

Innovation & Issues Concerning Over-The-Counter (OTC) Hearing Aids

A 2025 Perspective | Douglas Beck, PhD

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Presented for the Hearing and Balance Academy / Natus Sensory Incorporated

Learning Objectives

- ✓ Review the current OTC hearing aid landscape and market dynamics in 2025
- ✓ Evaluate the evidence for self-fitting vs. professionally dispensed hearing aids
- ✓ Understand the role of stigma and cosmetics in hearing aid adoption
- ✓ Examine emerging wearable eyewear technology as an OTC hearing solution
- ✓ Discuss the evidence base for OTC products, including nuance Audio hearing glasses
- ✓ Recognize the clinical imperative: diagnosis first, treatment second

1. The OTC Hearing Aid Landscape

FDA Approval & Market Context

- FDA approved OTC hearing aids in October 2022, citing access and affordability as primary goals
- OTC HAs represent approximately 3–5% of known U.S. hearing aid sales (HIA, 2024)
- Prescription hearing aids continue growing 4–5% per year — OTC has not cannibalized the market

- Prescription units from larger manufacturers are the primary measurement source; many OTC units (Amazon, FedEx, etc.) go uncounted

The Affordability Problem

- OTC was intended for access & affordability — but premium OTC devices now cost \$1,800–\$3,000/pair
- 60% of Americans don't have \$500 for an emergency (Suzy Orman, 2023)
- Consumer survey respondents willing to pay ~\$200 — yet the best OTC devices cost 10–15x that
- Bottom line: the patients OTC was designed to help often cannot afford the better OTC products

3–
5%

OTC hearing aids' estimated share of known U.S. hearing aid sales (HIA, 2024)

\$1,8
00–
\$3,0
00

Price range of premium OTC hearing aids per pair in 2025

2. Self-Fitting vs. Audiologist Fitting

The Ferrari Analogy

- ✓ If retired librarians and NASCAR drivers are both given the same car limited to 25 mph, they perform equally — because the car is the rate-limiting factor.
- ✓ The same logic applies to self-fit vs. audiologist-fit studies using OTC devices: the device itself caps outcomes.
- ✓ Audiologist-fit studies should compare professional-grade products fitted professionally against OTC products fitted by consumers.

Key Principle: Diagnosis First, Treatment Second

- All of medicine operates this way — rheumatoid arthritis → specific treatment; diabetes → specific medication
- OTC HAs allow patients to skip the diagnostic step entirely
- Experts (including Dr. Beck) recommended to FDA in 2016–2017 that a comprehensive audiometric evaluation should be mandated before OTC purchase — FDA declined
- Every OTC HA is unique; providers cannot assume aided outcomes will be consistent or equivalent to professionally dispensed products

Research: Do OTC HAs Improve Communication?

- Stadkowsky & Souza (2024): 30 adults with mild-to-moderate HL using pre-programmed OTC devices vs. unaided
 - Result: No significant improvement in conversation efficiency or auditory recall with OTC HAs
 - Published: Journal of Otolaryngology ENT Research, December 2024
- Peer-reviewed evidence on OTC HAs remains sparse — this is one of the most significant published studies to date

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3. Stigma, Cosmetics & Hearing Aid Adoption

Adoption Statistics

Metric	Data Point	Source
Adults with hearing loss (U.S. & EU)	~1 in 5	Global Burden of Disease, 2024
People with HL who wear hearing aids	~10–15%	Humes, 2023 / GBD, 2024
Hearing aid adoption (UK/EU — free HAs)	~60% still decline	Amlani & Valente, 2017–18
Americans who wear corrective eyewear	62% visible / 45M contacts	WebMD
Stigma belief — all ages (Forbes, 2024)	48% agree	Forbes 2024
Millennials who feel HA stigma	63%	Forbes 2024
Gen Xers who feel HA stigma	47%	Forbes 2024
Boomers who feel HA stigma	41%	Forbes 2024

Clinical Insight: Cost Is NOT the Main Barrier

- ✓ In countries where hearing aids are free (UK, EU, Canada, Australia), ~60% of eligible patients still decline them.
- ✓ The primary barrier is stigma — specifically the association of hearing aids with aging and disability.
- ✓ Telling patients 'your hearing loss is more visible than your hearing aid' is not the message they want — respect patient autonomy.
- ✓ Cosmetically appealing solutions (IICs, smart glasses) may

significantly improve adoption rates.

