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What Can Your Eyes Tell You About Your Ears?

Wednesday, May 24, 2023

Aren Bezdjian, MSc., PhD.
Clinical Research Manager
Oticon Medical LLC



Because
sound matters

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Disclosures

Presenter Disclosure: Aren Bezdjian is employed by Oticon Medical.

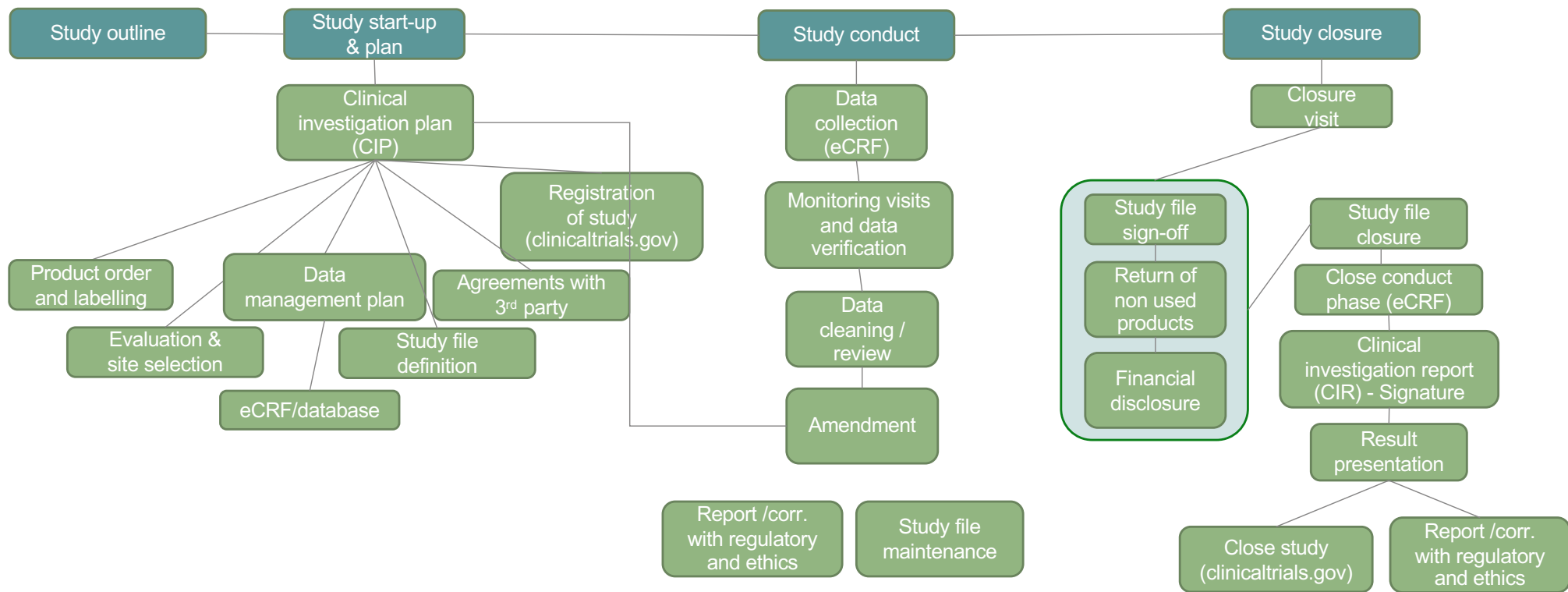
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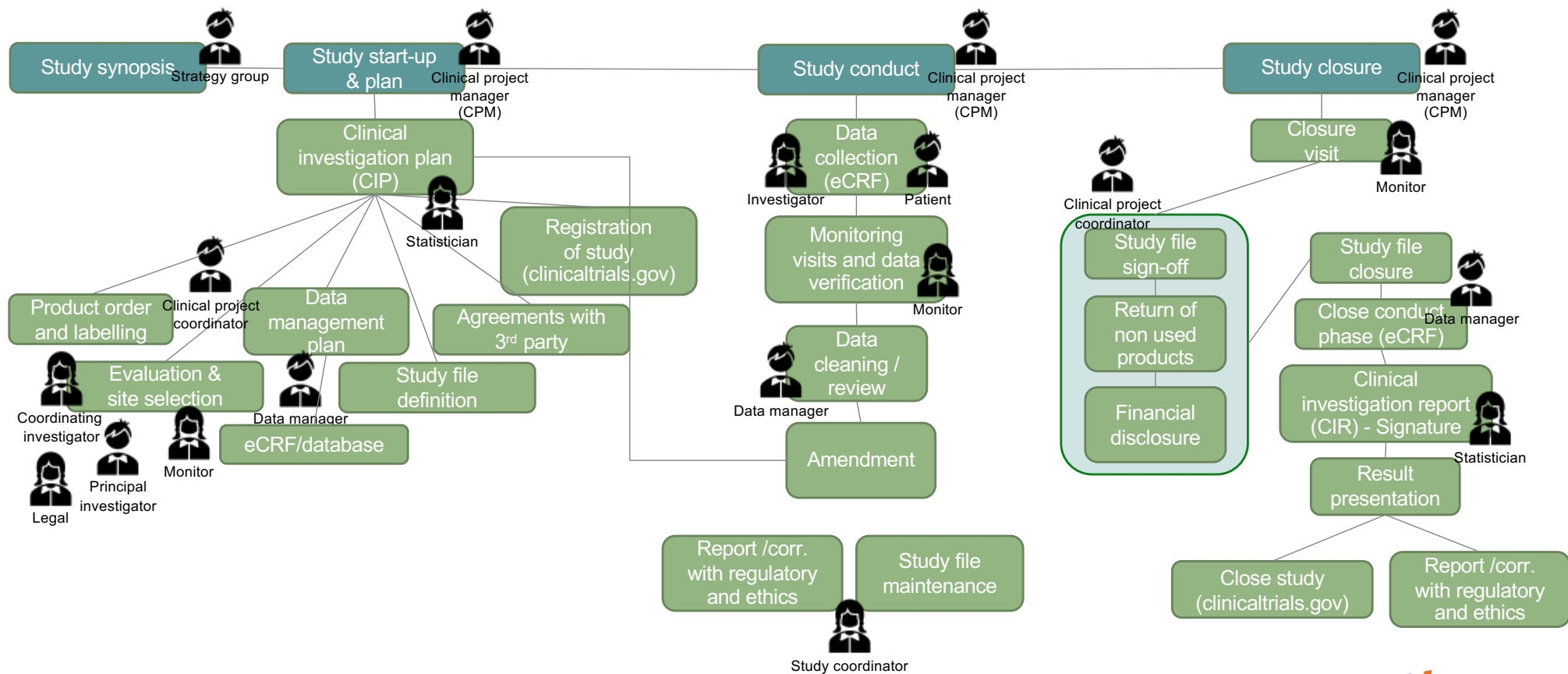
Learning Outcomes

1. After this course, participants will be able to learn about the effect of Open Sound Navigator for bone anchored hearing implants.
2. After this course, participants will be able to understand how pupillometry can be used to measure listening effort when using auditory implants.
3. After this course, participants will be able to differentiate speech understanding from listening effort and how they correlate.

Clinical Study Process

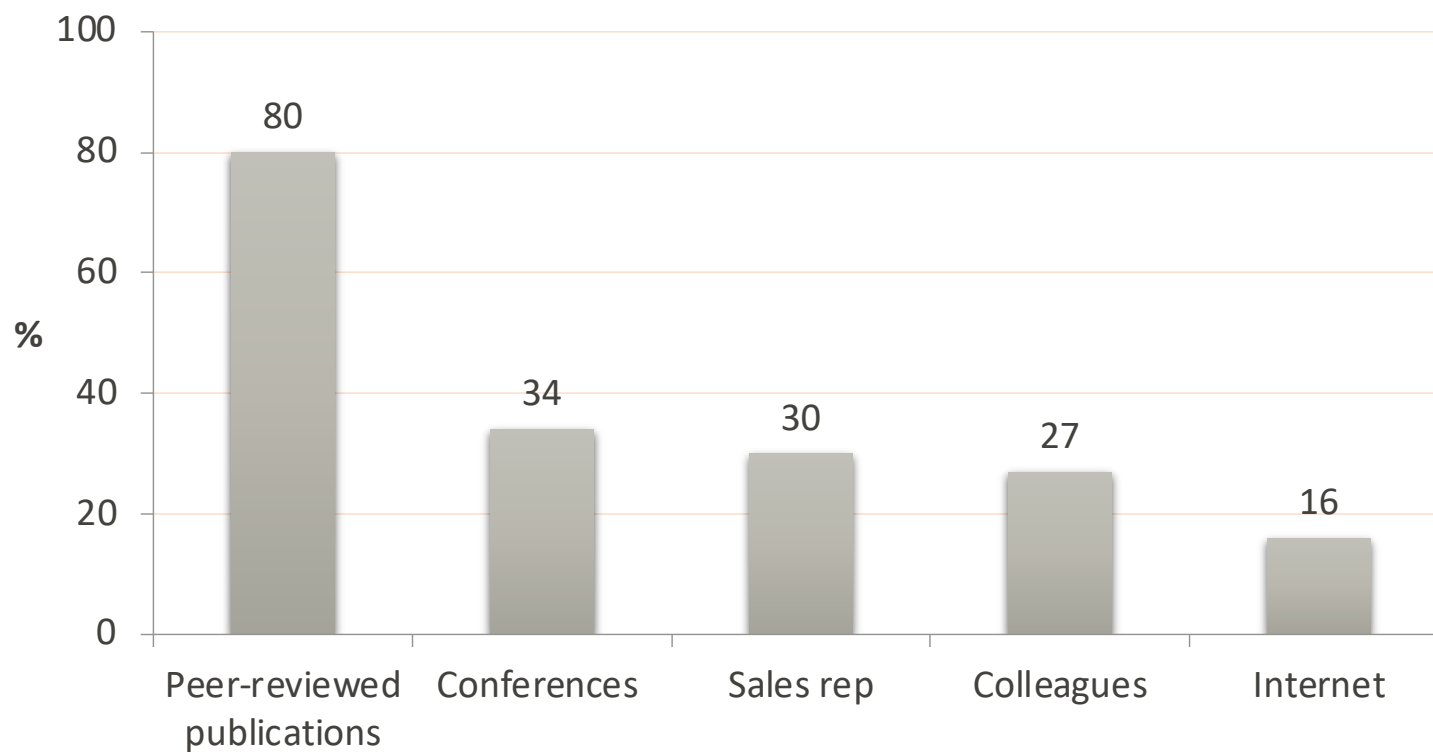


Clinical study process – a lot of people...



