



## **RESEARCH QUICK TAKES**

### **5.1: OTC Hearing Aids: All about the new product category**

Brian Taylor & Gus Mueller

## A little history . . .

- Serious discussions regarding the need for *access* and *affordability* of hearing aids for the general public began back in 2009 at an NIH conference.
- The topic later was picked up by the President's Council of Advisors on Science and Technology, and then by the National Academy of Science, Engineering and Medicine (NASEM). In 2016, the latter group issued a set of 12 recommendations concerning the OTC product.

## A little history . . .

- The NASEM recommendations led to the introduction of the over-the-counter hearing aid act by Senators Grassley and Warren in 2016.
- It was passed and signed into law by President Trump in 2017, requiring the FDA to have guidelines in place by August 2020. The pandemic, however, caused a delay.

## A little history . . .

- In October 2021 the FDA released the draft regulations with a 60-day comment period.  
Over 1000 comments were submitted.
- After five years of waiting, the 200-page document was finally filed on August 16, 2022, at 8:45 am (EDT), and went into effect on October 17, 2022.



# New Hearing Aid Categories

- **Basic OTC:** These products have minimal user controls, and many will not have Bluetooth streaming or rechargeability. For example, The Sony OTC product in this category selects a pre-set gain curve based on the consumer's responses to various chirps, delivered through the accompanying app. With the app, the patient has the basic controls of volume (~10 dB) and a ~15 dB range of treble control.
- **Self-fitting OTC:** The second category of OTC products is similar, but includes more patient-controlled adjustments, and accordingly is labeled "self-fitting OTC." It further is defined as: integrates user input with a self-fitting strategy, that enables users to independently derive and customize their hearing aid fittings and settings. Early models reveal that these products likely will also have Bluetooth streaming and rechargeability.

Note: It is required that this more advanced self-fitting products have FDA pre-market approval documentation, referred to as 510(k), a procedure that often requires clinical efficacy research.



# Prescription Hearing Aid?

To (supposedly) help avoid confusion, the FDA assigned a new prefix to what we have called hearing aids in the past—in the FDA-world they are now called *prescription* hearing aids, and as always, only can be dispensed by a licensed professional.

The term “prescription” has the potential to cause confusion among consumers and licensure boards—we’ll see how this all works out.



## And we also have these products . . .

**PSAP.** Personal Sound Amplification Product, commonly referred to by the acronym PSAP. The FDA defines these devices as sound amplifiers, used to increase sounds in certain environments *for non-hearing-impaired consumers* (e.g., used for hunting, bird watching, listening to a lecture with a distant speaker, etc.). They are not intended to compensate for hearing impairment, are not medical devices, and therefore are not subject to the FDA's medical device requirements.

**Hearables.** A market presence in recent years, these are a sub-set of what we call "wearables," which are defined as body-worn computers. Hearables have many forms and function, but a typical example related to our current OTC topic would be wireless earbuds that potentially can provide listening assistance in difficult speech-in-noise situations. You could call a hearable a PSAP, and they certainly are available over-the-counter.



## Today's Product Line-Up . . .

|                          | <u>Regulated by FDA</u> | <u>Direct to Consumer</u> |
|--------------------------|-------------------------|---------------------------|
| Prescription Hearing aid | YES                     | NO                        |
| Self-Fitting OTC         | YES                     | YES                       |
| Pre-Set OTC              | YES                     | YES                       |
| PSAPs                    | NO                      | YES                       |
| Hearables                | NO                      | YES                       |



And then, there is the category that really isn't a category, but maybe is the most popular . . .



The advertisement features a pair of large, silver, over-the-ear hearing aids with a plus sign above them, indicating a second pair is included. Below the image, the text reads: "FREE PAIR OF HEARING AIDS", "The BOGO Silver bundle includes:", followed by a bulleted list: "• X2 4-Program Hearing Aids" and "• CIC Rechargeable Hearing Aids". The price is listed as "only \$499.00" with "Normally \$894" crossed out. A "LEARN MORE" button is at the bottom.

**FREE PAIR OF HEARING AIDS**  
*The BOGO Silver bundle includes:*

- X2 4-Program Hearing Aids
- CIC Rechargeable Hearing Aids

only **\$499.00**  
Normally ~~\$894~~

[LEARN MORE](#)

Sold through the DTC channel:

- Are **not** “prescription”—not sold by licensed professional
- Are **not** “OTC” as do not have FDA stamp of approval
- Are **not** “PSAP” as they are designed for and marketed to people with hearing loss



## “Intended” Candidates for these products?

- The regulations state that the intended candidates are individuals with self-perceived mild-to-moderate hearing loss and who are at least 18 years of age.
- The maximum output levels (peak 2-cc coupler) are 111 dB SPL for linear processing and 117 dB SPL for devices with input compression. There is no restriction for gain, although indirectly this will be controlled by the maximum output (and probably indirectly by acoustic feedback).

*BUT . . . as the name suggests, these products are sold “over-the-counter,” meaning that someone with a profound hearing loss could buy them, someone with normal hearing could buy them, and a parent could buy them for their one-year-old hearing-impaired toddler.*



## Some early partnerships . . .

- WSAudiology and Sony
- Demant and Phillips
- Sonova and Sennheiser
- Nuheara and Hewlitt Packard



# And what do HCPs think about all this?



The *HearingTracker* conducted a survey of HCPs (October 2022; n=730).

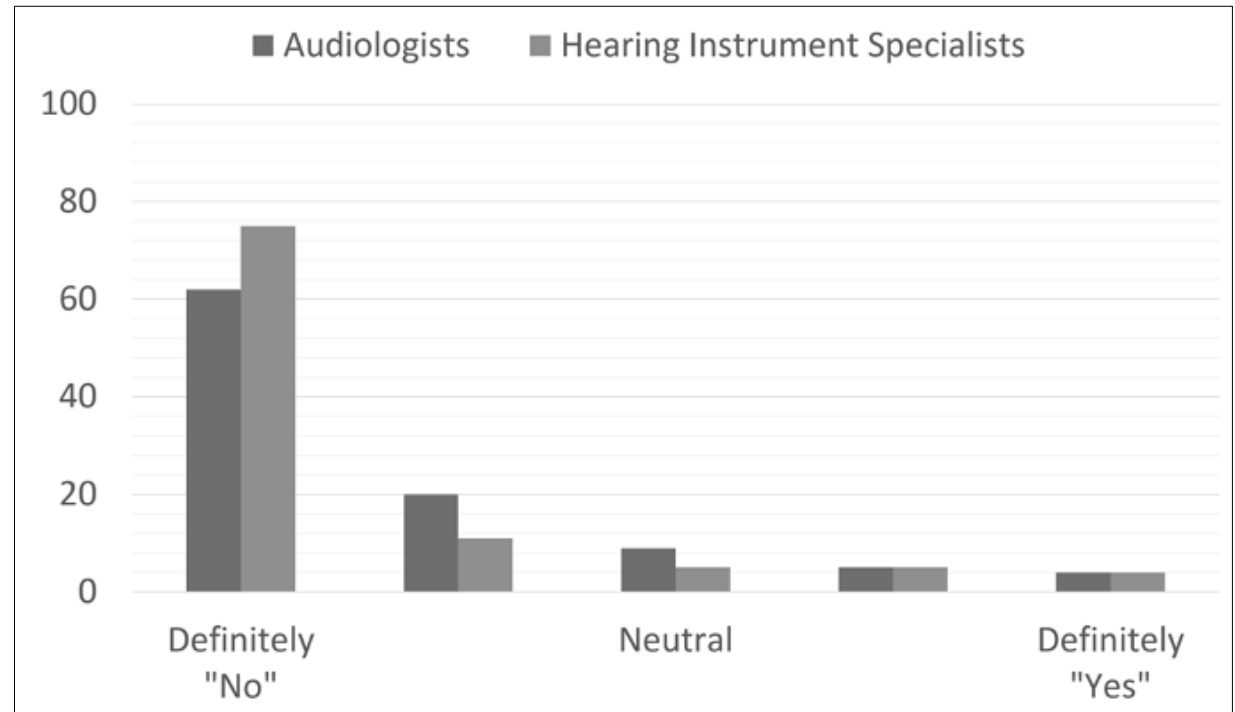
- 26% stated they plan on selling the OTC product
- 55% stated they plan to provide support for those who purchase elsewhere
- 19% do not plan to sell or service the products

The four leading concerns were:

- Consumers will struggle to identify and address common problems (like moisture and wax issues).
- Consumers who purchase OTC hearing aids will not be educated on realistic expectations.
- Consumers who purchase OTC hearing aids will not be educated on effective communication strategies.
- Consumers will miss medical red flags and fail to have pathologies diagnosed and treated in a timely manner.



