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The Sky is Rising: Integrating Hearables into Patient Centered Care

Brian Taylor



DISCLOSURE STATEMENTS

BRIAN TAYLOR, AUD

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Disclosure

- Employee, Turtle Beach
- Consultant, Fuel Medical
- Adjunct Professor, A.T. Still University
- Editor, Audiology Practices
- Editor, Hearing News Section, HHTM
- Co-Author, *Fitting & Dispensing Hearing Aids*
2nd Edition, September 2016



You may have heard.....

- October, 2015: PCAST report recommended the "FDA should approve this class of hearing aids (PSAPs) for over-the-counter (OTC) sale, without the requirement for consultation with a credentialed dispenser"
- June 2, 2016: NASEM report recommends the FDA create a new category of wearable, over-the-counter devices
- Senate bill: Over-the-counter hearing aid act of 2016, November 7
- December 7 : NAS Dissemination Meeting: Hearing Health Care for Adults: Priorities for Improving Access and Affordability



The Sky is Not Falling I

- ❑ 2015: 3.3 million hearing aids
- ❑ 2020: 3.9 million (estimated)¹
- ❑ Private market increased 13% (y-o-y) June 2015 to June 2016¹
- ❑ No significant market disruption within next 5 years²

Sources: 1. Bernstein Reports, July 2016 and 2. Nick Hunn, WiFore Consulting Nov 2016



The Sky is Not Falling II

- Traditional hearing aids are likely to remain to the “gold standard” as the recommended treatment for SNHL for several more years.
- Could be clinical advantages for self-contained hearing aids & hearables:

1. Free up time to provide higher levels of personalized care
2. Give patients more choices, allow for more unbundling of services



Sky May Not be Falling, but.....

- Between **67% to 86%** of adults aged 50 and over with hearing loss don't use hearing aids (NAS Report, June 2, 2016)
- Untreated age-related hearing loss is a looming **public health problem**
- The era of **consumer-driven healthcare** is here and these self-fitting products are not going to disappear



Circa 2010 - The Rise of the PSAP



2016 - The Rise of Hearables




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“Show Me the Money”

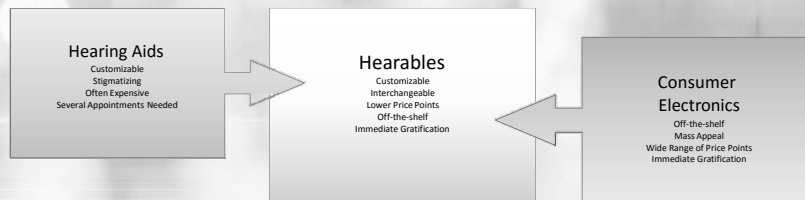
TechCrunch reports funding for hearables has nearly tripled from \$12.6 million to \$31.2 million between 2014 and 2015.

Some of these products are just hitting the market.


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“Hearables”: Morphing of Two Different Technologies




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“The Bizarre Bazaar”




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Spectrum of Hearables

1. Smartphone-enabled & Self-contained hearing aids
2. PSAPs
3. Directed Audio Devices
4. Augmented Reality Devices (Layered Listening Devices)
5. Amplification Smartphone-based Apps (one type of mobile health app)



Important Questions

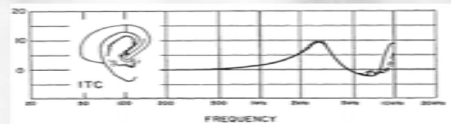
- What are the basic characteristics of amplification?
- Can it be delivered in an over-the-counter product?