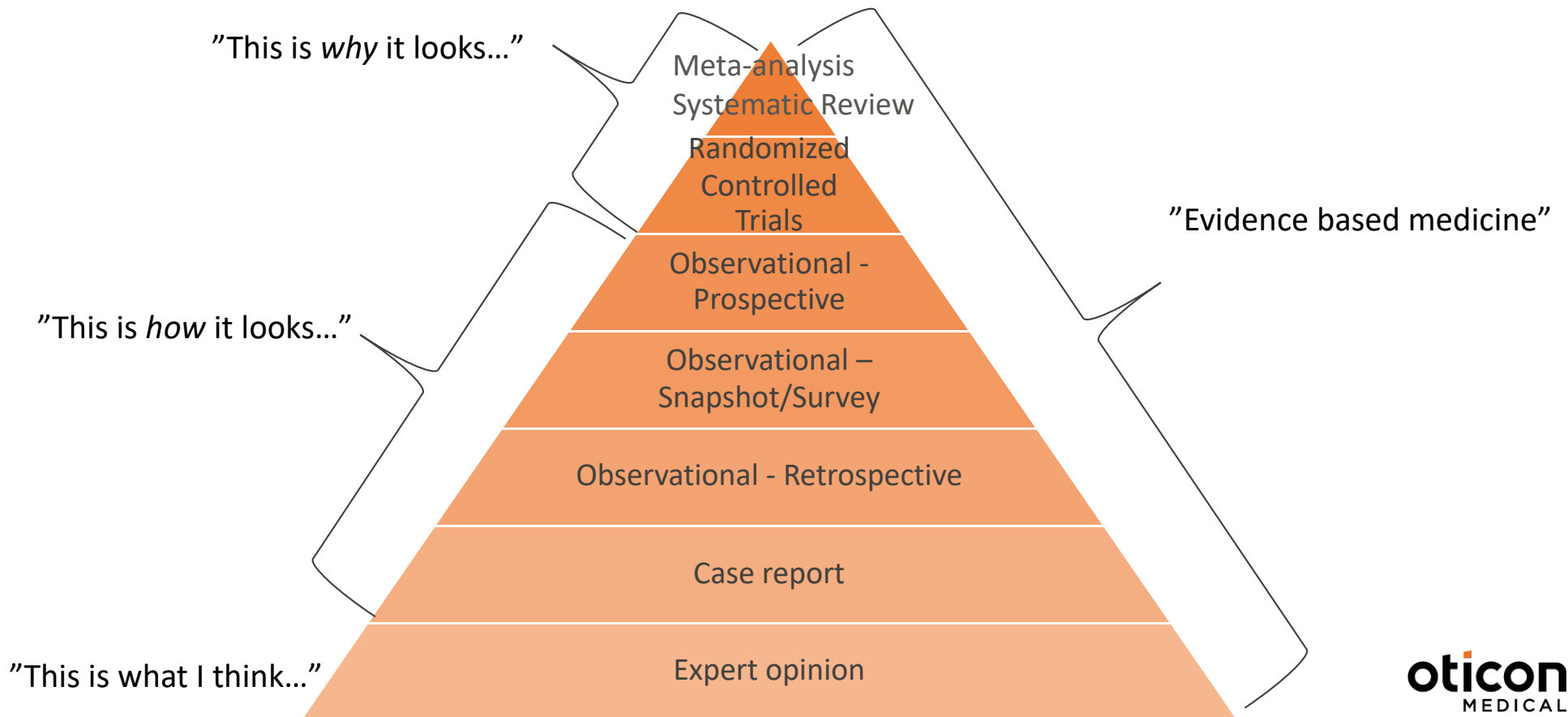
Are studies important?

Example: Influence on prescribing physicians*



Reference: Accenture HCP survey

What's a “good” study?

