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An Introduction to PSAPs & Hearables

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Chase Smith's Disclosures

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- Editor, Audiology Practices
- Editor, HHTM Hearing News

Agenda

1. How did we get here? Current state of technology & industry
2. The spectrum of PSAPs and Hearables
3. PSAPS vs. Hearing Aids: Chase's research
4. Thoughts on clinical implementation of PSAPs and Hearables

Learning Objectives

- Identify the differences between hearing aids, personal sound amplification products (PSAPs), and hearables in terms of federal regulation and device usage/purpose.
- Explain how to evaluate the performance capabilities and appropriateness of unfamiliar amplification products.
- Explain how to appropriately integrate low-cost PSAPs and hearables into your existing practice model.

How did we get here?

1. Moore's Law – the continual, incremental improvement (and limitations) of technology
2. Evidence supports age-related hearing loss is not a benign condition
3. Accessibility & affordability issues (PCAST & IOM guidelines)

The Microchip

- Faster
- Smarter
- Cheaper-to-Manufacturer
- Limitations for solving ARHL issues

Recent Studies

- Cox, Johnson, Xu, Gerontology, Aug 2014 (n=25)
- Cox, Johnson, Xu, Ear and Hearing, P-A-P, 2016 (n=45)
- New & experienced users with mild to moderate HL
- Blinded month long trials
- Outcomes measured:
  - Speech understanding
  - Standardized questionnaires
  - Diary entries/interviews

The Good-Enough Era?

- Off-the-shelf ear worn devices
- Companion mic in smartphone
- TV enhancement (eg, Hypersound)
- Cell phone enhancement (eg, Alango Technologies)
- Augmented Reality Devices (eg, Bragi Dash)

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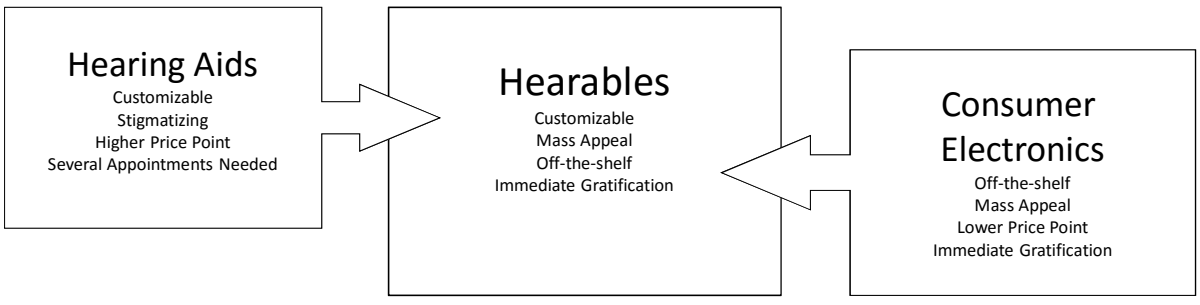
"Hearables": Morphing of Two Different Technologies



Co-morbid Factors Associated with ARHL

- Dementia & Cognitive Decline
- Social Isolation
- Cortical Size
- Overall Health and Wellness
- Science showing untreated ARHL has harmful, long-term effects

The relationship of hearing loss and declines in the cognitive and physical functioning of older adults

See: http://www.linresearch.org/research.html

Accessibility & Affordability

1. Amy Donahue, Judy Dubno & Lucille Beck, NIH Manuscript, 2010:

"Hearing loss is a public health issue and among the leading public health concerns. Untreated hearing loss has social and economic ramifications. Most hearing aid users have lived with untreated hearing loss for over 10 years and their impairments have progressed to moderate-to-severe levels before seeking a hearing aid….the current health care system in the US is not meeting the needs of the vast majority of adults with hearing loss."

2. Institute of Medicine holds 2-day workshop on Hearing Loss and Healthy Aging, January, 2014

The Unmet Need: Accessibility & Affordability

Unmet Hearing Health Care Needs: The Beaver Dam Offspring Study
SD Nash, KJ Cruickshanks, G-H Huang, BEK Klein, R Klein, FJ Nieto, TS Tweed
Am J Public Health. 2013 June; 103(6): 1134–1139.
doi: 10.2105/AJPH.2012.301031

Self-Reported Hearing Difficulties Among Adults With Normal Audiograms: The Beaver Dam Offspring Study.
Tremblay KL1, Pinto A, Fischer ME, Klein BE, Klein R, Levy S, Tweed TS, Cruickshanks KJ.
Ear Hear. 2015 Nov-Dec;36(6):e290-9. doi: 10.1097/AUD.0000000000000195

