Usability and Performance of Self-Fitting Over-the-Counter Hearing Aids

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ABSTRACT

Purpose: Over-the-counter (OTC) hearing aids can potentially improve access to hearing healthcare and enable individuals with mild-to-moderate hearing loss to self-manage their condition. This study compares usability and performance across a range of self-fitting over-the-counter (OTC-SF) hearing aids.

Research Design: A cross-sectional study evaluated six OTC-SF hearing aids.

Study Sample: 43 adults with self-perceived mild-to-moderate hearing difficulties participated.

Data Collection and Analysis: Participants were randomly assigned to self-fit two of six OTC-SF hearing aids using manufacturer-provided instructions and smartphone applications. These included the HP Hearing PRO, Jabra Enhance Plus, Lexie B2 Powered by Bose, Lexie Lumen, Soundwave Sontro, and Sony CRE-C10. Usability was assessed based on fitting time, Hearing Aid Skills and Knowledge (HASK), self-reported ease of the self-fitting process, and the Post-Study System Usability Questionnaire (PSSUQ). Performance was evaluated with the Judgement of Sound Quality (JSQ) test and speech-in-noise benefit using the Digits-In-Noise (DIN) and QuickSIN tests.

Results: Fitting time ranged between 14.4 and 27.1 minutes, with Lexie Lumen requiring the longest (27.1; SD 5.9) and HP Hearing PRO the shortest (14.4; SD 1.9). HASK scores varied, with Soundwave Sontro scoring highest (8.9/10) and HP Hearing PRO lowest (6.8/10). Self-reported ease of self-fitting and PSSUQ scores did not differ significantly between the OTC-SF hearing aids. Overall sound quality and clarity ratings significantly differed, with Lexie B2 receiving the highest ratings (8.1/10 and 7.5/10) and HP Hearing PRO the lowest (6.3/10 and 5.1/10). Speech-in-noise benefit did not differ significantly between devices. Thematic analysis identified seven themes regarding the participant's self-fitting experience and six themes related to the researcher's field notes. Participants generally found OTC-SF hearing

aids user-friendly, although issues with Bluetooth connectivity, handling and insertion, and sound quality were noted as common challenges by the researcher.

Conclusions: Usability and performance of OTC-SF hearing aids were similar across devices in terms of post-usability and speech-in-noise benefit. However, devices showed variations in fitting time, HASK, and sound quality, including overall impression and clarity. These findings can support consumers and healthcare professionals in decision-making and recommendations. Further research is needed on long-term usability and selection processes for OTC-SF hearing aids.

Key Words: Over-the-counter hearing aids, Direct-to-consumer hearing devices, Hearing aids, Usability, Performance

Abbreviations

DIN = Digits-In-Noise

FDA = Food and Drug Administration

HASK = Hearing Aid Skills and Knowledge

INFOQUAL = Information quality

INTERQUAL = Interface quality

JSQ = Judgement of Sound Quality

OTC = Over-the-Counter

OTC-SF = Self-fitting Over-the-Counter

OTC-PS = Pre-set Over-the-Counter

PSSUQ = Post-Study System Usability Questionnaire

QuickSIN = Quick Speech-in-Noise

REM = Real-ear measurement

SYSUSE = System usefulness

INTRODUCTION

Hearing loss is a prevalent sensory impairment that affects 430 million people worldwide (World Health Organization[1]). While hearing aids have long been the primary intervention for addressing hearing difficulties (World Health Organization[1]) barriers such as cost, limited access, and stigma have hindered their widespread adoption (Knoetze et al[2]; Knudsen et al[3]). Globally, less than 11% of individuals with disabling hearing loss use hearing aids (Bisgaard et al[4]). There have been significant developments in hearing technology over the last decade, including advanced prescription hearing aids and direct-to-consumer (DTC) devices, such as personal sound amplification products, hearables, and consumer audio devices (Manchaiah et al[5,6]; Tran & Manchaiah[7]). These innovations have paved the way for new service-delivery models, like the emergence of Over-the-Counter (OTC) hearing aids. OTC hearing aids have emerged as a promising alternative, potentially improving access to hearing healthcare and enabling people with mild-to-moderate hearing loss to self-manage their condition (Food and Drug Administration[8]).

On October 17, 2022, the Food and Drug Administration (FDA) established a rule for a new OTC hearing aid category. The final rule allows consumers with perceived mild-to-moderate hearing loss to purchase hearing aids directly from stores or online retailers without requiring a medical exam, prescription, or a fitting by an audiologist (Food and Drug Administration[8]). The FDA defined two sub-categories for OTC hearing aids, namely 1) OTC hearing aids with standardized output profiles (i.e., pre-set programs; OTC-PS) and 2) self-fitting OTC (OTC-SF) hearing aids, which allow users to program their hearing aids with a self-fitting strategy and customize their hearing aid settings according to their needs and preferences (Food and Drug Administration[8]).

The concept of self-fitting hearing aids were introduced over a decade ago (Convery et al[9]). Convery et al[10] evaluated the self-fitting process of a commercially available hearing aid and found that most participants could complete the process without error. However, the authors noted that the success rate could be improved by support from trained personnel and through improvements to the design and instructions. Keidser & Convery[11] further emphasized that with the appropriate design and support, self-fitting hearing aids can become a more affordable and accessible option.

Recent studies on OTC-SF hearing aids related to the newly established FDA category have demonstrated comparable benefit and satisfaction outcomes to audiologist-fit hearing aids for individuals with self-perceived mild-to-moderate hearing loss (Sabin et al[12]; De Sousa et al[13]). Sabin et al[12] validated an OTC-SF method using a Bose prototype hearing aid, enabling users to select their signal processing parameters using a mobile application consisting of two dials simultaneously controlling the gain and compression of all frequency bands. Their study found the self-fit group reported better sound quality, and there were no differences in clinical measures of speech-in-noise benefit or satisfaction (Sabin et al[12]). More recently, De Sousa et al[13] conducted a randomized controlled trial to compare the effectiveness of an OTC-SF hearing aid using in-situ audiometry and an audiologist-fitted hearing aid using best practices. The self-fitting parameters were determined by a proprietary algorithm using in-situ threshold measurements (at 0.5, 1.0, 2.0, 3.0, 4.0, and 6.0 kHz) conducted through the hearing aids by using the accompanying smartphone application. Their study found that the short-term benefit and satisfaction outcomes of the OTC-SF hearing aids were comparable to the audiologist-fit hearing aids using best practices. In another large-scale cross-sectional observational study, no difference in benefit and satisfaction hearing aid outcomes was observed between a group of individuals who had prescription hearing aids fit by hearing

healthcare professionals (n=406) and a group of individuals who had OTC-SF hearing aids (n=250) that demonstrated that it is possible to obtain positive benefit and satisfaction outcomes from OTC-SF hearing aids in individuals with mild-to-moderate hearing loss (Swanepoel et al[14]). However, we are not aware of any studies examining the benefit and satisfaction outcomes of commercially available OTC-SF hearing aids.