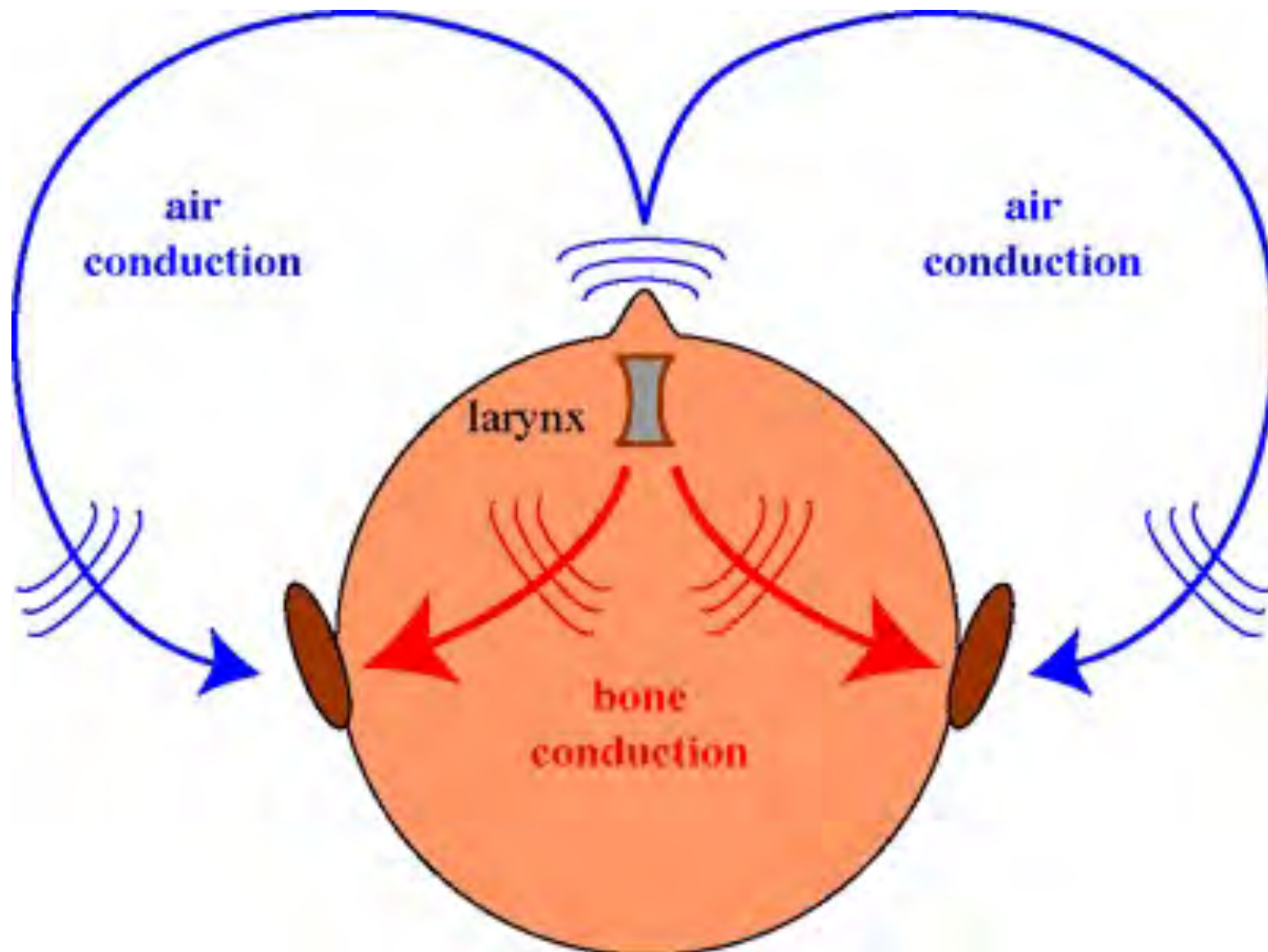


Source: e.g. The Centre for Evidence-Based Medicine <https://www.cebm.net/>



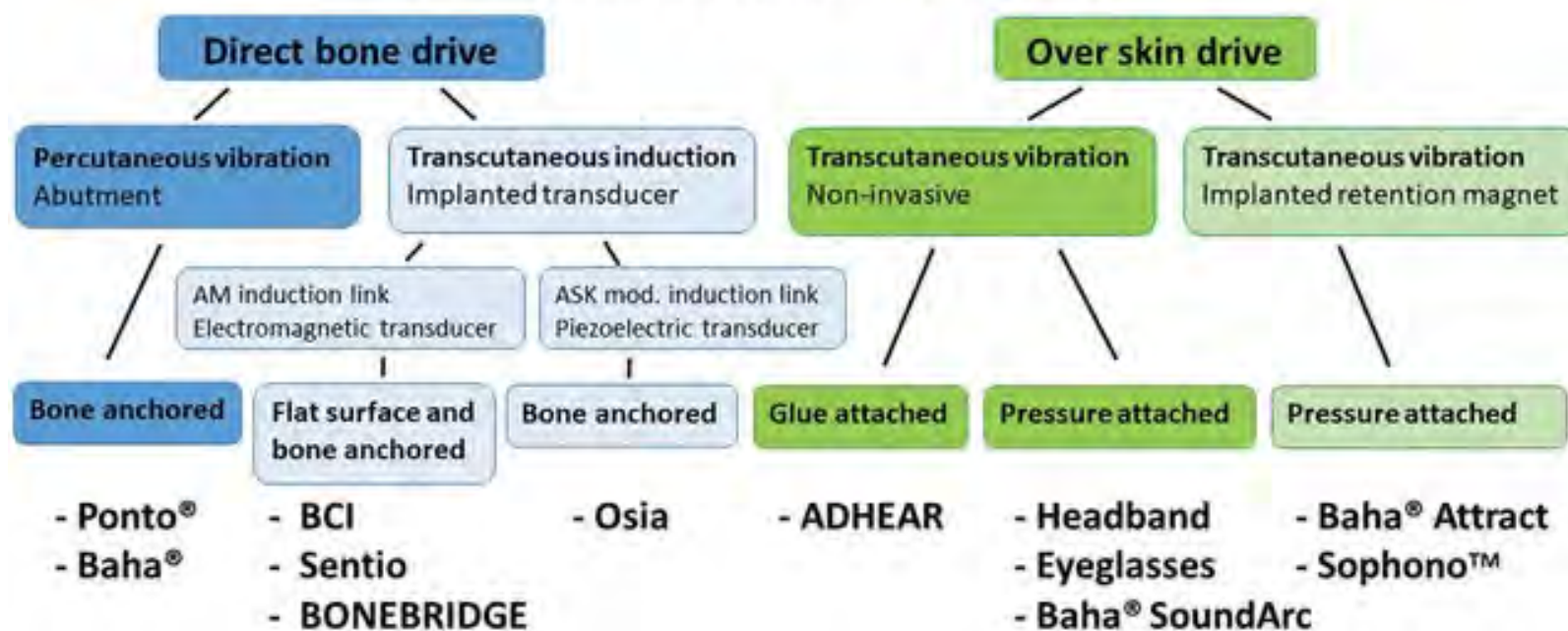
Bone Anchored Hearing Systems





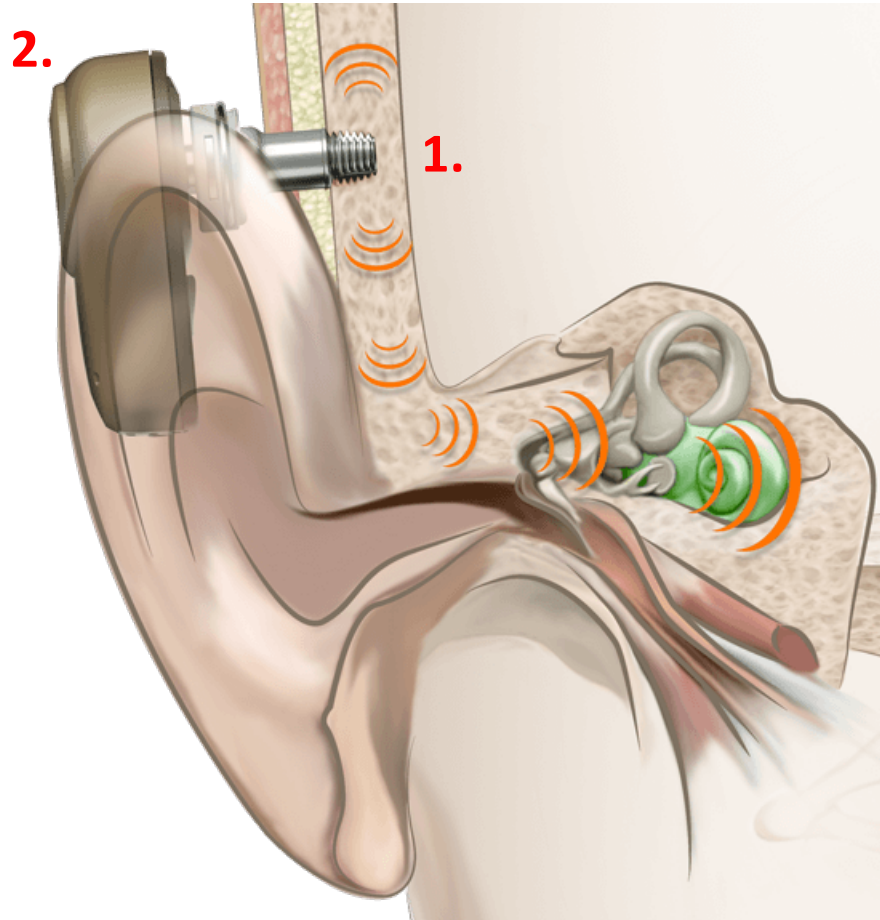
Bone Conduction Devices

Transmission and attachment modalities

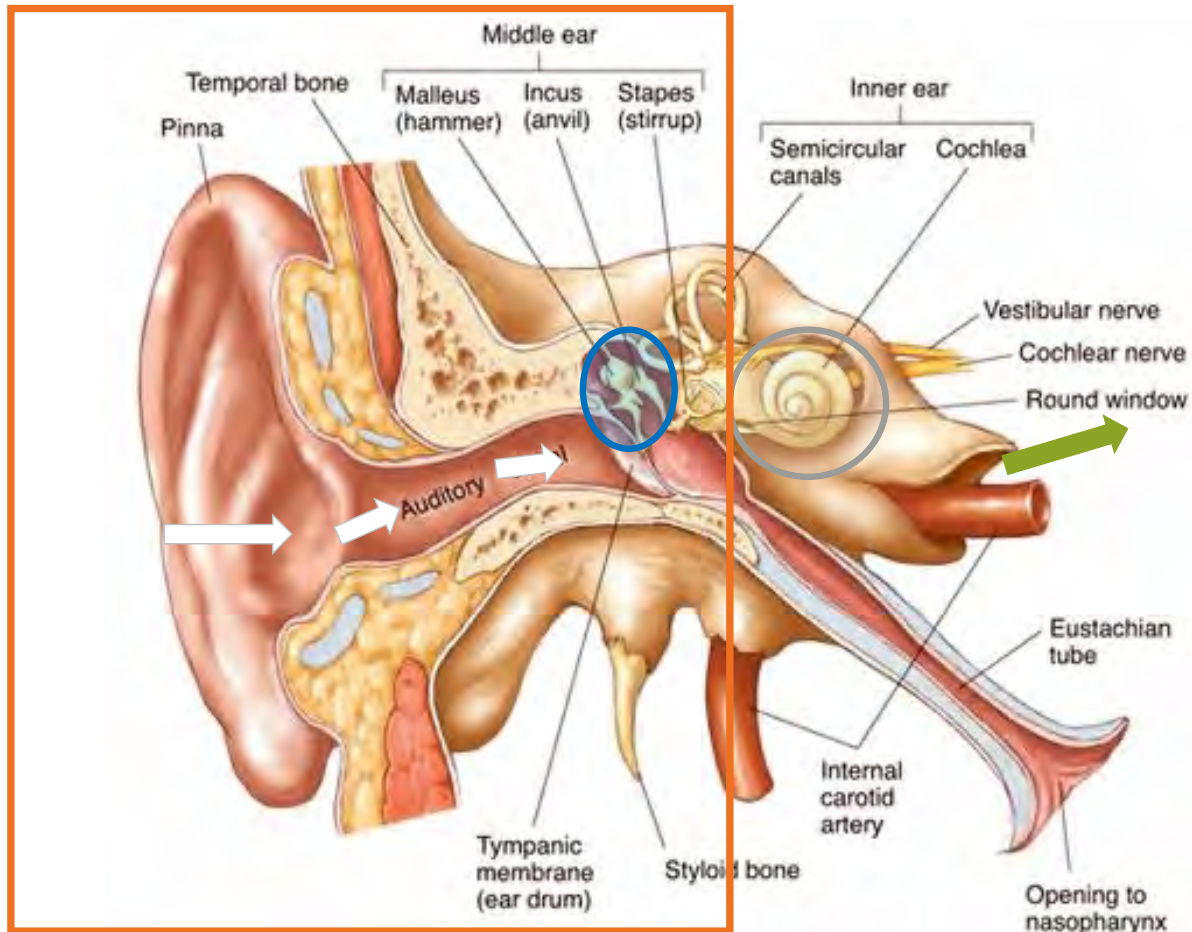


Bone anchored hearing implants

- Body's natural ability to transfer sound through bone conduction.
 - 1. Titanium implant in the temporoparietal bone
 - 2. Sound processor attached to the implant
- Sound processor converts sounds into vibrations

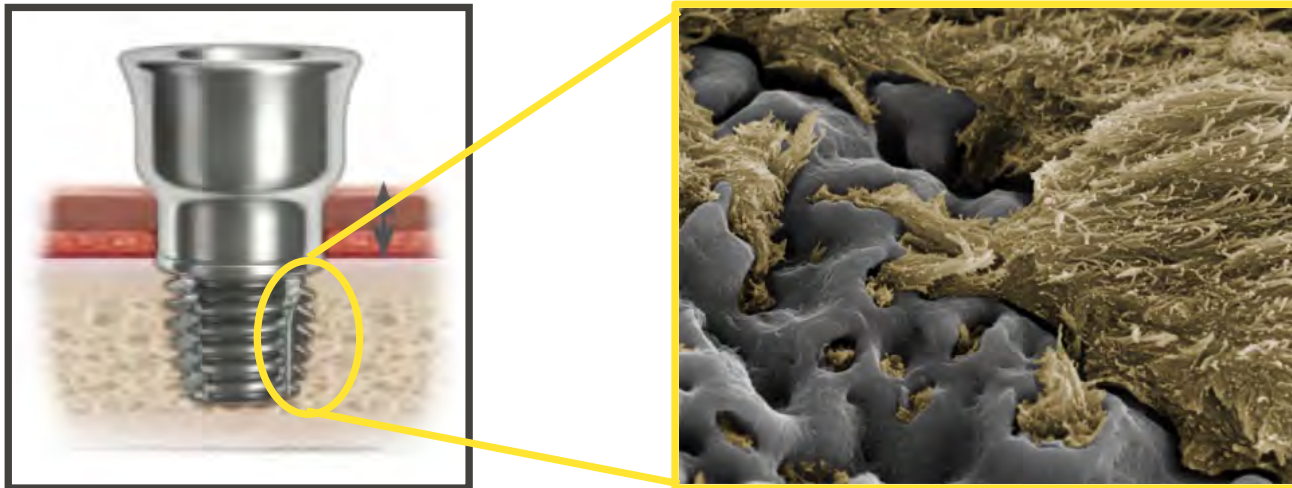


Anatomy of the Ear

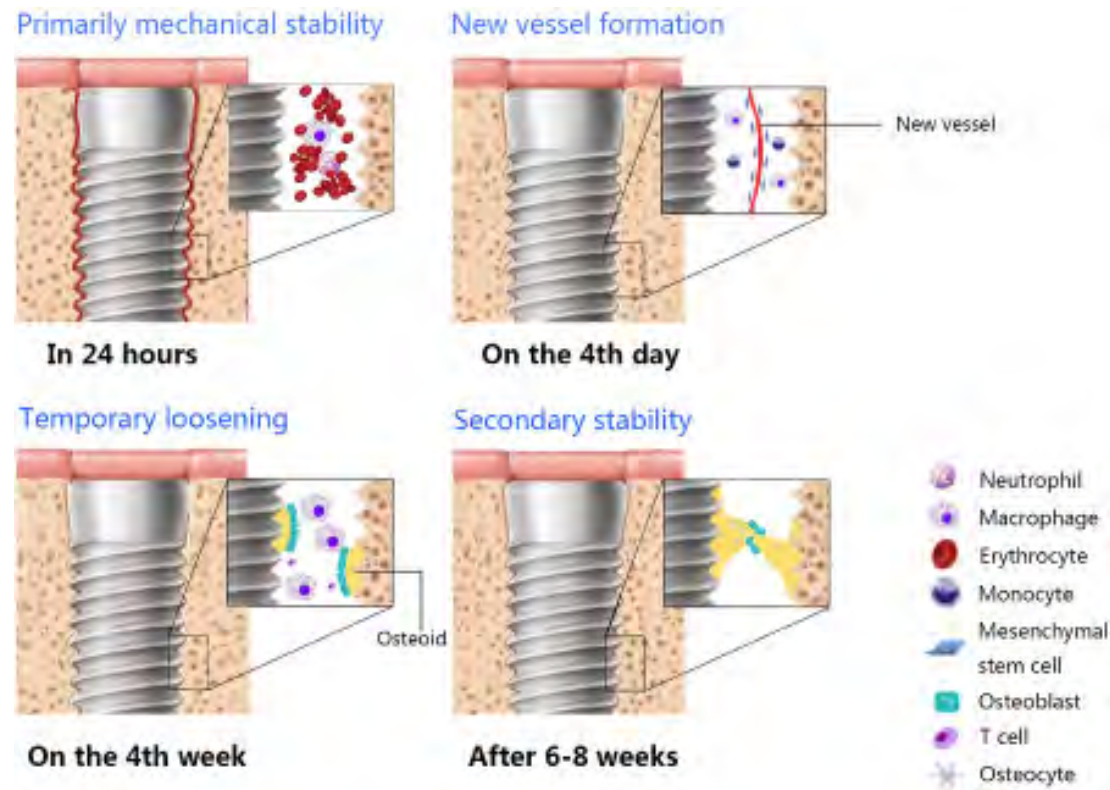


Osseointegration

- Structural integration of the implant surface in the surrounding bone



Osseointegration

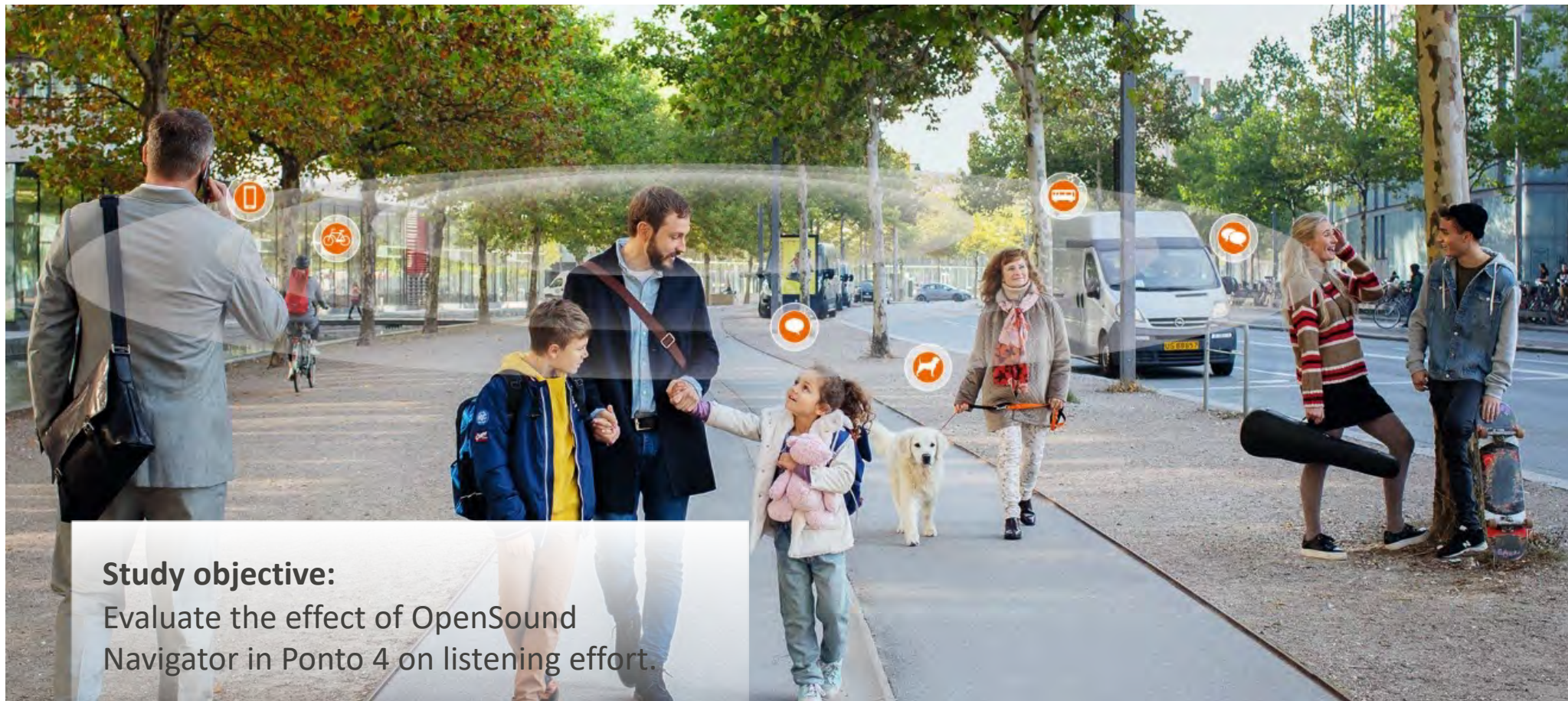


Bigueti CC, Cavalla F, Silveira EM, et al. Oral implant osseointegration model in C57Bl/6 mice: microtomographic, histological, histomorphometric and molecular characterization. *J Appl Oral Sci.* 2018;26:e20170601. Published 2018 Jun 11.

