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Direct-to-Consumer Hearing Devices: Capabilities, Costs, and Cosmetics

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Abstract

Direct-to-consumer (DTC) hearing devices can be purchased without consulting a hearing health professional. This project aims to compare 28 DTC devices with the most popular hearing aid supplied by the U.K. National Health Service (NHS). The comparison was based on technical performance, cosmetic acceptability, and the ability to match commonly used gain and slope targets. Electroacoustic performance was evaluated in a 2-cc coupler. Match to prescription target for both gain and slope was measured on a Knowles Electronic Manikin for Acoustic Research using a mild and also a moderate sloping hearing loss. Using an online blinded paired comparison of each DTC and the NHS reference device, 126 participants (50 were hearing aid users and 76 were nonhearing aid users) assessed the cosmetic appearance and rated their willingness-to-wear the DTC devices. The results revealed that higher purchase prices were generally associated with a better match to prescribed gain–frequency response shapes, lower distortion, wider bandwidth, better cosmetic acceptability, and higher willingness-to-wear. On every parameter measured, there were devices that performed worse than the NHS device. Most of the devices were rated lower in terms of aesthetic design than the NHS device and provided gain–frequency responses and maximum output levels that were markedly different from those prescribed for commonly encountered audiograms. Because of the absence or inflexibility of most of the devices, they have the potential to deliver poor sound quality and uncomfortably loud sounds. The challenge for manufacturers is to develop low-cost products with cosmetic appeal and appropriate electroacoustic characteristics.

Keywords

hearing aids, personal sound amplification products, gain, slope, direct-to-consumer

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Introduction

Hearing impairment is the most common sensory deficit affecting more than 466 million people around the world, and by 2050, this number is expected to increase to 900 million (Mathers, Smith, & Concha, 2003; World Health Organization, 2018).

Hearing aids are the primary intervention for permanent hearing loss (Kochkin, 2009). In many countries, the provision of such devices requires a licensed audiologist or hearing aid dispenser for both programing and fitting. Hearing aids have been successful in improving wearers' overall quality of life (Ferguson et al., 2017). However, despite the ability of hearing aids to overcome some of the detrimental effects of hearing loss, only 4% to 33% of individuals with hearing loss actually use them (Bainbridge & Ramachandran, 2014; Chien & Lin, 2012; Dawes et al., 2014). In addition, it takes 10 years, on average, for people with hearing loss to seek help (Davis, Smith, Ferguson, Stephens, & Gianopoulos, 2007). The low and slow adoption rate, and variable outcomes, can be attributed to a range of factors including

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psychosocial aspects, financial constraints, lack of need, and stigma associated with hearing aids (Knudsen, Oberg, Nielsen, Naylor, & Kramer, 2010).

Hearing aids that can be purchased online or through retailers, known as Direct-to-consumer (DTC) hearing devices, are ready to be used upon purchase or can be self-fitted at home. These types of hearing devices have been increasingly viewed as an alternative to the current clinical service delivery model. It has been speculated that they might improve hearing aid uptake because they are relatively affordable and do not require a visit to a clinician for fitting. Indeed, the United States has enacted a law (the Food and Drug Administration Reauthorization Act of 2017), which authorized the Food and Drug Administration to initiate a new classification for DTC hearing aids aimed at increasing the availability and the affordability of hearing aids. Shortly afterward, the American Hearing Care Associations (AHCA; 2018) released a consensus paper entitled, "Regulatory Recommendations for Over-The-Counter Hearing Aids: Safety and Effectiveness." This consensus paper outlined several evidence-based recommendations for the DTC hearing devices in order to protect the public from the potential drawbacks of using hearing devices not prescribed by a health-care professional. For instance, they recommended that the 2-cc coupler maximum output sound pressure level, with an input of 90 dB SPL, and high-frequency average full-on gain should not exceed 110 dB SPL and 25 dB, respectively, for moderate hearing loss and 105 dB SPL and 19 dB for mild hearing loss.

Previous peer-reviewed studies have examined a small sample of DTC devices in terms of their electroacoustic characteristics and also their ability to meet the prescribed gain targets (e.g., Callaway & Punch, 2008; Chan &McPherson, 2015; Cheng & McPherson, 2000; Reed, Betz, Lin, & Mamo, 2017). Cheng and McPherson (2000) examined 10 DTC devices in term of electroacoustic performance and their ability to provide low-distortion amplification for prescribed gain targets for a sloping hearing loss, typical of age-related hearing loss. The authors concluded that the examined devices were inappropriate for this purpose because most of them had high distortion and were unable to match the prescribed gain target. Callaway and Punch (2008) evaluated 11 DTC devices and reported that the cheaper DTC devices had a quality control issue (i.e., not functioning), narrow frequency bandwidth, high internal noise, and excessively amplified low-frequency sounds. In addition, they were, to a large extent, unable to meet National Acoustic Laboratory (NAL)-Revised prescription gain targets (Byrne & Dillon, 1986). In contrast, the higher priced DTC devices tended to give better electroacoustic performance and were more likely to meet the prescribed gain target for moderate and flat hearing losses. Chan and McPherson (2015) evaluated 10 DTC hearing devices and concluded that they had poor electroacoustic performance and the majority were unable to match the prescribed gain target for a sloping mild hearing loss. More recently, Reed, Betz, Lin, et al. (2017) examined 10 DTC devices in terms of their electroacoustic performance and ability to match the NAL-NL2 prescription gain target (Keidser, Dillon, Flax, Ching, & Brewer, 2011) for a variety of common audiometric configurations. The results revealed that 50% of devices had acceptable electroacoustic performance and 90% were within $\pm$10 dB of the prescribed gain targets. The authors concluded that, despite the large variation between DTC devices, some were able to match the prescribed gain targets for people with mild or moderate hearing loss. Most of the previous studies on DTC devices have examined the ability to meet prescribed gain but not slope. Deviation from the target slope (i.e., tilting the frequency response upward or downward) may degrade the sound quality. Moore and Tan (2003) found that, when spectral tilting was applied to both speech and music signals, the perceived naturalness of both signals was degraded with increasing tilt. Although their results were from normal hearing listeners, Tan and Moore (2008) found that the pattern of sound quality rating was quite consistent between listeners with and without hearing loss.

