

Audiologyonline.com Live Seminar  
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### Audiological considerations of the Ponto bone anchored hearing system before and after surgery

**Ravi Sockalingam**  
Director of Clinical Research,  
Oticon Medical LLC  
**Justin Pfeiffer**  
Vice President of Sales,  
Oticon Medical LLC



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#### Outline

- Introduction to bone anchored hearing systems (BAHS)
- Pre-surgical considerations
- Surgical techniques and skin responses
- Post Surgical considerations



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
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#### What is a Bone Anchored Hearing Device

- A well established hearing solution for conductive & 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



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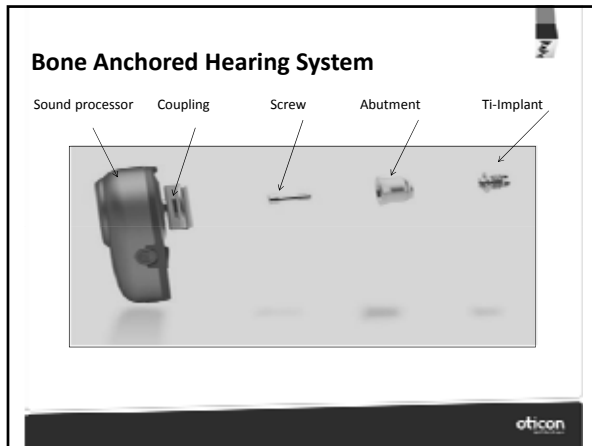
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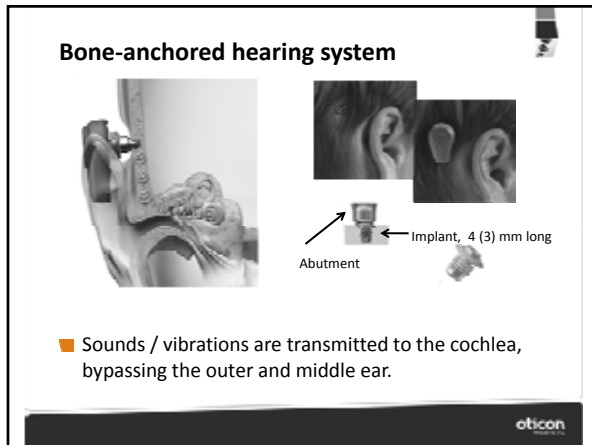
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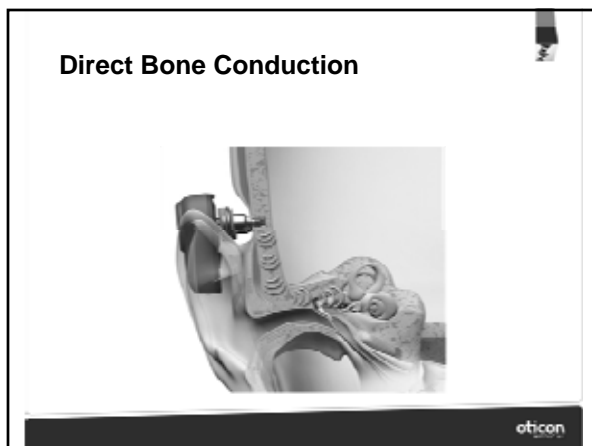
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### Direct Bone Conduction

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

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### Candidates for bone anchored hearing solution

- Conductive & mixed hearing losses
- Single-sided deafness



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### BAHS Candidate

#### 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)

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### Bone anchored hearing aids Typical audiograms

Conductive & Mixed HL

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### Bone anchored sound processor

Inner ear hearing threshold (BC)

Middle ear hearing loss (air-bone gap)

■ Vibrations bypasses the hearing loss in the middle ear.