# And just for fun, what were HCPs saying about OTCs 20 years ago?



Response to Hearing Journal survey question:  
"Should the FDA approve OTC hearing aids?"



## **RESEARCH QUICK TAKES**

5.2: OTC Hearing Aids: A good fitting without the help of a professional?

Brian Taylor & Gus Mueller

# OTC fittings: What could go wrong?

- The hearing test/listening task associated with the app, might not provide an accurate result.
- The pre-set gain and output for a given test result might not be appropriate (under-fitting is most probable). The range of adjustment for that pre-set might not be large enough to correct the error.
- Even with a larger range of adjustments (self-fitting products) the patients might not be a good judge of what is best for them

*Note: We are only referring to possible problems with the selection of gain and output. Many more problems could exist related to physical fit, care and handling, etc.*



# First things first . . . What is a “good” fitting?

- There is little evidence to select anything but the NAL-NL2 algorithm
- In research comparing the NAL-NL2 to other algorithms (most commonly those of manufacturers), the NAL-NL2 consistently has been equal to, or better than the comparative settings.
- For adults, the DSLv5 is similar enough to the NAL-NL2, that we would reach the same conclusion for this algorithm. Research has shown, that when averaged across a group of differing audiograms, the SII difference between the NAL-NL2 and the DSLv5 was .01.





## So, will OTC users fit their products to the NAL-NL2?

Catherine Palmer conducted a study using trainable hearing aids with 36 new hearing aids users, all fitted to the NAL-NL1; one group trained for one month, the other for two months.

- In general, after training, both groups ended up very close (within 1–2 dB) to the NAL-NL1 targets for average inputs.
- The Speech Intelligibility Index (SII) for soft speech was reduced 2% for one group, and 4% for the group that started training at the initial fitting.
- Interestingly, the new trained gain more or less consistent with the gain reduction applied in NAL-NL2.



## A Mueller-Hornsby study from a few years back with trainable hearing aids



Twenty participants who were regular hearing aid users; had used hearing aids for at least 2 years, and were happy with their hearing aids.

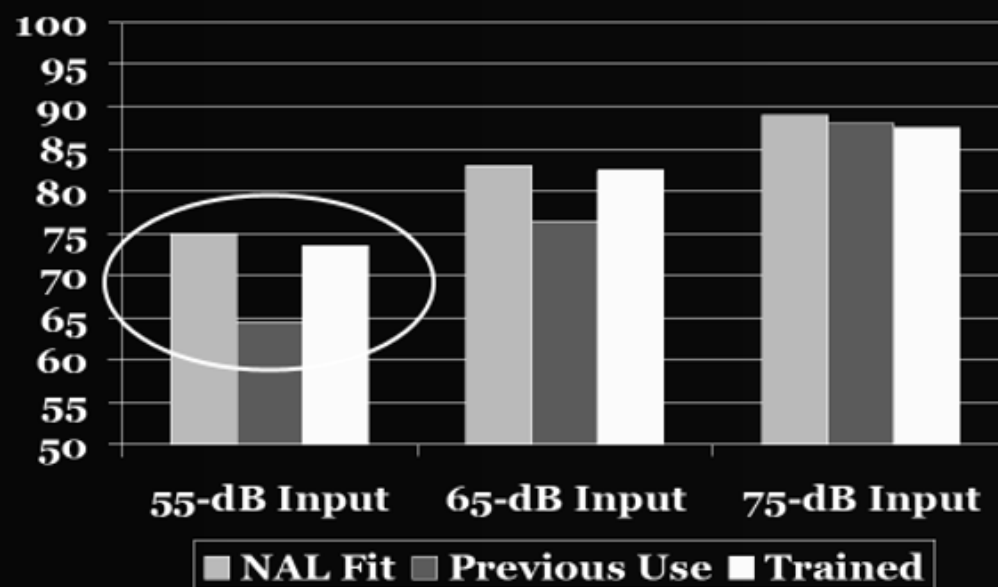
Participants selected because we knew that they had been “under-fit.” We knew clinic used manufacturer’s proprietary fitting.

Participants were fit with new trainable hearing aids, and used them in the real world for 2-3 weeks (+/- 16 dB training)

Data logging was used to ensure that the hearing aids were being used, and that VC changes were being made.

## Mueller & Hornsby: Comparison of trained gain to previous use gain (average of 2000-4000 Hz).

Compression training allowed for different input levels to be trained differently

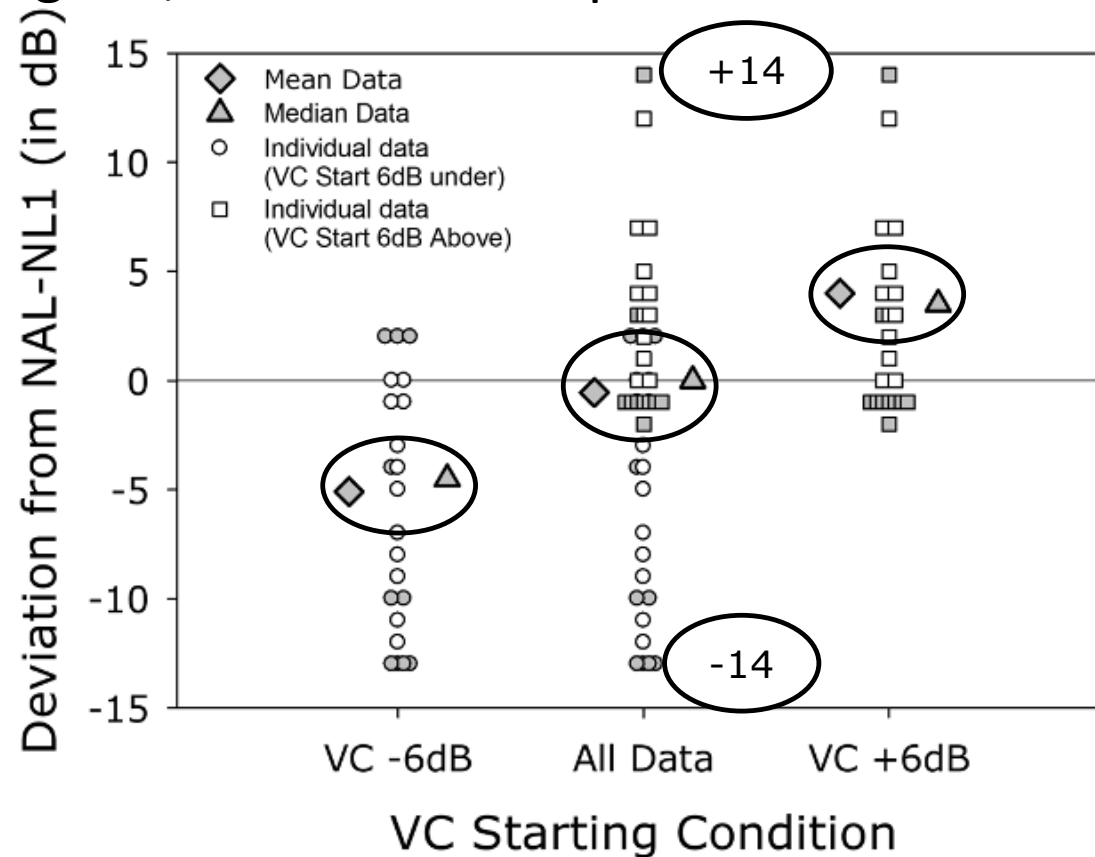


## And one more study . . . From the folks at the NAL

- In a more recent study using trainable hearing aids, participants fitted with the NAL-NL2 initial programming, trained for three weeks.
- The results of the training were assessed for *six different* listening situations. That is, the training was situation specific based on the hearing aid's classification system; for example, a given participant could train increased gain for music, and decreased gain for speech-in-noise.
- For all conditions, the participants did tend to train down slightly from the NAL-NL2, but only by an average of 1-2 dB.