Despite promising outcomes reported in some of these early studies, concerns regarding the safety, handling, self-adjustment, service delivery models, counseling, audiological care, and potential for optimal benefits and adverse events of OTC hearing aids persist among hearing healthcare professionals[15]. A study by Manchaiah et al[15] in 2023 revealed that over 50% of hearing healthcare professionals expressed opposition to OTC hearing aids due to these concerns. Additionally, consumer attitudes towards OTC hearing aids highlight apprehensions regarding the direct-to-consumer model, with 84% expressing discomfort and a preference for in-person consultation with hearing healthcare professionals[16]. Notably, older adults and individuals with less interest in hearing aids were less inclined towards OTC options, while those with prior experience with direct-to-consumer models and those lacking insurance coverage were more likely to pursue OTC hearing aids. Therefore, it is crucial to evaluate the usability and performance of OTC hearing aids to ensure both their safety and efficacy.

The market has seen a proliferation of OTC hearing aids with unique self-fitting strategies. However, there is limited research on OTC hearing aids currently on the market (Manchaiah et al[17]). No study has yet compared the self-fitting process between OTC-SF hearing aids in terms of usability and performance, leaving a significant gap in current research. Understanding the usability and performance of different OTC-SF hearing aids is essential

for several reasons. Firstly, it empowers consumers to make informed choices, offering them more accessible and affordable hearing solutions and potentially enhancing their quality of life. Secondly, it can guide healthcare professionals in recommending suitable OTC options. Thirdly, it can contribute to establishing regulations and standards in the industry, ensuring the safety and efficacy of OTC-SF hearing aids. Therefore, this study compared the usability and performance of several FDA-approved OTC-SF hearing aids available to consumers. The specific objectives included examining the following aspects: 1. Usability: a) Device fitting time, b) Hearing aid skills and knowledge, c) Ease of self-fitting process, and d) Usability of the device. 2. Performance: e) Device sound quality, and f) Speech-in-noise benefit.

MATERIALS AND METHOD

Study Design

This study used a cross-sectional design to compare the usability and performance of the HP Hearing PRO, Jabra Enhance Plus, Lexie B2 Powered by Bose, Lexie Lumen, Soundwave Sontro, and Sony CRE-C10 hearing aids. We selected these specific OTC hearing aids since they were the only available OTC-SF hearing aids under $1000 between December 2022 and February 2023 (see Table 1). Ethical clearance was obtained from the University of Pretoria Humanities Research Ethics Committee (HUM021/1122).

Table 1. Characteristics of Self-fitting Over-the-Counter Hearing Aids (n = 6)

Hearing Aid	Style	Price Per Pair	Rechargeable Battery	Bluetooth Streaming	Ingress Protection Rating	Application Name	Fitting Strategy
HP Hearing Pro	Earbud	$499	Yes	Yes	IP54	HP Hearing	In situ hearing test
Jabra Enhance Plus	Earbud	$799	Yes	Yes, iPhone only	IP52	Jabra Enhance	In situ hearing test
Lexie B2	Receiver in the canal	$999	Yes	Yes, iPhone only	IP67	Lexie	Self-adjustment
Lexie Lumen	Behind the ear	$799	No	No	IP67	Lexie	In situ hearing test
Soundwave Sontro	Receiver in the canal	$849	No	No	N/A	otoTune	In situ hearing test
Sony CRE-C10	Completely in the canal	$999	No	No	IPX4	Sony Hearing Control	In situ hearing test

N/A — not available.

Participants

Purposive sampling was used to recruit a total of 43 participants. We used various social media platforms to promote study participation and invited interested individuals to complete a Google Form in order to check their eligibility. On the form, participants were asked to describe their hearing ability (without a hearing aid) by selecting one of the following options: 1) my hearing is good, 2) I have little difficulty, 3) I have a lot of difficulty, or 4) I cannot hear at all. In addition, participants were required to rate their hearing difficulties as slight, mild, moderate, or severe. To be considered for the study, participants needed to report their hearing ability as having little or a lot of difficulty and rate their hearing difficulties as mild or moderate. Eligible participants included adults (>18 years) who self-reported mild-to-moderate hearing difficulties and no active outer- and middle-ear pathologies. Additionally, participants were required to have a high level of English proficiency, as determined by an online English proficiency test.

To minimize potential order effects, we used a Latin square method to assign 29 participants to two of the following self-fitting devices: the Jabra Enhance Plus, Lexie B2 Powered by Bose, Lexie Lumen, Soundwave Sontro, or Sony CRE-C10 hearing aids. An additional 14 participants were recruited and assigned to self-fit the HP Hearing PRO and Lexie Lumen or Sony CRE-C10 devices. This led to each of the six OTC-SF hearing aids being tested for usability and performance by 13 to 15 users. Five out of 43 participants reported previous hearing aid use.

Data Collection

The self-reported and clinical measures were aimed at examining the usability, including (a) *device fitting time* as observed and recorded by the researcher; (b) *hearing aid skills and*

knowledge using the validated Hearing Aid Skills and Knowledge (HASK) test (Saunders et al[18]); (c) *ease of self-fitting process* measured using a single item structured question and qualitative data including an open-ended question regarding the overall self-fitting experience and researcher field notes; (d) *usability of the device* measured using the validated Post-Study System Usability Questionnaire (PSSUQ; Lewis[19]) as well as hearing aid performance, including (e) *device sound quality and clarity* measured using the validated Judgement of Sound Quality (JSQ; Gabrielsson et al[20]) self-reported rating scale, and (f) *speech-in-noise benefit* using the validated Digits-In-Noise (DIN) and Quick Speech-in-Noise (QuickSIN) tests. Real-ear measurement (REM) data were obtained but will be presented in a separate article.

Baseline Assessments and Fitting

Before self-fitting the OTC-SF hearing aids, a baseline hearing assessment was conducted by a qualified audiologist. This assessment included otoscopic examination, tympanometry, pure-tone audiometry, and unaided speech-in-noise tests, such as the DIN and QuickSIN in a sound-proof booth. In addition, participants were required to complete an online English proficiency test to ensure a high level of proficiency (https://www.efset.org). Participants self-fit their assigned OTC-SF hearing aids using an iPhone X and the manufacturer-provided instructions on the accompanying smartphone application. If participants were unable to self-fit, they could request assistance from the researcher or accompanying family member.

Device Fitting Time

During the self-fit process, the researcher observed and recorded the time taken for each fitting. Time was measured using a stopwatch to ensure consistency and accuracy. The timer was started when the participant opened the smartphone application, and the measurement

was continuous throughout the fitting process, including periods of participant inquiry and researcher assistance. This approach aimed to capture the entirety of the fitting experience, from initial setup to final adjustments, offering a comprehensive understanding of the self-fit process.