BAHS research

1. Surgical development “surgery”
2. Processor updates “technology”
3. Outcomes “patient”

Surgical → technology → patient



Study objective:

Evaluate the effect of OpenSound Navigator in Ponto 4 on listening effort.



OpenSound Navigator

Access the full 360° soundscape

OpenSound Navigator – more sound to the brain

speech-enhancement algorithm

Analyse



Balance

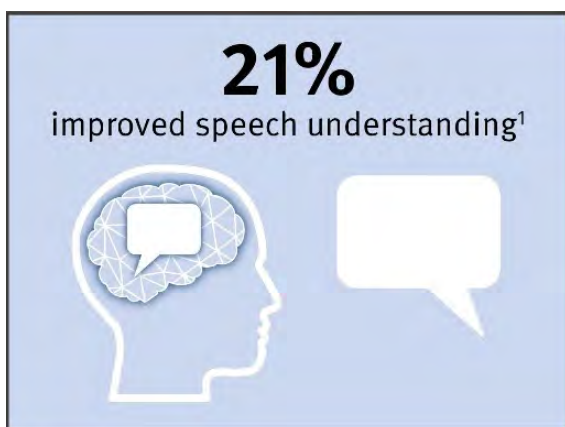


Noise removal



Two clinical studies behind the Ponto 5 family

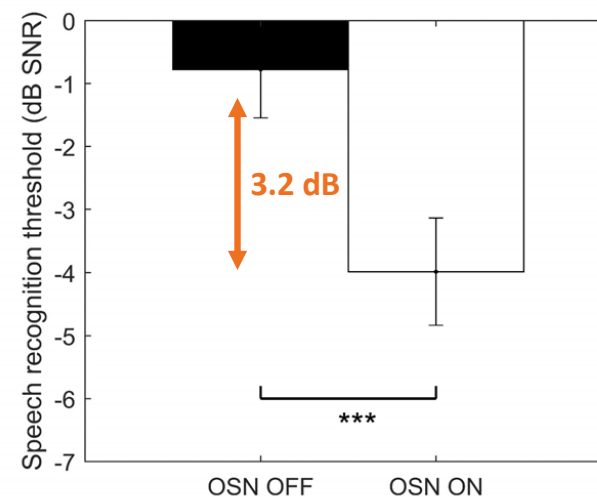
Study 1: Clinical data on OpenSound Navigator



Study 2: First clinical data on Ponto 5 SuperPower



32% improved speech understanding in noise²

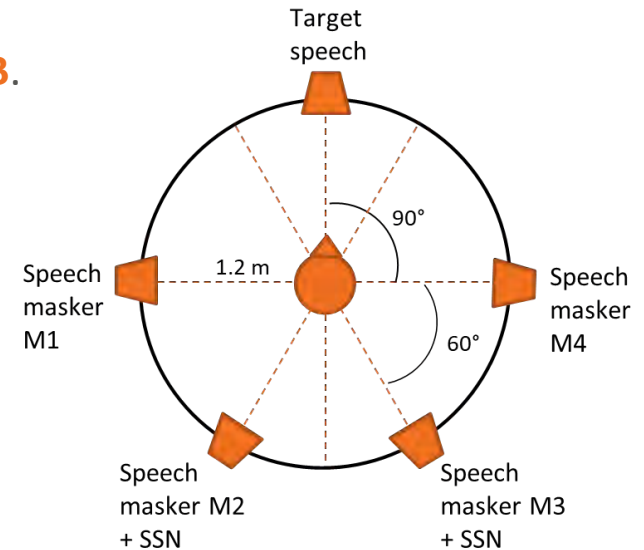
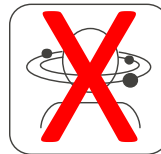


METHOD 1

- **Aim:** effect of OSN at a fixed signal-to-noise ratio (**SNR**) at **+4 dB**.
- Presented HINT sentences at 74 dB SPL (0 ° azimuth).
- Noise at an overall level of 70 dB SPL:
 - 4-talker babble at $\pm 90^\circ$ and $\pm 150^\circ$ azimuth;
 - Unmodulated speech-shaped noise at $\pm 150^\circ$ azimuth.

One list of HINT (25 sentences) was presented for each condition:

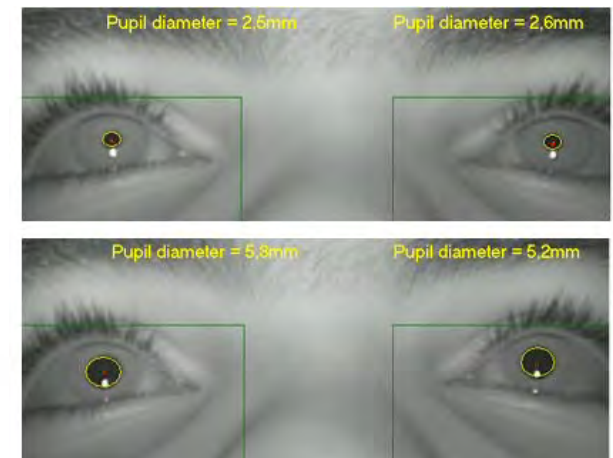
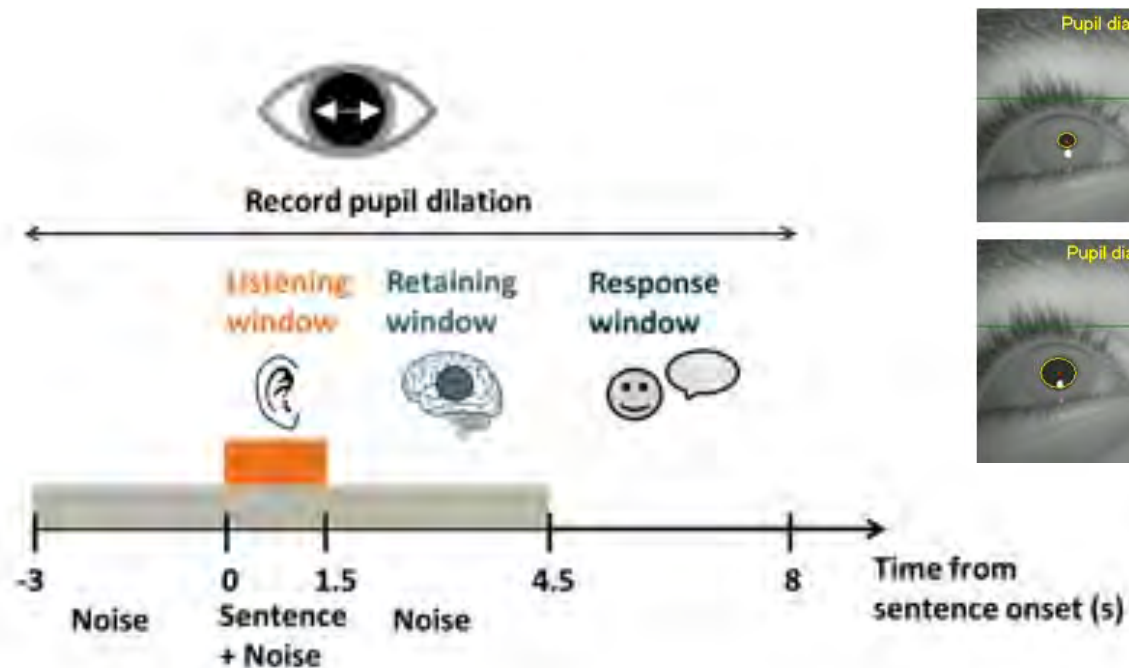
1. OpenSound Navigator activated (**OSN ON**);
2. OpenSound Navigator deactivated (**OSN OFF**).



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METHOD 2

- For each trial, noise started 3 s before sentence onset and ended 3 s after sentence offset.
- Subjects' task: Listen to the sentence in noise, retain the sentence for 3 s, repeat the sentence after noise offset.
- An eye-tracking camera monitors pupil dilation, as a measure of listening effort.



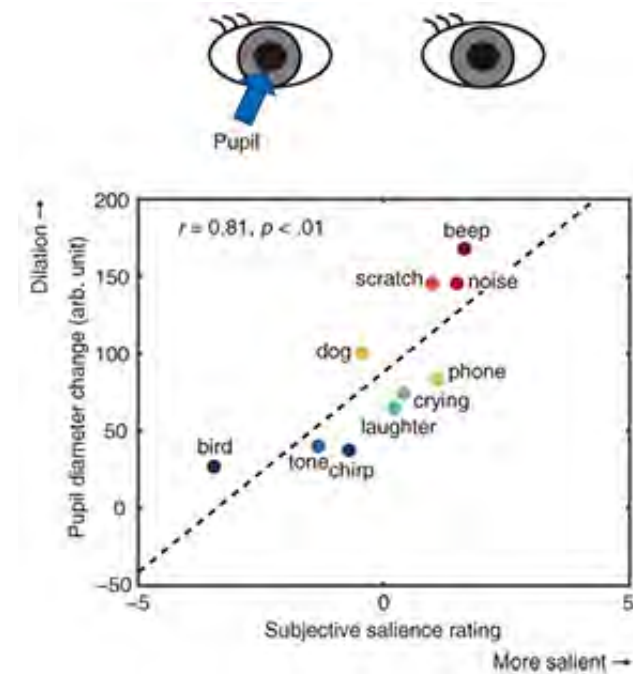
Definitions

1. **Pupillometry**: the measurement of pupil size and reactivity.
2. **Listening effort**: the deliberate allocation of mental resources to overcome obstacles when carrying out a listening task.

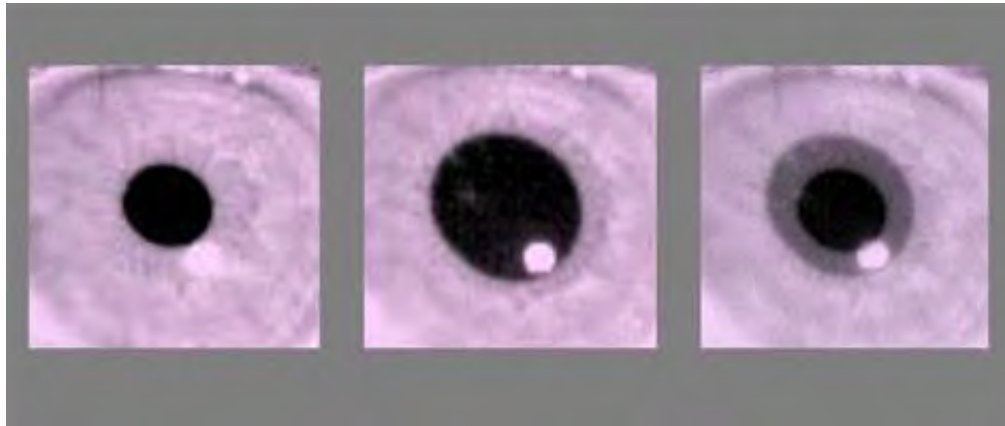
Pupillometry

- Pupillometry has emerged as a useful tool for studying listening effort.
- Past work involving listeners with normal audiological thresholds has shown that switching attention between competing talker streams evokes pupil dilation indicative of listening effort

McCloy, Lau, Larson, Pratt, and Lee (2017). J. Acoust. Soc. Am. 141(4), 2440-2451

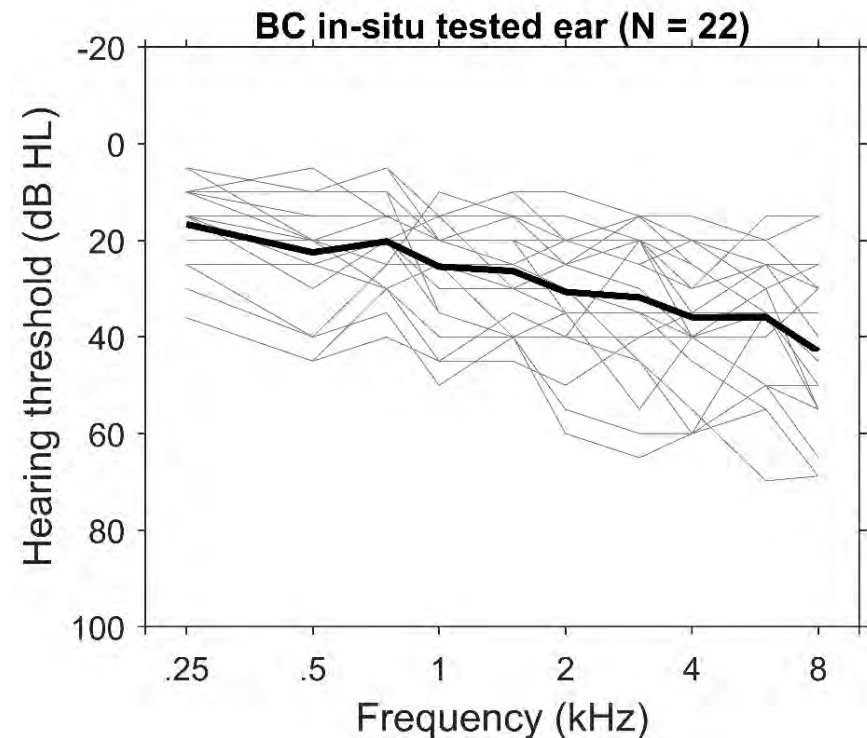


| What does dilation/constriction mean?