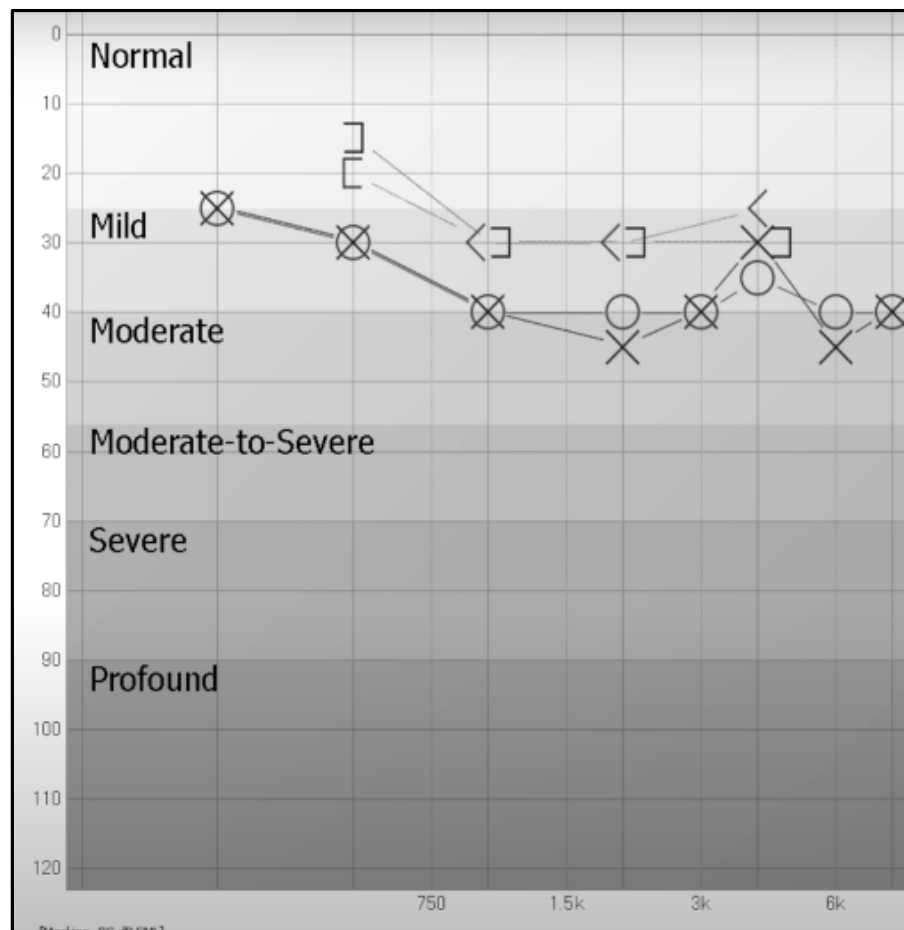
All sounds good, but here is the problem . . .