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### Traditional HA versus bone anchored HA

■ Traditional HA	■ Bone anchored HA
■ Need <u>high</u> gain.	■ Need <u>little</u> gain.
[gain(BC) + gain(ABG)]	[gain(BC)]

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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



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**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



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**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



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### Candidates for bone anchored hearing solution

- Conductive & mixed hearing losses
- Single-sided deafness



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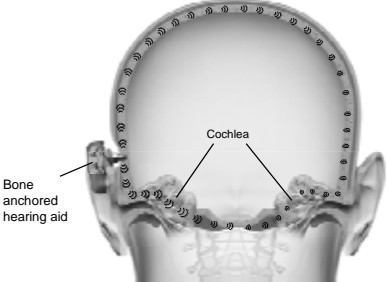
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### Bone anchored hearing solution



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

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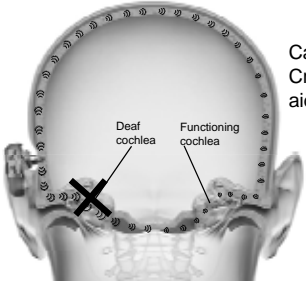
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### Bone anchored sound processor



Can work as a Cross hearing aid

One cochlea is picking up sound from both sides.

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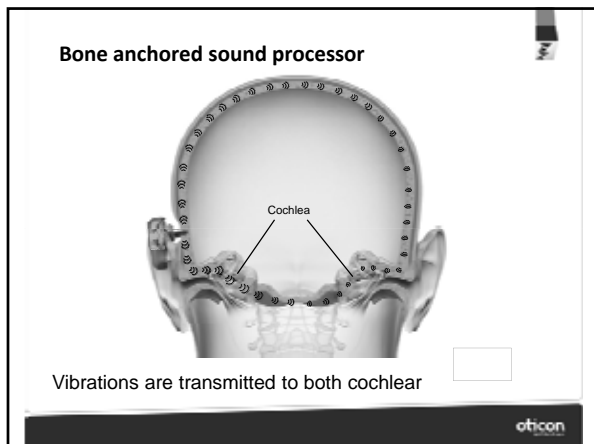
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### Candidates

Single-sided deafness

- A patient with Single-sided deafness (SSD) has
  - a profound sensorineural hearing loss in one ear (aka unilateral sensorineural hearing loss)

- Sudden deafness
- Acoustic neuroma
- .....

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### Single sided deafness

- $\geq$  5years of age
- Intended to improve speech recognition
- Intended for patients with SSD or unilateral sensori-neural hearing loss when the other ear is normal
- Normal hearing is defined as PTA AC threshold equal to or better than 20 dB at .5, 1, 2 and 3kHz
- For patients who cannot or will not use AC CROS HA
- Functions by transcranial routing of the signal

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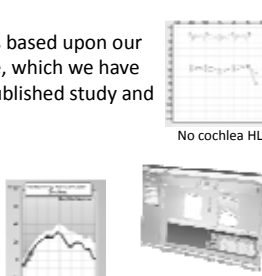
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### Rationale - Conductive HL

- The prescription of gain is based upon our own proprietary rationale, which we have developed based upon published study and clinical tests.<sup>1,2</sup>

No compression.



No cochlea HL

Mild cochlea HL

1. P.U. Carlsson and B. E. Håkansson, "Force threshold for hearing by direct bone conduction", J. Acoust.Soc.Am. 97(2) Feb 1995  
2. T. Rosenbom and A. Specht Petersen, "Test with a new Direct Bone Conductor", Poster at Otosco Conference 2009.

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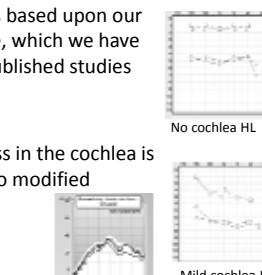
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### Rationale - Conductive and mixed HL

- The prescription of gain is based upon our own proprietary rationale, which we have developed based upon published studies and clinical tests.<sup>1,2</sup>
- Mixed HL: Any hearing loss in the cochlea is compensated according to modified NAL-NL1.



