

OTC hearing aids: a rapidly changing world

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Sources of information

Forbes Health

<https://www.forbes.com/health/hearing-aids/over-the-counter-hearing-aids/>

NIDCD (National Institute of Health, Institute on deafness and other communication disorders)

<https://www.nidcd.nih.gov/health/over-counter-hearing-aids>

National Council on Aging

<https://www.ncoa.org/adviser/hearing-aids/>

Treatment for sensorineural hearing loss

Two classes of hearing aids now:

- **Prescribed hearing aids** fit by hearing specialist (audiologist or hearing device dispenser)
 - Based on audiogram
 - Gain profile is fit to target values
 - Gain is verified and validated by professional care
- **Over the counter (OTC) hearing aids** (certified by FDA)
 - Based on self-perceived mild to moderate hearing loss
 - Gain profile is adjusted by the user; maximum values are regulated by FDA
 - Performance is evaluated by the user

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Other direct-to-consumer amplifiers

<https://www.forbes.com/health/hearing-aids/over-the-counter-hearing-aids/>

- **Personal Sound Amplification Products (PSAP)**

PSAPs are wearable devices purchased from retail and online outlets that provide amplification of certain environmental sounds and are often used while hunting, bird watching, listening in background noise or listening to a public speaker. They should not be marketed as devices that help people with hearing loss;

some are cheap and terrible.

- **Assistive Listening/Technology Devices (ALD)**

ALDs help people with hearing loss manage specific listening environments, using light, vibration or intense sound to alert someone to things like phones, lights, doorbells and smoke alarms.

- **Wireless Hearing Aid Accessories**

Designed to supplement a hearing aid, these accessories allow someone to stream information from a phone or other electronic device to improve their listening experience.

- **Hearables**

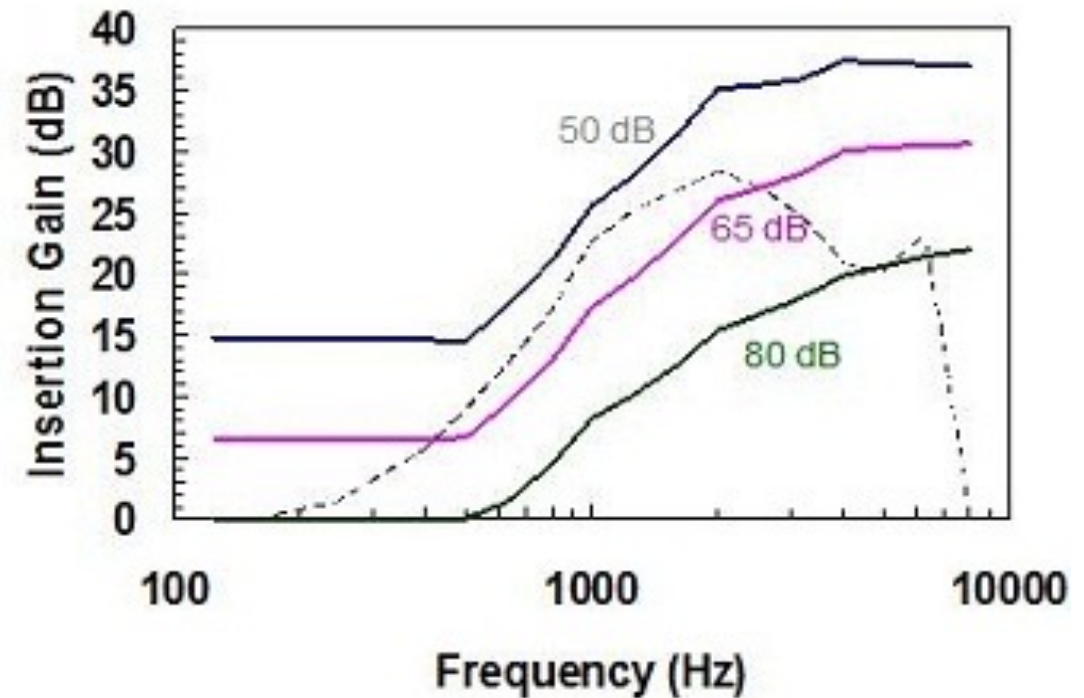
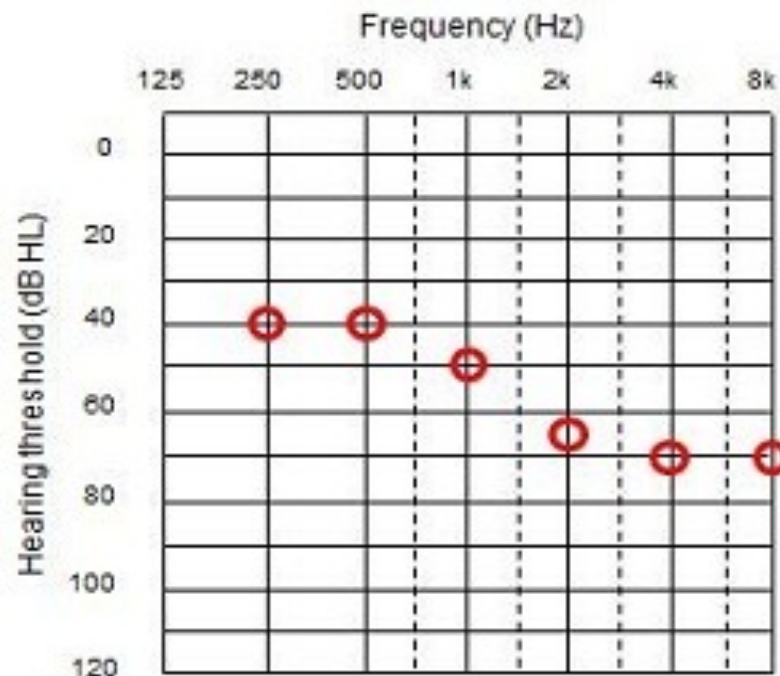
Earbuds or headphones can enhance listening experiences like music streaming and face-to-face communication. Some hearables have no hearing enhancement function.