Characteristics of High Fidelity Hearing Aids

(Villchur, 1973; Killion, 1979)

1. Smooth, wide-band frequency response closely matching a prescription target (e.g., NAL)
2. Undistorted output within patient's dynamic range
3. Unity gain: adequate gain for soft and average, transparent for loud sounds
4. A CORFIG that looks like this:



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Smartphone-enabled hearing aids



- Programming & adjustment
- Remote mic capability

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Self-contained hearing aids



Blamey
Saunders
hears

- Tablet PC or Smartphone:
- Hearing test
- Fitting
- Programming
- Adjustments



Self-programming & self-contained hearing aids

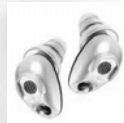
- Could older adults self-fit hearing aids following written instructions with help from spouse?
- Convery et al (2016) Evaluation of the self-fitting process with a commercially available hearing aid. JAAA. P-A-P
- 40 adults (20 experienced & 20 inexperienced hearing aid users) aged 68 to 88 provided Sound World Solutions HD1000 device
- 73% able to successfully insert devices
- 55% able to complete entire 10-step process



Personal Sound Amplification Products



SoundHawk



ER QSR



ICOT



Sound World Solutions



Exsient Qleaf Lite



Hearing Aids vs. PSAPS

- | | |
|---|---|
| <ul style="list-style-type: none"> • Regulated by the FDA • \$800 to \$3000 per device • Minimal insurance benefit (no Medicare benefit) • Accepted gold standard of care | <ul style="list-style-type: none"> • Unregulated by the FDA • Cost \$20-400 per device • E-commerce/OTC • Tremendous range of quality |
|---|---|



Classification	Personal Sound Amplifiers CONSUMER PRODUCTS	Hearing Aid FDA-registered MEDICAL DEVICE
		
Warranty	90-day	1-year
Style	Headset	Behind-the-Ear
Color Options	Black	Black Pearl Metallic Steel Grey Metallic White Gold Metallic
16-Channel Compressor	✓	✓
Noise Reduction and Feedback Suppression	✓	✓
Directional Microphones for Noisy Environment	✓	✓
Rechargeable Batteries	✓	✓
Battery Life (Amplification Mode)	2x Detachable Up to 15 hours	Built in Up to 18 hours
Bluetooth Streaming (phone calls and music)	\$449 Very Good	Good \$349

Recent Comparative Studies: PSAPs vs. hearing aids

- Chan & McPherson, 2015
- Reed, et al NCRAR, Sept 2015 (Johns Hopkins U)
- Xu, et al March 2015 (U of Memphis)
- Mamo et al 2016 Am J of Med (Johns Hopkins U)
- Chase Smith et al July, 2016 Hearing Review (Northwestern U)
- Ronne & Rossing, Nov 2016 Hearing Review (Eriksholm, Oticon)



Quick Sidebar






•Laboratory Studies:
Contrived environment



• Real World Studies:
Gold standard of patient benefit



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	Bean T-Coil	CS-50+	Tweak Focus	Soundhawk	Songbird
					
Frequency Output	Too much low frequency gain	1. Within prescribed targets 2. Smartphone programming matches gain to hearing loss	Within prescribed targets	1. Within prescribed targets 2. Customize gain preferences with Smartphone	Within prescribed targets
Signal-to-Noise Ratio	T-Coil feature	1. Directionality setting 2. Speech enhancement software	Directionality	Remote microphone	X
Listening Comfort	X	Noise reduction processing	Low internal noise	Low internal noise	Low internal noise
User Features	User manual only	1. User videos on Sound Word Solution's Web site 2. Large rechargeable battery	DVD with: 1. User demonstrations 2. Expectation guidance	1. User videos on Sound Word Solution's Web site 2. Rechargeable (USB)	User manual only
Web site	www.etymotic.com/consumer/personal-sound-amplifiers/bean-tcoil.html	www.soundword.com/store/personal-sound-amplifiers-psa/cs50	www.tweakhearing.com/shop/tweak-focus-personal-sound-amplification-product/	www.soundhawk.com/product-products/songbird-ultra-20-77009-1	www.songbirdhearing.com/products/songbird-ultra-20-77009-1
Price	\$349/each; \$599/pair	\$349	\$224.99	\$349.99	\$395/each; \$745/pair

✓ Fully available
⊖ Partially available
X No special feature

The Frequency Output was tested using simulated real-ear measures consistent with best practice hearing aid verification procedures. The Signal-to-Noise Ratio (SNR) ratings were based on expected improvement in SNR given the processing approach. For Listening Comfort, a true noise reduction algorithm is best; however, "Low internal noise" as measured via electroacoustic analysis indicates no unpleasant circuit noise and so was included as a comfort feature.