Hearing Aid Skills and Knowledge

The researcher assessed the participants' hearing aid skills and knowledge using selected items from the HASK test (Saunders et al[18]) immediately after self-fitting. It is important to note that participants were not expected to have prior knowledge of hearing aids upon entering the study. Instead, the HASK test aimed to assess participants' ability to perform essential tasks related to OTC-SF hearing aids, which would have been explained through the self-fitting app's instructions. These items included distinguishing left from right, inserting the right hearing aid, inserting the left hearing aid, changing the volume, and switching the hearing aids on and off. The items related to the batteries (as some of the OTC-SF hearing aids were rechargeable), cleaning (as the devices were clean when taken out of the box), telephone use, program use, troubleshooting, and storage were excluded as they were not relevant for all the OTC-SF hearing aids. Each item was given a score out of two points. Participants who did not know the information or could not complete the task received zero points. Those who were aware of the information but required assistance from the researcher received one point. Participants who demonstrated knowledge and performed the task correctly received two points. The total score was out of 10 points, with possible scores ranging from 0 to 10.

Ease of Self-fitting Process

After each self-fitting, participants were asked to rate the ease of the self-fitting process using a 5-point Likert scale, with one being very easy and five being very difficult. The question was: "How easy was the self-fit process?" Additionally, they were asked to complete an open-ended question that was phrased as follows: "Tell us about your overall experience." The researcher also took field notes during each fitting.

Post-use Usability of the Device

Participants completed version 3 of the PSSUQ to measure their post-use usability of the OTC-SF hearing aids (Lewis[19]). The PSSUQ comprised 16 standardized questions, following a 7-point Likert scale and a not-applicable option. The overall result is determined by averaging the scores across the 7-point scale. The possible scores range from 1 to 7, with lower scores indicating higher post-use usability. The PSSUQ consists of three sub-scales, namely system usefulness (SYSUSE; possible scores range between 1 to 7, information quality (INFOQUAL; possible scores range between 1 to 7, and interface quality (INTERQUAL; possible scores range between 1 to 7).

Device Sound Quality

To assess the sound quality of the OTC-SF hearing aids, we used specific items from the Judgement of Sound Quality (JSQ) rating scale (Gabrielsson et al[20]). Given the potential challenges in evaluating certain items, such as fullness and spaciousness, especially immediately after fitting the OTC-SF hearing aids, we focused on easily understandable and reliable items for rating. These items included the overall impression (i.e., very bad to very good) and clarity of sound (i.e., very unclear to very clear). Participants rated sound quality

on a scale of zero to ten (11-point Likert scale), with higher scores indicating better sound quality.

Speech-in-Noise Benefit

Aided speech-in-noise tests (DIN and QuickSIN) were conducted after each fitting in a sound-proof booth at 70 dB HL. Speech-in-noise benefit was assessed by subtracting the aided scores from the unaided scores.

Data Analysis

We used IBM SPSS version 28.0.1.0 to analyze the data. Preliminary analysis showed that the data violated the assumption of normality ($p < .05$) for all variables according to Shapiro-Wilk's test. We conducted descriptive statistics to provide a comprehensive overview of the data, which included calculating measures such as mean, median, standard deviation, and range. To evaluate possible differences among the various OTC-SF hearing aids in terms of usability and performance measures, we employed the Kruskal-Wallis test. Afterward, we conducted pairwise comparisons using Dunn's (1964) procedure, as it corrects for multiple comparisons. Additionally, we examined the qualitative feedback on the open-ended questions and researcher field notes to gain insights into the participants' experiences and opinions. Recognizing the need for a deeper understanding beyond quantitative measures, we employed inductive thematic analysis. This method allowed us to derive themes and patterns directly from the data without applying pre-existing theoretical frameworks or assumptions (Braun & Clarke[21]). The primary researcher coded the data into meaningful units of information, which were then grouped into similar themes (Braun & Clarke[21]). To include additional perspectives, co-authors, both experienced in thematic analysis, cross-checked the

coding, and any inconsistencies were resolved through discussion until an agreement was reached.

RESULTS

Participants were 55.8% male and 44.2% female (Table 2). The mean age was 59.7 years (SD 14.3). Regarding self-perceived hearing difficulty, 44.2% reported having a little trouble, while 55.8% reported having a lot of trouble. Self-perceived degree of hearing loss was reported to be mild in 23.3% of cases and moderate in 76.7% of participants. The mean Pure-Tone Average (PTA) for frequencies 0.5, 1, 2, and 4 kHz was 36.5 (SD 16.5) for the left ear and 32.8 (SD 16.7) for the right ear (Supplementary Figure 1).

A summary of usability and performance measures of OTC-SF hearing aids is presented in Table 3. The device fitting time, hearing aid skills and knowledge, and device sound quality (clarity and overall ratings) differed significantly between OTC-SF hearing aids. See Supplementary Table 1 for pairwise comparisons. The self-reported ease of self-fitting, PSSUQ scores, and speech-in-noise benefit were not significantly different between OTC-SF hearing aids. These results are discussed in detail in the following section.

Table 2. Demographic Characteristics of Participants

	All Participants ($n = 43$)	HP Hearing PRO ($n = 14$)	Jabra Enhance Plus ($n = 15$)	Lexie B2 ($n = 15$)	Lexie Lumen ($n = 14$)	Sontro ($n = 14$)	Sony CRE-C10 ($n = 13$)
Sex, n (%)							
Male	24 (55.8)	6 (42.9)	9 (60)	8 (53.3)	7 (50)	11 (78.6)	6 (46.2)
Female	19 (44.2)	8 (57.1)	6 (40)	7 (46.7)	7 (50)	3 (21.4)	7 (53.8)
Mean age, years (SD)	59.7 (14.3)	60.5 (12.1)	62.6 (13.1)	60.9 (16.3)	55.9 (15.2)	60.4 (14.1)	56.5 (16.1)
Self-perceived hearing difficulty, n (%)							
I have little trouble	19 (44.2)	4 (28.6)	7 (46.7)	7 (46.7)	4 (28.6)	8 (57.1)	7 (53.8)
I have a lot of trouble	24 (55.8)	10 (71.4)	8 (53.3)	8 (53.3)	10 (71.4)	6 (42.9)	6 (46.2)
Self-perceived degree of hearing loss, n (%)							
Mild	10 (23.3)	4 (28.6)	2 (13.3)	3 (20)	2 (14.3)	4 (28.6)	4 (30.8)
Moderate	33 (76.7)	10 (71.4)	13 (86.7)	12 (80)	12 (85.7)	10 (71.4)	9 (69.2)
Mean PTA for 0.5, 1, 2, and 4 kHz (SD)							
Left	36.5 (16.5)	35.1 (18.2)	35.0 (17.7)	39.4 (15.9)	35.6 (15.7)	37.5 (15.8)	33.7 (15.9)
Right	32.8 (16.7)	34.2 (19.1)	35.7 (14.0)	36.1 (16.7)	31.4 (19.4)	28.6 (13.9)	28.1 (15.6)

PTA = pure tone average; SD = standard deviation.