Prescription hearing aids

Fit by licensed professional, based on audiogram

Can fit unusual losses

State laws apply



Today's special focus: OTC

WHY?

Poor uptake of hearing aids for many decades

Barriers to adoption: cost and accessibility (distance, audiologist shortage)

Inequities tied to longstanding access barriers based on geographic (rural) location, minority background, income, and insurance status (Arnold et al., 2019)

Today's focus: OTC

- Intended for people at least 18 years old with perceived mild to moderate hearing loss.
- Now available at stores and online retailers (who aren't required to be licensed sellers) without the need for a medical exam, prescription or fitting adjustment by an audiologist or hearing health professional.
- OTC hearing aids must be controllable by the user, allowing them to make volume and frequency-dependent changes based on preferences without the assistance of a professional.

OTC requirements from FDA

a. Labeling requirements.

OTC hearing aids must carry labeling that addresses candidacy, safety warnings, and reporting information

b. Technical specs:

To minimize the risk of over-amplification, FDA requires a general output limit of 111 dB SPL (or 117 dB SPL if the hearing aid has activated an input-controlled compression)

OTC requirements from FDA

C. Design requirements.

To help ensure proper fit and minimize risk of injury, FDA requires the insertion depth of OTC hearing aids to be at least 10 mm from the eardrum.