No cochlea HL

Mild cochlea HL

1. P.U. Carlsson and B. E. Håkansson, "Force threshold for hearing by direct bone conduction", J. Acoust.Soc.Am. 97(2) Feb 1995  
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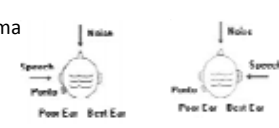
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### Rationale - Single-sided deafness

The dilemma



Hörbar Hörbar

Poor Ear Best Ear Poor Ear Best Ear

The rationale:

- Reduced LF amplification compared to prescription for conductive HL, as there is no head shadow effect at low frequencies.
- Compensates for trans-cranial attenuation – additional HF amplification.

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### Single Sided Deafness SSD

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



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### Clinical Aspects *Single Sided Deafness*

- For adults:
  - Difficulties to understand in group conversations, or with noise.
  - Difficulties to localize sounds,
  - Difficulties to understand a person situated on the deaf side.
- For children:
  - School handicap.



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### How does a bone anchored system work for single sided deafness?



- The prescribed gain is based upon the good ear's BC.



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### Single sided deafness

- People with single-sided deafness obtain a different gain prescription than people with conductive and mixed hearing loss.
- The BC on the better hearing ear is used.
- Compensation for the transcranial attenuation is added (more HF amplification).
- The low frequency sounds are less amplified (than in conductive and mixed cases), because the head doesn't shadow for LF sounds




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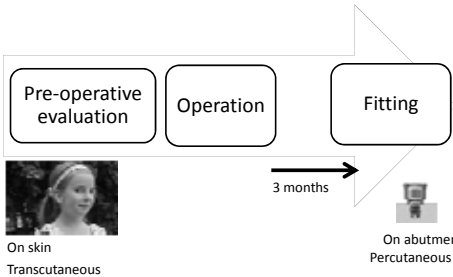

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### Pre-operative evaluation and fitting with soft band


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### FAQ's regarding the Bone Anchored System

- What will be implanted in my head? – The fixture that is implanted in the skull bone is only 3-4 mm and the abutment which attaches to the implant can hardly be seen behind the ear
- Does it hurt ? – No. Surgery takes 30-60 minutes, is mostly performed under local anaesthesia and the patient can go home after
- How long will it take until I get my sound processor? – Approximately 3 months, the time for the implant to integrate with the skull bone. This process is called osseointegration
- Can you see the sound processor behind the ear? – It depends on your hair, if your hair is very short it will show a little, with longer hair it does not show at all




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### Pre-Operative Evaluation and Testing

- Basic Evaluation
  - Air and bone conduction thresholds
  - Speech testing
  - Impedance Audiometry (Objective)
  - Tympanometry
  - Stapedial reflexes
  - OAE
- Soundfield Testing with device using softband (functional gain)
- Presenting choices
- Patient centered counseling – VERY IMPORTANT




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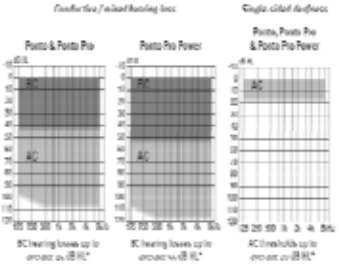
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### Ponto Fitting Ranges




*Transferable / shared fitting data*

**Ponto & Ponto Pro**  
AC hearing losses up to around 40 dB HL\*  
\*range of e.g. 1, 2 and 3 only

**Ponto Pro Power**  
AC hearing losses up to around 40 dB HL\*

**Ponto, Ponto Pro & Ponto Pro Power**  
AC hearing losses up to around 40 dB HL\*




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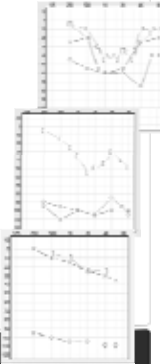

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### Candidates for Ponto Pro Power

- Patients with mixed hearing losses
  - long history of ear diseases
  - often older than the patient group with conductive hearing losses
  - e.g. chronic otitis media plus presbycusis
- Single sided deafness
  - Including patients whose hearing in the better ear is on the decline


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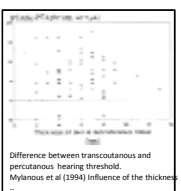
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### Pre-operative evaluation