Mamo, et al Am Journal of Medicine, 2016

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PSAPs vs Hearing Aids

- Smith et al *Hearing Review*
- July, 2016
 - 11 devices
 - 2 cc and real ear measurements



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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 LiNX² 9 (\$3,200)

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Part 1: Electroacoustic Analysis



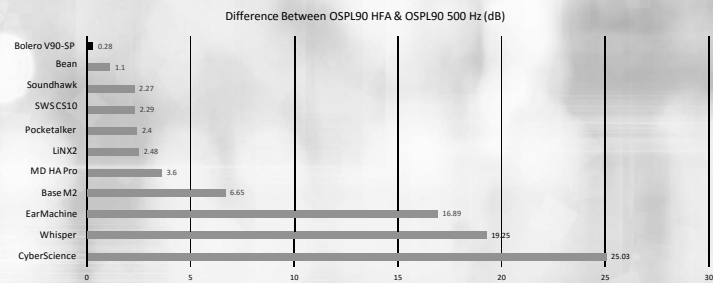
Part 1: EAA

- 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



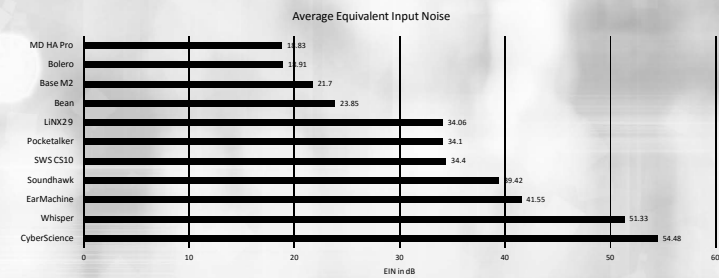
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Part 1: OSPL90 HFA vs. 500 Hz



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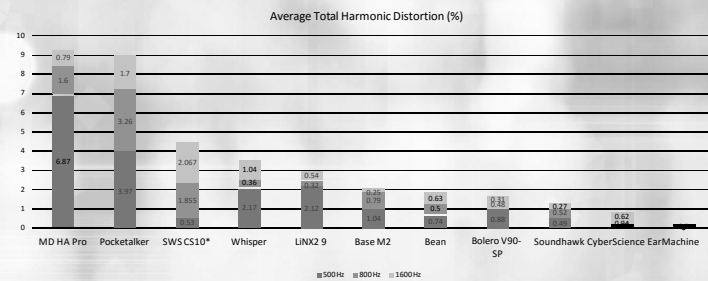
Part 1: Equivalent Input Noise



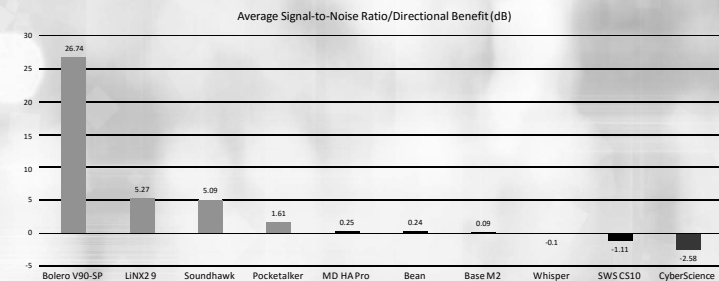
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Part 1: Total Harmonic Distortion



Part 1: Directionality



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Part Two: Probe Mic Measurements



