The prevalence of hearing loss (HL) among the South Korean population is approximately 22.73% [1]. HL becomes more common with age, with individuals aged 60 years and above accounting for 53.6% of all patients with HL. The consequences of HL in the elderly include impaired interpersonal communication, social isolation, depression, and limited employment opportunities. Moreover, HL in adult patients has recently gained attention because it has been identified as the most significant modifiable risk factor for dementia [2]. Consequently, the importance of hearing rehabilitation has again been emphasized.

Hearing aids (HAs) are considered the gold standard for hearing rehabilitation. However, due to financial constraints, social biases, stigma, and other factors, only 17.4% of patients with HL in South Korea acquire HAs, and a scant 12.6% utilize them in daily life [3]. The use of HAs in individuals with HL is crucial not only for auditory compensation but also for reducing the frequency and severity of cognitive impairment, depression, and other health issues. Therefore, proactive steps should be taken to encourage the widespread adoption of HAs among patients with HL.

In October 2022, the U.S. Food and Drug Administration (FDA) established a category for over-the-counter (OTC) HAs to improve accessibility for individuals with HL [4]. Like prescription HAs, OTC HAs are also regulated as medical devices by the FDA. However, the key distinction from prescription HAs is that OTC HAs can be purchased and used by patients without the need for a prescription or medical counseling. The FDA has specified that OTC HAs are indicated for adults with mild to moderate HL.

The global market for OTC HAs was valued at $1.06 billion in 2022, with a projected compound annual growth rate of 6.6% from 2023 to 2030 [5]. OTC HAs hold a competitive edge in terms of pricing and accessibility when compared to traditional HAs. While the average price of a pair of traditional HAs is around $4,600, the average price of OTC HAs is approximately $1,600. Given the absence of a reimbursement system for age-related HL in South Korea, OTC HAs are anticipated to swiftly capture a substantial share of the HA market.

In light of these environmental shifts, traditional audio manufacturers are now venturing into the OTC HA market. Representative products include the E10 by Sony, SoundControl by Bose, and Enhance by Jabra. These products are anticipated to be popular among individuals with HL due to their affordable pricing and sleek designs relative to traditional HAs. Although they are regulated as medical devices by the FDA, ensuring their safety and clinical effectiveness, further research is required to gather real-world evidence. OTC HAs are distinct from traditional devices in that they require patients to self-assess their hearing and make corresponding adjustments. This could potentially result in discrepancies between laboratory-based clinical data and real-world outcomes. Additionally, evaluating the cost-effectiveness of these OTC HAs may require a significant amount of time and effort due to the need to gather data from real-world users and consider various factors affecting their experiences.

PSAPs, frequently mentioned as alternatives to HAs, differ
from OTC HAs in two primary ways [6]. First, PSAPs are indicated for individuals without HL and are primarily designed to enhance sound perception in specific settings, such as birdwatching or listening to lectures from afar. However, due to their amplification capabilities and lower cost compared to traditional HAs, many individuals with HL utilize PSAPs as substitutes for HAs. Second, PSAPs are not regulated as medical devices but are rather classified as electronic products by the FDA; thus, many of them lack verified safety and efficacy. Prior to the use of PSAPs as hearing assistive devices, it is advisable to conduct electroacoustic analysis, real-ear measurement, and clinical measures such as functional gain and speech audiometry to ensure their safety and clinical effectiveness [7,8].

Recently, global smartphone manufacturers, including Apple and Samsung Electronics, have demonstrated an interest in sound amplification capabilities. For instance, Apple provides a feature termed Headphone Accommodations on its iPhones. This feature enables users to tailor sound settings according to their individual hearing needs. Sound adjustments can be made by directly entering audiogram data or through a series of hearing tests provided on the iPhone. The adjusted sound output can then be experienced through AirPods. However, limited research currently exists on the effectiveness of Apple’s Headphone Accommodations as a hearing assistive device.

Samsung Electronics provides a feature similar to Apple’s, enabling users to modify sound via the Amplify Ambient Sound feature on Galaxy smartphones and Galaxy Buds. The distinction between the sound amplification features of Apple and Samsung Electronics lies in the fact that Apple permits frequency-specific sound adjustments, while Samsung Electronics provides overall sound amplification. Nevertheless, Samsung Electronics’ sound amplification feature has demonstrated meaningful results under controlled laboratory conditions [9], and real-world clinical evidence on the feature has also been obtained [10].

The introduction of OTC HAs by the U.S. FDA has prompted a major transformation in the HA market. This shift has broadened the range of options for individuals with HL, increasing the accessibility of hearing assistive devices—a positive development. However, when selecting a hearing assistive device, it is essential to carefully evaluate its safety and clinical efficacy. Hearing healthcare professionals, such as physicians and audiologists, should thoroughly review the safety and clinical effectiveness of each hearing assistive device. This will aid individuals with HL in making informed and optimal choices.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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ORCID

Ga-Young Kim https://orcid.org/0000-0002-8945-4927
Il Joon Moon https://orcid.org/0000-0002-3613-0734

AUTHOR CONTRIBUTIONS

Conceptualization: GYK, IJM. Methodology: GYK, IJM. Project administration: GYK, IJM. Funding acquisition: IJM. Writing–original draft: GYK, IJM. Writing–review & editing: GYK, IJM.

REFERENCES