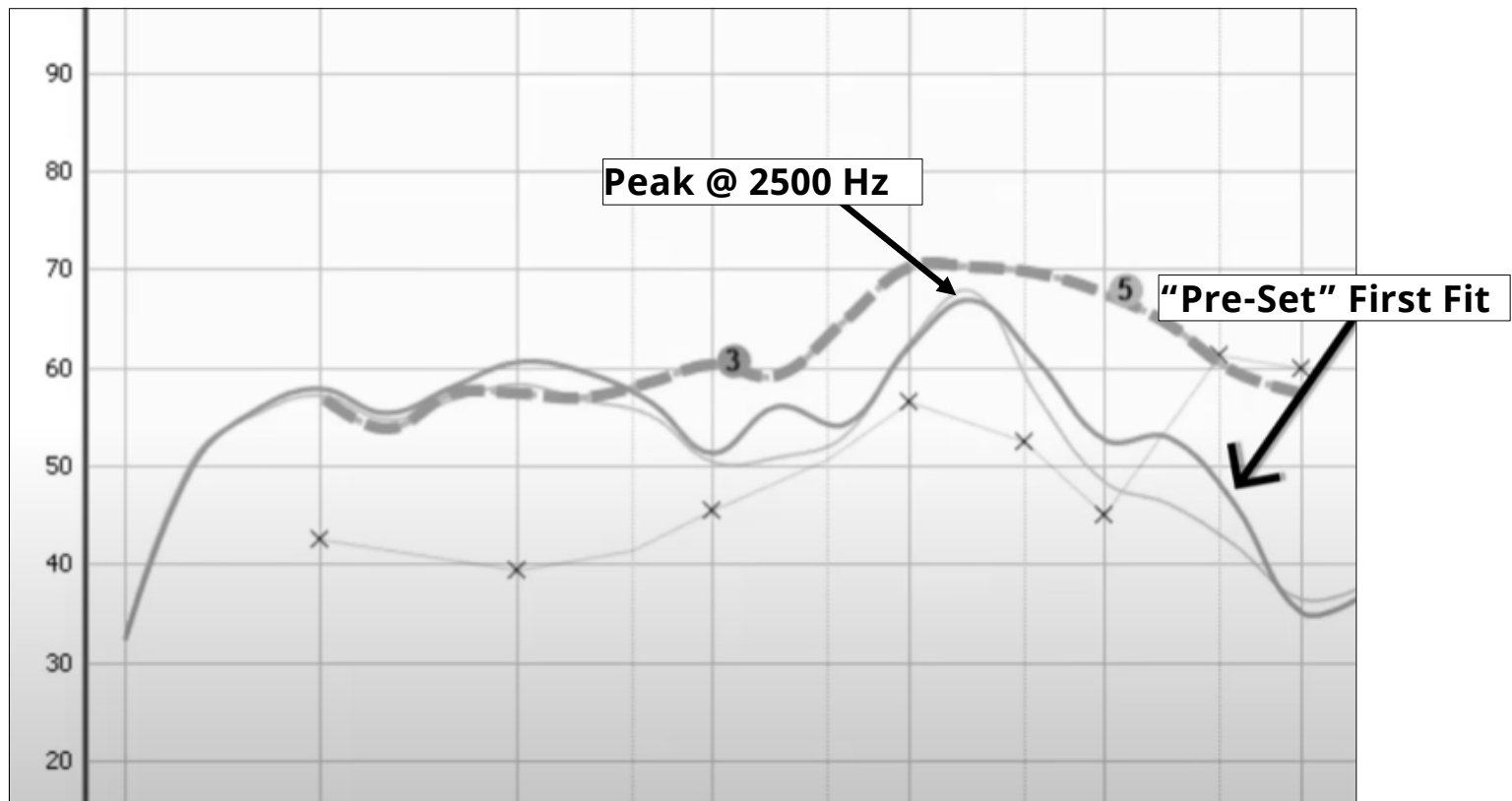
## A Case Study From Dr. Cliff



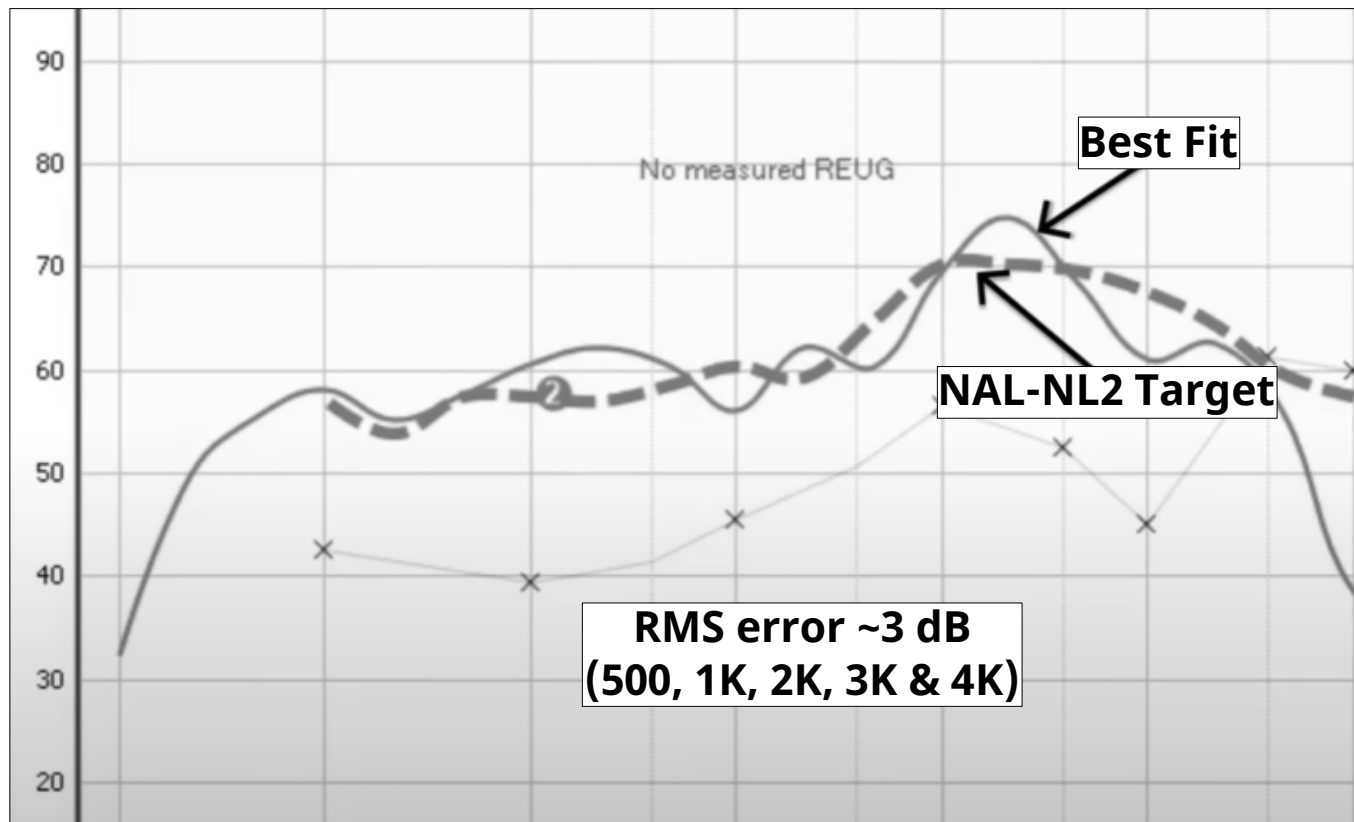
## Audiogram of sample patient



# Pre-Set output for the measured hearing thresholds

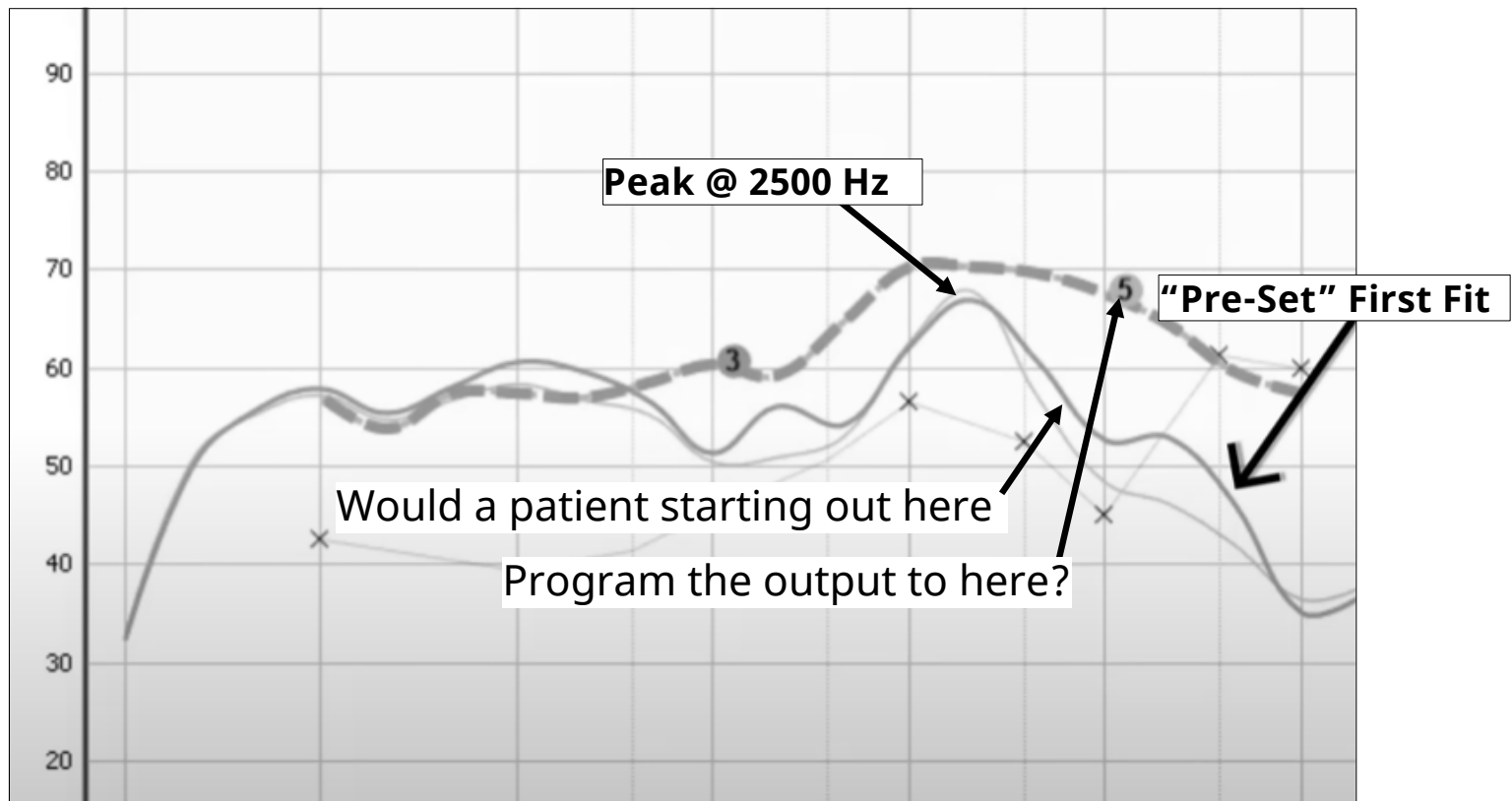


# Best fit-to-target following gain and treble adjustments





But, we have to ask . . .



And, there are these data from the large Humes et al (2017) study:

|                         |   | Best for participant<br>based on NAL-NL2 algorithm |    |    |
|-------------------------|---|----------------------------------------------------|----|----|
|                         |   | X                                                  | Y  | Z  |
| Selected by participant | X | 12                                                 | 41 | 10 |
|                         | Y | 1                                                  | 13 | 11 |
|                         | Z | 2                                                  | 8  | 4  |

- When audiologists compared the pre-programmed hearing aids to the patient's audiograms, they selected the hearing aids with the "medium" amount of gain for 61% of the 102 ears—See Figure.
- The patients themselves, however, only selected these products 14% of the time, and rather, usually (62%) selected the product with the least amount of gain.
- Across all three hearing aid categories, the audiologists and the patients were only in agreement 28% of the time.

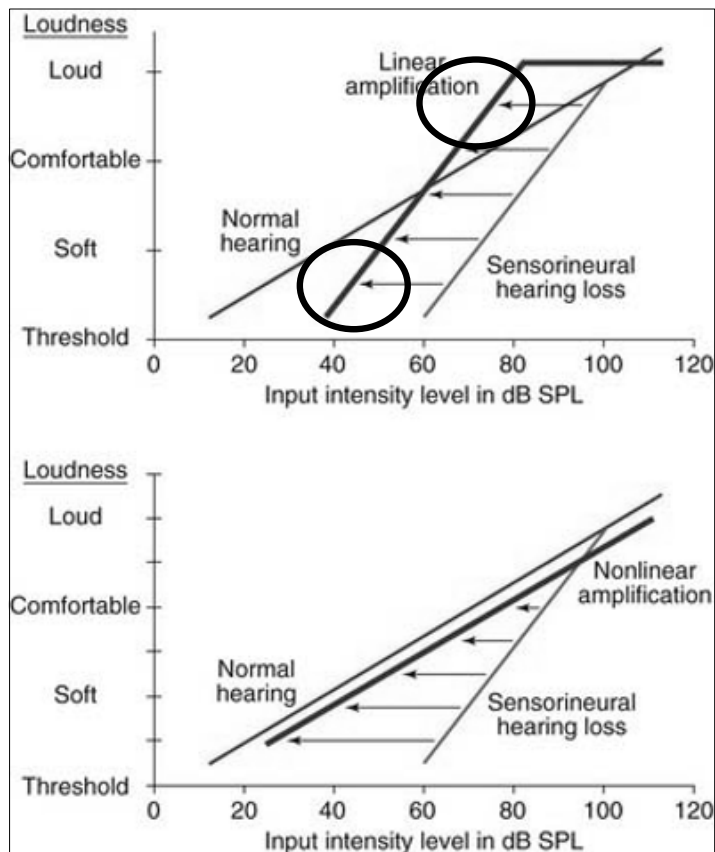
## More from the Humes et al (2017) research:

All participants paid for their hearing aids at the beginning of the study, knowing that they could return them for credit at the end.

- Only 53% of the participants who fitted themselves choose to keep the hearing aids, compared to 81% for those fitted by an audiologist.
- The most interesting finding of the study was that for the Placebo group, those who wore hearing aids with little or no gain for six weeks, 36% chose to keep their hearing aids!



## Will most of the OTC products have linear amplification?



What we know about linear amplification:

- When average inputs are set “just right” soft sounds are too soft.
- When average inputs are set “just right” loud sounds are too loud.

