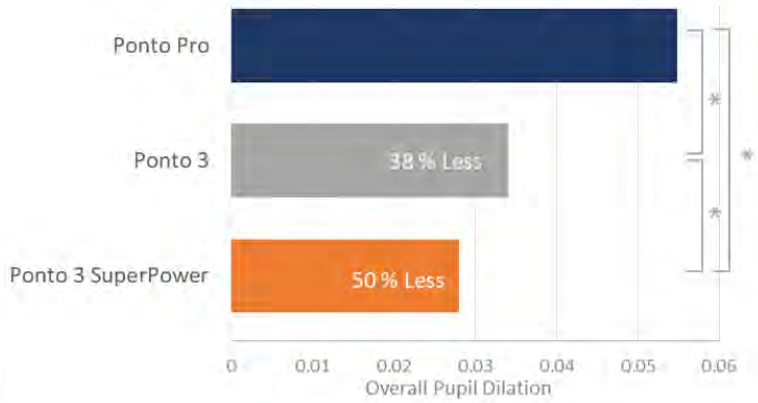


- Task:
  Listen to and repeat sentences, while an eye-tracking camera monitors pupil dilation, as a measure of listening effort.

Bianchi, F. et al 2019

Clinical Evidence
Less Effort





A significant decrease in listening effort can be achieved with the **Ponto 3 SuperPower,** as indicated by reduced pupil dilation.[3]

Pediatric Case Study

The Importance of Providing Early Amplification

- Age at fitting of amplification is predictive for speech perception, speech production, and spoken language skills. *(Sininger et al 2010)*

- Auditory system development, and particularly development of speech perception, is guided by access to relevant acoustic and linguistic information early in life. *(Kuhl PK, 2000)*

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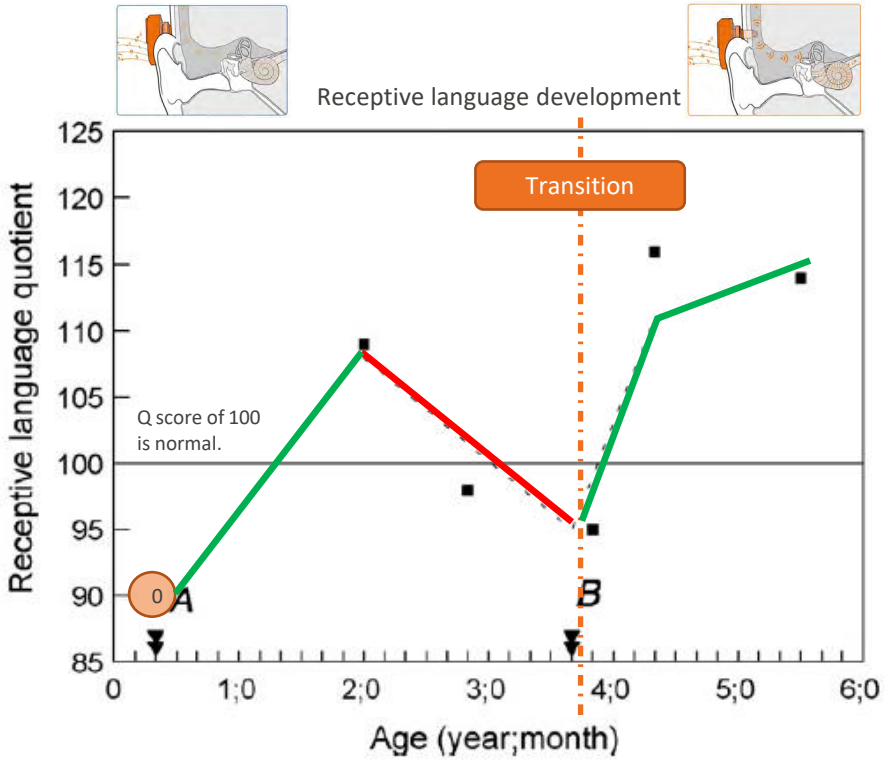
Pediatric Case Study: Importance of Timely Transition

- Transition to Direct Sound Transmission was necessary to maintain normal language development
- ”Language development testing showed an accelerated improvement in speech development after implantation”



Verhagen et al (2008)

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Pediatric Summary

- Children need to wear a hearing solution:
  - With maximum audibility in the high frequency region in order to facilitate word learning
  - That can be worn all day to develop language and communication skills, both in school and during social activites
  - That is not easily lost

- Soft band is the only choice before age of surgery
- After minimum age for surgery, for normal development:
  - Best access to high frequencies must be provided in order to facilitate word learning
  - Full day of use must be secured

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Ponto evidence – Impact beyond better hearing

LEARN FASTER

System level
Direct Sound Transmission vs.
Skin Transmission
(Children)

2.5 x faster learning

REMEMBER MORE

System level
Direct Sound Transmission vs.
Skin Transmission
(Adults)

13 % better recall

LESS EFFORT

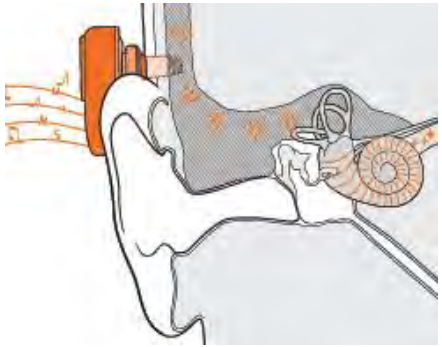
Product level
Ponto Pro, Ponto 3 vs.
Ponto 3 SuperPower

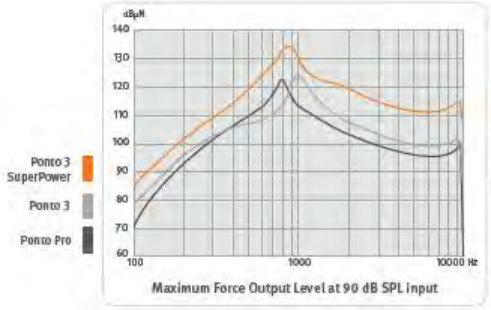
Significantly less effort

Ponto - A direct way to Easier Listening

- Results show - Direct Sound Transmission and sound processor with higher max output provides best outcomes.

Ponto System™





Ponto 3 SuperPower

The Ponto System uses Direct Sound Transmission with an abutment.

Ponto 3 SuperPower is the most powerful abutment-level bone anchored sound processor in the market.

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Take-aways

- Direct sound transmission delivers the optimum sound quality
- Increased sound quality leads to a reduction in listening effort
- This is especially important in the pediatric population as it can have a significant effect on other areas such as language development
- There are a wide array of considerations to take into account that the patients may be aware of, or misconceptions they may hold
- It is important the patient makes an informed decision whichever device they choose; they can only do this when armed with the correct information

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Thank you