Table 3. Summary of Usability and Performance Measures of Six Over-the-Counter Hearing Aids

	Usability								Performance		
Hearing Aid (Participants)	Device Fitting Time, Mean (SD) Min*	Self-reported Ease of Self-fitting, Mean (SD)	Overall PSSUQ Score, Mean (SD)	PSSUQ SYSUSE Score, Mean (SD)	PSSUQ INFOQUAL Score, Mean (SD)	PSSUQ INTERQUAL Score, Mean (SD)	HASK Total Score,* Mean (SD)	JSQ Clarity Score,* Mean (SD)	JSQ Overall Impression,* Mean (SD)	QuickSIN Benefit, Mean (SD)	DIN Benefit, Mean (SD)
HP Hearing PRO (n = 14)	14.4 (1.9)	2.1 (0.7)	2.0 (1.3)	2.1 (1.3)	1.8 (1.1)	2.2 (1.8)	6.8 (1.3)	5.1 (2.1)	6.3 (1.7)	1.2 (2.4)	−0.2 (1.7)
Jabra Enhance Plus (n = 15)	19.7 (6.1)	1.7 (0.6)	1.8 (0.7)	1.6 (0.7)	1.7 (0.7)	2.1 (1.3)	7.3 (1.8)	6.9 (2.1)	6.8 (1.9)	1.0 (2.5)	0.4 (1.8)
Lexie B2 (n = 15)	21.9 (11.4)	2.1 (1.0)	1.8 (0.7)	1.8 (0.9)	1.8 (0.7)	1.7 (0.8)	8.8 (1.5)	7.5 (1.8)	8.1 (1.2)	1.1 (3.6)	2.4 (4.7)
Lexie Lumen (n = 14)	27.1 (5.9)	1.7 (0.7)	1.5 (0.7)	1.6 (1.0)	1.5 (0.5)	1.4 (0.7)	7.2 (2.0)	6.8 (1.7)	7.6 (1.8)	−0.8 (3.2)	−0.0 (1.8)
Soundwave Sontro (n = 14)	15. 7 (5.2)	1.8 (0.4)	1.9 (0.9)	1.8 (0.8)	2.0 (1.1)	1.8 (0.9)	8.9 (1.4)	6.4 (1.8)	6.5 (1.8)	0.00 (2.2)	−0.2 (2.2)
Sony CRE-C10 (n = 13)	24.2 (6.6)	2.4 (1.0)	1.8 (1.0)	1.7 (0.8)	1.9 (1.2)	1.8 (1.0)	8.1 (1.9)	6.2 (1.7)	7.0 (1.5)	−0.5 (1.4)	0.3 (1.2)
All devices (n = 85)	20.5 (8.0)	2.0 (0.8)	1.8 (0.9)	1.8 (0.9)	1.8 (0.9)	1.8 (1.1)	7.8 (1.8)	6.5 (2.0)	7.1 (1.7)	0.4 (2.7)	0.5 (2.7)

*Significant difference between hearing aids according to the Kruskal-Wallis test ($p < 0.05$).
DIN = digits-in-noise; HASK = hearing aid skills and knowledge (scores ranging from 0 to 10, with higher scores indicating better skills and knowledge); INFOQUAL = information quality; INTERQUAL = interface quality; JSQ = judgment of sound quality (scores ranging from 0 to 10, with higher scores indicating better sound quality); PSSUQ = Post-Study System Usability Questionnaire (scores ranging from 1 to 7, with lower scores indicating better usability); QuickSIN = quick speech-in-noise; SD = standard deviation; SYSUSE = system usefulness.

Usability

Device Fitting Time

The average device fitting time ranged between 14.4 to 27.1 minutes across all devices, with mean and median times as 20.5 and 17.0 minutes, respectively. Lexie Lumen had the longest average fitting time (27.1; SD 5.9), followed by Sony CRE-C10 (24.2; SD 6.6). HP Hearing PRO had the shortest (14.4; SD 1.9), followed by Soundwave Sontro (15. 7; SD 5.2). Device fitting times differed significantly (Kruskal-Wallis; $\chi 2(5) = 33.755$, $p < .001$) between OTC-SF hearing aids. Post hoc analysis revealed that Lexie Lumen exhibited significantly longer fitting times compared to all other OTC-SF hearing aids except for Sony CRE-C10 (Figure 1). Furthermore, there were significant differences in device fitting times between HP Hearing PRO and all the other OTC-SF hearing aids except Soundwave Sontro, with HP Hearing PRO showing significantly shorter fitting times (Figure 1).

Hearing Aid Skills and Knowledge

The average hearing aid skills and knowledge scores ranged between 6.8 and 8.9, with mean and median scores of 7.8 and 8.0 out of 10, respectively. Soundwave Sontro (8.9; SD 1.4) and Lexie B2 (8.8; SD 1.5) had the highest average scores, whereas HP Hearing PRO (6.8; SD 1.3) had the lowest average score (Figure 2). Hearing aid skills and knowledge scores (Kruskal-Wallis; $\chi 2(5) = 17.700$, $p = .003$) were significantly different between hearing aids. Soundwave Sontro and Lexie B2 scored significantly better than HP Hearing PRO, Lexie Lumen, and Jabra Enhance Plus (Figure 2). The five previous hearing aid users had an average HASK score (8.2; SD 2.2), which was similar (7.8; SD 1.8) to the 38 new hearing aid users.