**There is no way to fix this!**





## RESEARCH QUICK TAKES

### 5.3: OTC Hearing Aids: Some encouraging self-fitting research findings

Brian Taylor & Gus Mueller

# In episode 5.2 we talked about some OTC fitting issues that could go wrong:

- The hearing test/listening task associated with the app, might not provide an accurate result.
- The pre-set gain and output for a given test result might not be appropriate (under-fitting is most probable). The range of adjustment for that pre-set might not be large enough to correct the error.
- Even with a larger range of adjustments (self-fitting products) the patients might not be a good judge of what is best for them

*But . . . Are there data that suggest that things might be mostly okay?*



# Going back to the Humes et al (2017) research:

In 5.2 we reported that the majority of participants under-fit themselves (lower SII ~6-7%), and in only 24% of the cases did the audiologist's recommendation agree with what the participant selected.

How did this impact rating on self-assessment inventories?

| <u>Domain</u>           | <u>Best Practice vs. Consumer Decides</u> |
|-------------------------|-------------------------------------------|
| Benefit (PHAP)          | No Significant Difference                 |
| Satisfaction            | >Best Practice                            |
| Use                     | No Significant Difference                 |
| Reduced Handicap (HHIE) | No Significant Difference                 |

Is this finding because:

- What we think matters, doesn't matter as much as we think?
- Self-assessment inventories aren't very sensitive?



# A self-fitting vs clinician-fit study

(Keidser G, Convery E. [2018] Outcomes With a Self-Fitting Hearing Aid Trends In Hearing

- Participants conducted self-directed threshold measurements leading to a prescribed hearing aid setting, and fine-tuning, without the need for professional support.
- Participants consisted of 27 experienced and 25 new hearing aid users who completed the self-fitting process—some of the participants required professional assistance, resulting in 38 user-driven and 14 clinician-driven fittings.
- Following 12 weeks' experience with self-fitting products in the field, outcomes measured included: coupler gain and output, handling and management skills, speech recognition in noise, and self-reported benefit and satisfaction.
- Irrespective of hearing aid experience, the type of fitting (user- or clinician-driven) had no significant effect on coupler gain, speech recognition scores, or self-reported benefit and satisfaction.

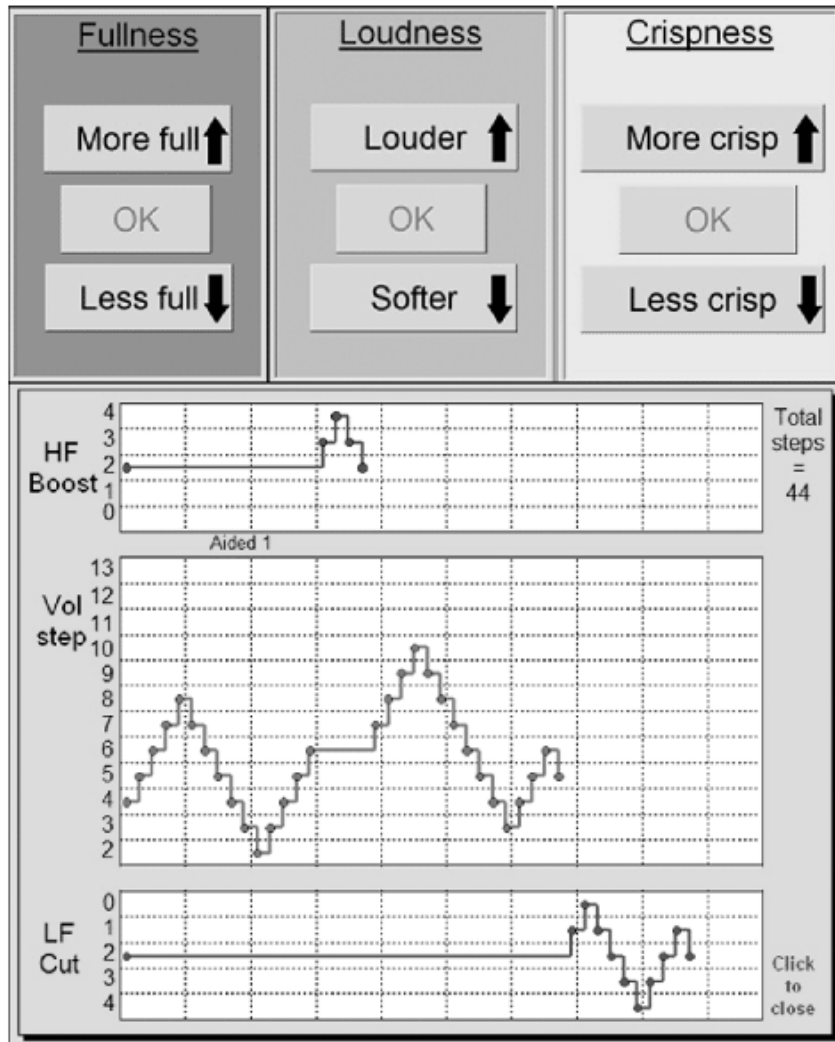




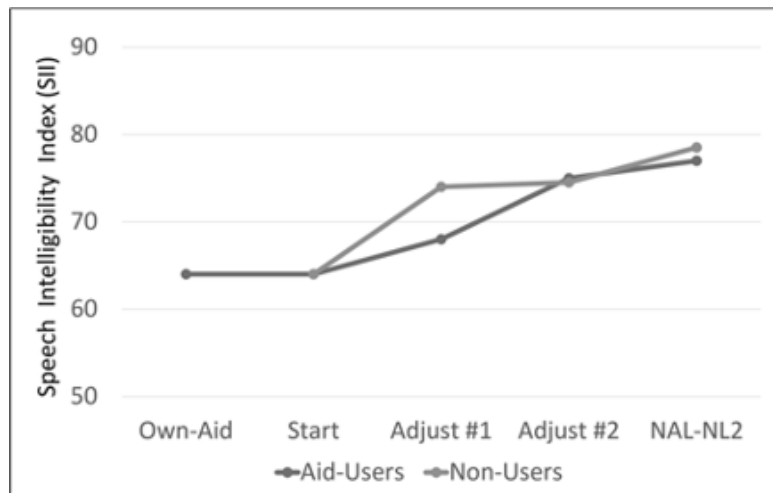
# The “Goldilocks’ Approach”

An adaptive fitting approach that has been developed for self-fitting.