Several studies have investigated specific DTC devices in terms of speech perception, self-reported benefit, and satisfaction (e.g., Keidser & Convery, 2018; McPherson & Wong, 2005; Reed, Betz, Kendig, Korczak, & Lin, 2017; Sacco et al., 2016). McPherson and Wong (2005) used a variety of self-reported benefit and open-ended interviews to evaluate the effectiveness of a single DTC hearing device, a ReSound Avance HE4, which was fitted to adults with mild-to-moderate hearing loss. The authors found that the outcomes of the DTC device were similar to those obtained in another normative study where participants utilized conventional hearing aids (Cox, Alexander, & Beyer, 2003). In spite of the reported benefits and positive comments of wearing the DTC device, most participants complained about acoustic feedback and bothersome ambient noises. Sacco et al. (2016) reported improvements in aided speech recognition and self-report benefit in adults fitted with a DTC device (TEO First). However, the post-use acceptability rating was relatively low. Reed, Betz, Kendig, et al. (2017) found that the aided speech-in-noise performance obtained with four of five tested DTC devices was within 5% of that achieved with the conventional hearing aid among new hearing aid users. For the remaining DTC device, the average unaided speech recognition score was higher than that of the aided score, meaning that this device had a detrimental effect on hearing. More recently, Keidser and Convery (2018) evaluated aided speech recognition in noise as well as self-reported benefits and satisfaction with one DTC device, the Companion by Sound World Solutions. They found that there is no significant difference between the speech recognition scores obtained by a conventional hearing aid and this DTC device. However, the DTC device was rated significantly lower than a conventionally fitted hearing aid on some subscales related to the tolerance of aversive sounds and the physical appearance. Although the majority of the previous studies used unblinded designs and were limited to short-term outcomes, most of them showed that the DTC devices could provide outcomes similar to those of traditional hearing aids (Tran & Manchaiah, 2018).

The standard hearing aid delivery model (i.e., the audiologist fits the hearing aid to match the prescribed target using real ear measurements) has been widely known as the audiological best practice because the output of the hearing aid is verified in situ at the tympanic membrane and with consideration of the effects of the head-related transfer function. Indeed, this method of hearing aid delivery has been endorsed by American Speech-Language-Hearing Association (ASHA Ad Hoc Committee on Hearing Aid Selection and Fitting, 1998) and British Society of Audiology (BSA; 2018). The new DTC model (i.e., preprogrammed hearing aids using typical audiograms without real ear measures or audiological intervention) has been presented as a potential way to increase the accessibility and affordability of hearing aids and enable the utilization of time saved to address more advanced cases of hearing loss. Humes et al. (2017) conducted a 6-week randomized placebo-controlled trial to evaluate the efficacy of the DTC delivery model. The authors found that the standard model and DTC model were both efficacious and had a similar effect. Indeed, the two models were comparable on the majority of the outcome measures.

In summary, previous studies that have examined the outcomes of DTC devices have raised concerns in terms of quality control and satisfaction with their sound quality and cosmetic appearance. Indeed, little information has been published about these aspects of DTC devices.

The main aims of this study were to compare a large sample of DTC devices, currently available over the Internet within the U.K. market, with the hearing aid most commonly fitted in the U.K. National Health Service (NHS), which is free at point-of-delivery and is the main route for obtaining hearing aids within the United Kingdom. The comparison was made based on: (a) electroacoustic performance, (b) the ability to match commonly used gain *and* slope targets, and (c) cosmetic appearance and willingness-to-wear. While addressing these aims, this study surveyed the participants' preferred method of obtaining a hearing aid, and compared, for the first time, electroacoustic performance with the recent recommendations of the AHCA for DTC devices.

Methods

Hearing Devices

Twenty-eight DTC devices were included in this study. The inclusion criteria were as follows: (a) available for purchase online at a cost of less than £400 each and (b) marketed as hearing devices (or able to function as a hearing device). The reference device was the Oticon Spirit Zest (Smørum, Denmark), the most commonly fitted NHS hearing aid at the time the study was completed (Summer 2018). This hearing aid is an eight-channel programmable thin-tube-delivery behind the ear (BTE) device most commonly used with an open dome. The output can be modified at eight frequencies from 0.25 to 6 kHz. Listening checks were carried out on every device. Two devices were faulty and excluded from all measurements, except cosmetic evaluation.

The characteristics of the devices were compared in terms of cost per unit, style, on-off switch, volume control, volume control range, number of programs, directional microphone, streaming capability, smartphone customizer, user manual, battery size, and duration of the warranty (detailed in Table 1).

Electroacoustic Coupler Performance

The electroacoustic characteristics of the devices were performed in accordance with British Standards Institution and European Standard (BS EN 60118-0:2015). The electroacoustic measurements included (a) input–output curve; (b) maximum output sound pressure level with an input level of 90 dB (OSPL90); (c) peak frequency with an input of 90 dB SPL; (d) frequency bandwidth; (e) high-frequency average full-on gain (HFA FOG); (f) total harmonic distortion (THD) at 0.5, 0.8, and 1.6 kHz; and (g) equivalent input noise (EIN). The default program of each device was used when making these measurements. Adaptive features, such as noise cancellation, were disabled whenever possible. Fourteen DTC devices had multiple programs, typically containing low-frequency or high-frequency cuts. The electroacoustic characteristics of only the default program are therefore reported in this article. New batteries were inserted prior to electroacoustic measurements or, for rechargeable devices, the batteries were fully charged before any tests commenced.

The electroacoustic characteristics of the selected devices were measured by an audiologist using a calibrated test chamber (Aurical HIT chamber; Otometrics). Behind-the-ear hearing devices were coupled to an HA2 2 cc coupler; all other hearing

Table 1. Characteristics of the DTC Devices.