Part 2: Probe Mic 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: Results

	FLAT/GENTLY-SLOPING							STEEPLY SLOPING		
	Very Mild	Mild	Moderate	Moderate-Severe	Severe I	Severe II	Profound	Very Mild	Mild	Moderate-Severe
LINK2 9	99%	100%	100%	100%	97%	90%	85%	98%	98%	99%
Bolero V90-SP	98%	100%	99%	97%	79%	61%	26%	97%	96%	91%
Base M2	93%	98%	95%	92%	40%	8%	1%	90%	93%	72%
Soundhawk	99%	98%	96%	65%	13%	0%	0%	99%	98%	68%
SWS CS10	98%	96%	91%	84%	23%	0%	0%	96%	86%	69%
EarMachine	93%	97%	88%	57%	27%	12%	0%	91%	88%	48%
Bean	99%	94%	69%	14%	0%	0%	0%	94%	67%	23%
Pocketalker	90%	88%	75%	72%	47%	21%	3%	87%	82%	63%
MD HA Pro	80%	78%	71%	65%	36%	14%	0%	77%	82%	60%
CyberScience	52%	46%	37%	35%	39%	21%	2%	47%	36%	31%
Whisper	38%	37%	31%	30%	21%	14%	0%	44%	38%	31%



Results

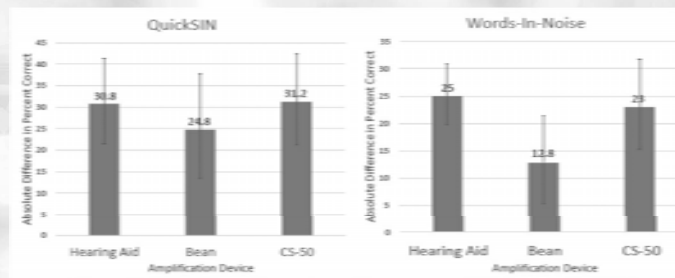
- High-end hearing aids were the most versatile in their fitting capabilities
- Certain high-end PSAPs can target-match similar to high-end hearing aids up to a moderate loss
- Based on prescriptive fitting alone, certain high-end PSAPs could be appropriately fit to a patient with up to a moderate degree of hearing loss



“Objective Analyses and Comparisons of Personal Sound Amplification Products”

- ❑ Reed NR, Mamo SK, Polyak N, Grabowski J, Korczak M, Lin FR
- ❑ NCRAR Conference Sept., 2015
- ❑ Compared 9 “high end” PSAPS & 1 low-end device





- Premium Hearing Compared to 2 PSAPs
- Fixed 55 dB HL, +5 dB SNR
- Speech in Noise: % correct: unaided vs. aided
- Conclusions: 4 PSAPs performed similar to a hearing aid

The Skinny on PSAPs

- Many are “de-featured” hearing aids with low gain and output
- Huge range of sound quality & prices
- Better ones can be paired with smartphone that enable some user control
- Gather basic acoustic facts: You can evaluate in your clinic
- In ideal listening situations, some PSAPs perform similar to HAS

Smart Wireless Earbuds &
Augmented Reality or “Layered Listening” Devices




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AirPods




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Several recently introduced

- Nuheara's IQ Buds(\$250)*
- Apple AirPods (\$159)
- Jabra Elite Sport (\$250)*
- Samsung IconX (\$200)
- Bose Soundsport (\$150)
- Francois Mimi Earphones (\$20)
- AZBro (\$20)

* Incorporates hearing aid technology



More...

- Earin
- Motorola Verve One
- Erato Apollo 7
- Kanoa
- SMS Biosport
- SkyBuds
- Go to hearable.world for latest

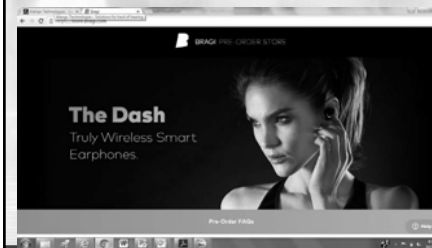


Product Features

- Hearing Protection
- Biometrics (Monitoring)
- Audio Curation
- Music/Audio Playback
- Internet of Voice (Siri-like applications)
- Amplification