12% of adults
have heari
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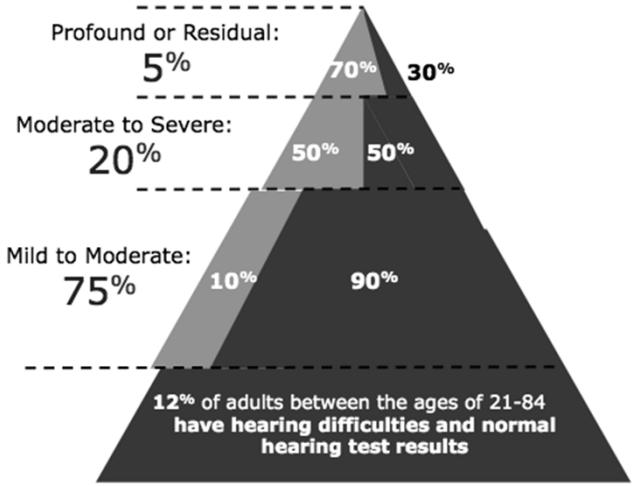

Prevalence and Number of Individuals 50 years or older with > 25 dB hearing loss

See:
Prevalence of Hearing Aid Use Among Older Adults in the United States
Wade Chien, M.D. & Frank R. Lin, MD, PhD
Arch Intern Med (2012), 172(3), 292-293
Doi: 10.1001/archinternmed.2011.1408

CHEIN & LIN, 2012 19

PCAST Recommendations

1. Create a new category of basic, direct-to-consumer hearing aids
2. FDA withdraw it's draft guidance that PSAPs be marketed to people with normal hearing
3. FTC require clinicians provide customers with audiogram and "audio profile" at no charge
4. FTC should define a process authorizing hearing aid vendors to have the ability to obtain the patient's test results at no additional change to the consumer

The Spectrum of Hearables

1. Made for iPhone Hearing Aids
2. PSAPs
3. Directed Audio - Hypersound
4. Augmented Reality Devices
5. Amplification Apps

Recommended direct to consumer hearing devices and key technological and user features

See:
Personal Sound Amplifiers for Adults with Hearing Loss.
Mamo SK, Reed NS, Nieman CL, Oh ES, Lin FR.
Am J Med (2016, March), 129(3), 245-250.
Doi: doi: 10.1016/j.amjmed.2015.09.014

Mamo, et al Am Jl of Medicine, 2016

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What is a PSAP?

- "Personal Sound Amplification Product"
- Intended to amplify environmental sounds for non-hearing impaired users
  - Single-environment only
  - Environments in which normal-hearing individuals would have trouble
    - Bird-watching/listening
    - Listening at great distances
- Not currently regulated by Food & Drug Administration (Draft Guidance in progress)
- Range in price from $1 to $400+

What is a hearable?

- Multi-purpose wireless earbuds, with features including:
  - voice/music streaming
  - built-in music & data storage
  - touch/voice/gesture control
  - health-tracking functionality
  - sound enhancement/"augmented reality"
  - noise protection
  - amplification
- Intended to interface with other devices (computer, mobile phone, tablet)
- Not regulated by Food & Drug Administration
- Range in price from $200 - $600+

Hearables

See:

Bragi Dash: https://store.bragi.com/us_en/
Moto Hint: http://www.amazon.com/Moto-Hint-Mono-Bluetooth-Headset/dp/B00N63V39K
Here Active Listening: https://www.hereplus.me/pages/product/

Comparing hearables, PSAPs & hearing aids

HEARABLES & PSAPS

- Amplifies/alters sound
- Varying features with price
- Can be purchased without audiologist consultation
- SHOULD NOT be marketed as treatment for hearing loss

HEARING AIDS

- Amplifies/alters sound
- Varying features with price
- Can be purchased without audiologist consultation
- CAN BE marketed as treatment for hearing loss

FDA Guidance

PSAP

SHOULD NOT:

- Intend to compensate for impaired hearing
- Describe types/severities of hearing loss
- Suggest device is a hearing aid alternative

HEARING AID

REQUIRES:

- Adequate and appropriate labelling
- User instructional brochure
- Medical clearance/waiver
- Three-year record retention

FDA Guidance

- "PSAPs are intended to amplify environmental sound for non-hearing impaired consumers."
- "They are intended to accentuate sounds in specific listening environments, rather than for everyday use in multiple environments."
- Example environments:
  - Hunting
  - Bird watching
  - Lectures
- "Represents the FDA's current thinking on the matter, but is not legally enforceable."
- This guidance is not legally binding.
- Latest draft guidance was published in 2013.

Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products. (2013, November 7). Retrieved February 5, 2016, from http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM373747.pdf

CEA Voluntary Guidance

- The Consumer Electronics Association (CEA) has partnered with the American National Standards Institute (ANSI) to create a voluntary set of guidelines for the manufacture and marketing of PSAPs.
- Such a standard, if developed, would seek to address the issue of variable degrees of quality in the PSAP market.
- Unfortunately, this would still be a voluntary set of guidelines, and manufacturers would not be bound to follow them, nor would there be consequences for violating this guidance.

IOM's 4th Meeting Reviews Range of Hearing Health Issues. (2015, October 22). Retrieved March 1, 2016, from http://www.hearingreview.com/2015/10/ioms-4th-meeting-reviews-range-hearing-health-issues/

Where did these devices come from?

- The rise in popularity of "wearable" technology demonstrates the desire for consumers to connect with technology (music, apps, phone, etc.) in an unobtrusive and streamlined manner.
- The ear represents a less-distracting method of communicating important information discreetly and with less distraction than visual and touch modalities
- Manufacturing a hearing aid requires compliance with FDA regulations regarding marketing, sales, and paperwork.
- **The expense of hearing aids has created a demand for an over-the-counter treatment option for those with hearing loss.**
  - **31% of those diagnosed with hearing loss did not purchase hearing aids due to expense**
  - **25% of those diagnosed with hearing loss did not purchase hearing aids due to no insurance coverage**

Personal Sound Amplification Products: A Study of Consumer Attitudes & Behavior. (2014, August). Retrieved March 3, 2016, from http://www.cta.tech/CorporateSite/media/Government-Media/GLA/Report-Personal-Sound-Amplification-Products-A-Study-of-Consumer-Att.pdf

Why is this important?

- Legislative changes to the American healthcare system (The Affordable Care Act) emphasize increased accessibility and affordability of care, with an emphasis on positive patient outcomes.
- The industry has been subject to increased scrutiny recently in an effort to improve patient outcomes and make hearing healthcare more accessible to those with hearing loss:
  - Presidents Council of Advisors on Science & Technology (PCAST)
  - The Institute of Medicine (IOM)
- Research into patient outcomes with hearing aids and PSAPs suggests lower-cost hearing aids and PSAPs can offer benefits typically associated with high-end hearing aids.
  - Brietbart (2014): *Is there a preference between hearing aids and personal sound amplification products?*
  - Johnson, Xu & Cox (2015): *Does premium listening require premium hearing aids?*
  - Amlani, Taylor, Levy & Robbins (2015): *Utility of smartphone hearing aid applications as a substitute to traditional hearing aids*
  - Smith (2016): *PSAPs vs. Hearing Aids: An electroacoustic analysis of performance and fitting capabilities*
- Hearables could change the way in which consumers interact with in-the-ear hearing technologies, offering features which may accommodate hearing losses and mimic those features previously found in traditional hearing aids.

Research

- Brietbart (2014): *Is there a preference between hearing aids and personal sound amplification products?*
  - PSAPs performed as well as hearing aids in music and everyday sounds, with hearing aids outperforming PSAPs in speech.
- Johnson, Xu & Cox (2015): *Does premium listening require premium hearing aids?*
  - No difference in listening performance between premium and basic-level hearing aid technology
- Amlani, Taylor, Levy & Robbins (2015): *Utility of smartphone hearing aid applications as a substitute to traditional hearing aids.*
  - Hearables and PSAPs offer an entry-level option for those with hearing loss and have potential to increase overall number of hearing aid users and decrease average length of time consumers wait before pursuing hearing aids.
- Smith (2016): *PSAPs vs. Hearing Aids: An electroacoustic analysis of performance and fitting capabilities*
  - Certain PSAPs and hearables can be adequately fit to NAL-NL2 targets up to a moderate degree of hearing loss.