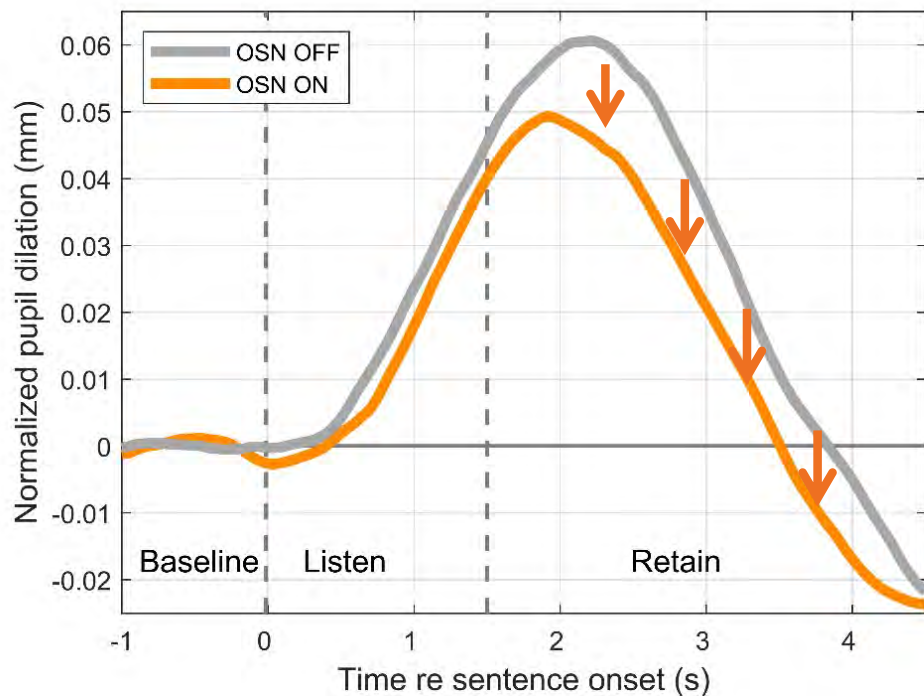


Participants

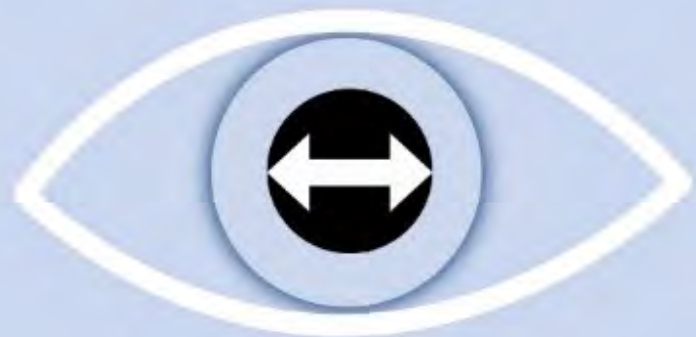
- 22 experienced P4 users
 - Mean age: 58 years
 - [21 years; 81 years]
- Etiology of hearing losses:
 - 10 mixed, 8 conductive, 4 SSD
- BC thresholds:
 - Mean PTA4 = 27.6 dB HL
 - [11.3 dB HL; 45 dB HL]



Results in overall pupil dilation



36%
reduction in pupil dilation¹



Bianchi, et al. (in preparation)

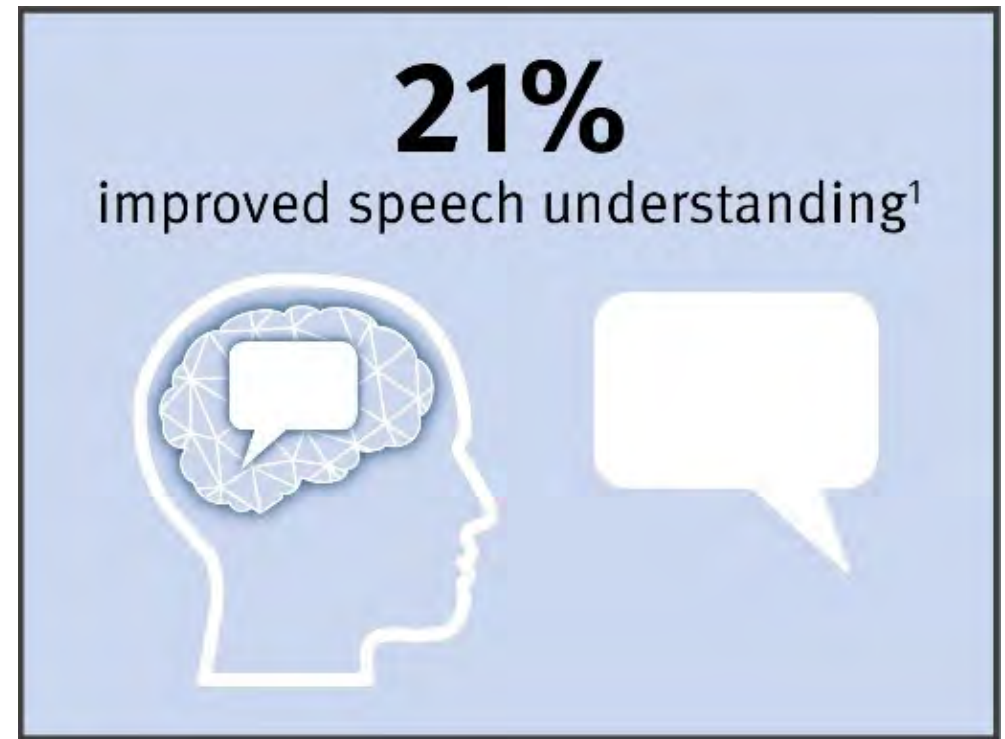
Results in speech understanding

Sentences correctly repeated (FIXED SNR at +4 dB)



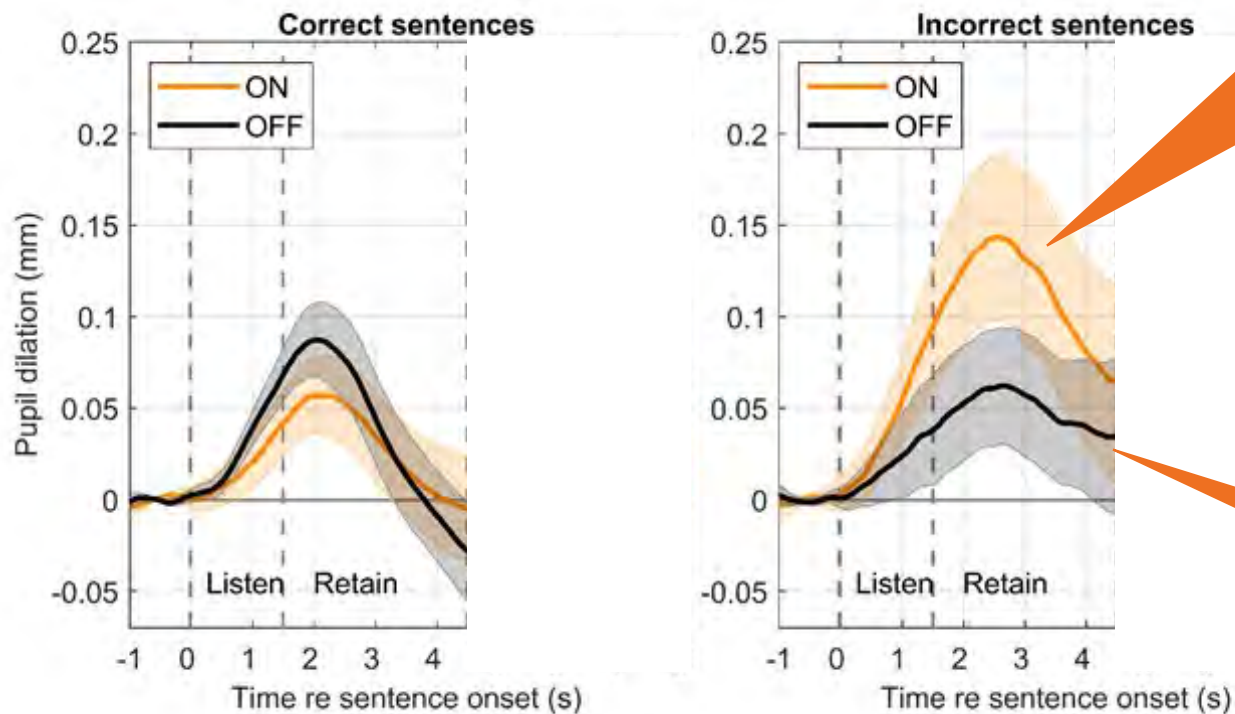
About 30% **incorrect** sentences with OSN ON and 42% with OSN OFF...pupil dilation?

Bianchi, et al. (in preparation)



Pupil dilation for correct and incorrect sentences

OSN ON helps "not giving up"



OSN ON

Allocation of resources to process the (few) incorrect sentences.

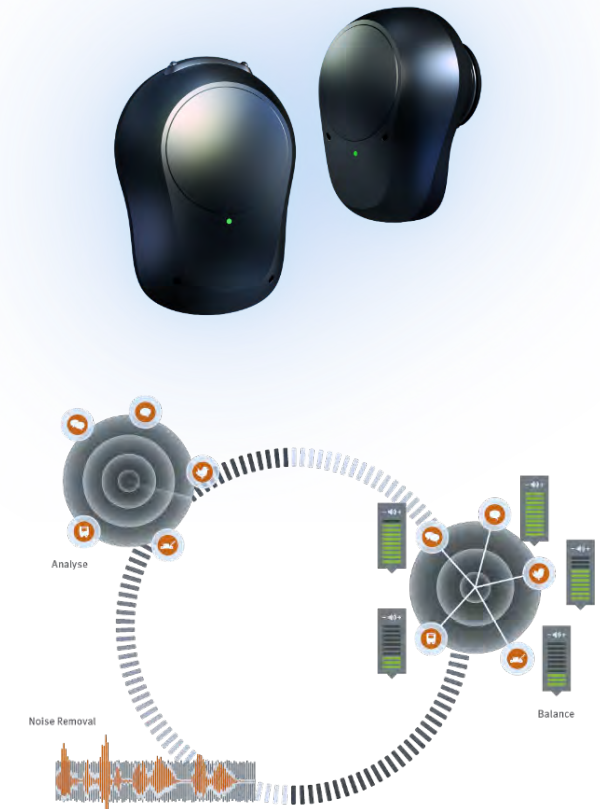
Higher engagement

OSN OFF

"giving up" to process the incorrect sentences.