Difference between transcutaneous and percutaneous hearing threshold.  
Mylanus et al (1994) Influence of the thickness

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### Pre-operative evaluation

#### Transcutaneous attenuation

- Sound (vibrations) are damped when passing through skin and tissue.  
This transcutaneous attenuation varies from person to person, but is mainly in the high frequency area<sup>1,2</sup>.
- Gain should be increased to compensate for the loss through skin and tissue.  
(increase 10 dB at 1 kHz and above)

1. Mylanus, E.A.M. et al. (1994), Influence of the thickness of the skin and subcutaneous tissue covering the mastoid on bone-conduction thresholds obtained transcutaneously versus percutaneously. *Scandinavian audiology*, vol. 23, no.3  
2. Verstraeten, N. et al. (2009), 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*, vol. 30, no 1

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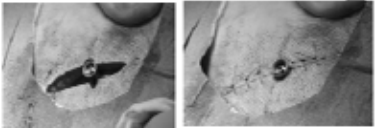
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### Surgery Overview


Punch / minimal invasive



Dermatome



Linear incision



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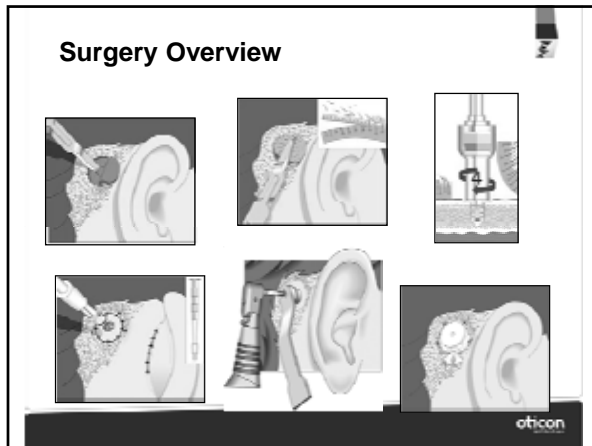
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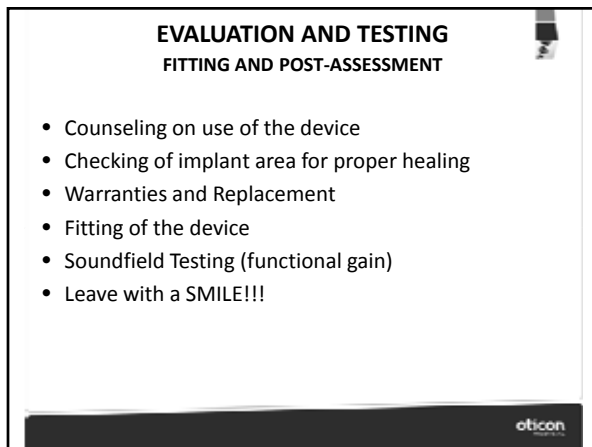
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**Post fitting technical considerations**




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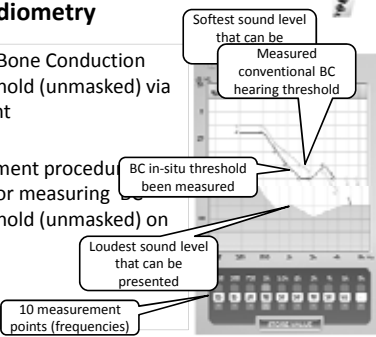

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**BC In-situ Audiometry**

- Measure the Bone Conduction hearing threshold (unmasked) via the instrument
- The measurement procedure is the same as for measuring hearing threshold (unmasked) on audiometer.


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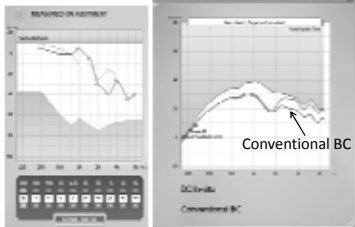
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**BC In-situ audiometry (example: large gain difference)**

- Man, 25 years old.
- Atresia



- Large difference in high freq. gain prescribed by BC In-situ and conventional audiometry. With BC In-situ he receives more HF gain.