Problems with Hearables & PSAPs

- Due to a lack of formal regulation, the PSAP market demonstrates extreme variability in quality, performance, and pricing.
- Inconsistent marketing to an already vulnerable consumer population leads to increased confusion regarding these devices and their appropriateness.
- Major corporations soon to enter PSAP/hearables market (changing soon)
  - Starkey/Bragi partnership
  - Google
  - Samsung
  - Apple

Evaluating Unfamiliar Technologies

- Audiologists have the necessary training and resources to evaluate new and/or unfamiliar amplification technologies encountered in the clinic.
  - EAA test box & on-ear setup (Verifit, Aurical, etc)
  - Test subject
  - Device
- These can be used to evaluate devices you may decide to offer in your clinic or devices purchased elsewhere by your patient.
- Verification (real-ear measurement) is the gold-standard for all hearing aid fittings
  - Abrams, Chisholm, McManus & McArdle (2013): APHAB scores for those fit to prescriptive targets were higher than those only programmed to manufacturer first-fit algorithms.

Abrams HB, Chisolm TH, McManus M, McArdle R. Initial-fit approach versus verified prescription: comparing self-perceived hearing aid benefit. J Am Acad Audiol. 2013;23(10):768-778.

PSAPs vs. Hearing Aids: My Research

- Research conducted as part of capstone research project at Northwestern University in the summer of 2015.
- Examined electroacoustic properties of eleven hearing aids and personal sound amplifiers.
- At that time, research had mostly examined differences in perceived sound quality between devices, little research conducted regarding overall appropriateness of devices.

Research Questions

- Question #1:
  - What is the electroacoustic output of a PSAP in comparison to a hearing aid?
- Question #2:
  - Can a PSAP be adjusted to appropriately fit the most common audiometric configurations associated with age-related hearing loss?

Devices

PSAPS

- Low-End
  - CyberScience Amplifier ($49)
  - EarMachine ($1)
  - Woodland Whisper ($8)
- High-End
  - Pocketalker ($117)
  - Sound World Solutions CS10 ($149)
  - Soundhawk ($349)

HEARING AIDS

- Low-End
  - Etymotic Bean ($299)
  - Hansaton Base M2 ($399)
  - MD Hearing Aid Pro ($199)
- High-End
  - Phonak Bolero V90-SP ($3,200)
  - ReSound LiNX^2 9 ($3,200)

Part 1: Electroacoustic Analysis

Part 1: EAA

- Each device placed in Aurical HIT test box with 2 cc coupler
- Examining:
  - OSPL90 High Frequency Average vs. 500 Hz
  - Equivalent Input Noise Level
  - Total Harmonic Distortion
  - Directionality

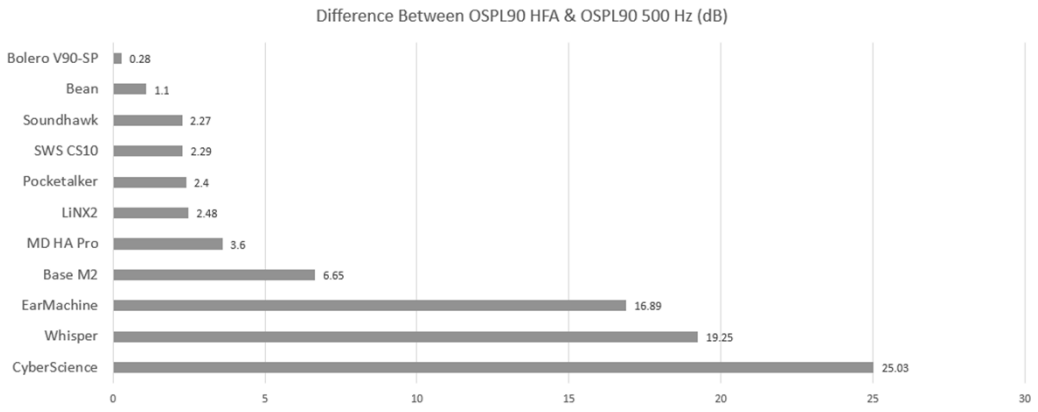
Part 1: EAA

- Hypothesis:
  - High-end PSAPs are acoustically and electroacoustically similar to hearing aids.
- Predictions:
  - Little difference in electroacoustic output between high-end PSAPs and hearing aids.
  - Low-end PSAPs will exhibit high amounts of distortion.