Ease of Self-fitting Rating

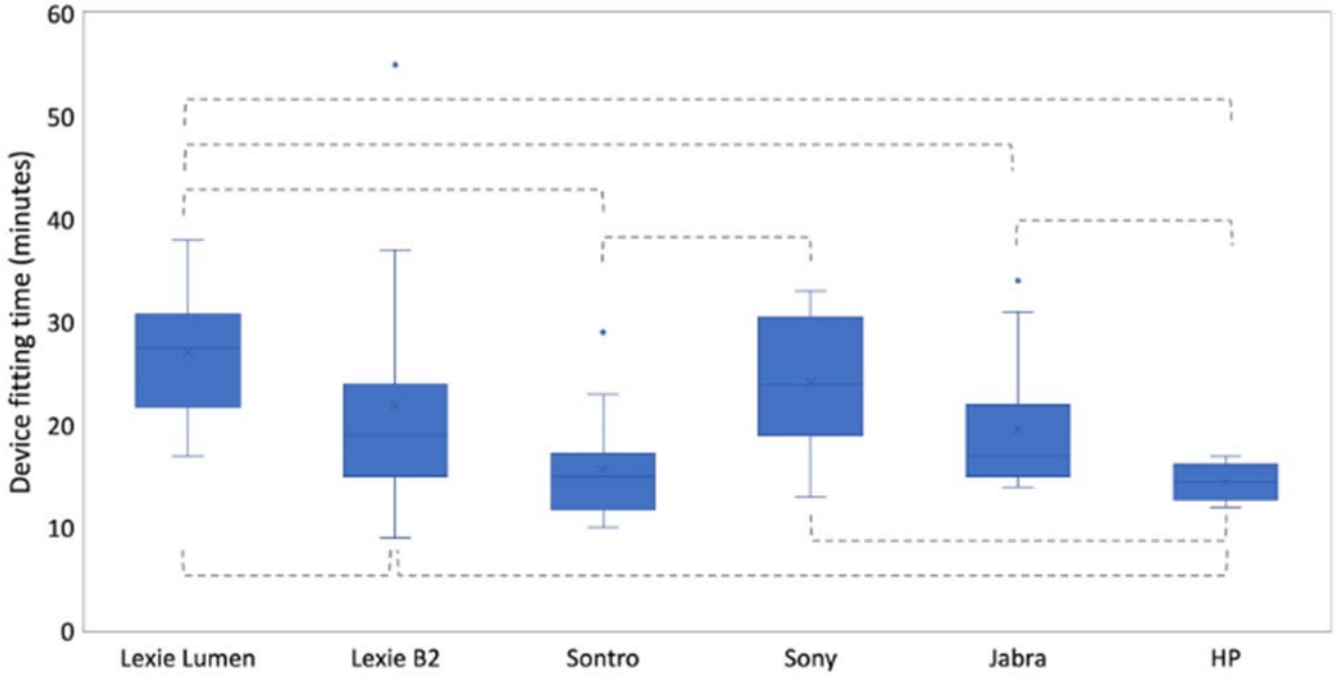

Figure 1. Device self-fitting duration. Boxplots include outliers, minimum (min), quartile 1 (Q1), median, quartile 3 (Q3), and maximum (max). Dashed lines represent pairwise comparisons that were significantly different ($p < 0.05$).

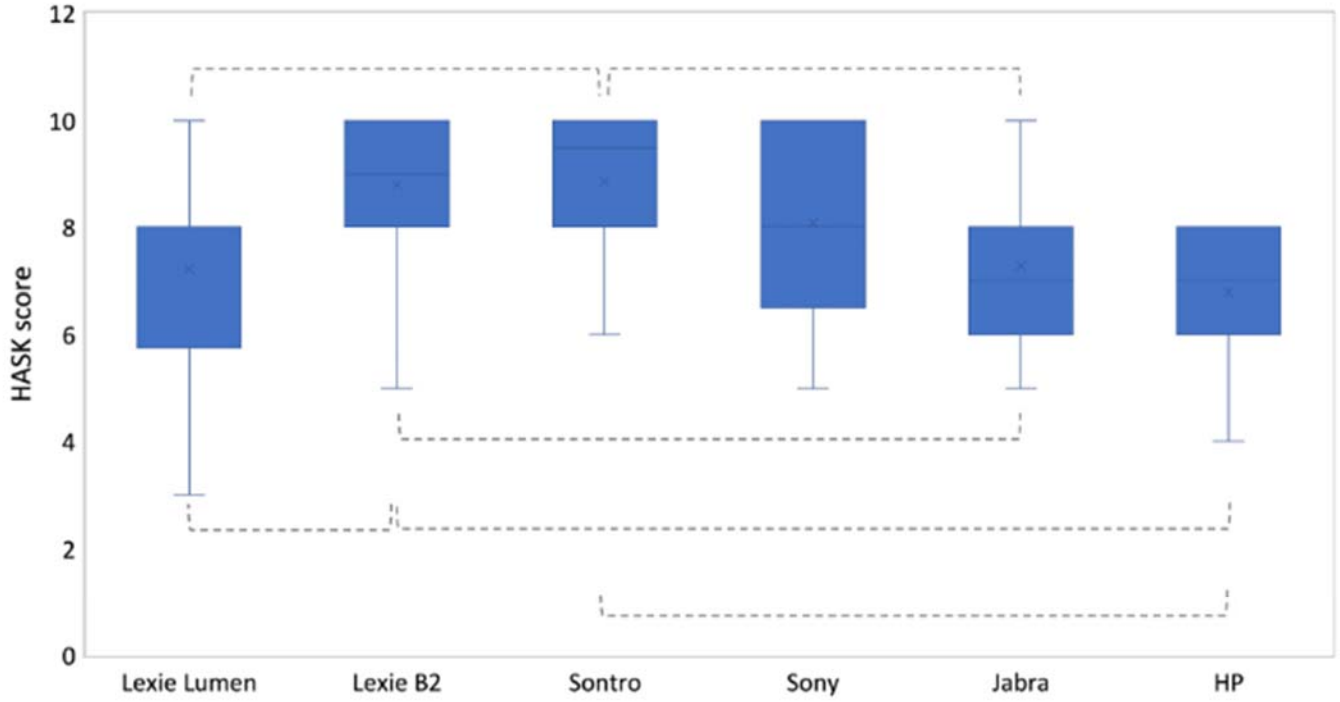

Figure 2. Hearing aid skills and knowledge (HASK) scores. Boxplots include outliers, minimum (min), quartile 1 (Q1), median, quartile 3 (Q3), and maximum (max). Dashed lines represent pairwise comparisons that were significantly different ($p < 0.05$).

The average self-reported ease of self-fitting scores ranged between 1.7 and 2.4 out of 5, with mean and median ratings of 2.0 and 2.0, respectively. Lexie Lumen had the best average self-reported ease of self-fitting score (1.7; SD 0.7). There was no significant difference between self-reported ease of self-fitting across devices. Additionally, the five previous hearing aid users had an average self-reported ease of self-fitting score (2.1; SD 0.9), which was similar (2.0; SD 0.8) to the 38 new hearing aid users.

Thematic Analysis of the Overall Self-fitting Experience

For the open-ended question, seven themes were identified in the thematic analysis, including (a) ease of use and fit, (b) physical comfort and feel, (c) app functionality, (d) instruction clarity, (e) improved hearing, (f) sound quality and noise-related problems, and (g) user satisfaction (Table 4). Participants generally reported ease in self-fitting for most OTC-SF hearing aids, except for Sony CRE-C10. However, mixed responses were recorded regarding the physical comfort and feel of the OTC-SF hearing aids. For example, Lexie B2 users found them comfortable to wear, whereas some HP Hearing PRO users found them bulky and uncomfortable, and some Sony CRE-C10 users had trouble inserting them. Participants generally provided favorable feedback regarding the accompanying smartphone applications, although a few mentioned the need for improvement or review. Clear instructions were appreciated by most users, contributing to their overall satisfaction with the self-fitting process. Users generally expressed satisfaction with the self-fitting process, especially the Lexie Lumen and Sontro Soundwave users. Many users reported improved hearing and enhanced clarity as a positive outcome while using the OTC-SF hearing aids. However, some concerns were raised about the sound quality, particularly with completely-in-canal (CIC) or earbud-style designs such as Sony CRE-C10, Jabra Enhance Plus, and HP Hearing PRO. Users also reported issues with their own voices, echoing sounds, and feedback.