	Model name	Manufacturer	Cost per unit (£)	Hearing aid style	On/off switch	Volume control/ range	Number of programmes	Processor	User manual	Battery size	Microphone type	Streaming capability	Noise/ speech processing	Smartphone Customizer	Package includes	Warranty
1	Mini In-Ear Sound Amplifier	Unknown	7.70	RIC	Yes	Yes/no marking	1	Linear	Yes	AG 13/LR44H	OD	No	No	No	3 dome sizes	No information
2	Personal Mini Sound Amplifier	PMS	7.99	RIC	Yes	Yes/no marking	1	Linear	Yes	AG 13/LR44H	OD	No	No	No	3 dome sizes	No information
3	BTE Sound Amplifier	MEDca	8.99	RIC	Yes	Yes/no marking	NT	Nonfunctional	Yes	AG 13/LR44H	NT	NT	NT	No	3 dome sizes	No information
4	8397 Micro Plus	Bell & Howell	9.11	Bluetooth headset	Yes	Yes/no marking	1	Linear	Yes	AG 3/ LR 41	OD	No	No	No	3 dome sizes	90 Days
5	Silver Sonic XL Personal Sound Amplifier	JML	12.95	Bluetooth headset	Yes	Yes/no marking	2	Linear	Yes	AG 13/LR44H	OD	No	No	No	3 dome sizes	1 Year
6	Mini Ear Amplifying Aid FK-162	Global Care Market	12.96	RIC	Yes	Yes/1–5	1	Linear	Yes	AG 13/LR44H	OD	No	No	No	2 dome sizes	No information
7	HA 20	Beurer	19.00	RIC	Yes	Yes/1–4	1	Linear	Yes	AG 5/LR754	OD	No	No	No	3 dome sizes	3 Years
8	In the Ear Hearing Amplifier	GPFATTRY	21.19	ITE	No	Yes/no marking	1	Linear	Yes	A 10	OD	No	No	No	3 dome sizes	1 Year
9	AXON Hearing Aid rechargeable	Enshey	21.99	ITE	Yes	Yes/no marking	1	Nonlinear	Yes	Rechargeable	OD	No	No	No	4 dome sizes	No information
10	Digital Hearing Amplifier VHP-202 S	SGDOLL	24.99	RIC	Yes	Yes/no marking	2	Linear	Yes (NIE)	Rechargeable	OD	No	No	No	4 dome sizes/ cleaning brush/ charger	No information
11	Rechargeable Ear Hearing Amplifier ZDB-100 A	MEDca	27.99	RIC	Yes	Yes/1–4	1	Linear	Yes	Rechargeable	OD	No	No	No	6 dome sizes/ cleaning brush/ charger	No information
12	Hearing Amplifier	Lifemax	28.15	RIC	Yes	Yes/1–4	NT	Nonfunctional	Yes	Rechargeable	NT	NT	NT	No	3 dome sizes/ cleaning brush/ charger	No information
13	Micro Plus ITE Hearing Amplifier	Unknown	29.95	Bluetooth headset	No	Yes/no marking	1	Linear	Yes	AG 3/ LR 41	OD	No	No	No	3 dome sizes	No information
14	HA 50	Beurer	29.99	RIC	Yes	Yes/1–4	1	Nonlinear	Yes	AG 5/LR754	OD	No	No	No	3 dome sizes	No information
15	ITE voice amplifier ZDC-901 A	G&M	39.00	ITE	No	Yes/no marking	1	Linear	Yes (NIE)	A 10	OD	No	No	No	7 dome sizes/ cleaning brush/ screwdriver	No information
16	Digital Hearing Amplifier VHP-221 T	SGDOLL	49.99	RIC	Yes	Yes/1–8	2	Nonlinear	Yes (NIE)	Rechargeable	OD	No	No	No	4 dome sizes/ cleaning brush	No information
17	BTE Amplifier V-185	Q&Y	77.00	RIC	Yes	Yes/1–4	2	Linear	Yes (NIE)	675	OD	No	No	No	3 dome sizes/ cleaning brush	No information

(continued)

Table 1. Continued

	Model name	Manufacturer	Cost per unit (£)	Hearing aid style	On/off switch	Volume control/ range	Number of programmes	Processor	User manual	Battery size	Microphone type	Streaming capability	Noise/ speech processing	Smartphone Customizer	Package includes	Warranty
18	Digital Personal Audio Amplifier C-125	XUAN	78.78	BTE	Yes	Yes/1–4	2	Linear	Yes (NIE)	Rechargeable	OD	No	No	No	6 dome sizes/ charger	No information
19	In Ear Mini	FIIL	109.00	ITE	No	Yes/no marking	1	Linear	Yes	A 10	OD	No	No	No	3 dome sizes	1 Year
20	IQ Buds	NuHeara	127.49	Bluetooth headset	Yes	Yes/no marking	7	Linear	Yes	Rechargeable	OD	Bluetooth	Yes	Yes	16 dome sizes/ charging case	1 Year
21	BLJ-BS05R Mini RIC	Banglijian	149.99	RIC	No	Yes/ 1–10	4	Nonlinear	Yes	312	OD	No	Yes	No	12 dome sizes/ cleaning brush	No information
22	VA-3000	Esonic	160.00	Bluetooth headset	Yes	Yes/1–10	4	Nonlinear	Yes	Rechargeable	OD	No	No	No	2 dome sizes/ charger/ headphones	1 Year
23	RPSA05 Symphonix	RCA	197.02	Thin tube BTE/BTE	No	No	3	Nonlinear	Yes	312	OD	No	No	No	2 dome sizes	2 Years
24	G2090 Hearing Amplifier	FIIL	199.00	Thin tube BTE	No	Yes/1–9	4	Nonlinear	Yes	312	OD	No	No	No	3 dome sizes/ cleaning brush	1 Year
25	821 Receiver In The Canal Hearing Amplifier	AcoSound	219.00	RIC	No	Yes/no marking	4	Nonlinear	Yes	312	OD	No	Yes	No	5 dome sizes/ cleaning brush	2 Years
26	CS50+ Personal Sound Amplifier	Sound world solution	262.17	Bluetooth headset	No	Yes/1–8	3	Nonlinear	Yes	Rechargeable	AD with DM	Bluetooth	Yes	Yes	3 dome sizes/ charger/extra battery/ cleaning kit	90 Days
27	Companion Hearing Aid	Sound world solution	337.29	RIC	Yes	Yes/1–8	3	Nonlinear	Yes	Rechargeable	AD with DM	Bluetooth	Yes	Yes	3 dome sizes/ charger/ cleaning tool	1 Year
28	Super Mini VHP-902	MEYLEE	355.08	Thin tube BTE	No	Yes/1–8	2	Nonlinear	Yes (NIE)	13	OD	No	No	No	7 dome sizes	No information

Note. RIC = receiver in the canal; ITE = In the ear; BTE = behind the ear; NT = not tested; OD = omnidirectional; NIE = not in English; AD with DM = advertised with directional microphone; DTC = direct-to-consumer.

device styles were coupled to an HA1 coupler. All electroacoustic measurements were repeated after the devices were removed from and replaced in the coupler. The first measurement was used whenever the retest was within the preset tolerance values (±3 dB for gain/output and EIN; ±0.5 kHz for peak frequency and frequency bandwidth; and, 3% for THD). More attempts were performed whenever the retest measurements exceeded the tolerance values, which was the case with ⩽4% of the measurements. The measurements took place in a sound-treated cubicle with ambient conditions within the recommended ranges according to British Standards and European standards (BS EN 60118-0:2015). The collected data of the hearing devices along with the NHS hearing aid were reported and plotted against their price. The price of the NHS hearing aid was estimated to be £300, and this price includes the additional costs for the required services (i.e., assessment and fitting).

Matching to the Prescribed Target

The ability to match the NAL-NL2 (Keidser et al., 2011) prescription targets, with the device fitted to a Knowles Electronic Manikin for Acoustic Research (G.R.A.S. Sound and Vibration) containing a Zwislocki acoustic coupler, was carried out using a calibrated clinical probe-tube microphone system (Aurical Freefit, Otometrics) for each of two audiograms, N2 and N3 (Bisgaard, Vlaming, & Dahlquist, 2010). The hearing thresholds of these audiograms are shown in Figure 1 and they were chosen because N3 (moderate high-frequency hearing loss) is typical of current new hearing aid users and N2 (mild high-frequency hearing loss) is potentially representative of individuals with less hearing loss who may be attracted to a DTC device. The fitting parameters used to generate the NAL-NL2 targets were real ear insertion gain, measured real ear unaided response, bilateral amplification, nontonal language, adult, male, headphone transducer for hearing thresholds, and new user.