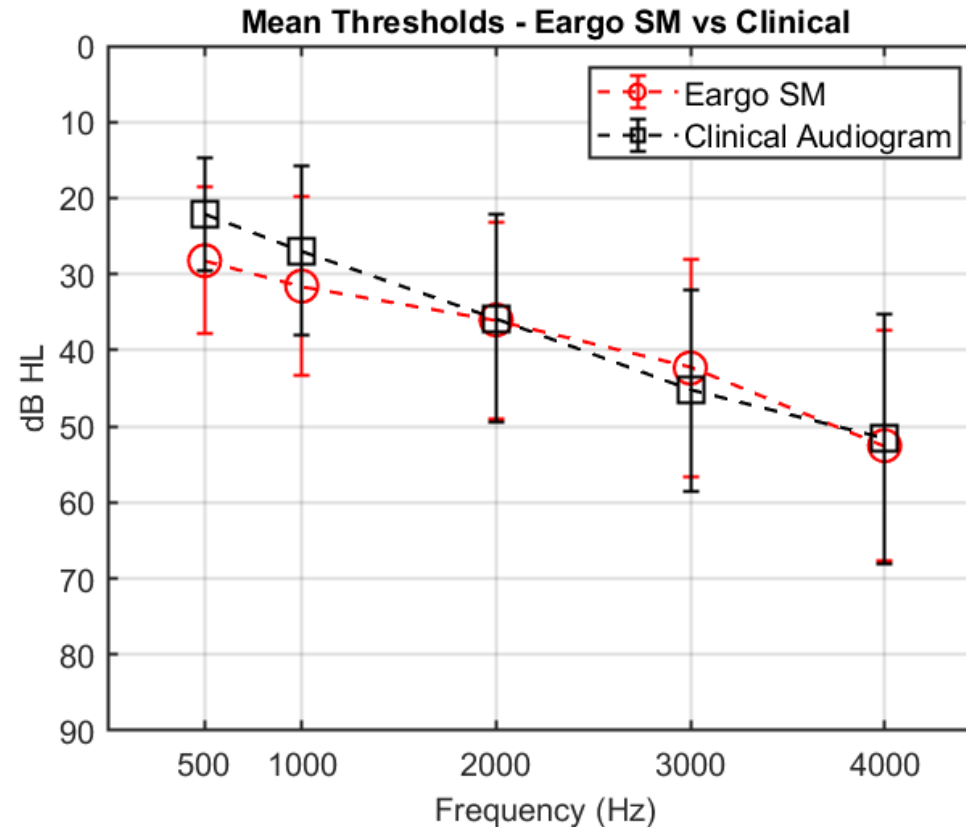
There are rules regarding the use of safe materials for the ear tip. Nonetheless, the user must open the box and figure out how to put them on the ear appropriately.

FDA also stipulates that the device must contain “tools, tests, or software” that allow the user to control and customize the device (FDA, 2021)

In situ audiograms? (hearing tests through the devices?)

Hearing test or no?