Take home message

- The improvements of OSN is evident but obtained in experienced P4 users.
- The improvement of OSN in speech understanding was **similar across hearing losses** (about 3 dB improvement¹)



Unpublished data

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Conclusion: clinical outcomes with the Ponto 5 family

- OpenSound Navigator™:
 - 21% improved speech understanding¹ (at +4 dB SNR)
 - 36% reduction in overall pupil dilation¹ → listening effort is significantly reduced
 - 32% improved speech understanding² (at SRT70)

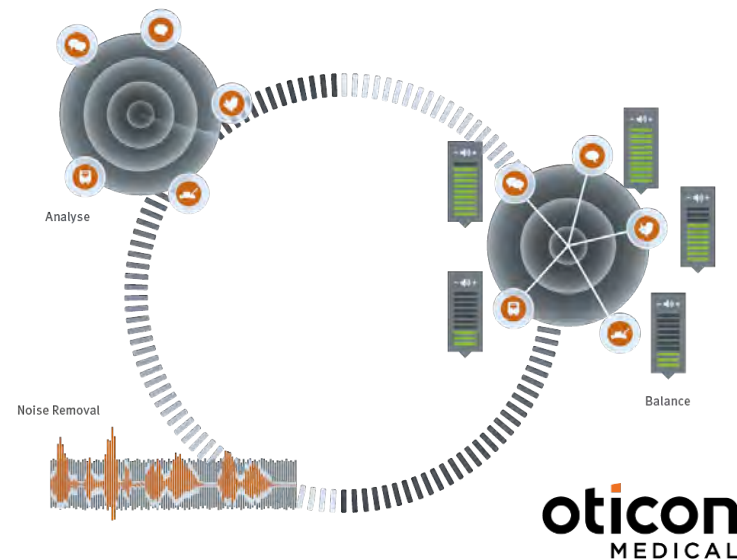


Agenda

1. Study 1: Clinical data on OpenSound Navigator
 - a. Improved speech understanding
 - b. Less listening effort
2. Study 2: First clinical data on Ponto 5 SuperPower

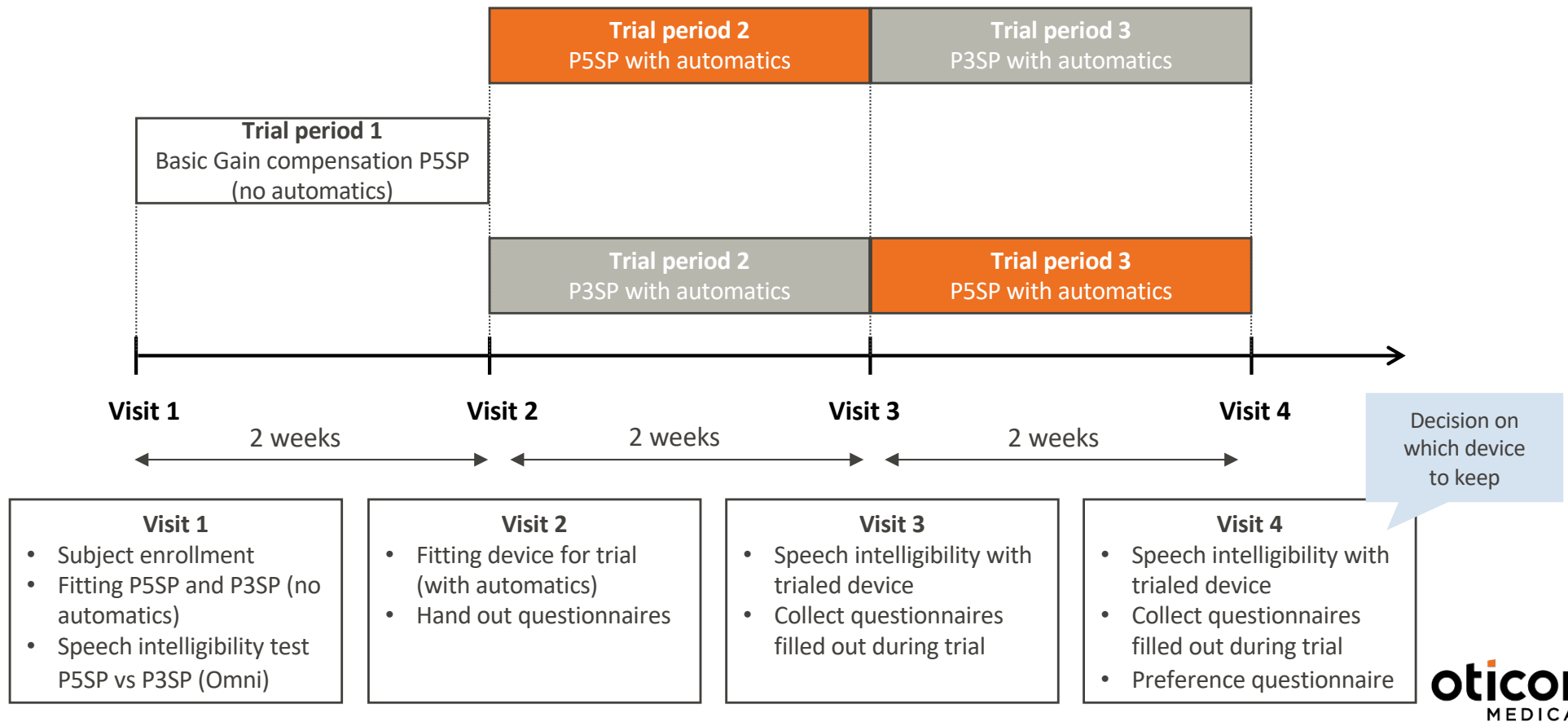
Purpose of the study

- The study was designed as a comparative crossover study with within-subject control design to evaluate performance with Ponto 5 SuperPower in the lab and in everyday life.
- The main goal of the study was to evaluate:
 1. Speech intelligibility with Ponto 5 SuperPower: effect of OpenSound Navigator™ (OSN)
 2. Preference between Ponto 5 SuperPower and Ponto 3 SuperPower



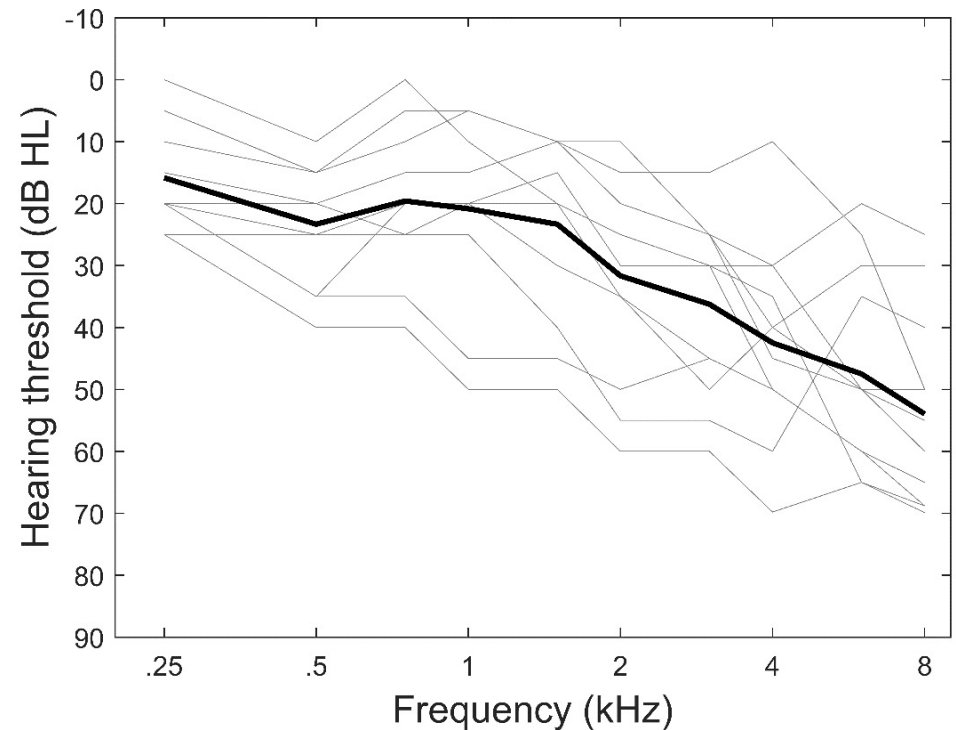
Study design

Crossover: 4 Visits, 3 trial periods

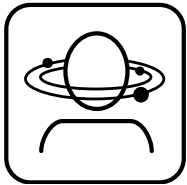


Participants

- 12 experienced P3SP users
 - Mean age: 64 years (min: 32 years; max: 80 years)
- Hearing Losses: 7 mixed, 2 conductive, 3 SSD
- Large range of BC thresholds:
 - Mean PTA4 = 29.6 dB HL (min: 15 dB HL; max: 55 dB HL)
- Randomization:
 - Sequence P5SP-P3SP: N=7
 - Sequence P3SP-P5SP: N=5

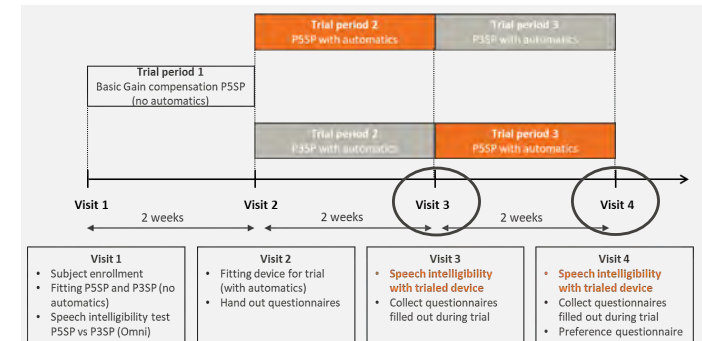
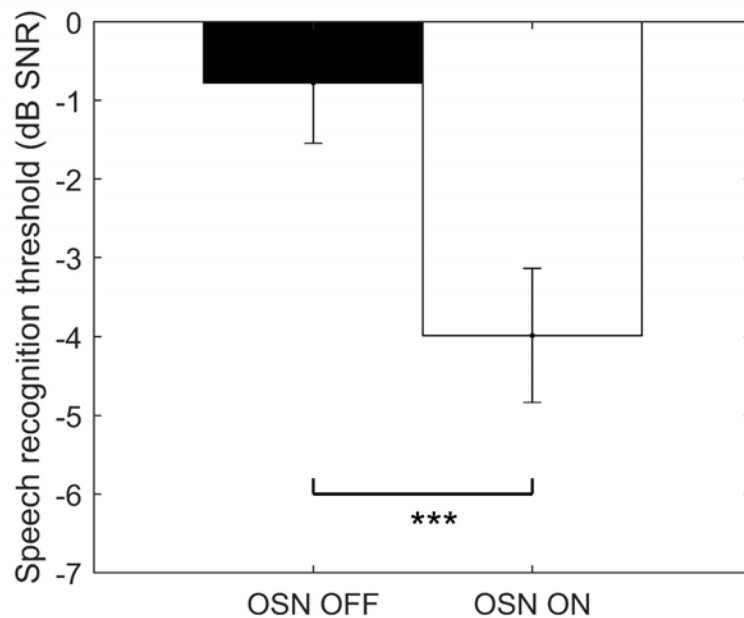


Improved speech intelligibility with OpenSound Navigator

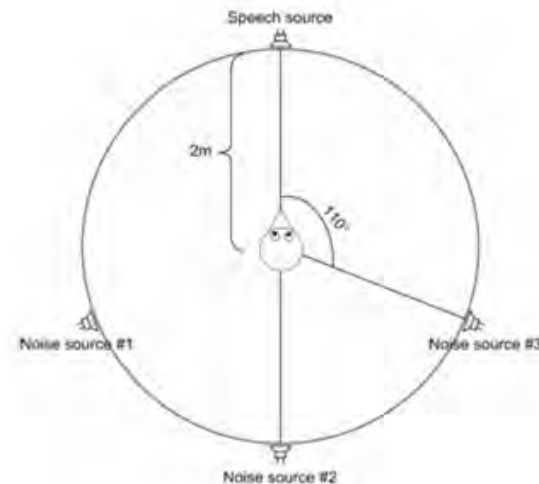


3.21 dB improvement with OSN ON (** $p < 0.0001$)