User makes continued adjustments while listening to speech

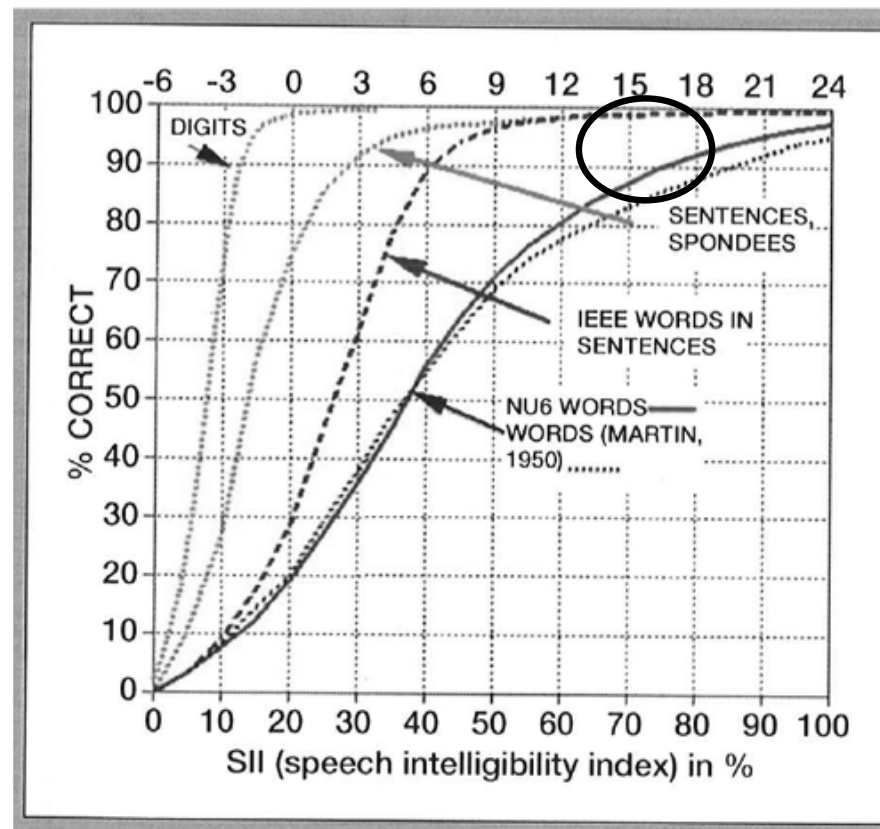


**No difference for new users vs. previous users**

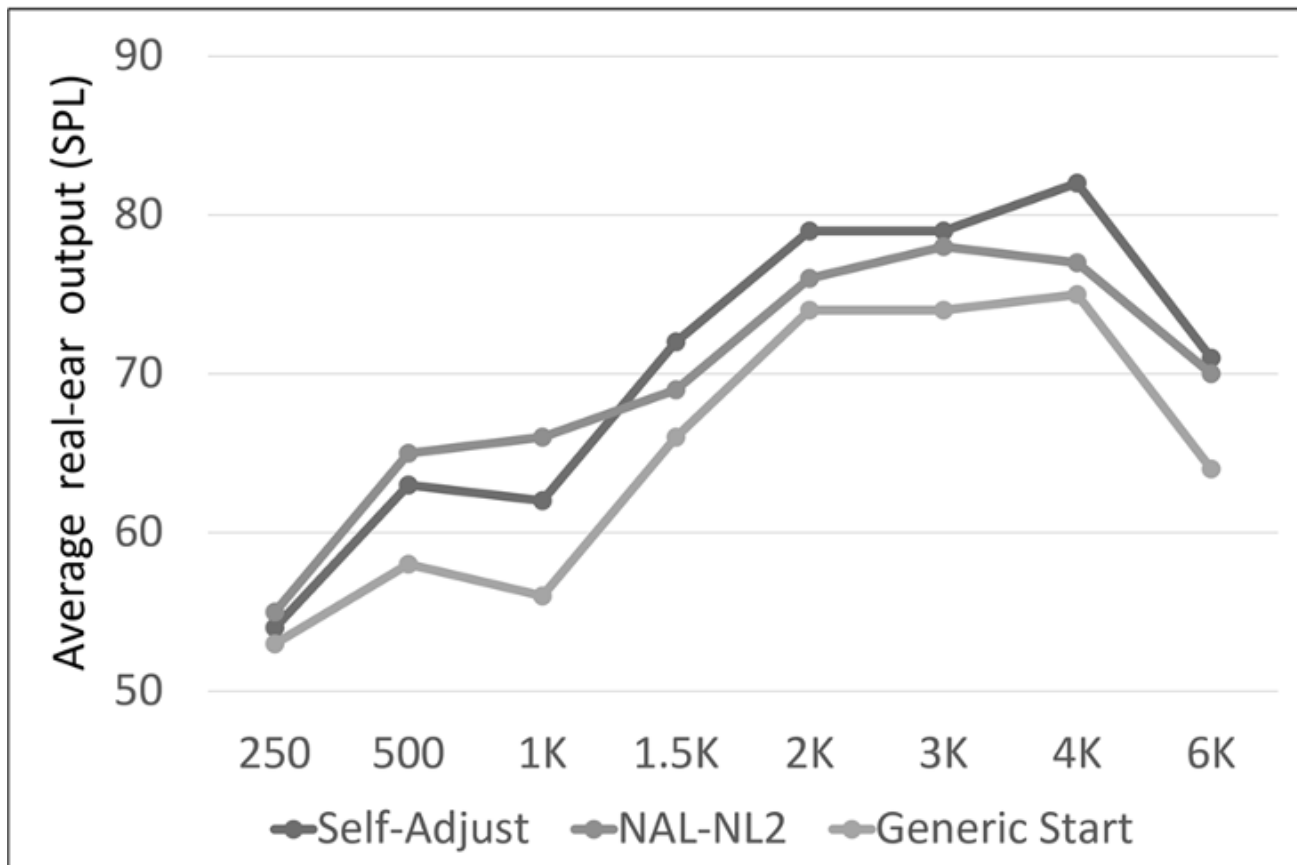
- A group of 26 individuals (13 of which were previous hearing aid users) with mild-to-moderate hearing loss, listened to prerecorded sentences.
- Starting with a generic level and spectrum, participants adjusted (1) overall level, (2) high-frequency boost, and (3) low-frequency cut.
- The participants adjusted the hearing aids for two trials and Speech Intelligibility Index (SII) was calculated following the adjustment; the generic starting condition provided outputs and SIIs that were significantly below those prescribed by NAL-NL2.
- After the second adjustment, the SIIs for both groups were not significantly different from what was achieved with the NAL-NL2 prescription fitting.



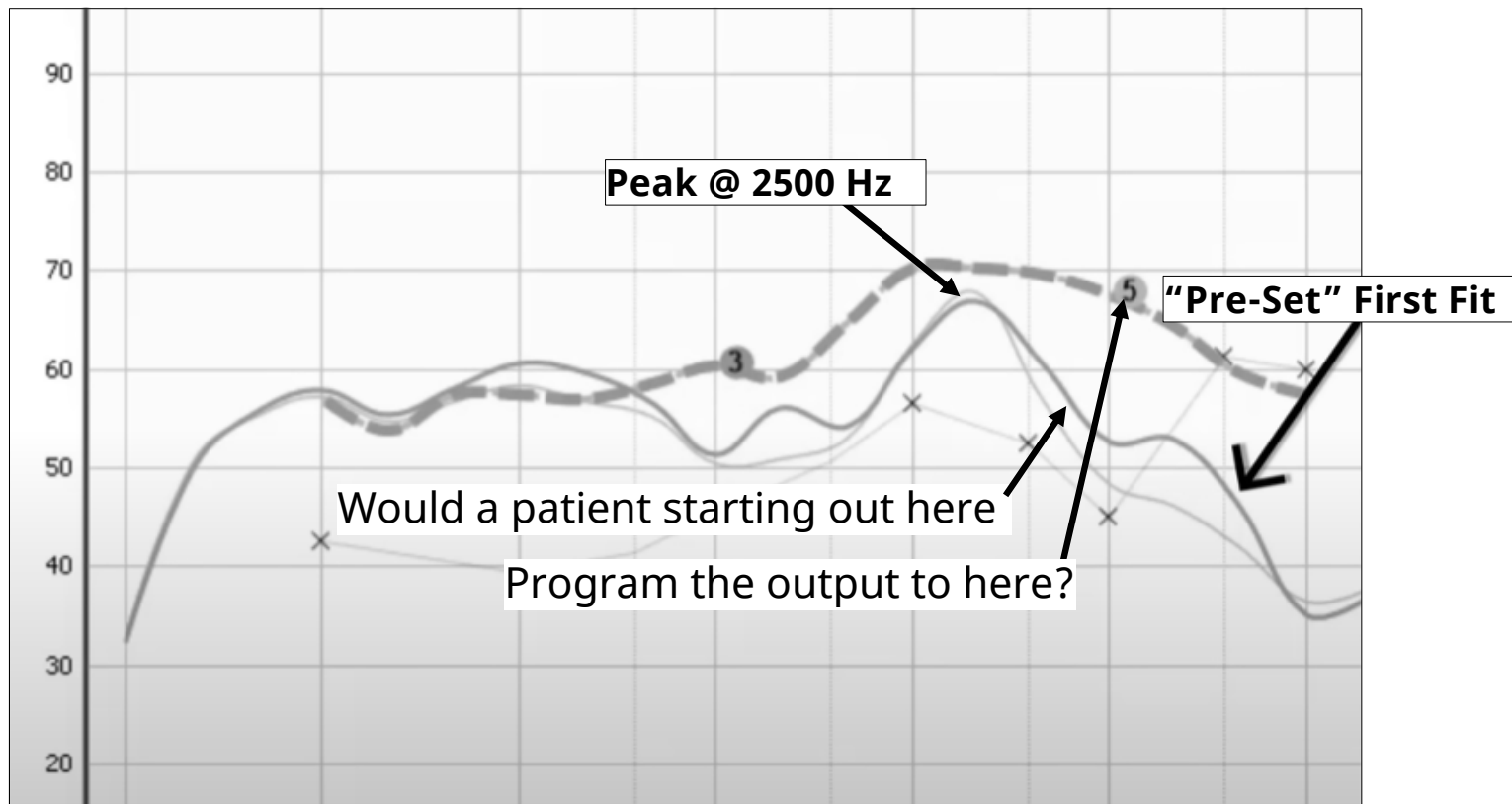
In case you haven't thought about the SII lately:



## A related study from Goldilocks' group:



Going back to our QuickTakes 5.2 episode . . .we have to ask?