To perform these measures, the Knowles Electronic Manikin for Acoustic Research was placed at 0° azimuth; on the same horizontal level and 0.6 m from the Aurical loudspeaker. The real ear unaided gain (the difference between the reference and the probe tube microphones in the open ear canal) was measured with a pink noise at 65 dB SPL, following the insertion of a 1.1 mm probe tube into the unoccluded left ear canal. The DTC

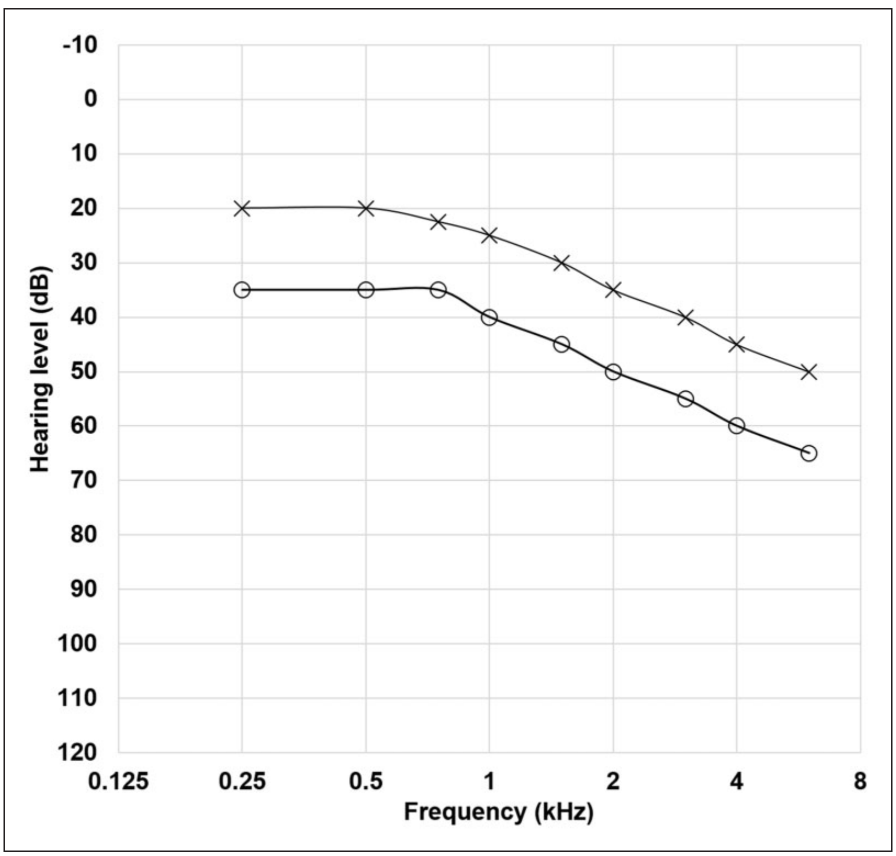

Figure 1. The two standard audiometric configurations used. The crosses represent the audiometric configurations for the mild audiogram (N2), and the circles represent the audiometric configuration for the moderate audiogram (N3; Bisgaard, Vlaming, & Dahlquist, 2010).

devices were then inserted while the probe tube remained in the same position. The real ear aided gain (REAG; the difference between the reference and the probe microphones with the hearing device in place and turned on) was measured using the International Speech Test Signal (Holube, Fredelake, Vlaming, & Kollmeier, 2010) at an input of 65 dB SPL. The system automatically calculated the real ear insertion gain (REIG; the difference between the aided and unaided gains). Using a measurement procedure analogous to that for REAG, the real ear saturation response (RESR; the measured sound pressure level in-situ with a sufficiently high input level) was measured using a swept warble tone with an input of 85 dB SPL. To measure the REAG and RESR for the DTC devices with open domes, the reference microphone was deactivated and the modified pressure stored-equalization method was used. The volume control was set so that the obtained and prescribed gains were equal when averaged across the frequency range from 0.25 to 6.3 kHz. The data were collected primarily by an audiologist and repeated for five devices by a second audiologist to estimate the repeatability of the measurements obtained. The root-mean-square (rms) value of the deviations from the prescribed target for each device, from 0.25 to 6.3 kHz inclusive, was calculated and reported for both audiograms and input levels.

Physical Appearance Rating

An online survey was designed to determine the participants' aesthetic evaluation of, and willingness-to-wear, the DTC devices, when compared with the reference NHS hearing aid. This part of the project (involving participants) was approved by the University of Manchester's Division of Human Communication, Development, and Hearing Ethics Review Panel (reference number: 2018-4855-6791).

The survey link was e-mailed to staff and students at the University of Manchester and members on an audiology research volunteer database. Advertising posters were also placed around the university. Before completing the comparison of aesthetic evaluation, the participants were asked to provide their gender and answer two questions: (a) Do you wear, or have you ever worn, a hearing aid? and (b) What is your preferred method if you need to obtain a hearing aid in the future (via a health-care professional or online)? One hundred and twenty-six people completed the survey. Of those who completed the survey, 50 were hearing aid users (20 males and 30 females) and 76 were nonhearing aid users (28 males, 47 females, and 1 other).

To examine the cosmetic appearance of the DTC devices, one male and one female member of staff were photographed wearing each device. The photographs were taken in a professional photographic studio. Each hearing device was photographed from two different angles (level with the ear at azimuths of 45° and 90° from the front). The four photos of each hearing device (two males and two females, each at two angles) were presented in a panel. Each panel with a DTC device was placed beside a panel with the reference NHS hearing aid, forming 28 paired comparisons (Figure 2). In addition, the panel of the NHS hearing aid was placed beside an identical panel of the same aid to measure the willingness-to-wear of the NHS hearing aid. Five out of the 28 paired comparisons were repeated to measure the reliability of the obtained ratings. Supplement Material 1 illustrates a sample of the DTC devices and the NHS hearing aid used. The participants were blinded to both the device's price and brand.

In the paired comparison tasks, the participants were asked to indicate on a 5-point Likert-type scale whether they preferred the appearance of the device in Panel A or Panel B. The paired comparison included a magnitude estimation scale (-2 = *I prefer the appearance of Panel A a lot more than Panel B*, -1 = *I prefer the appearance of Panel A a little more than Panel B*, 0 = *I have no preference*, $+1$ = *I prefer the appearance of Panel B a little more than Panel A*, and $+2$ = *I prefer the appearance of Panel B a lot more than Panel A*). Once the participants had indicated their preference, they were asked to complete another 5-point Likert-type scale regarding their willingness-to-wear the DTC device in Panel A (-2 = *not at all willing*, -1 = *not very willing*, 0 = *neutral*, $+1$ = *willing*, and $+2$ = *very willing*).