→ Approximately **32% improvement in speech understanding**

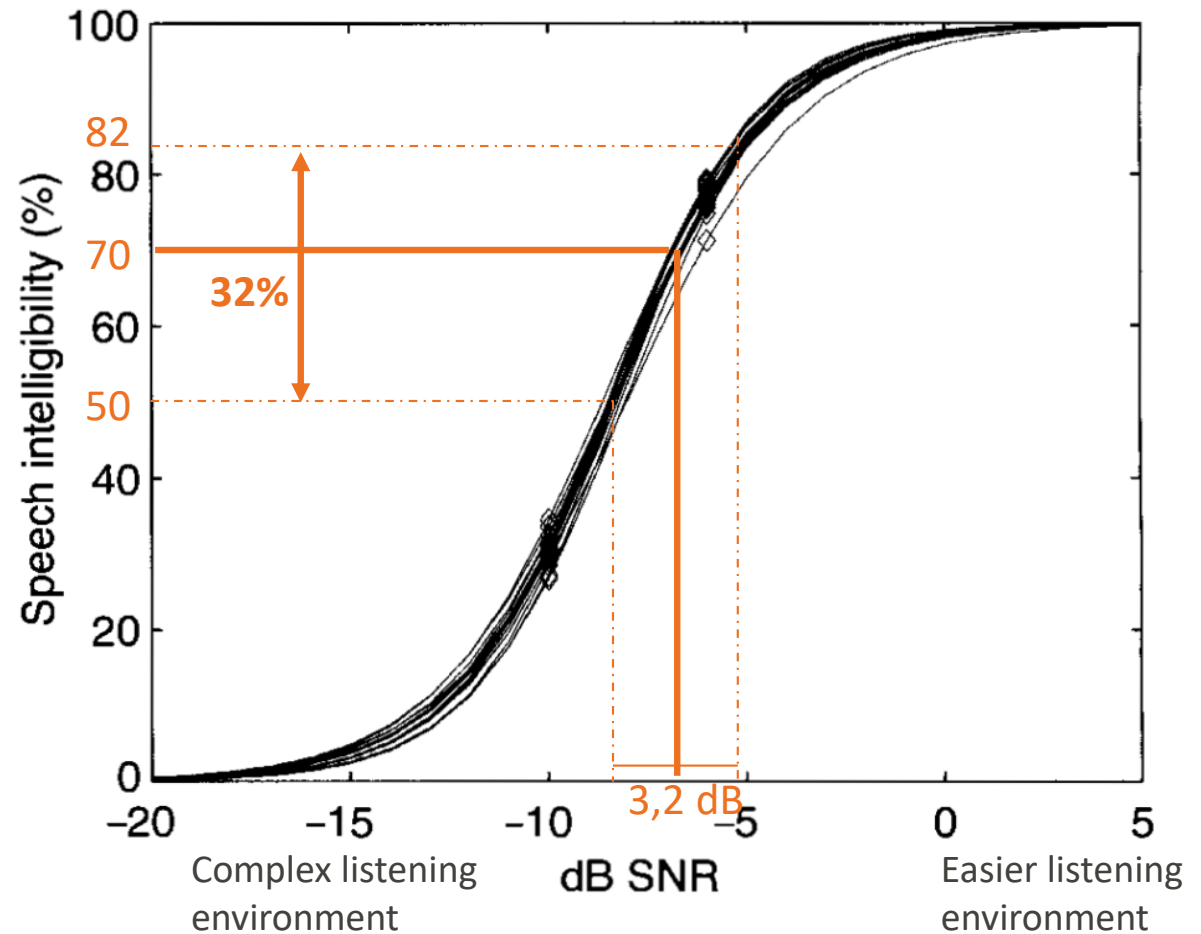


Measured at Visit 3 or 4 after field trial with P5SP



OpenSound Navigator improves speech understanding by **more than 30%**

A 3.2 dB difference around SRT70 corresponds approximately to **32% improvement** in speech intelligibility in a matrix test.



OpenSound Navigator™ user benefits

“After being upgraded to the Ponto 5 Superpower, I experience a much wider soundscape than I used to have.”

— Thorleif, Ponto 5 SuperPower User, Denmark

“I’ve gotten a lot of really good sound with the change to Ponto 5 SuperPower. It all seems more natural and harmonious in the way I get the sound coming in.”

— Christian, Ponto 5 SuperPower User, Denmark

“Ponto 5 SuperPower gives me clearer sound and I can hear more from my surroundings than I could with Ponto 3 SuperPower. The sound scene is cleaner, clearer and more natural, which allows me to hear better.”

— Flemingg, Ponto 5 SuperPower User, Denmark



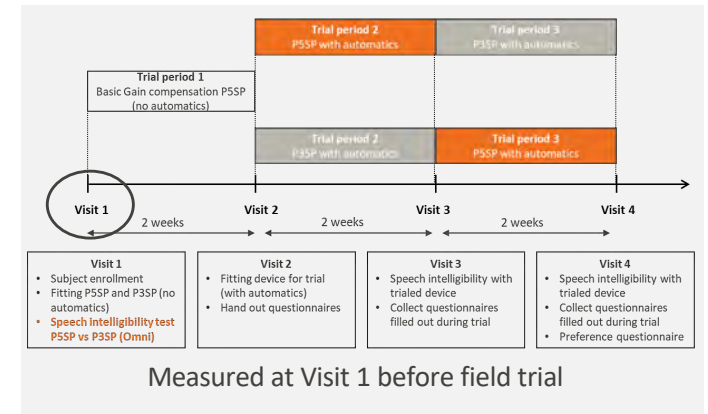
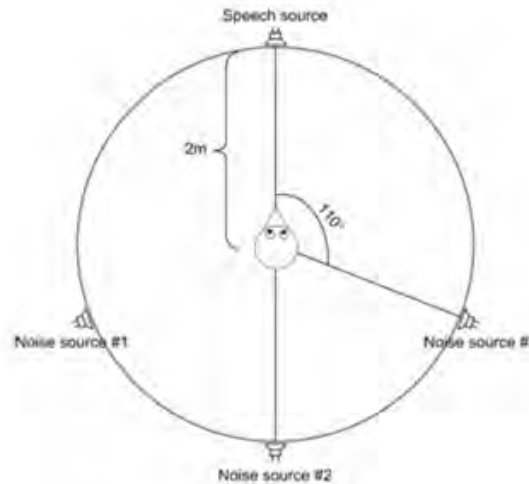
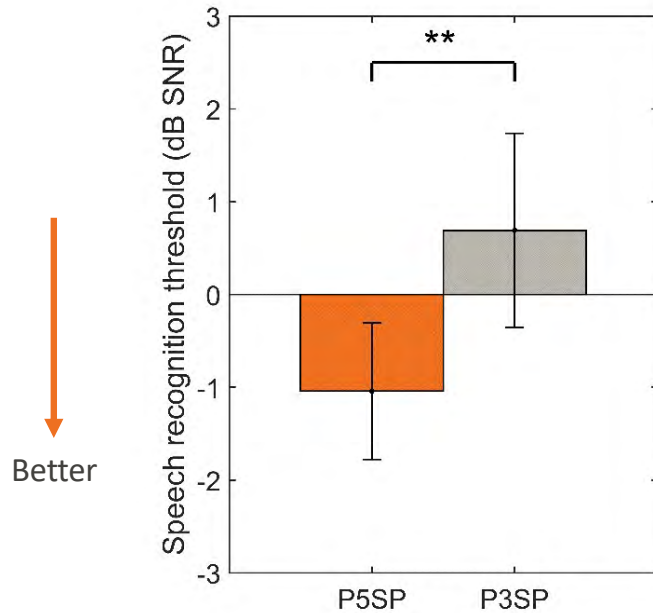
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Improved speech intelligibility with P5SP vs. P3SP

Without automatics (Omni settings, noise reduction deactivated)

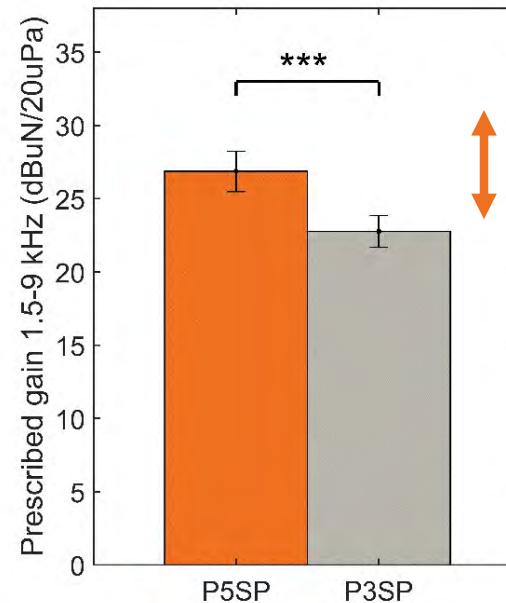
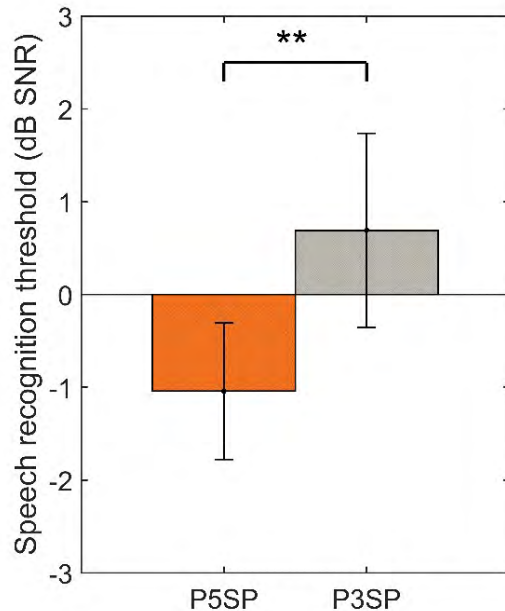
1.73 dB improvement with P5SP vs. P3SP (**p = 0.002)

→ Approximately **17% improvement in speech understanding**



Improved speech intelligibility vs. increased gain in P5SP

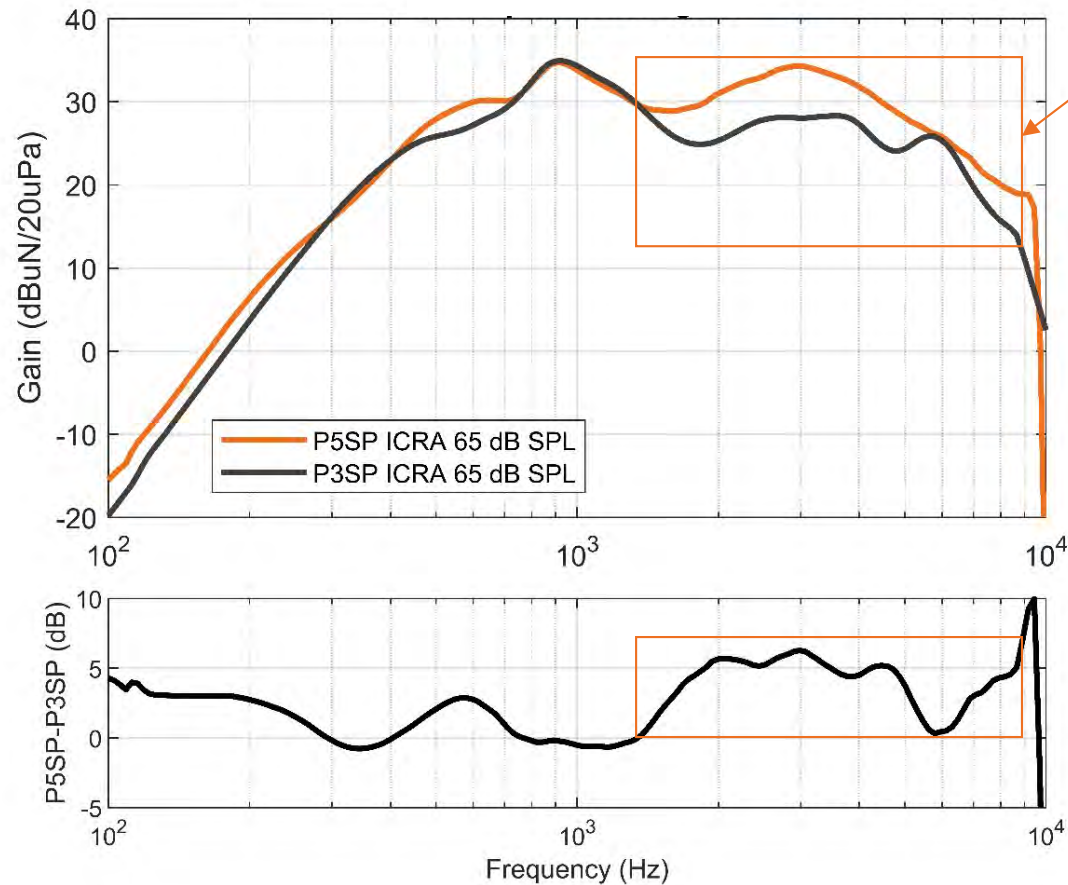
- The improvement in speech understanding obtained with P5SP in Omni (OSN OFF) is linked to the improvements in the FBM system that allows more gain to be prescribed at frequencies important for speech intelligibility.