## The “Bose Study” (later used for FDA 510(k) approval)

- In this research participants used an interface with the hearing aid that allowed them to select their own gain and compression in each of 12 frequency bands.
- They were all first fitted using clinical best practices: audiogram, fit to target, real-ear verification, and subsequent fine tuning. Then, in their everyday lives over the course of a month, participants either selected their own parameters using this new interface (Self-fitting group;  $n = 38$ ) or used the parameters selected by the clinician with limited control (Best Practices Group;  $n = 37$ ).
- What made this study unique (compared to others), was that the initial position of the interface corresponded to *0 dB real-ear insertion gain (REIG)* for all participants in the self-fitting group.
- Outcome measures: selected gain values, sound quality assessments, and paired comparisons between self-fitting and audiologist-selected settings. At the conclusion of the study additional self-assessments outcomes were administered, and also speech recognition-in-noise was conducted.



## Gain settings following starting at 0 dB?

- *The final fitting was compared to the Best Practice NAL fitting after fine-tuning (which in nearly all cases reduced gain below the NAL prescription). For the self-fitting group, 50% of users were with 2.6 dB and 90% of users were within 6.7 dB.*
- *The Best Practice group also adjusted gain, and their final settings were within 1.9 dB and 4.4 dB, respectively—closer to clinician-fit than the self-fitting group, but this difference was not significant.*

*Important to know: Following the initial “fit-to-target” the clinician adjusted the programmed output based on patient comments—this adjustment nearly always was less gain. Hence, the deviation from “clinician fit” is smaller than what would have been deviation from the NAL targets.*



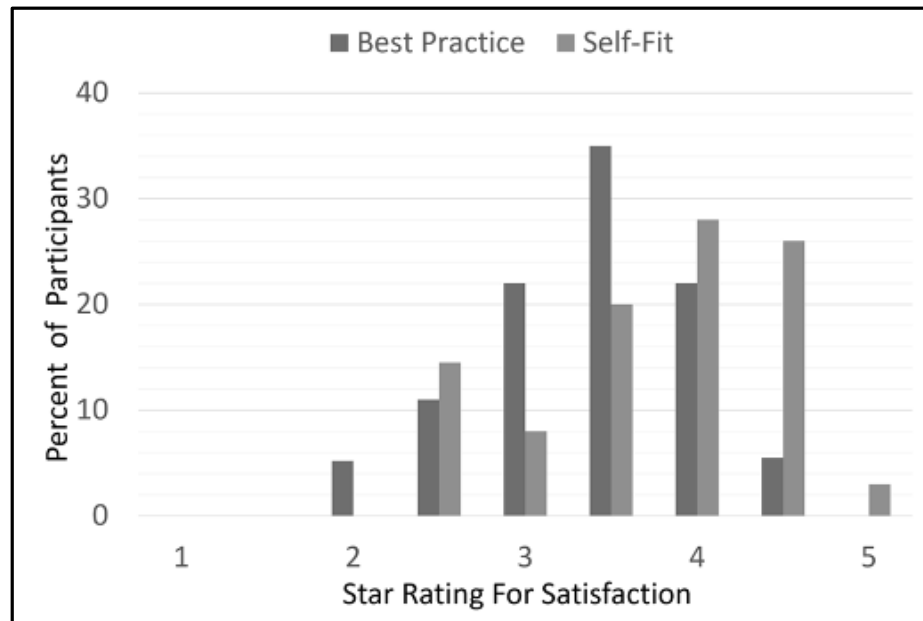


## Other outcome findings:

- *A/B comparison.* The participants also completed an A/B comparison with the original clinician-fit and their self-fitting. Although 31% of the ratings were “no preference,” when a preference was noted, it nearly always was for the self-fitting, 53% vs 16% for the clinician fit.
- *Outcome measures.* The self-assessment benefit inventories used in this research were the APHAB and the SSQ12. There was no difference in benefit between the Best Practice and self-fitting groups for either of these measures.
- *Speech recognition:* There also was no difference in aided speech-in-noise recognition, as measured using the QuickSIN. We need to point out, however, that the QuickSIN was conducted at 60 dB HL—the authors did not state the more important SPL values, but we would assume that they were ~72-75 dB, considerably louder than normally used for aided speech testing. We don’t know, therefore, if the under-fitting of gain for the self-fitting group had an impact on speech-in-noise for more common listening situations.



# “Star Ratings” of real-world satisfaction



- During the field trial, the participants rated their satisfaction for a variety of listening situations using a “one star” to “five star” system, much like you’d rate your Uber driver.
- Overall, the ratings for satisfaction were significantly better for the self-fitting group. Notice for example, only ~26% of participants of the Best Practice group had an average star rating of “4” or better, whereas, ~57% of the self-fitting group had average star ratings this high.



# One more issue related to self-fitting OTC products

## Health Locus of Control

- **Internal HLOC:** Patient believes that they are in control of their health (hearing loss), and can take care of things themselves
- **External HLOC:** Patient believe that others (physicians, HCPs) are in control of their health (hearing loss) and depend on them for their care

A given individual can have an external HLOC for some things, and in internal HLOC for others.

Not surprisingly, research with self-fitting OTC hearing aids has found that those with external HLOC were more apt to request assistance for their fittings.





## **RESEARCH QUICK TAKES**

### **5.4: OTC Hearing Aids--Practical issues related to sales and service**

Brian Taylor & Gus Mueller

## Mostly good things for HCPs surrounding the OTC product:

- **Affordability.** It has been reported, that for some individuals, obtaining a pair of hearing aids is the 3<sup>rd</sup> most expensive purchase they will make in their lifetime. The (before-tax) median income for a family of two in the U.S. is only around ~\$75,000, and much lower in several states.
- **Accessibility.** For many, especially the poor, the elderly, and those living in rural areas, travel to an HCP office is difficult, sometimes impossible. Research has shown that nearly 90% of Americans live within 5 miles of a pharmacy, and about 50 percent of the population lives within 1 mile of one.
- **Market penetration.** It is reasonable to assume, that if hearing aids are more affordable and more accessible, the percent of hearing-impaired individuals using hearing aids will increase. Most believe that many OTC users will move on the prescription hearing aids at some point in their journey.



## Mostly good things for HCPs surrounding the OTC product:

- **Public Awareness.** As more players enter the OTC market, we know we will be seeing more ads for these products on television, magazines, news sources and social media. This will encourage potential hearing aid users to start thinking about their hearing loss, and just maybe, contact a local HCP for a hearing test.
- **Improved prescription hearing aids.** As more and more new players enter into OTC hearing aid arena, it is probable that new and innovative technology will be introduced. Very likely, some of this technology will exceed what is available in prescription products, and we could see prescription hearing aids adopting some of these new features.
- **More HCPs following Best Practice.** As self-fitting OTC hearing aids become common place, it's important for HCPs to offer services that go beyond what the patient can do themselves—such as a “prescription fitting.”
- **Unbundling of product vs. services.** OTC services will need to be unbundled. Many argue that it is best for the profession if an unbundled approach is used for all hearing aid sales.



## Some reasons an HCP might consider the sale of OTC products

- To retain a product sale, and ultimately the patient, when he or she does not want to commit to traditional hearing aids. The OTC product can serve as a gateway to prescription products.
- For a patient that is tech savvy, wants to pay less, and believes that they do not need follow-up appointments or the services included with the standard hearing aid fitting approach.
- For patients who believe that their hearing loss is not a big enough problem for the purchase and use of traditional hearing aids. The OTC product can assist the patient hearing-aid journey sooner than typical.



## Some reasons an HCP might consider the sale of OTC products

- To offer a variety in product price point, for patients who have different budgets, or opinions regarding the cost of hearing care services.
- To have something for all customers that walk through the door. This might include patients with very mild hearing loss, part-time users, and those who only want to use amplification for select listening situations.
- To offer a unique product for those patients who consider the self-fitting process more desirable than the professional fitting, or prefer the unique style of some of the OTC products.





## Services that could be associated with OTC products:

- ***Pre-purchase hearing test:*** Many consumers will not be satisfied with the quality of the “app” hearing test, and prior to purchase, will want to have a “real” hearing test from a professional. Others likely will fail the app test, and the app will likely refer them to a hearing professional.
- ***Pre-purchase evaluation for candidacy:*** In addition to the standard audiogram, some consumers might want a professional’s opinion if they are a candidate for OTC (or any hearing aid). Speech-in-noise testing and self-assessment inventories (e.g., HHIE) would be helpful.
- ***Pre-purchase OTC selection guidance:*** Many consumers will be overwhelmed with the number of OTC hearing aids that are available, even for the same price point. HCPs offering “OTC purchase consultations” could be a welcome service.
- ***Orientation and training:*** Assist the patient with learning how to correctly insert and remove the hearing aids. Assist in operation of app and streaming features.