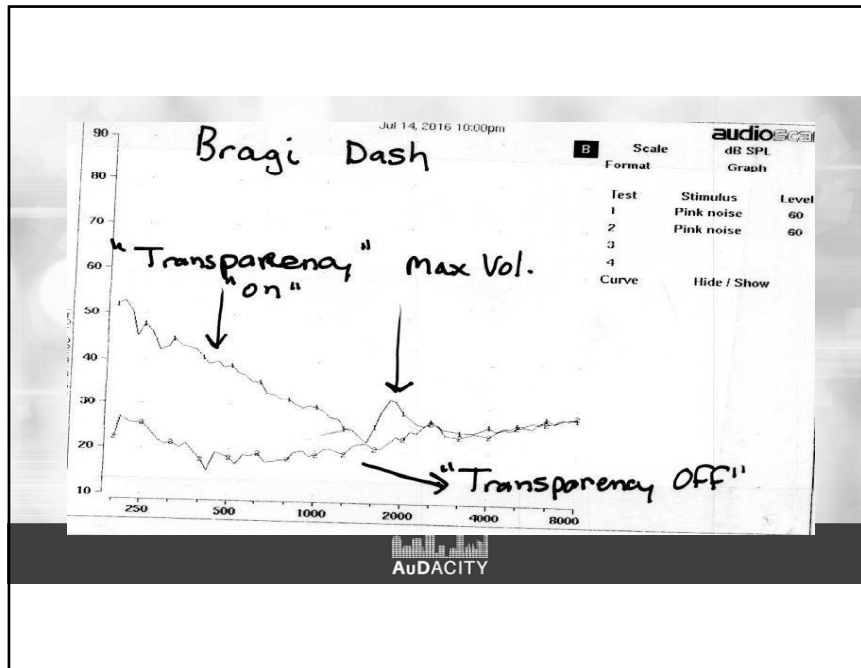


Bragi Dash



- Pair to smartphone
- Rechargeable
- Fitness Tracker Feature
- “Smart” Wireless Ear Phones
- Stores/Plays Music
- Transparency On vs. Transparency Off Function



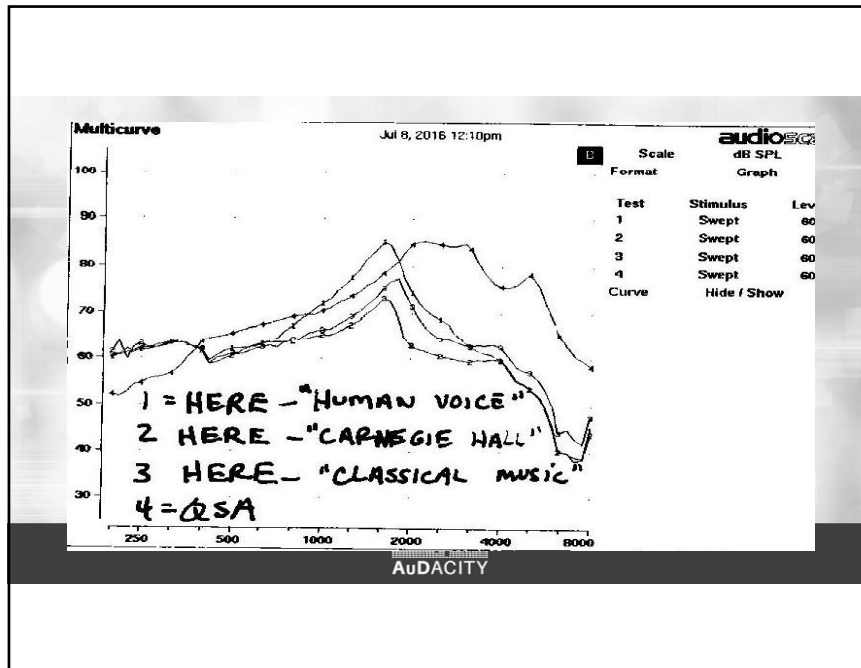


Doppler Labs 'Here'

- Pair to smartphone
- Rechargeable
- Tune in vs. Tune out Function
- Tune-in: 15 filters allow you to change quality of sound. "studio mixing and sound effects in the ear"
- Tune-out: 9 attenuation settings
- New model, Nov. 2016

The image shows a black case with two white earbuds inside. The AuDACITY logo is visible at the bottom.