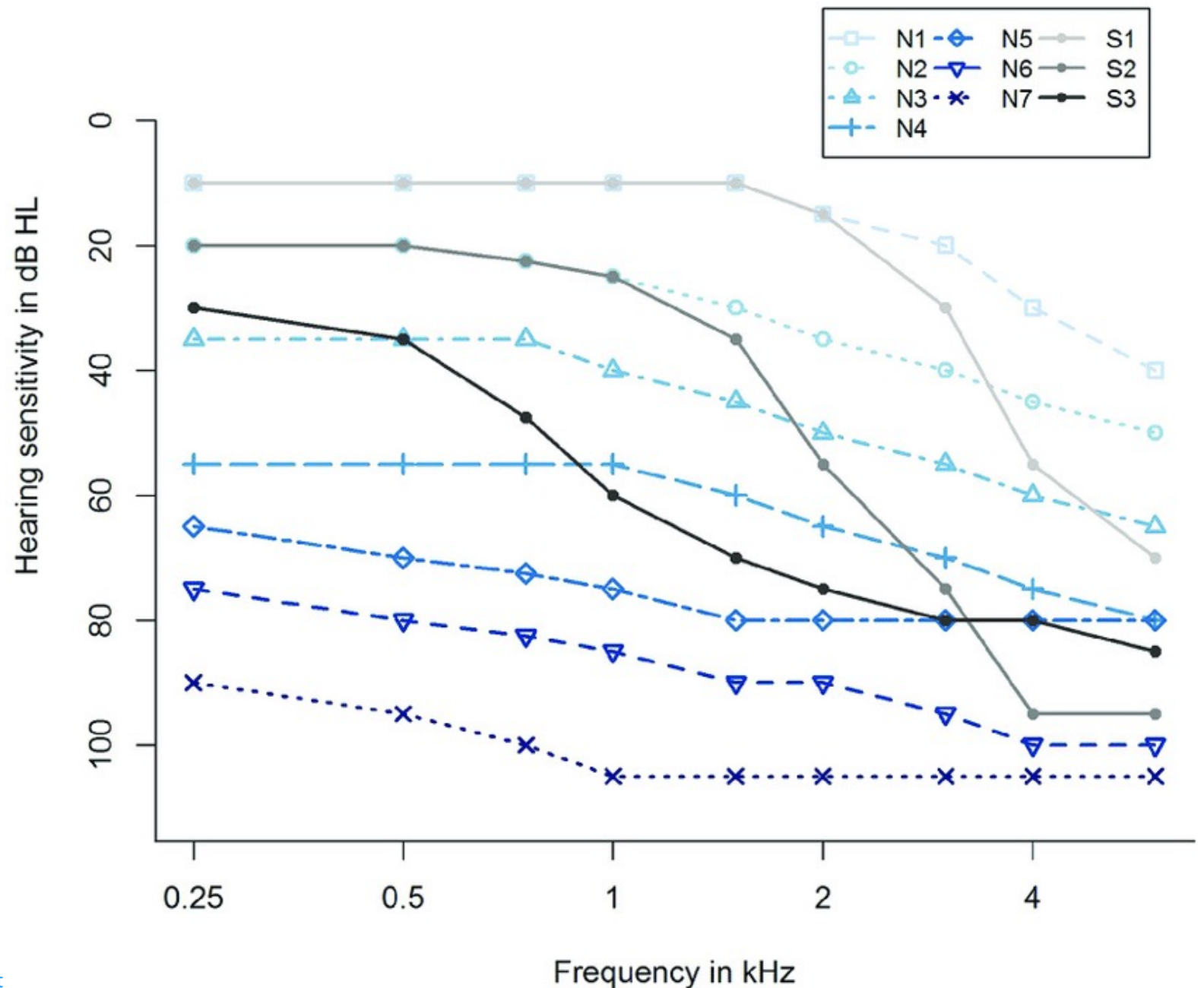
Some involve a
self-assessment
of hearing;
Others do not.



From our
ongoing clinical
trial of Eargo
devices

Hearing test or no?