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### Directionality in more situations with Multiple Directionality Modes

Typical use time spent in directional modes

- 8% Full Directionality: Responds to movement in all directions. Typical use in many hearing aid situations.
- 72% Dual Directionality: Responds to movement in front and back. Typical use in many hearing aid situations.
- 20% Split Directionality: Responds to movement in front and back. Typical use in many hearing aid situations.

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### Feedback limit

Feedback limit (black curve)

Feedback limit is either

- Default – non individualized
- Measured – individualized

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### Feedback Limit

Default feedback limit (non-individual)

- Prohibits gain initially to be higher than the limit, and thereby
- minimize the risk of having feedback just when the instrument is on the patient.

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### Default Feedback Limits

.. is below max gain

.. is at max gain

- Prohibits gain initially to be higher than the limit, and thereby
- minimize the risk of having feedback just when the instrument is on the patient.

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### Feedback Manager

Measure individual FB limit

- Click Start and the Feedback measurement is automatically conducted.

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### Fittings/trials on soft band, head band

- Sound is attenuated when passing through the skin.

Difference between transcutaneous and percutaneous hearing threshold.  
Mylanous et al (1994) Influence of the thickness

- For fittings on soft band and abutment
  - the BC In-situ threshold and
  - the Feedback limit
 are different

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**Patients' with mixed HL reactions  
– immediately when they are fitted**

- Some may find Ponto softer/weaker than their previous instrument, but at the same time it is easier to understand speech with Ponto.
- The patients won't experience the full benefit from the advanced signal processing until they come into challenging listening environments.
- Generally – for all patient groups - we don't see a big need for fine tuning the instruments.



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**Single-sided deafness patients' reactions  
– immediately when they are fitted**

- "It sounds clearer", and some tell there is less noise in the instrument.
- Some patients with Single-sided Deafness wonder whether the instrument is loud enough while in the fitting room.

**Careful not to increase LF,**  
as it will deteriorate their speech understanding in noise (upward spread of masking).



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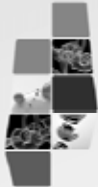
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**Implant and Surgery  
Related Considerations**

- Wide Implant Advancements
- Introduction to surgery
- Current Surgical technique
- New surgical techniques
- Retrospective implant study



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### Target specification

- New "OptiGrip" implant design for improved stability
  - Based on proven methods and surface
  - Minimized bone intervention\*
  - Universal hexagon implant interface
- Widened abutment range
  - Maintained design concept
  - Respond to more patient needs
  - Respond to new surgical techniques
- Simplicity for clinics and patients

\*In relation to the implant diameter



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### Maximized implant surface

**+ 10 % bone contact surface\***  
**+ 72% bone contact surface vs previous Ponto**



Wide (∅ 4,5mm) Ponto implant      B1300 by Cochlear      Ponto (∅ 3.75 mm) implant

\*Compared to any other available bone anchored hearing implant



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### Oticon Medical Surgical Instrumentation



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### Oticon Medical Surgical Improvements

- Same disposable surgical drills, extended lengths for better vision
- 6mm standard abutment  
6mm angled abutment  
9mm extended abutment  
12mm extended abutment
- Wide Diameter implant  
3 & 4mm
- Wider diameter healing cap for better surgical site coverage (26mm)



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### Surgical Procedure



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
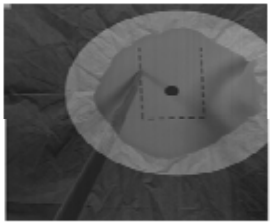