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The Skinny on Wireless Earbuds & Augmented Reality Devices

- First generation of "smart" wireless ear phones
- A few provide minimal amplification, similar to low quality PSAP
- Not a viable alternative to hearing aids.... yet

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Smartphone-based Amplification Apps

- Turn the combination of smartphone (mic & signal processor) and earphones (receiver) into hearing aid
- Amplification parameters (gain, output, freq. response) can be adjusted by user
- Stored music can be played through amplification feature



EarMachine App



"When you move an EarMachine wheel, you are changing more than 100 different values that control our state-of-the-art signal processing"



Jacoti Hearing Suite



The Skinny on Amplification Apps

- Still require a pair of wired earphones to be plugged into smartphone
- Some have advanced signal processing: multichannel WDRC, DNR
- Perform similar to “bare-bones” hearing aid – Amlani, et al 2013



continuedTM

Directed Audio Devices/ALDs



TEO First study here

- 31 adults aged 60 and over with mild to moderate SNHL
- 40 day trial with TEO First device
- 48% mean improvement words-in-noise recognition in aided condition
- Self reports of outcome (5 point Likert scale):
 - 20% improvement: conversations with several people
 - 18% decrease in negative emotions while watching TV

Source: Sacco, et al 2016 BMC Geriatrics

Directed Audio Devices

- Hypersound Clear 500 P
- Ultrasonic Home Audio System



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HyperSound Clear™ 500P



Directional 3D sound designed to improve the TV listening experience

Immersive sound delivers clarity and speech intelligibility that they may have been missing

Spotlight of sound allows patients to experience the benefit of directed audio without disturbing others

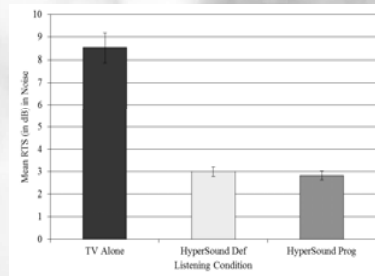
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Washington University Hypersound Study

- 23 adults with mild to moderate hearing loss
- At a preferred listening level Hypersound compared to conventional, TV alone audio
- Results show ~6dB dB improvement in Hypersound condition

Source: Oeding, et al Hearing Review (in press)



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The Skinny on Directed Audio

- Provide situational amplification but require extra equipment
- Often used in combination with other devices like hearing aids or headphones
- “the 21st century ALD”

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Important Question

- How could PSAPs and Hearables be used in your clinic?



Gateway Solution

- “Starter” device for milder losses and/or situational help



continuedTM

Effectiveness of Smartphone-Based Hearing-Aid Applications to Change Attitudes in Impaired Listeners about Amplification and Hearing Loss

Amy M. Amlani¹, Joseph Smaldino², Donald Hayes³, Brian Taylor⁴, Erich Gessling⁵



¹Department of Speech and Hearing Sciences, University of North Texas, Denton, Texas
²Department of Audiology and Speech Pathology, University of Tennessee Health Science Center, Knoxville, Tennessee
³University of Waterloo, Waterloo, Ontario, Canada
⁴Hypersound Hearing Solutions, Turtle Beach Corporation, San Diego, California



-30 subjects: ½ refused hearing aids, ½ returned hearing aids, all subjects had typical mild sloping to moderate losses

-4 standardized scales: PIADS, SHAPIE, PERVAL, HARQ used to measure attitude pre and post 4 week trial with Ear Machine Smartphone App

-Results: All scales showed favorable changes in attitude toward amplification after just 4 weeks of use

-Implications: Smartphone amplification apps may be useful first step in preparing resistant individuals for hearing aids.



“Immediate” Care Device

- 40-50% of adults aged 85 and older have dementia or MCI
- Less than 50% wear hearing aids
- Cognitive screening tests (MMSE) require reasonably good hearing
- Provide high quality off-the-shelf devices that can be used during patient's appointment



Things you can do:

- Today: Download a couple of amplification apps & experiment
- Next week: Replace your PockeTalker with Ear Machine App paired to wired ear phones
- Next Month: Set up a hearable listening station, educate patients on all their options
- Next Year: Develop an interventional audiology strategy in your clinic



Questions

- Thanks!
- brian.taylor.aud@gmail.com