User chooses
from a fixed
set of profiles



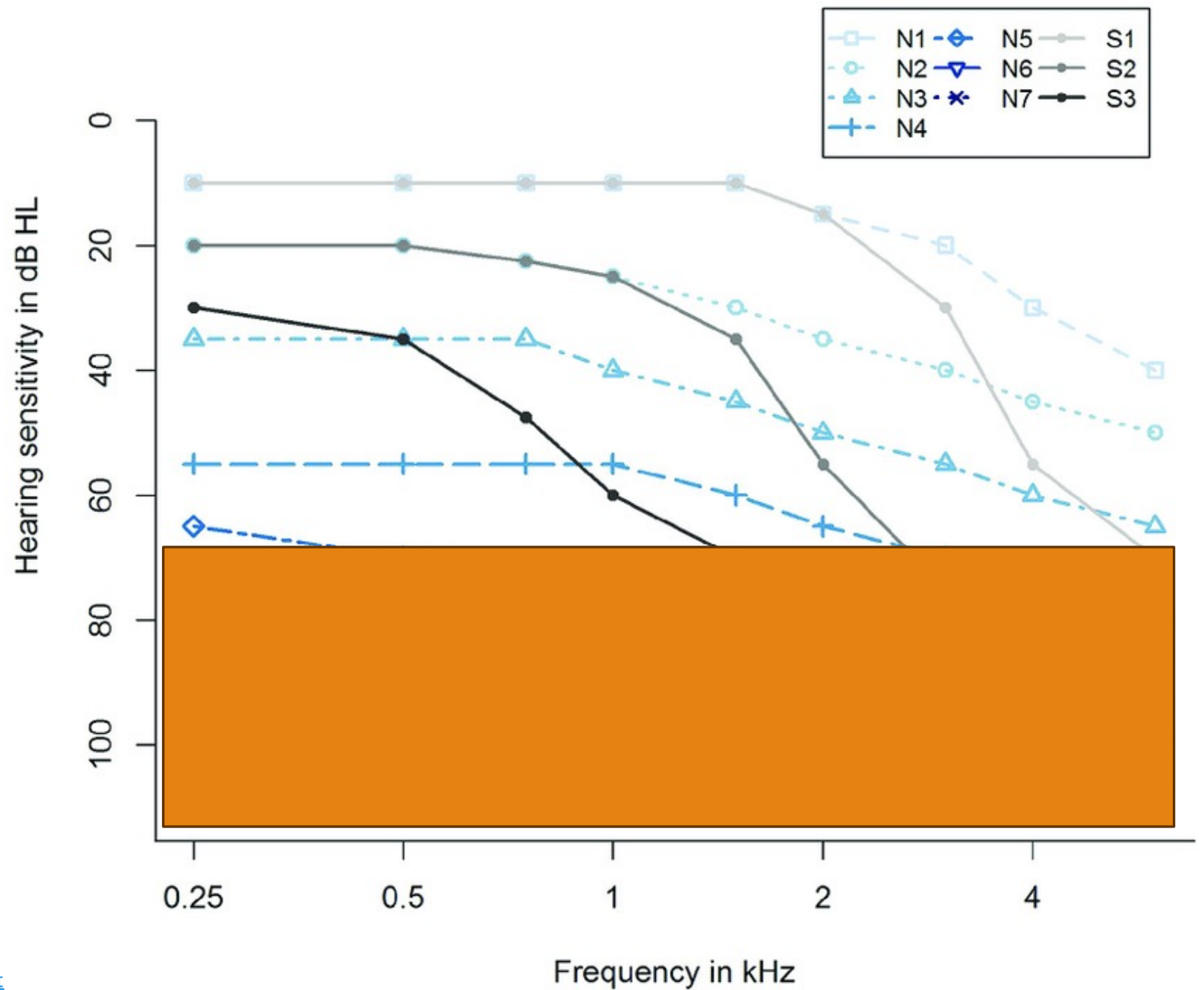
•2010 Jun;14(2):113-20.

doi: 10.1177/1084713810379609.

**Standard audiograms for the IEC 60118-15
measurement procedure**

[Nikolai Bisgaard](#)¹, [Marcel S M G Vlaming](#), [Martin Dahlquist](#)

Hearing test or no?