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### Surgical Procedure



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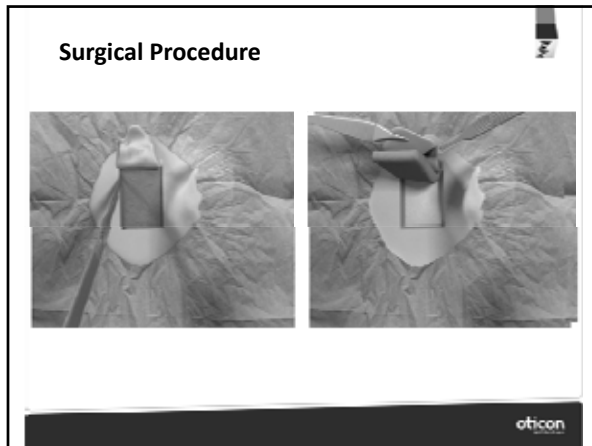
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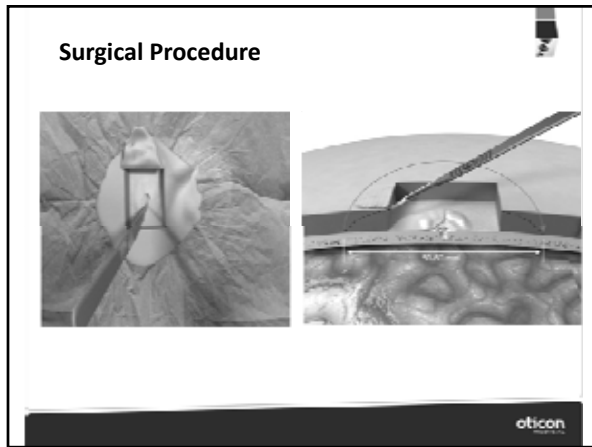
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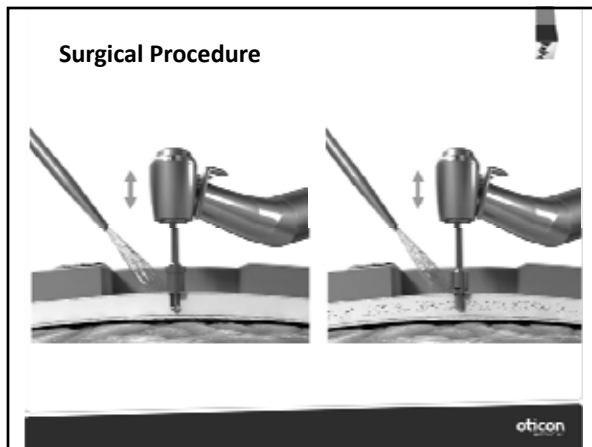
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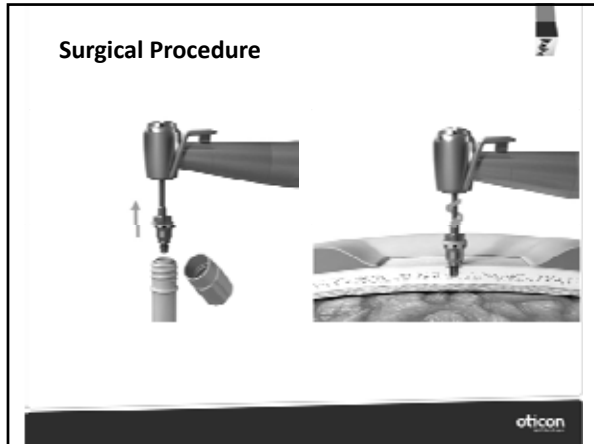
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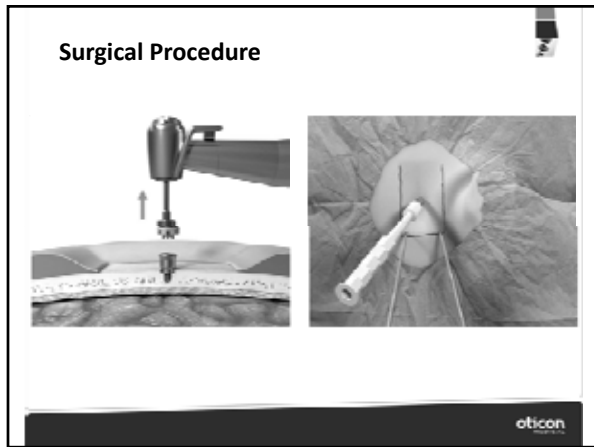
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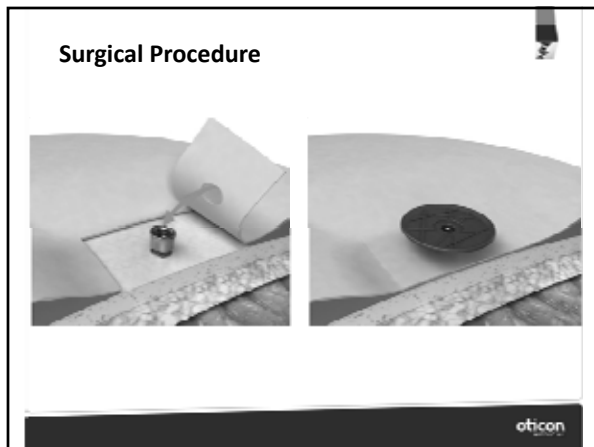
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### Surgical Procedure