Table 4. Thematic Analysis of Participant Responses to the Open-ended Request for Information Regarding the Overall Experience of the Self-fitting Process (n = 43)

Theme	Example Responses
Ease of use and fit	*It is very easy. You will just have to get used to insert the hearing aids. It will take practice*—*ITE user*
	It was very easy and quick to learn—*BTE user*
Physical comfort and feel	*I find them bulky and uncomfortable*—*ITE user*
	Light on ear—*BTE user*
Application functionality	*App is easy to understand*—*ITE user*
	App needs review—*BTE user*
Instruction clarity	*Easy to follow instructions*—*ITE user*
	Very clear instructions—*BTE user*
Improved hearing	*I can hear better*—*ITE user*
	I could immediately hear better—*BTE user*
Sound quality and noise-related problems	*Sound is hollow*—*ITE user*
	Sounds clear and crisp—*BTE user*
User satisfaction	*Wow, fantastic fit and sound*—*ITE user*
	World-changing experience—*BTE user*

ITE refers to earbud-style or completely-in-the-canal hearing aids and BTE refers to behind-the-ear or receiver-in-the-canal hearing aids.
App = application.

Thematic Analysis of the Researcher's Field Notes

Six themes emerged, including (a) assistance with device handling and insertion, (b) difficulties with smartphone usage, (c) connectivity issues, (d) technical errors and retesting, (e) family involvement, and (f) user experience and feedback (Table 5). During the self-fitting process, many of the participants (n = 14) struggled with inserting and handling the devices, in particular, the Lexie Lumen and HP Hearing PRO hearing aids. Some participants required assistance with inserting the HP Hearing PRO earbuds, changing the Lexie Lumen slim tubes, or inserting the Sony CRE-C10 batteries. Difficulties with smartphone usage were noted, ranging from participants being uncomfortable with smartphones to specific issues with using certain devices. Connectivity problems with Bluetooth were also evident, with many participants (n = 18) struggling to pair or connect their OTC-SF hearing aids, often requiring assistance. Technical errors, such as offline servers or app malfunctions, were documented, leading to the need for retesting or encountering obstacles during the testing phase.

Furthermore, family members played an active role in assisting some participants throughout the self-fitting process. Participants provided diverse feedback on their experiences, with some expressing concerns about sound quality or app functionality. For instance, some participants reported hearing their voices while wearing the Jabra Enhance Plus hearing aids, and a few were unsure when the Lexie B2 hearing aids were switched on because they had not yet placed them in their ears to hear the activation tune when connecting the devices to the smartphone. In one case, a participant was unable to complete the Sony CRE-C10 fitting because the application indicated that their hearing loss was too severe for the hearing aids, according to the in-situ hearing test performed.

Table 5. Thematic Analysis of Field Notes Taken by the Researcher During the Self-fitting Process

Theme	Example Notes
Assistance with device handling and insertion	*Required assistance with insertion as earbuds kept falling out—ITE user*
	Required assistance with inserting batteries—BTE user
Difficulties with smartphone usage	*Participant owns Nokia and struggled using iPhone—BTE user*
	Participant is not so comfortable with technology.—ITE user
Bluetooth connectivity issues	*Required assistance with pairing and clicked "my earbuds are not flashing blue"—ITE user*
	Required assistance with connectivity and prompt to click on circles—BTE user
Technical errors and retesting	*Cloud server offline—ITE user*
	App only recorded in situ test results for one ear or no results were recorded—BTE user
Family involvement	*Daughter assisted a lot—ITE user*
	Husband assisted—BTE user
User experience and feedback	*Participant mentioned that his own voice echoes—ITE user*
	Participant mentioned that the app's text could be bigger (not the first to mention)—BTE user

ITE refers to earbud-style or completely-in-the-canal hearing aids and BTE refers to behind-the-ear or receiver-in-the-canal hearing aids.
App = application.

Post-use Usability

On the PSSUQ, a lower score equals higher post-use usability. The average PSSUQ overall scores ranged between 1.5 and 2.0, with mean and median scores of 1.8 and 1.5, respectively. Lexie Lumen had the best average score for the overall PSSUQ and all the sub-scales (see Table 3). HP Hearing PRO had the worst average score for the overall PSSUQ (2.0; SD 1.3), PSSUQ SYSUSE (2.1; SD 1.3), and PSSUQ INTERQUAL (2.2; SD 1.8). However, there was no significant difference between OTC-SF hearing aids across these measures.

Performance

Device Sound Quality

Average overall impression ratings ranged between 6.5 and 8.1 out of 10, with mean and median scores of 7.1 and 7.0, respectively. Lexie B2 (8.1; SD 1.2) and Lexie Lumen had the highest average overall impression ratings (7.6; SD 1.8), whereas HP Hearing PRO (6.3; SD 1.7) and Soundwave Sontro (6.5; SD 1.8) had the lowest average overall impression ratings (Figure 3). Overall impression ratings (Kruskal-Wallis; $\chi 2(5) = 11.168$, $p = .048$) were significantly different between OTC-SF hearing aids, with HP Hearing PRO significantly lower than Lexie Lumen and Lexie B2. Soundwave Sontro was also significantly lower than Lexie B2 (Figure 3).

The average clarity ratings ranged between 5.1 and 7.5, with mean and median ratings of 6.5 and 7.0, respectively. Lexie B2 had the highest average clarity rating out of 10 (7.5; SD 1.8), whereas HP Hearing PRO had the lowest clarity rating out of 10 (5.1; SD 2.1). Clarity ratings (Kruskal-Wallis; $\chi 2(5) = 12.988$, $p = .023$) significantly differed between OTC-SF hearing aids, with HP Hearing PRO being significantly lower than Lexie B2, Lexie Lumen, and Jabra Enhance Plus. Lexie B2 was also significantly higher than Sony CRE-C10 (see Figure 4).