The appearance and willingness-to-wear responses were averaged and reported for each hearing device. The correlation coefficient between these two variables was calculated. In addition, the difference in aesthetic and willingness-to-wear ratings for the five repeated devices was reported in terms of the mean absolute error.

Results

Hearing Devices Characteristics

Table 1 summarizes the device characteristics. Most of the DTC devices were relatively inexpensive. Five had noise reduction algorithms, two were advertised with directional microphones, and eleven DTC devices had nonlinear processing. Bluetooth streaming capability and smartphone application customizers were incorporated into three DTC devices. The latter feature allows wearers to fine-tune their devices' output based on their listening needs; they can manipulate several parameters, such as output at different frequencies, listening programs, and the amount of noise reduction. However, they cannot change the maximum output.

Two devices in this study (MEDca BTE and Lifemax Hearing Amplifier) were excluded from all

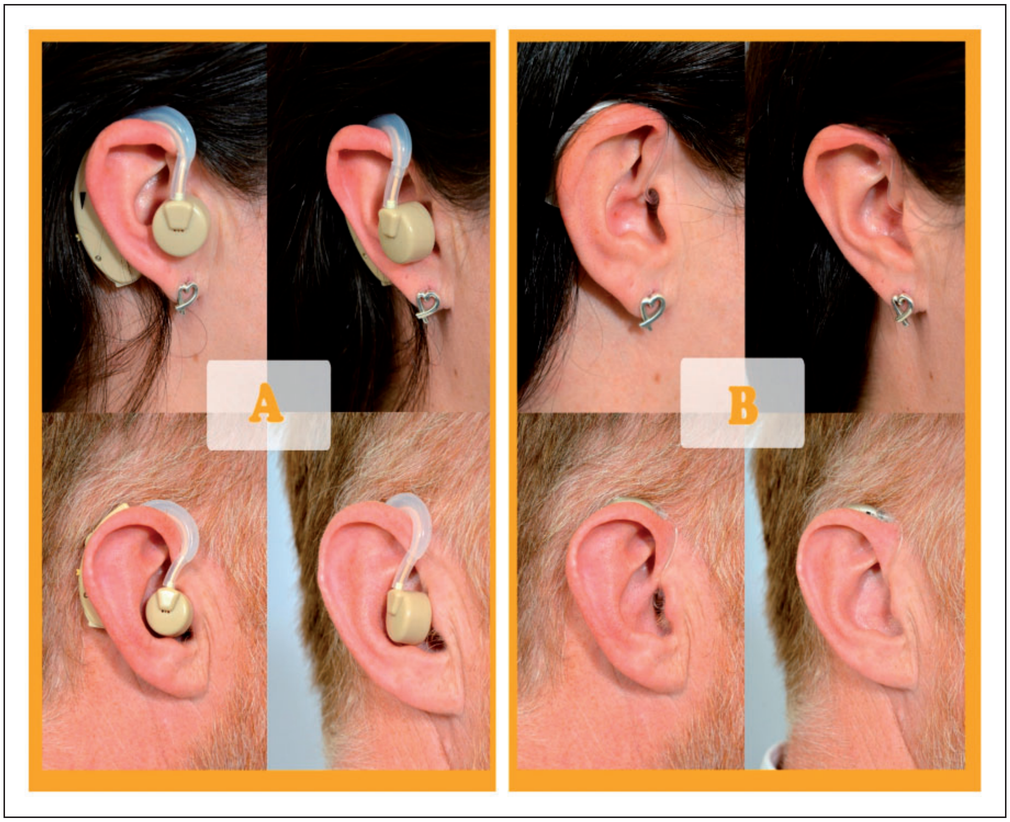

Figure 2. An example of the panels for physical appearance rating and willingness-to-wear the DTC devices. Each panel contains the same device photographed from two angles and on two ears.

measurements, except the aesthetic rating, because they were nonfunctioning. Six arrived with a user manual that was not in English, and half of the devices were received without any information about their technical specifications. Almost half of them had a poorly functioning volume control (i.e., the volume control did not move freely or it moved but changed the volume in large jumps of uneven level) and some had a malfunctioning rechargeable battery.

Electroacoustic Performance

Figure 3 summarizes the electroacoustic performance of each device as a function of their price. Half of the DTC devices had a maximum output peak that exceeded 120 dB SPL, 14 had a peak frequency that was lower than 1.4 kHz, 13 had THD that was $\geqslant$1.8% or narrow frequency bandwidth. However, other DTC devices had a THD of $\leqslant$2% and wide frequency bandwidth similar to or even wider than that of the NHS hearing aid (Supplement Material 2).

The maximum OSPL90 and HFA FOG values (along with data from published studies) are shown in Figures 4 and 5, respectively. These figures compare the aforementioned values to (a) the AHCA-recommended limits for moderate hearing loss and (b) the estimated maximum OSPL90 proposed by Dillon and Storey (1998) to avoid loudness discomfort. The data in Figures 4 and 5 revealed that the proportions of the DTC devices in this study that exceeded the AHCA-recommended limit for maximum OSPL90 and HFA FOG for moderate hearing loss were 80% and 57%, respectively. In addition, more than 95% of the devices in this study had a maximum OSPL90 that exceeded the estimated limits that are recommended by Dillon and Storey (1998) to avoid loudness discomfort for moderate hearing loss.

Matching to the Prescribed Target

The rms error of the difference between prescribed and measured REIG is shown in panels A and B of Figure 6. In general, the lower the price, the higher the rms deviation. Only three devices had an rms error that was similar to, or lower than, the NHS hearing aid. The majority had an rms deviation of $\geqslant$5 dB and the less expensive ones often exceeded 15 dB.