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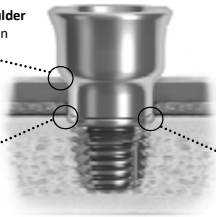
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### A skin-friendly design concept

**Minimal skin movement,  
minimum pockets and pathways for bacteria**

**Soft supporting shoulder**  
Designed to delay skin thickening



**Perfectly matched interface**  
Full skin support from underlying bone and periosteum

**100% tight conical seal**  
Prevents any bacterial migration via the abutment-implant interface

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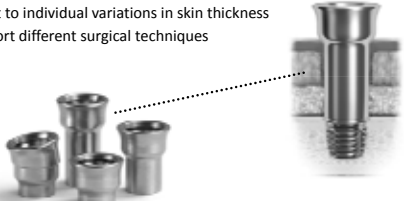
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### Widened Ponto abutment range

**Flexibility**

- To adapt to individual variations in skin thickness
- To support different surgical techniques



**NEW 12mm Ponto abutment**

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EE1      Could be blue or sand colored  
got\_eve, 12/13/2011

### Smooth transition for the clinic

**Universal hexagon interface**

- Full backwards compatibility
- No alterations to the surgical technique or required non-disposable instruments

**Note.** Preparation for the wide Ponto implant requires one the **NEW wide Ponto countersinks**



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### Less invasive surgery without skin thinning

Alternative 1:  
Placement aside the incision. Skin punching over abutment and then skin pressed over abutment. Abutment length 9 or 12 mm. (Published method by Prof Hultcrantz)



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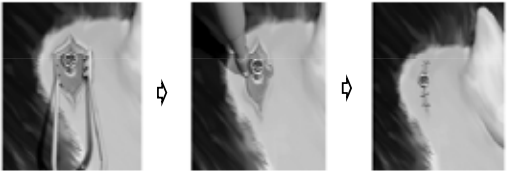
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### Less invasive surgery without skin thinning

Alternative 2:  
Placement in the incision. Partial skin punching on each side to accommodate abutment. Abutment length 9 or 12 mm.



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### Less invasive surgery without skin thinning

Alternative 3:  
Placement in the incision. Minor subcutaneous undermining on each side just to accommodate abutment, but not more than that. Abutment length 9 or 12 mm.

oticon

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### Outcome of the Bone-Anchored Hearing Aid Procedure Without Skin Thinning: A Prospective Clinical Trial

Makoto Hoshimatsu  
Department of Otorhinolaryngology, Kansai Medical University Hospital, Suita-shi, Osaka

**Study conclusions:**

- Minimal scar tissue. Intact skin with good blood supply.
- Less numbness and pain in the area.
- Quick healing.
- Less skin infections
- No bold spot, more cosmetic
- Less invasive, quicker and more predictable surgery.
- Most abutments were 9 mm but Ponto 12 mm abutment was also used.