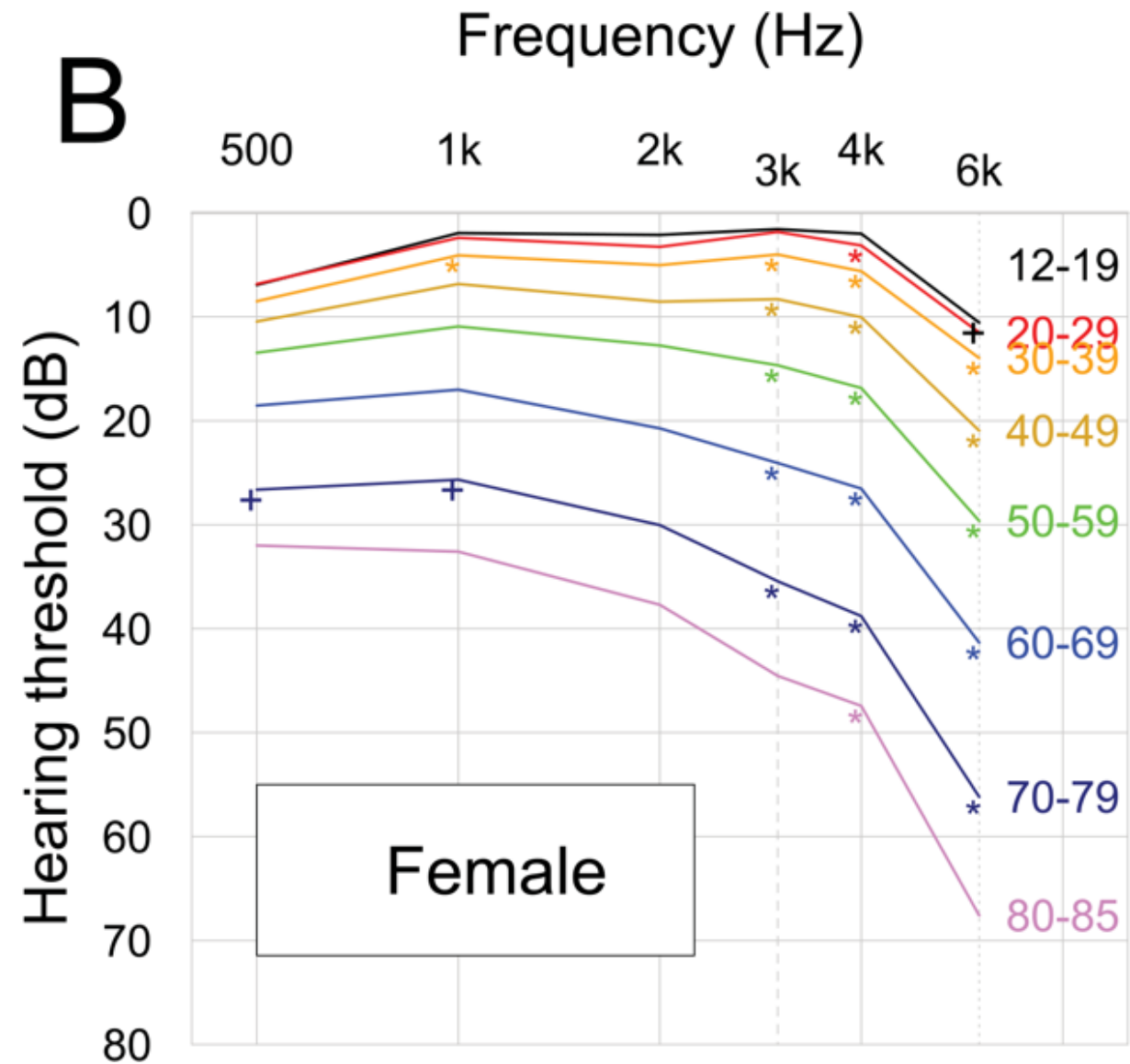
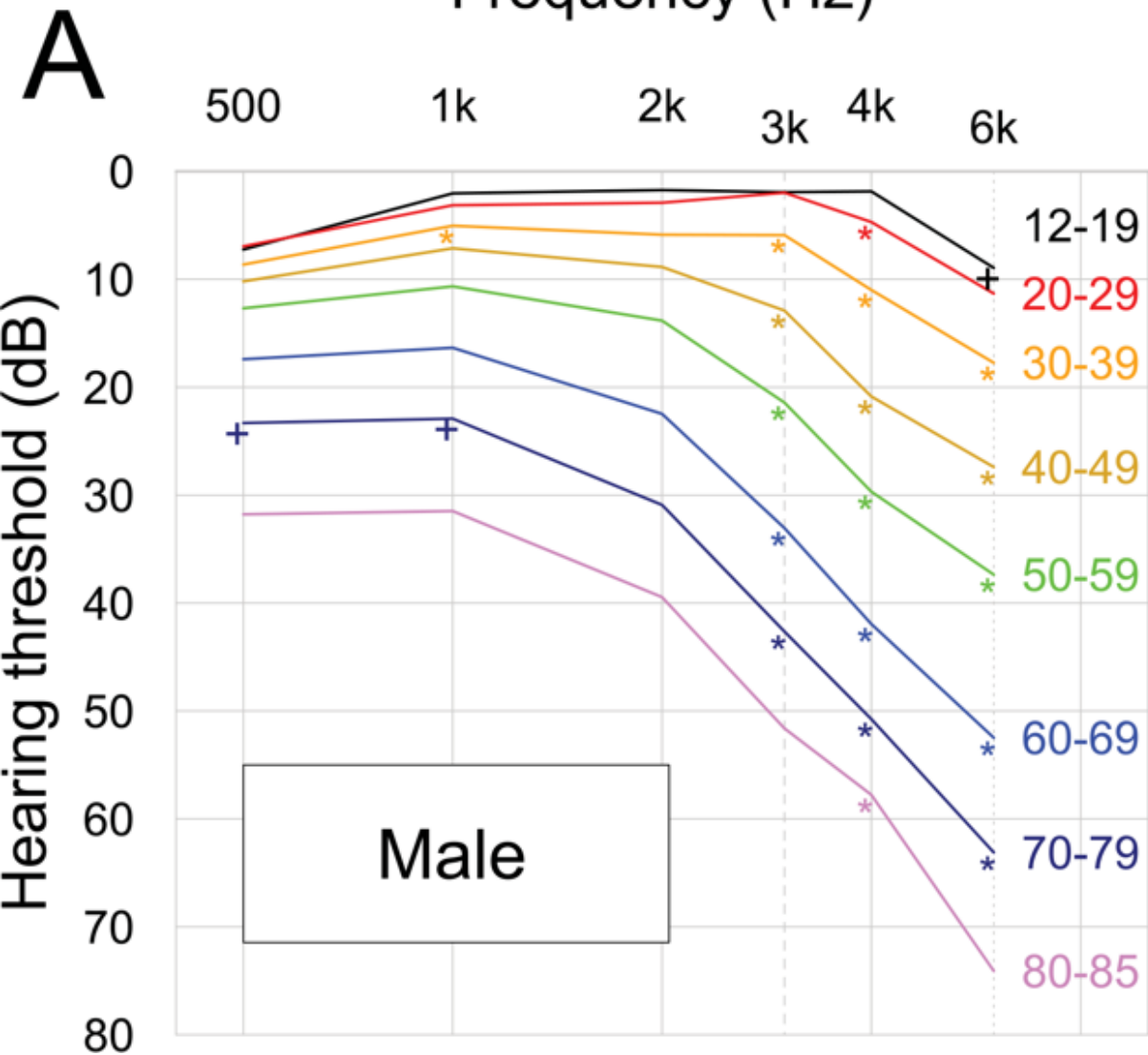
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Typical hearing loss can be predicted by age and sex