The rms deviation between the measured and prescribed maximum output (RESR) when the volume control was set to FOG is shown in Panel C of Figure 6. Generally, the rms error was higher for the low-cost

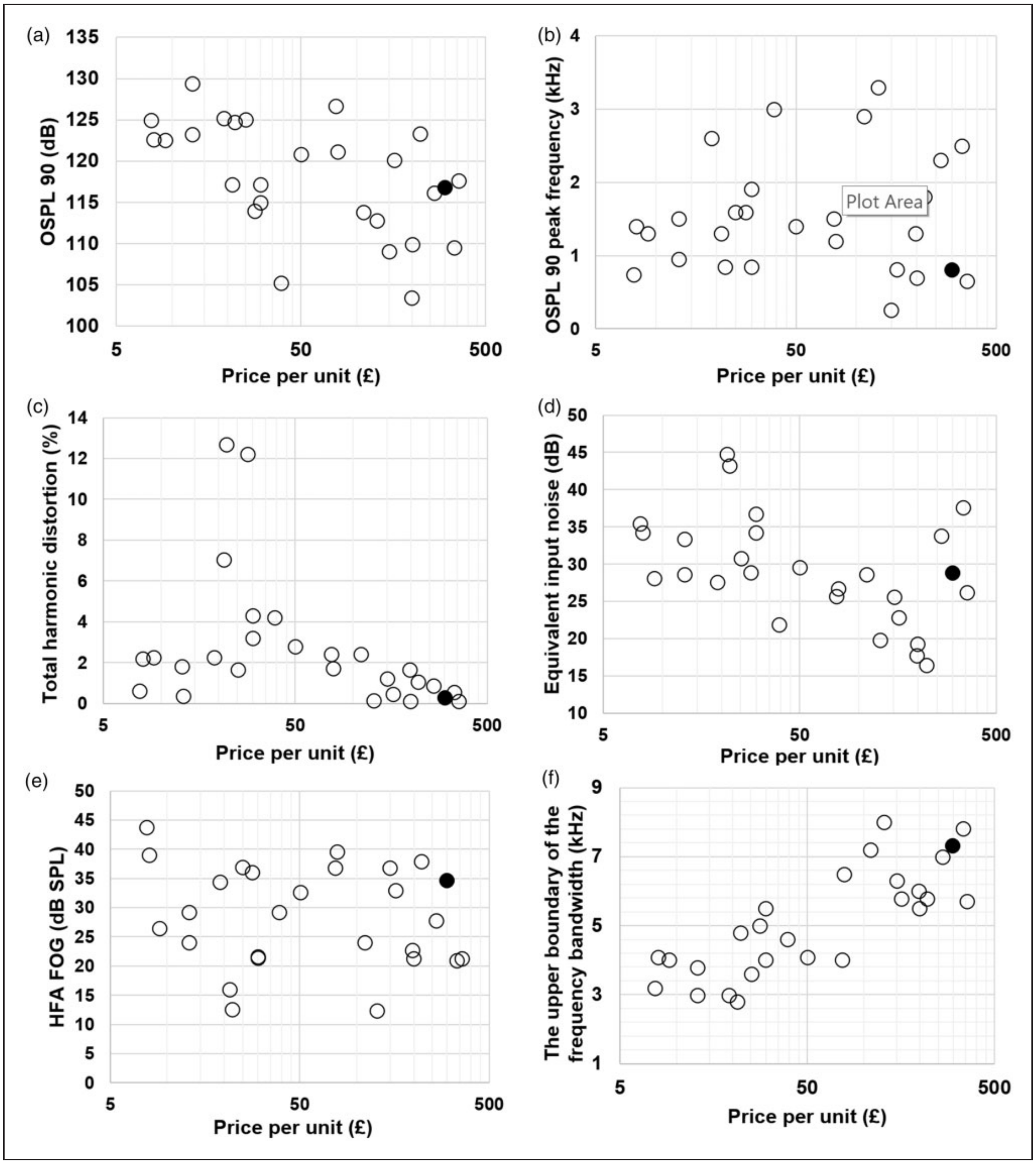

Figure 3. The electroacoustic characteristics of the hearing devices as a function of price: (a) maximum output at any frequency for an input level of 90 dB; (b) peak frequency with an input level of 90 dB SPL; (c) total harmonic distortion averaged across 0.5, 0.8, and 1.6 kHz; (d) equivalent input noise in dB; (e) high-frequency average full-on gain in a 2 cc coupler with an input of 50 dB SPL; and (f) the upper boundary of the frequency bandwidth. Note that the upper boundary of the measurement device was limited to 8 kHz. The filled marker is the most popular NHS hearing aid.

devices. Only two DTC devices had an rms deviation of $\leqslant 5$ dB. Further inspection revealed that 88% of the devices exceeded the maximum output target by $\geqslant 5$ dB in at least one frequency.

Measurements for 5 of the 26 hearing aids were repeated by a second person. Both the interrater correlation coefficient estimates and their 95% confidence intervals were calculated based on a mean rating ($k = 2$), absolute agreement, two-way mixed-effects model. An excellent degree of interrater reliability was found between the measurements. The average measure of interrater correlation coefficient was 0.98, with a 95% confidence interval from 0.93 to 0.99, $F(4, 20) = 55.56$, $p < .001$.

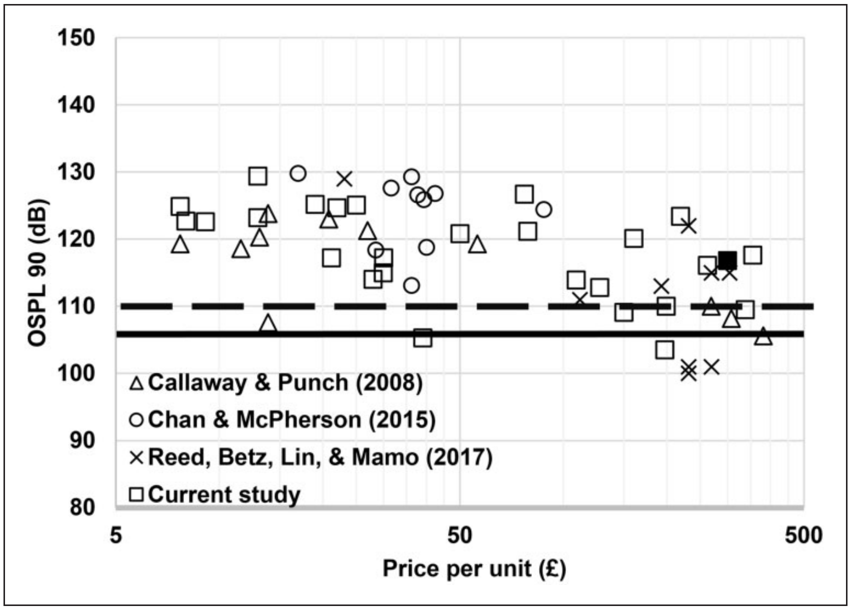

Figure 4. Measured maximum OSPL90 for DTC devices in this study (squares). The dotted line represents the AHCA's recommended limits for moderate hearing loss (AHCA, 2018). The solid line represents the estimated maximum OSPL90 to avoid loudness discomfort based on Dillon and Storey (1998) for the N3 hearing loss used in this study. Data from previous studies have been included for comparison. The triangles are the data from Callaway and Punch (2008), the circles are the data from Chan and McPherson (2015), the crosses are the data from Reed, Betz, Lin, and Mamo (2017). The filled marker represents the NHS hearing aid. Devices that were reported in more than one study are plotted only once. Costs were estimated using the USD to GBP exchange rate from 10 September 2018 of \$1.30 to £1.00.