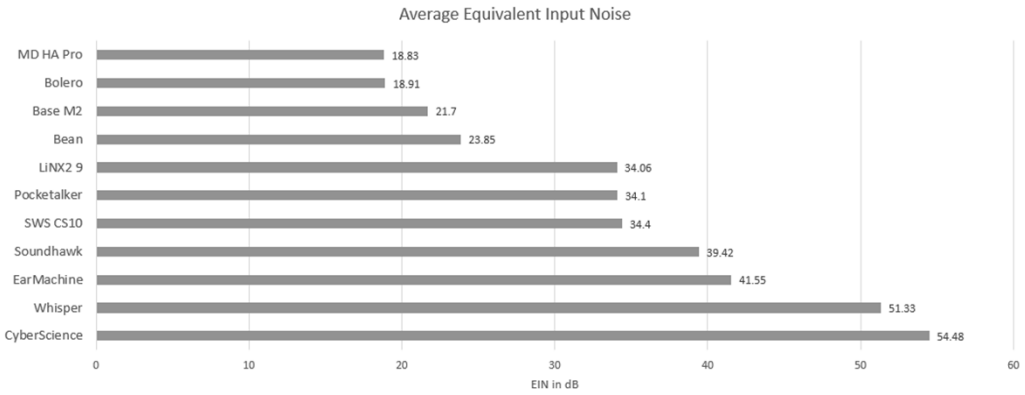
Part 1: Results

- Low-end PSAPs had higher amounts of low-frequency gain
- Low-end PSAPs had higher equivalent input noise (EIN)
- Most PSAPs had low levels of distortion
- Most PSAPs had no directional benefit

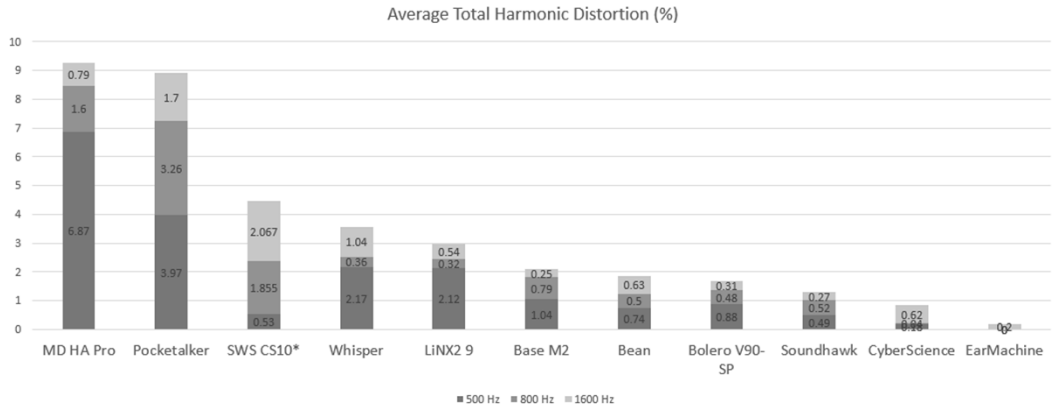
Part 1: OSPL90 HFA vs. 500 Hz



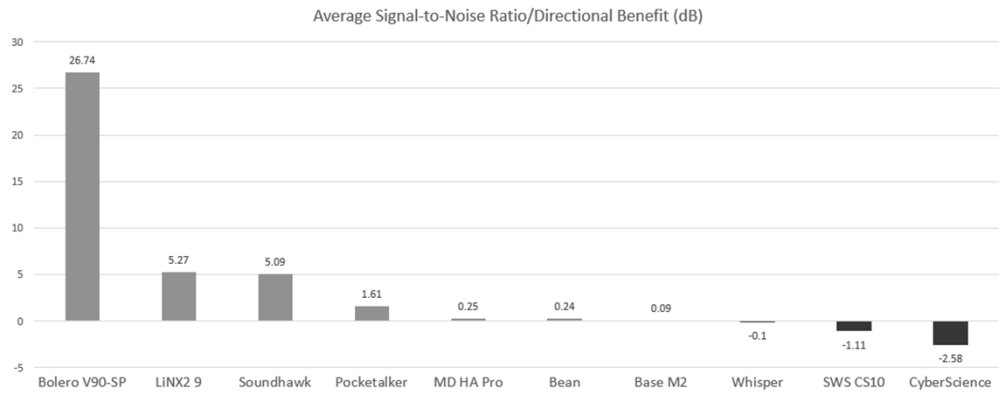
Part 1: Equivalent Input Noise



Part 1: Total Harmonic Distortion



Part 1: Directionality



**Killion, M. (2004, February). Myths About Hearing in Noise & Directional Microphones. Retrieved February 27, 2016, from http://www.etymotic.com/media/publications/erl-0051-2004.pdf