Today's focus: OTC self-perception

Other devices simply rely on the user's perception of hearing loss

DO potential users really perceive the need for hearing devices?

E-2. Does a hearing problem cause you to feel frustrated when talking to members of your family?

YES SOMETIMES NO

S-3. Do you have difficulty hearing when someone speaks in a whisper?

YES SOMETIMES NO

E-4. Do you feel handicapped by a hearing problem?

YES SOMETIMES NO

S-5. Does a hearing problem cause you difficulty when visiting friends, relatives or neighbors?

YES SOMETIMES NO

S-6. Does a hearing problem cause you to attend religious services less often than you would like?

YES SOMETIMES NO

E-7. Does a hearing problem cause you to have arguments with family members?

YES SOMETIMES NO

Can consumers adjust the gain? Do they want to do this themselves?

FDA requires that the devices be adjustable by the user

We have studied >100 participants with hearing loss using 3 platforms

Very few (2 or 3) were unable to adjust the parameters reliably and consistently

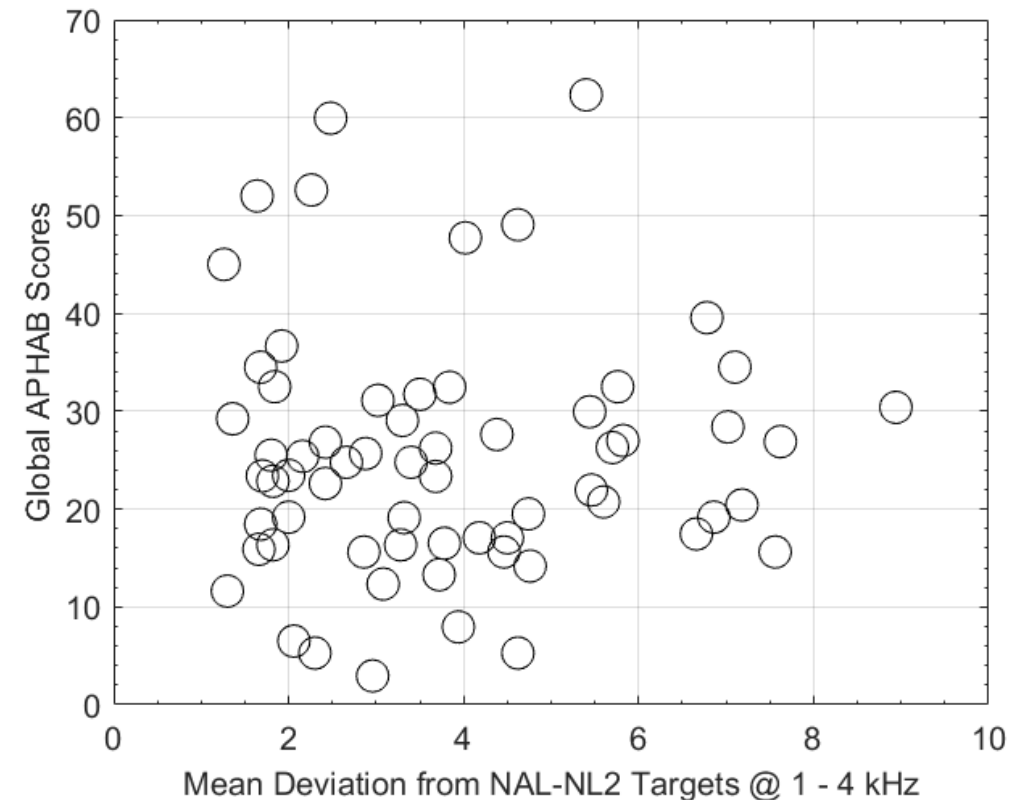
- Test-retest was good and satisfaction was high

(NOTE: Those are people who are willing to come to the U for studies.
Will others be as successful?)

OTC Target gain

Should we worry that we don't fit to a prescribed gain target?
(maybe not as much as we thought)

Satisfaction and benefit were high
even when we "missed" target



Can users figure out what to do “out of the box”?

Convery study: Big challenges in putting together earpieces, figuring out what size to use, connecting to app.

What will the instructions look like?

What will the apps look like?

Will audiologists offer support?

We just don't know yet

What's available

Forbes Health:

Eargo,

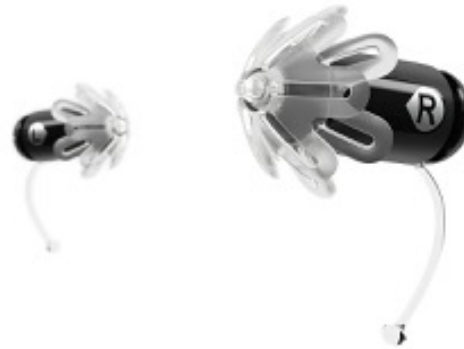
Jabra (part of GN ReSound)

Lexie (Bose)

Lively (now merged with Jabra)

Audicus?

More to come in 2023-24



OTC: a grand experiment

- Taking them out of the box: Many challenges still exist
- Will retailers accept returns? (major retailers are doing so)
- Will we miss other conditions that will go undiagnosed?
- Will people who use OTC devices eventually go to professionals for help?

We're living in an experiment to increase access and use to important tools to improve quality of life for people with hearing loss.