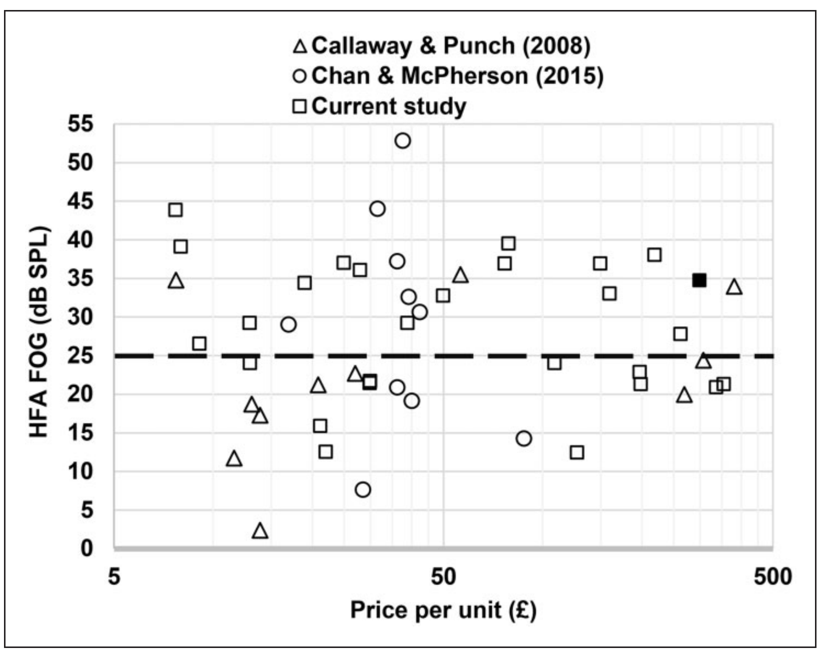

Figure 5. Measured maximum HFA FOG for DTC devices in this study (squares). The dotted line represents the AHCA's recommended limits for moderate hearing loss (AHCA, 2018). Data from previous studies have been included for comparison. The triangles are the data from Callaway and Punch (2008), the circles are the data from Chan and McPherson (2015). The filled marker represents the NHS hearing aid. Devices that were reported in more than one study are plotted only once. Costs were estimated using the USD to GBP exchange rate from 10 September 2018 of \$1.30 to £1.00. HFA FOG = high-frequency average full-on gain.

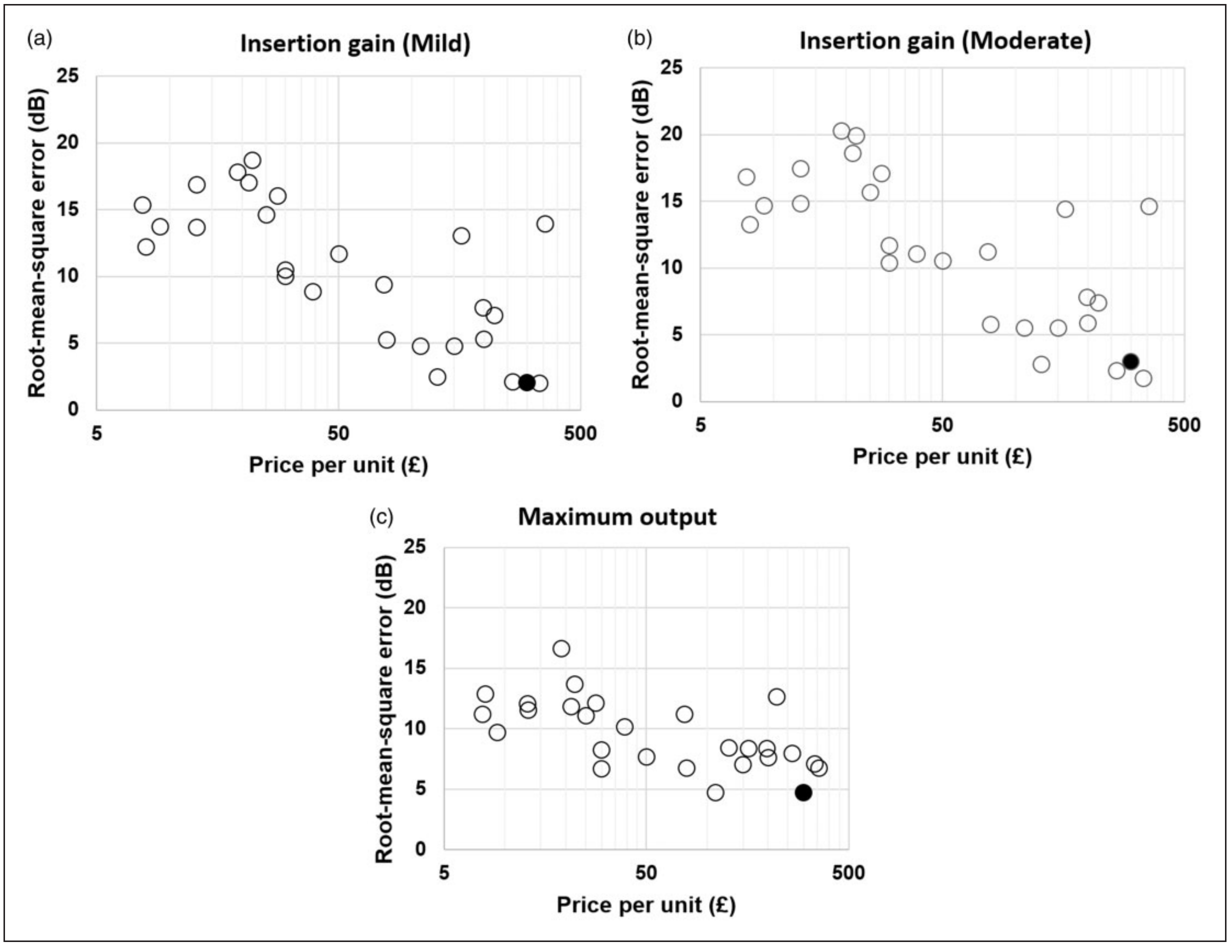

Figure 6. The root-mean-square of the difference between the NAL-NL2 insertion gain target and the measured insertion gain for an input level of 65 dB are shown in Panels A and B for mild (N2), and moderate (N3) hearing loss, respectively. The root-mean-square of the difference between measured and the prescribed NAL-NL2 85 dB SPL maximum output target while the hearing aid's volume control was set to full-on gain are shown in Panel C. The results for DTC devices are shown as open markers, and the filled marker represents the NHS hearing aid.