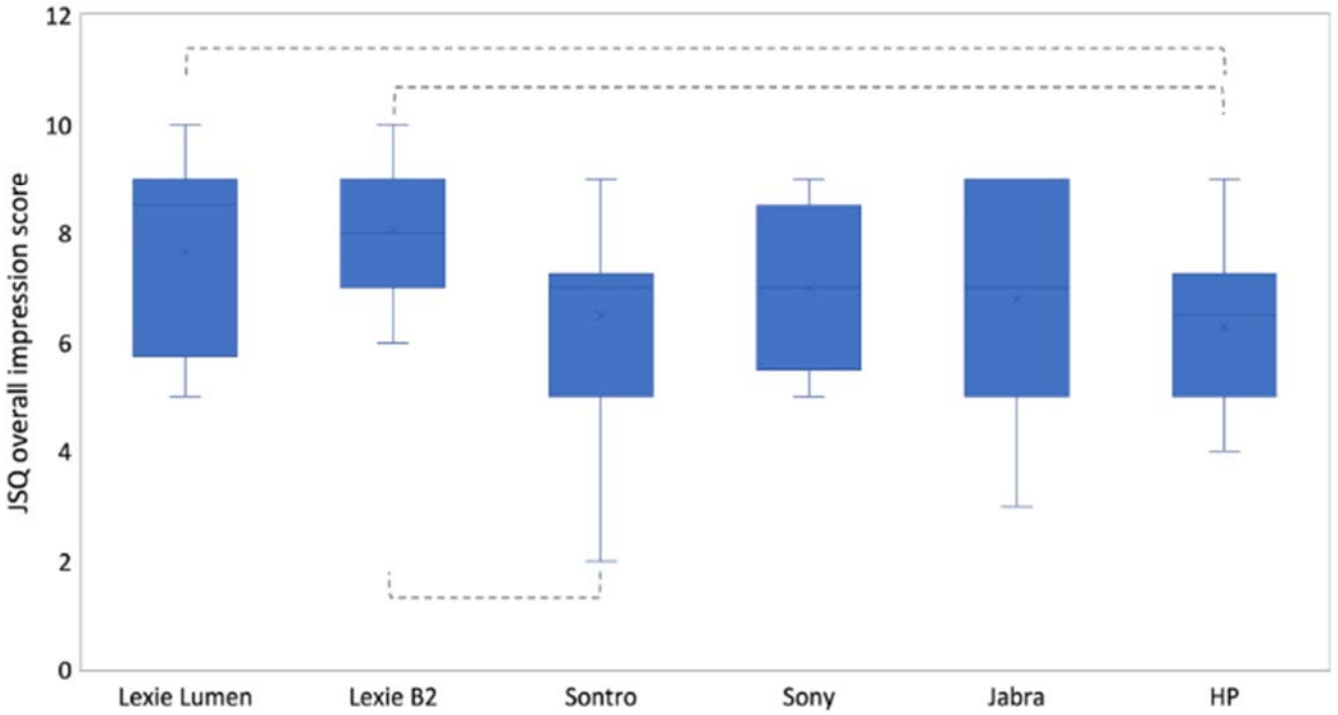

Figure 3. Judgment of sound quality (JSQ) overall impression scores. Boxplots include outliers, minimum (min), quartile 1 (Q1), median, quartile 3 (Q3), and maximum (max). Dashed lines represent pairwise comparisons that were significantly different ($p < 0.05$).

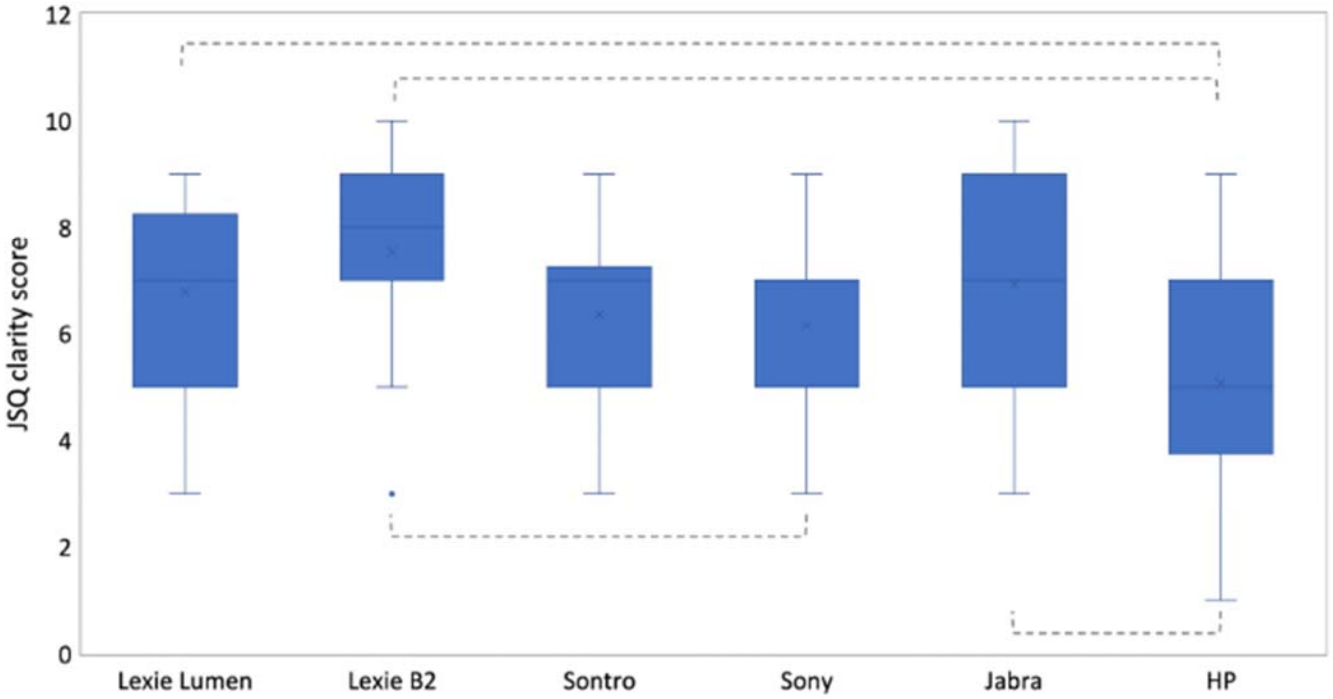

Figure 4. Judgment of sound quality (JSQ) clarity scores. Boxplots include outliers, minimum (min), quartile 1 (Q1), median, quartile 3 (Q3), and maximum (max). Dashed lines represent pairwise comparisons that were significantly different ($p < 0.05$).

Speech-in-Noise Benefit

Average speech-in-noise benefit on the QuickSIN ranged between -0.8 and 1.1, with a mean and median of 0.4 and 0, respectively. The average speech-in-noise benefit for the DIN ranged between -0.2 and 2.4, with a mean and median of 0.5 and 0.2, respectively. Speech-in-noise benefit was not significantly different between OTC-SF hearing aids.

DISCUSSION

The usability and performance across the six FDA-approved OTC-SF hearing aids demonstrated similar general trends, including aspects like post-use usability (i.e., PSSUQ) and speech-in-noise benefit (i.e., QuickSIN). However, differences were evident for certain measures, like fitting time, hearing aid skills and knowledge, and sound quality, including overall impression and clarity.

Overall, the post-use usability scores on the PSSUQ were similar across devices and better than the means determined by Sauro & Lewis[22] from 21 different studies. This suggests that OTC-SF hearing aids were generally found to be user-friendly. Lexie Lumen consistently demonstrated higher scores on the overall PSSUQ and all the sub-scales, potentially due to clear app-based instructions and demonstrational videos that support usability, similar to findings by Convery et al[23]. Device fitting time, however, varied among different OTC-SF hearing aids, and Lexie Lumen required the longest initial setup time. This may be partly due to some users who struggled to measure and select the right size slim tubes before learning to insert them. These differences in fitting time may have implications for user satisfaction and convenience, although not observed in the current study. Users who prioritize a comprehensive introduction to OTC-SF hearing aids and precise adjustments may prefer devices like Lexie Lumen. At the same time, those who value a faster fitting process may opt

for other OTC-SF hearing aids with shorter duration fittings. Ultimately, the user's preference should be considered alongside other usability and performance measures.