oticon

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### Surgery without skin thinning

oticon

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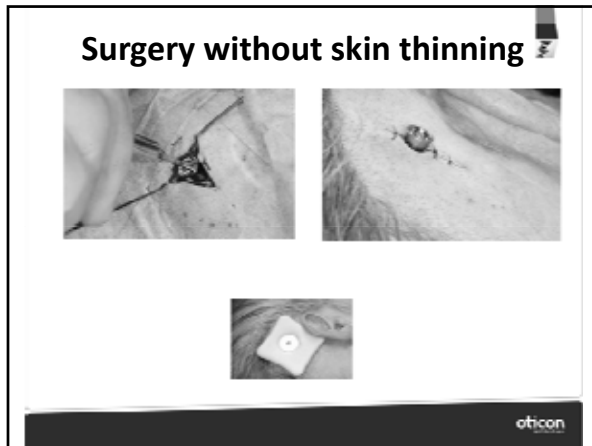
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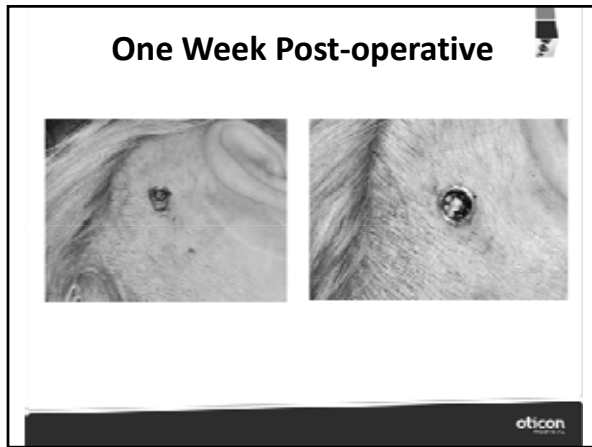
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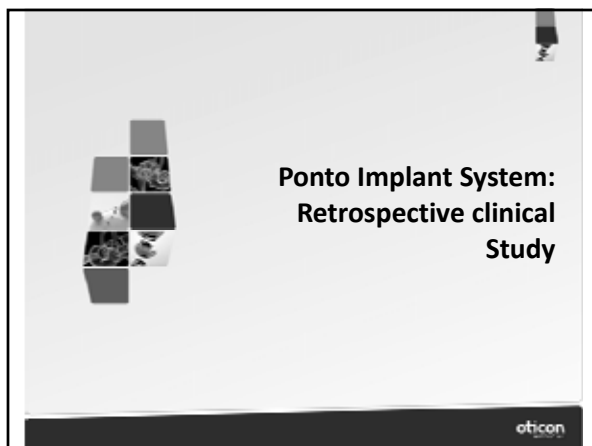
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### Retrospective Implant Clinical Study

- A total of 98 patients were examined retrospectively
  - Participating institutions: Arizona (N=24), GHSU (N=11) and MEI (N=63)
  - Mean Age and range: 51.5 years; 5 years to 79 years
  - Gender : 39% Males 61% females

Collected data:

- Patient demographic data, length of implant and abutment used, type of surgical technique employed
- Incidence of skin reactions, implant extrusion, and revision surgery




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### Summary of Results

Observations	
Implant Loss	0%
Revision Surgery	0%
Implant length	3mm: 2% ; 4mm: 98%
Abutment length	6mm: 69% ; 9mm: 31%
Surgery type and stages	Linear: 96% ; Flap and Semi Elliptical: 4% One stage: 100%
Skin Reactions	No adverse skin reactions: 85% Adverse skin reactions: 15% (All of these patients exhibited moderate adverse skin complications that were successfully managed as part of standard care in clinic)




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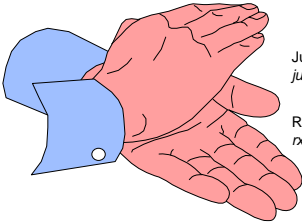
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### Thanks for listening



Justin Pfeiffer  
[jup@oticonmedicalusa.com](mailto:jup@oticonmedicalusa.com)

Ravi Sockalingam  
[rxs@oticonmedicalusa.com](mailto:rxs@oticonmedicalusa.com)

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