Part Two: Real-Ear Measurements

Part 2: Real-Ear Measurements

- Each device coupled to KEMAR with probe-microphone
- Aurical FreeFit speaker placed in front of KEMAR
- NAL-NL2 targets generated for ten audiometric configurations
- Each device adjusted to match nine targets at three speech intensities (+/- 10 dB)
  - 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000 Hz
  - 50 dB (soft), 65 dB (medium), 80 dB (loud)
- Sum of targets matched for each intensity / 27 = total score
- Each device tested ten times per audiogram

Part 2: Audiograms

FLAT/MODERATELY SLOPING

- Very Mild
- Mild
- Moderate
- Moderately – Severe
- Severe I
- Severe II
- Profound

STEEPLY SLOPING

- Very Mild
- Mild
- Moderately - Severe

Part 2: Real-Ear Measurements

- Hypothesis:
  - High-end PSAPs can be appropriately fit to specific audiometric configurations.
- Prediction:
  - High-end PSAPs will target-match as well as hearing aids and significantly better than low-end PSAPs.

Part 2: Results

		Flat & Gently-Sloping							Steeply-Sloping		
Device	Category	Very Mild	Mild	Moderate	Moderate-Severe	Severe I	Severe II	Profound	Very Mild	Mild	Moderate-Severe
LiNX2 9	HA - HE	99%	100%	100%	100%	97%	90%	66%	98%	98%	99%
Bolero V90	HA - HE	98%	100%	99%	97%	79%	61%	36%	97%	96%	91%
Base m2	HA - LE	93%	98%	95%	92%	40%	8%	1%	90%	93%	72%
Soundhawk	PSAP - HE	99%	98%	96%	65%	13%	0%	0%	99%	98%	68%
EarMachine	PSAP - LE	93%	97%	88%	57%	27%	12%	0%	91%	88%	48%
SWS CS10	PSAP - HE	98%	96%	91%	84%	23%	0%	0%	96%	86%	69%
Bean	HA - LE	99%	94%	69%	14%	0%	0%	0%	94%	67%	23%
Pocketalker	PSAP - HE	90%	88%	75%	72%	47%	21%	3%	87%	82%	63%
MD HA Pro	HA - LE	80%	78%	71%	65%	36%	14%	0%	77%	82%	60%
Cyberscience	PSAP - LE	52%	46%	37%	35%	39%	21%	2%	47%	36%	31%
Whisper	PSAP - LE	38%	37%	31%	30%	21%	14%	0%	44%	38%	31%

Implications

- High-end hearing aids were the most versatile in their fitting capabilities, and can appropriately provide amplification for the greatest range of hearing losses.
- Based on prescriptive fitting alone, certain high-end PSAPs could be appropriately fit to a patient with up to a moderate degree of hearing loss
- Some low-end devices are appropriate for mild hearing losses.
- FDA approval does not necessarily dictate quality or appropriateness of a particular device.

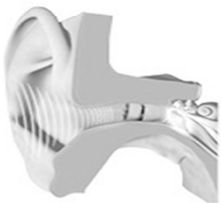
In summary…

- PSAPs and hearables have the potential to drastically alter hearing healthcare.
- While unregulated, these devices are offering innovative features at lower price-points than traditional hearing aids.
- Some PSAPs & hearables can be adjusted to meet NAL-NL2 targets for mild and moderate degrees of high-frequency hearing loss.
- Further research is necessary to understand performance differences between PSAPs/hearables and hearing aids.
- Ultimately, as audiologists we should familiarize ourselves with these new technologies so that we can appropriately guide our patients.

Thoughts on Clinical Implementation

- Intervene earlier – 30 to 60% of working age adults have some degree of difficulty in common listening situations (Taylor, et al 2016)
- Utilize patient decision aids (See Gilligan & Weinstein article)
- Practice Shared Decision Making & Patient Centered Communication

The Spectrum of Hearing Solutions

Non Customizable Solutions		Customizable Solutions		
At-Home Listening Devices (ALD)	Ear or Body Worn Devices (Hearables)	Directed Audio (Hypersound)	Daily Wear Devices (Multiple Levels of Technology)	Extended Wear & Implantable Devices
	 		 	 
Advantages				
Low cost	Low cost, mild losses only	Maximum performance for home audio (#1 leisure activity)	Use in all listening situations. Multiple price points and technology levels	Special purpose only

Questions

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