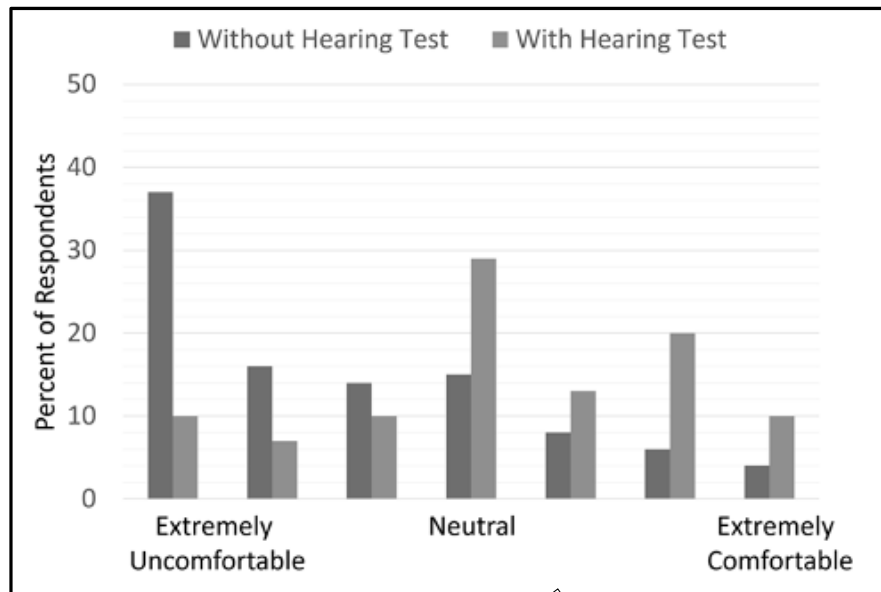


## Services that could be associated with OTC products:

- **Quality control:** Conduct electroacoustic 2-cc coupler analysis of the hearing aids to ensure proper function.
- **Prescription fitting:** Conduct probe-microphone measures and adjust the hearing aids as much as possible to optimize fitting based on validated prescriptive targets.
- **Benefit assessment:** Conduct unaided and aided speech-in-noise testing to ensure appropriate benefit is present. Findings also can be used for counseling regarding real-world expectations.
- **Assist in self-assessment of benefit and satisfaction:** Using validated self-assessment inventories (e.g., IOI-HA, HHIE, APHAB) determine if patient is experiencing expected benefit and satisfaction. Results can be used for counseling regarding real-world expectations.
- **Rehabilitative audiology:** Provide aural rehabilitation services including auditory training options.



# Online OTC sales and the need for a hearing test



- Respondents were asked to rank the following pathways in order of preference for the purchase of hearing aids: (1) through an HCP (in-person), (2) online that requires a hearing test, or (3) online that does not require a hearing test.
- Eighty-four percent of respondents (874 of 1037) ranked the in-person pathway as their first choice. Further analysis showed that with every additional year of age, the odds of purchasing hearing aids online decreased by 5%.
- The respondents also rated their comfort in purchasing hearing aids online, relating to whether they had a hearing test.

# More useful data from the large Humes et al (2017) study:

## **From the Consumer-Decides Group:**

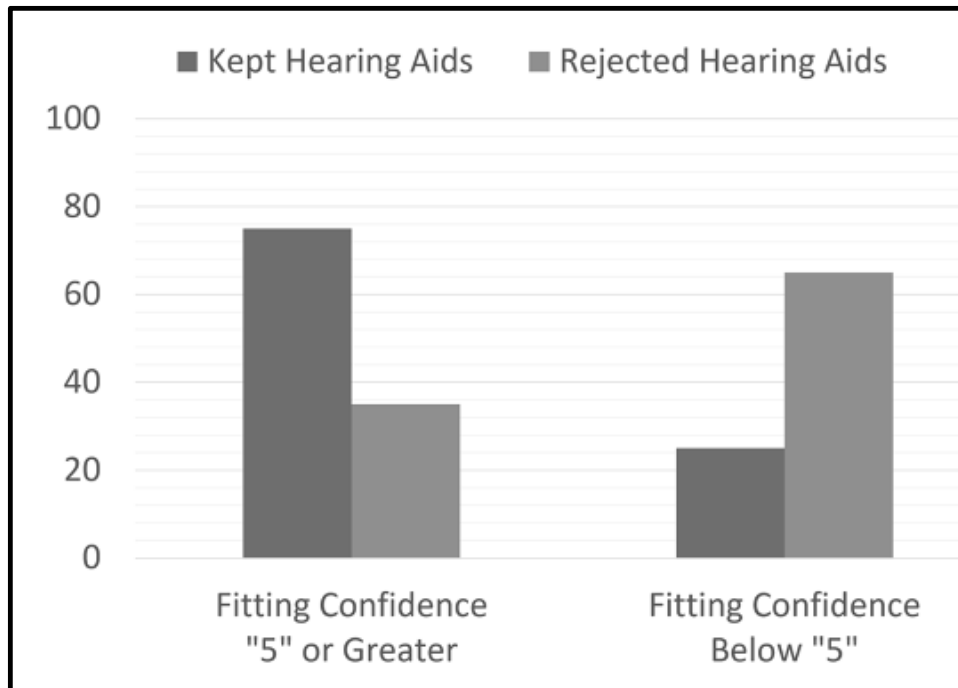
- 50% indicated at the end of the 6-week trial that they did not want to keep their hearing aids.
- However, over 90% of these opted for a second 4-week follow-up trial after they were re-fitted using Best Practices.
- This suggests that perhaps, even when the initial self-fitting is not successful, patients won't "give-up" on using hearing aids.

## **From the Placebo Group:**

- Initially 33% of those in the Placebo group (0 dB gain—presumably the “worst case” for a self-fit OTC) chose to keep their hearing aids.
- When they were re-fitted employing Best Practice and had another 4-week trial, the success rate went to 92%.
- This points out the value of the HCP (assuming Best Practice is followed), even when the initial OTC fitting is very poor.

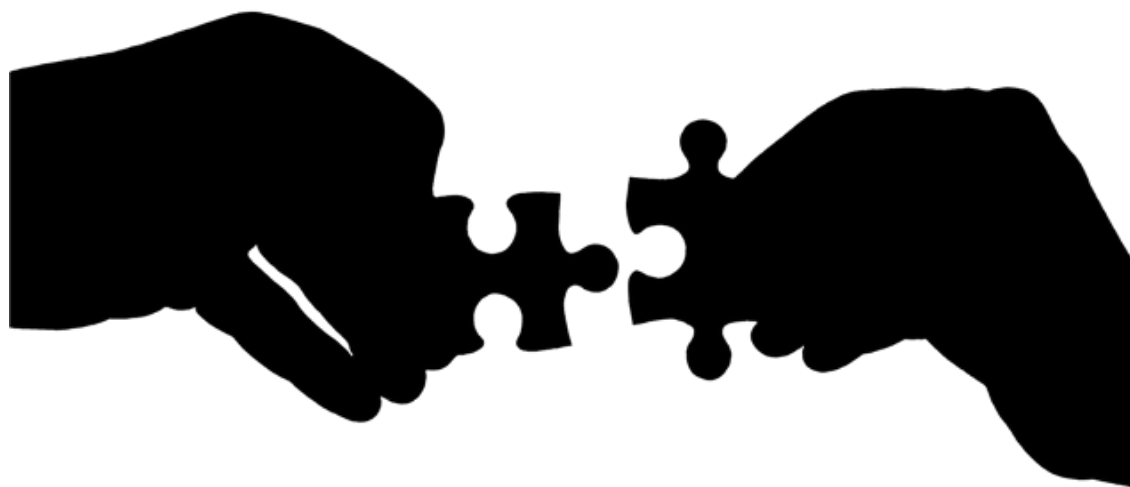


## More useful data from the large Humes et al (2017) study:



- A related study of 40 of the older adults who self-selected and fit their hearing aids using the consumer-decides approach.
- Participants rated their confidence in the fitting on a 1 to 10 scale (10=Very Confident).
- "Fitting confidence" then was compared to whether the participant chose to keep using the hearing aids.
- Confidence in the self-fitting impacted the decision whether to keep the hearing aids—75% vs. only 25% when the participant was not confident.

Maybe, just maybe, OTC hearing aids and the HCP are a better fit than some believe!





## **RESEARCH QUICK TAKES**

5.4: OTC Hearing Aids--Practical issues related to sales and service

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