Why Patients Resist Hearing Aids

- Millions invest in: Invisalign, contacts, laser eye surgery, hair care, Botox — all to minimize visible signs of aging
- Hearing aids carry a strong association with old age and disability
- Only ~10% of people offered traditional hearing aids accept them when visible stigma is a factor
- Invisible solutions (IIC, deep canal, smart glasses) may dramatically improve this figure

4. Wearable Eyewear & Smart Hearing Technology

Market Context

Market	Size (2023)	Notes
Global smart/wearable eyewear	~\$6.2 billion	SkyQuest Research
Global hearing aid market	~\$8 billion	Grandview Research
U.S. hearing aid market	~\$2–3 billion	Grandview Research

Technology Evolution

Google Glass (early 2010s)	Too expensive; privacy concerns; banned in many venues; not designed with optometry; no longer widely available
Virtual Reality	Down ~\$85B since 2020 Metaverse launch; used in

(Meta Quest)	healthcare & training; now shifting toward augmented reality (AR) platforms
Ray-Ban Meta Glasses	~\$350–400; AI-powered translation, photos, video; used by blind individuals for navigation; Bluetooth to phone; distributed by EssilorLuxottica
Nuance Audio Glasses	FDA approved Jan. 31, 2025; OTC HA for mild-to-moderate HL; open-ear design; 6 microphones; SNR up to +4.5 dB; ~\$1,100–\$1,200

Nuance Audio: Key Clinical Features

- ✓ FDA Approved: January 31, 2025 as OTC hearing aid for mild-to-moderate hearing loss
- ✓ Open-ear design: nothing in the ear canal — sound delivered via frame above the ear
- ✓ 6 microphones + 4 directional amplifier settings + noise reduction algorithms
- ✓ Beamforming directionality: up to 4–4.5 dB SNR improvement (vs. 2–3 dB for premium prescription HAs)
- ✓ No hearing aid stigma — fashionable eyeglass design; 2 frame styles, 3 sizes each
- ✓ Prescription lenses can be added by any optometrist (made by EssilorLuxottica)
- ✓ Available through: audiologists, dispensers, Walmart, Target Optometry
- ✓ Retail: ~\$1,100–\$1,200 — approximately one-third the price of comparable premium OTC devices
- ✓ Disclosed: Dr. Beck consults for EssilorLuxottica

Published Evidence (Beck et al., 2025)

- Journal of Otolaryngology ENT Research, February 2025

- Compared Nuance Audio to two major premium prescription HA manufacturers on speech-in-noise performance
- Nuance achieved equal or better SNR improvement vs. premium brands
 - Premium HAs: +2–3 dB SNR improvement
 - Nuance Audio: up to +4–4.5 dB SNR improvement
- To find: Google 'J OENT nuance OTC hearing aid option self perceived mild moderate hearing loss'

Eyeglass Hearing Aids: Not a New Idea

- Eyeglass-based hearing technology has existed for ~100 years — now miniaturized and cosmetically modern
- Multiple microphone separation enables superior beamforming directionality
- Key advantage: eliminates hearing aid stigma entirely for many patients
- Other wearable options emerging: Lucid Viture, Vos X — search 'wearable eyewear' or 'smart eyewear' for full market

5. Untreated Hearing Loss & Cognitive Decline

Why This Matters

- ✓ 1 in 5 adults in developed nations has hearing loss — yet only ~10% do anything about it.
- ✓ In people at risk for dementia, untreated hearing loss over years tends to exacerbate cognitive decline.
- ✓ This is a mainstream public health issue, not a niche concern.