The study also highlighted differences in hearing aid skills and knowledge across different devices, potentially linked to the effectiveness of user instructions provided within the associated apps of these OTC-SF hearing aids. Most users appreciated the clear instructions the accompanying smartphone applications provided, as evident from the thematic analysis. Incorporating strategies, such as using larger fonts, pictogram illustrations or videos, and using everyday language, may aid users in self-fitting and managing their hearing aids (Convery, Keidser, Hartley, et al[24]). The app design and access to clear and comprehensive user instructions can significantly impact users' ability to self-fit and manage their hearing aids, which is important for successful benefit and satisfaction outcomes (Saunders et al[25]). Better hearing aid handling can increase hearing aid use and improve user satisfaction (Mothemela et al[26]). Overall, it is noteworthy that the quality and suitability of hearing health information are important to improve the adoption, use, benefit, and satisfaction of hearing devices (Manchaiah et al[27]).

In the open-ended responses, participants generally reported ease in self-fitting for most OTC-SF hearing aids, except for Sony CRE-C10. The researcher documented several challenges faced by the participants when self-fitting the Sony CRE-C10 hearing aids. Firstly, some participants had trouble inserting the batteries and distinguishing between the left and right markers since they were very small. Secondly, many participants attempted to close both battery doors simultaneously before connecting the hearing aids, which caused connection failures as the devices could only connect one at a time. Thirdly, one participant could not complete the fitting process for the Sony CRE-C10 hearing aids as the Sony

Hearing Control app indicated that their hearing loss was too severe for the hearing aids to be effective based on the in-situ hearing test. Lastly, as with the other In-The-Ear (ITE) devices (i.e., Sony CRE-C10, Jabra Enhance Plus, HP Hearing PRO), participants raised concerns about hearing one's voice, echoing sounds and feedback. This information underscores the importance of form factors, device design, and user interface, which can significantly impact the overall user experience. Individuals who are looking for more situational use may prefer this form factor, whereas those who like to use their devices all day long may prefer BTE styles, although this needs to be investigated in further studies.

Similar to Convery et al[23], not all participants were able to perform the self-fitting independently, as some required assistance from the researcher or family members during the self-fit process. The need for assistance with Bluetooth connectivity for most OTC-SF hearing aids suggests that improvements may be necessary in terms of user-friendly Bluetooth pairing and connectivity. These findings highlight that despite the generally user-friendly nature of OTC-SF hearing aids, some individuals might still require assistance during the self-fitting process. OTC users need to recognize the potential need for assistance, perhaps involving their significant others in the self-fitting process. Audiological rehabilitation models recommend the involvement of significant others in the rehabilitation process, as it can significantly improve benefit and satisfaction outcomes (Hickson et al[28]; Manchaiah et al[29]). Moreover, hearing healthcare professionals can also offer valuable support services to some individuals utilizing OTC-SF hearing aids who still require additional support, ensuring a smoother self-fitting process and usage experience.

In terms of performance, behavioral outcomes such as speech-in-noise benefit were similar across devices. Device sound quality ratings, however, varied significantly among different

OTC-SF hearing aids, suggesting that some OTC-SF hearing aids may provide a more satisfactory listening experience regarding overall sound quality and clarity. For users, this may influence their perception of the effectiveness of the OTC-SF hearing aids and their overall satisfaction (Mothemela et al[26]). In line with Manchaiah et al[6], our study showed that higher-priced devices, like Lexie B2 or Sony CRE-C10, might provide better sound quality compared to lower-priced devices, like HP Hearing PRO (Table 1). However, such benefits were not replicated in behavioral measures of speech-in-noise. Users may consider sound quality as an important factor when selecting OTC-SF hearing aids while hearing healthcare providers can use this information to guide users toward options aligning with their expectations and preferences. These results suggest the need for consumer-centric metrics of audio performance that can aid consumers in decision-making while evaluating OTC hearing aids for purchase.

Study Limitations and Future Directions

This is the first study to examine the usability and performance of OTC-SF devices that are currently in the market using a structured way of providing timely knowledge. However, the study has a few limitations. The study was limited to six OTC-SF hearing aids. This selection might not encompass the entire spectrum of available OTC-SF devices rapidly entering the market. Moreover, very little is known about the OTC-PS devices, which potentially limits broader generalizability. We recruited 43 participants with self-perceived mild-to-moderate hearing difficulties and good English proficiency. This specific demographic might not represent the entire population that could benefit from OTC-SF hearing aids. Conducting the study in a controlled environment where users were observed might have influenced their behavior and responses. Participants might have been more attentive or felt pressured to perform better than they would in their typical day-to-day settings. This controlled

environment might not fully replicate real-world conditions where various distractions and environmental factors could impact the usability and performance of OTC-SF hearing aids differently. Speech-in-noise tests were not counterbalanced between aided and unaided conditions. The selective inclusion of HASK items offers a focused evaluation aligned with the study objectives but may compromise construct validity and potentially introduce bias, which should be considered in interpreting the scale results. The comparisons were, however, within subjects and between devices, which mitigates potential bias effects.

In future research, longitudinal studies to evaluate the performance and usability of OTC-SF hearing aids over extended periods would provide valuable insights into long-term effectiveness and user satisfaction. Furthermore, investigating individuals' decision-making process when selecting OTC-SF devices would offer useful information about user preferences and factors influencing their choices. It would also be beneficial to investigate whether previous hearing aid use affects the usability and performance of OTC devices, which could provide essential insights into potential differences in user experience.

Investigating the level of assistance needed during self-fitting and its potential impact on user experience could provide valuable insights for family members or healthcare professionals, helping them better support OTC-SF users in optimizing their hearing aid experience. Incorporating assessments of vision and dexterity could enhance our understanding of how these factors influence the usability and performance of OTC devices, thereby contributing to more comprehensive user-centric evaluations. Moreover, exploring the usability, performance, benefit, and satisfaction outcomes of OTC-PS hearing aids can help improve our understanding of the benefits and limitations of pre-set OTC hearing aids. Finally,

researchers could compare the benefit and satisfaction outcomes of different OTC-SF hearing aids to determine their effectiveness.

CONCLUSION

This study demonstrated similar usability and performance across multiple OTC-SF hearing aids, except for a few dimensions, including device fitting time, hearing aid skills and knowledge, and sound quality regarding overall impression and clarity. These areas of differences may be important for users, providing valuable insights into the trade-offs associated with different devices. Qualitative feedback from participants using the ITE designs emphasizes the need for further refinement in acoustics and fitting techniques to mitigate challenges related to self-perception of sound. Furthermore, improvements may be necessary regarding user-friendly Bluetooth pairing and connectivity. The design and user interface of OTC-SF hearing aids play an important role in the user experience, and further improvements in these areas, such as clear and comprehensive instructions, may enhance overall usability and satisfaction. These findings can support consumers and hearing healthcare professionals in making informed decisions and recommendations regarding OTC-SF hearing aids. Further research is needed to explore the device selection process, long-term usability, and satisfaction with OTC hearing aids, including the OTC-PS hearing aids.

DATA AVAILABILITY STATEMENT

The datasets generated and/or analyzed for the current study are available from the corresponding author upon reasonable request.

CONFLICT OF INTEREST

DWS is the co-founder, director, and scientific advisor for hearX SA (Pty) Ltd. VM serves as the scientific advisor for hearX SA (Pty) Ltd.

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