Increased gain in P5SP due to improvements in FBM system (OpenSound Optimizer™ and safety margins)

More gain at frequencies important for speech

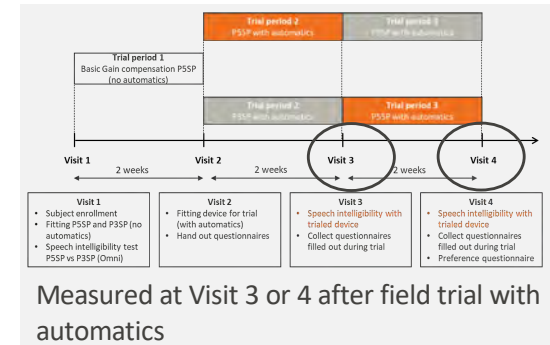
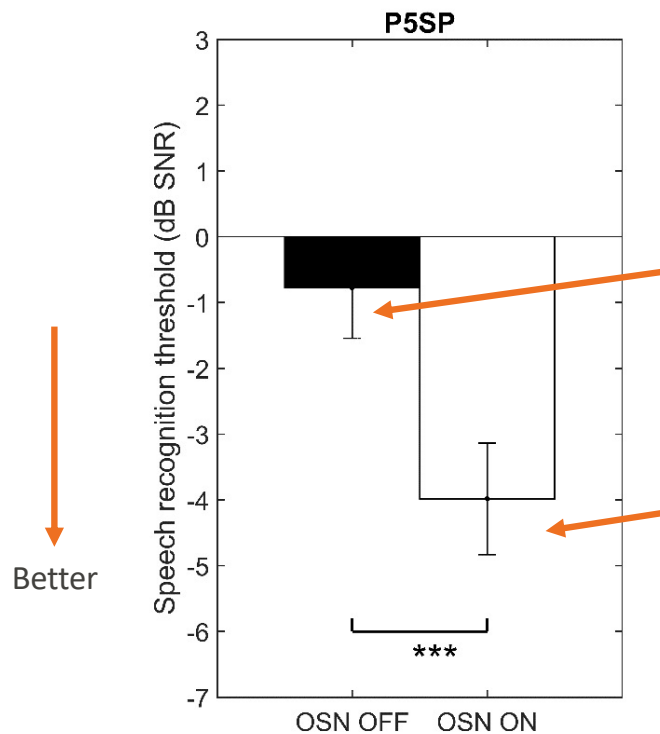
These are the simulated gain curves (ICRA 65 dB SPL), averaged across participants, that have been exported from Genie Medical



Improvements in FBM system (OpenSound Optimizer™ and safety margins) allow higher max stable gain in P5SP

Improved speech intelligibility with P5SP vs. P3SP

With and Without automatics



Overall better performance with P5SP
(both in Omni and with Automatics)

OpenSound Optimizer™ user benefits

“

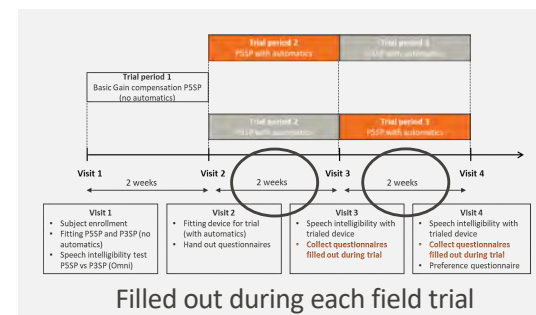
There's also been less wind sensitivity, and the device is much less sensitive to touch, so you don't get feedback howling, which was very common with the Ponto 3 SuperPower. But now, I can put on my hat without any howling noise. I can put my arms behind my head and watch TV without experiencing any feedback, which just makes everyday life easier for me.”

Christian, Ponto 5 SuperPower User, Denmark

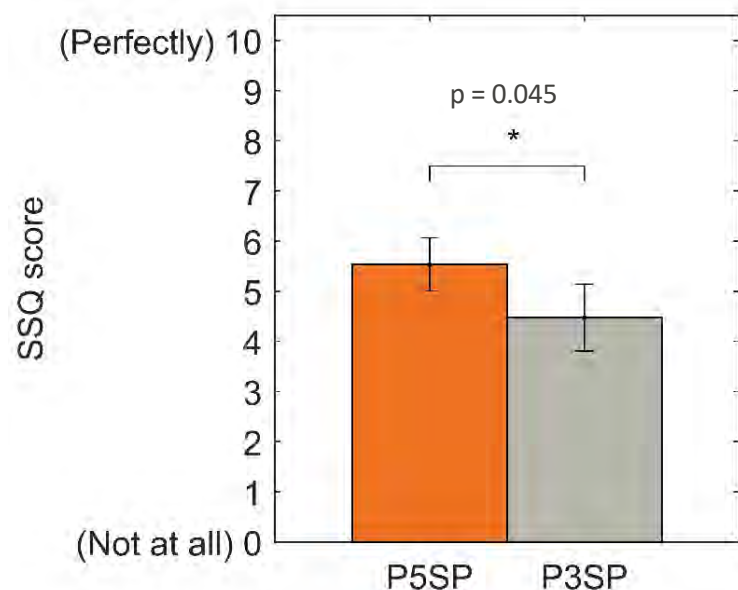


Self-reported performance (SSQ12)

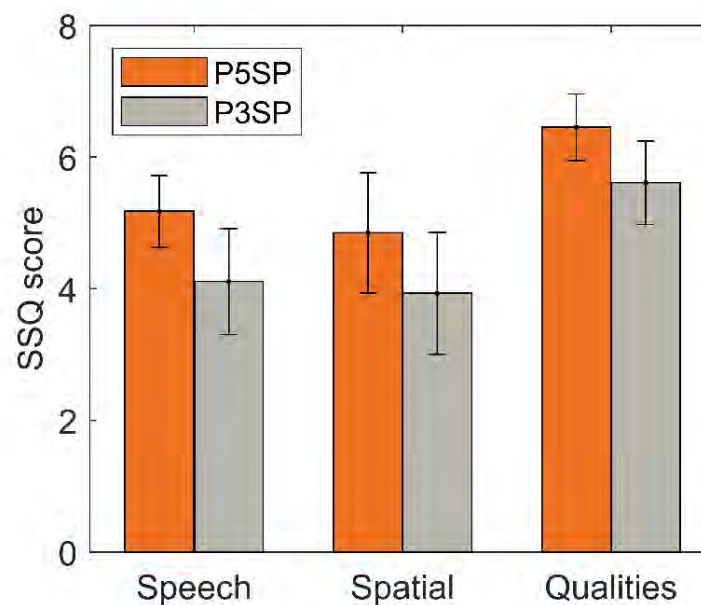
- The participants report significantly better performance with P5SP (the two questionnaires were filled out independently for each device!).



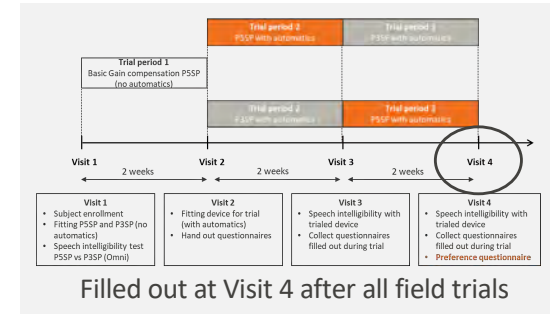
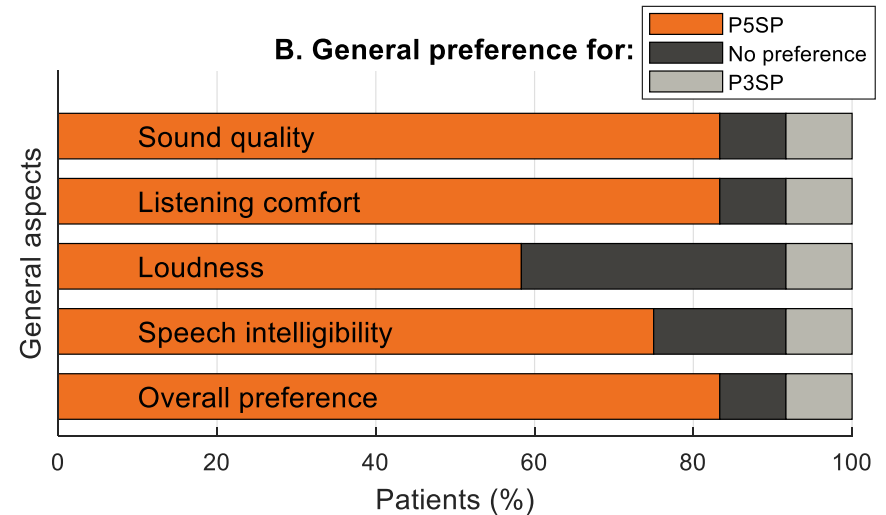
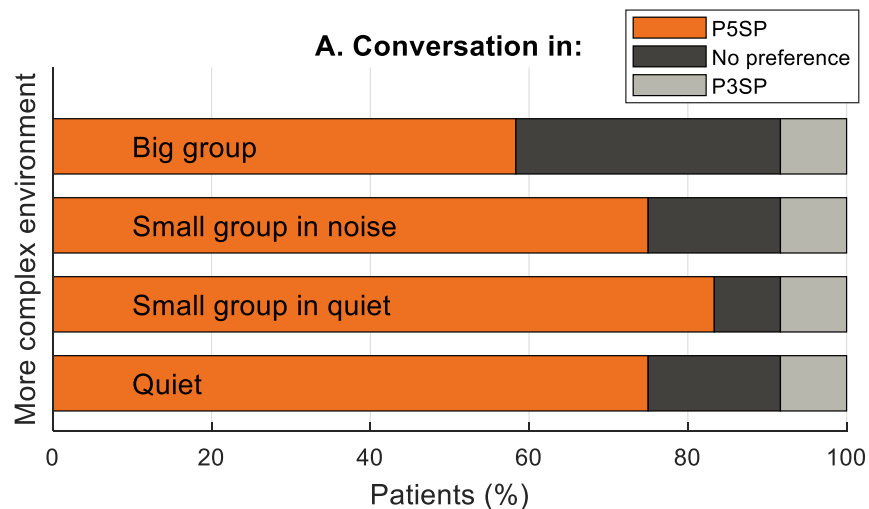
Total score



Score for each subscale



Preference questionnaire



- **Overall preference for P5SP: 83.3%**
- The participants report to prefer P5SP based on an **overall better sound experience** (“Hear better”, “Better sound in all situations”, “Overall better sound quality”, “More natural sound”). There were also a few comments on better speech intelligibility.
- Note that preference was not due to wireless (no connectivity throughout the study)

At the end of the study: More than 90% chose Ponto 5 SuperPower over Ponto 3 SuperPower

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Summary

The results of this study showed that:

- **OpenSound Navigator** gives Ponto 5 SuperPower users **more than 30%** improved **speech understanding**;
- **P5SP** is **preferred by 83% of the participants**, mostly due to an overall better sound experience;
- **P5SP** was **chosen by** more than 90% (11/12) of the study participants.





Better speech understanding with less listening effort

- OpenSound Navigator can significantly increase speech understanding.
- Significantly reduce the overall effort to process a sentence in noise.

21%
improved speech understanding¹



36%
reduction in pupil dilation¹



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5 ways Ponto 5 family sets the standard

1. No compromise on size or power

The world's smallest and most powerful abutment-level SuperPower sound processor

2. Feedback? Prevented

With the OpenSound Optimizer™*1

3. Access the full 360° soundscape

With the OpenSound Navigator™

4. A world of connectivity

Direct streaming and smart accessories

5. Patient care from anywhere

With Genie Medical and RemoteCare

* For prescribed fittings, according to best practice and during normal use

1 Data on file at Oticon Medical

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QUESTIONS ?

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