Key Article (Beck et al., 2025)

- Published on HearingTracker.com with 25 co-authors: 3 past AAA presidents, multiple neuroscientists and physicians
- Editor: Carl Strom (The Hearing Review)
- Reached 85,000+ impressions within weeks of publication
- Available at HearingTracker.com — search 'Beck untreated hearing loss cognitive decline 2025'

6. Canal Aids, IICs & Market Trends

Hearing Aid Market Segments (Projected to 2030)

- BTE: Stable/slight growth — largest category when pediatric population included
- RITE/RIC: Slow steady growth
- Canal/IIC: Small now but projected to reach ~20% of market by 2030 — fastest growth

The Case for Canal & IIC Hearing Aids

- ✓ Invisible-in-canal (IIC) solutions dramatically reduce hearing aid stigma
- ✓ Only ~10% of patients with significant hearing loss accept traditional visible hearing aids when offered
- ✓ IIC/deep canal fittings require a video otoscope — hand-held otoscope is insufficient for taking impressions past the second bend
- ✓ Digital scanning (e.g., Otoscan) is as good or better than traditional deep canal impressions and more comfortable for patients
- ✓ Dr. Beck personally wears IIC (Starkey) and recommends the category for cosmetically-motivated patients

7. Clinical Q&A Highlights

OTC + Prescription HAs together?	Research is emerging. Anecdotally, some patients wearing IICs find Nuance glasses provide a slight enhancement. Dr. Beck recommends one or the other until studies are published. Patients with cochlear implants: Nuance is FDA approved only for mild-to-moderate HL.
Nuance available internationally?	Not yet (as of early 2025). Global rollout expected by end of 2025. FDA approved in U.S.; distribution rollout underway.
OTC HAs under \$500 — any recommendations?	Dr. Beck states he has personally evaluated 8+ OTC brands sent by global manufacturers and would not recommend any under \$500 he has tried. Sound quality, fit, and open dome designs are the primary concerns.
Should patients self-select OTC or see a professional?	Best practice: Diagnosis first, treatment second. Even if a patient ultimately chooses OTC, they benefit enormously from a professional audiometric evaluation and consultation first.
\$500 price point	\$500 is roughly the threshold below which consumers

significance?

can typically pay out-of-pocket without financing. Above this, financing options (e.g., CareCredit) are common — but then the value proposition vs. professionally fitted devices weakens.

Key Clinical Takeaways

Summary for Practice

- ✓ OTC hearing aids have a legitimate role — but are appropriate only for select patients with self-perceived mild-to-moderate hearing loss
- ✓ Diagnosis first, treatment second: advocate for audiometric evaluation even for patients who plan to self-select OTC
- ✓ Affordability is not the primary barrier to adoption — stigma is. Cosmetically appealing solutions matter
- ✓ Wearable smart glasses (e.g., Nuance Audio) offer a compelling OTC alternative with published evidence of SNR benefit
- ✓ IIC and deep canal aids are the fastest-growing segment — video otoscopy is strongly recommended for these fittings
- ✓ Untreated hearing loss is a public health issue with links to cognitive decline — early intervention matters
- ✓ Audiologists and dispensers are the experts: OTC does not replace professional hearing healthcare

Key References & Resources

OTC Self-Fit Study

Stadkowski & Souza (2024). J Otolaryngology ENT Research, December 2024

Self-Fit vs. Audiologist Fit

Beck (2024). J Otolaryngology ENT Research

Response	
Hearing Aid Stigma	Amlani & Valente (2017–18). American Academy of Otolaryngology Head & Neck Surgery
Hearing Aid Stigma (Forbes)	Forbes (2024). Consumer survey on hearing aid perception
Nuance Audio Study	Beck et al. (2025). J Otolaryngology ENT Research, February 2025
Untreated HL & Cognition	Beck et al. (2025). HearingTracker.com — 25 co-authors
Two-Minute Speech & Noise Test	Beck (2019). Available via AudiologyOnline or Hearing Review
Consumer Reports OTC Evaluation	Roberts, K. Consumer Reports, January 2025. Brands: Audien, Ergo, Lexie, Lucid, Sony
Smart Glasses Market Size	SkyQuest Research (2025). Global wearable eyewear ~\$6.2 billion
Global Hearing Aid Market	Grandview Research (2023). Global ~\$8B; U.S. ~\$2–3B

Notes

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