Compared with the NAL-NL2 targets, the gain–frequency response sloped upward too steeply within the octave band from 0.25 to 0.5 Hz. For the octaves from 1 to 2 kHz and from 2 to 4 kHz, the gain–frequency response for the majority of the devices had negative slopes (i.e., high-frequency cut), whereas the NAL-NL2 target responses required positive slopes (i.e., high-frequency emphasis). Only two of the DTC devices (both relatively expensive) alongside the NHS hearing aid were within ±5 dB of the target for all three octave bands and for both mild (N2) and moderate (N3) hearing loss (see the Supplement Material 3).

Physical Appearance Rating

The average physical appearance and willingness-to-wear ratings of the hearing aids are shown in Figure 7. The physical appearance of all DTC devices was rated lower than 0, indicating that the respondents preferred the appearance of the NHS hearing aid (thin-tube-delivery BTE) over all DTC devices. In general, the lower the price, the more aesthetically unappealing the device. A similar trend was found with the willingness-to-wear rating. There was a very strong positive correlation between ratings of physical appearance and patients' reported willingness-to-wear ($r = .96$, $p < .0001$; Supplement Material 4). As expected, the results revealed that the least visible models of DTC devices received the highest preference ratings. In terms of physical appearance and willingness-to-wear, thin-tube delivery was the preferred style for the DTC hearing devices. Indeed, participants were willing to wear only five of the DTC devices—the least visible of those tested. The mean absolute difference between the test and retest values of both

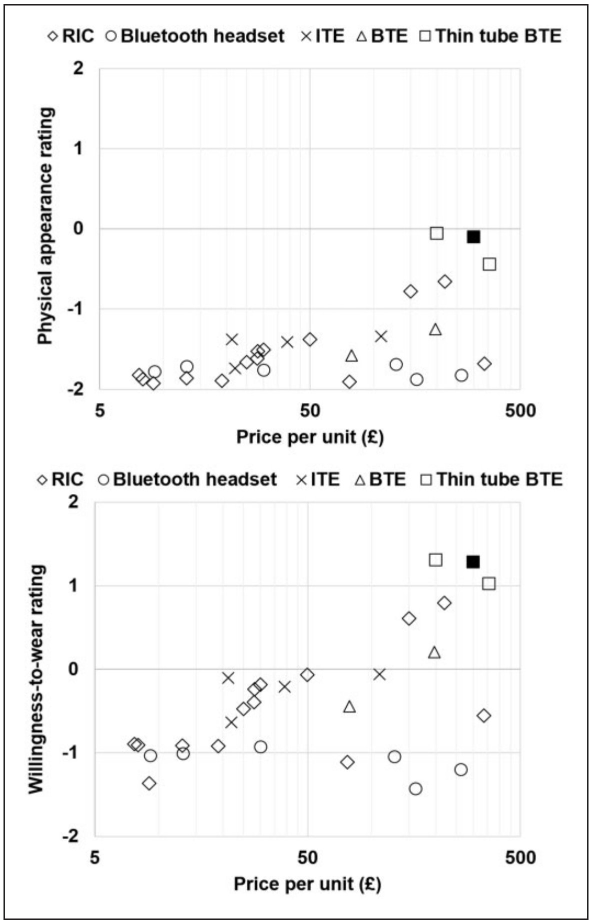

Figure 7. The average physical appearance (top panel) and willingness-to-wear (bottom panel) ratings of the hearing devices as a function of device price. For appearance, positive values represent a preference for each device compared with the reference NHS hearing aid. For willingness, positive values indicate willingness-to-wear the device. Each hearing device style is given a different marker. The filled marker represents the ratings for the NHS hearing aid. ITE = in the ear; BTE = behind the ear.

cosmetic and willingness-to-wear ratings were 0.28 and 0.75, respectively.

In terms of the respondents' preferred method for obtaining a hearing aid, almost no one had a preference for purchasing without the involvement of a health-care professional, irrespective of whether they were current hearing aid users or not (Supplement Material 5).

Overall Quality

A DTC device might have a good performance on one measure but not on another. To determine the overall quality of each device separately, the *z* scores (i.e., number of standard deviations by which a score deviated from the mean) were computed from the raw scores of each of frequency bandwidth; THD averaged across 0.5, 0.8, and 1.6 kHz; rms fitting error for the mild (N2) audiogram with an input level of 65 dB SPL; and physical appearance ratings. These were selected because they seem more likely to have an impact on the wearer's self-reported benefit and satisfaction. Table 2 details the *z* scores for each device individually. Figure 8 shows the standardized total scores for each device as a function of device price; the data show that the higher the price, the greater the total *z* scores, the higher the overall quality of the device.

Discussion

Hearing Devices Characteristics

More than 60% of devices cost less than £77, which is within the reasonable range for more than two thirds of individuals who completed a survey about DTC hearing aids in the United States (Plotnick & Dybala, 2017). Notably, the typical cost for NHS-style hearing aids in the commercial sector, including fittings, ranges from £500 to £3,500. The NHS's bulk purchasing power (buying ca 1.2 million units per year) cuts the total price of each NHS hearing aid to around £300. This includes the additional costs for assessment and fitting by a qualified audiologist, which most DTC devices do not offer.

Electroacoustic Performance

This study's first objective was to compare the electroacoustic performance of DTC devices available in the U.K. market with a current hearing aid from the NHS. In addition, the electroacoustic of the DTC devices was compared with the recent recommendations of the AHCA for DTC devices. The maximum OSPL90 for 78% of DTC devices measured in this study, and three other studies (Callaway & Punch, 2008; Chan & McPherson, 2015; Reed, Betz, Kendig, et al., 2017), as shown in Figure 4, was higher than the AHCA-proposed limits for both mild and moderate hearing loss. In addition, more than 85% of the devices that are shown in Figure 4 exceeded 106 dB SPL which is the estimated maximum OSPL90 proposed by Dillon and Storey (1998) for moderate hearing loss like the N3 profile. These DTC devices therefore have the potential to produce uncomfortably loud sounds for these degrees of loss and might therefore lead to hearing aid rejection and hearing aid-induced hearing loss (Dillon & Storey, 1998). Similarly, the measured HFA FOG of more than half of the devices evaluated in this, and two other studies, was higher than the recommended limits proposed by the AHCA for both mild and moderate hearing loss, which again might lead to loudness discomfort. Although nonlinear processors and noise reduction features can potentially minimize the adverse effects of

Table 2. Summary of z Score for Each Device.

	Device name	THD (mean of 0.5, 0.8 and 1.6 kHz)	Frequency bandwidth	Deviation (rms) from target gain, input 65 dB SPL	Physical appearance	Total z score
NHS	Oticon Spirit Zest	0.73	1.43	1.55	2.44	2.04
1	Mini In-Ear Sound Amplifier	0.62	−1.21	−0.96	−0.73	−0.76
2	Personal Mini Sound Amplifier	0.14	−0.63	−0.37	−0.82	−0.56
4	8397 Micro Plus	0.10	−0.73	−0.65	−0.64	−0.64
5	Silver Sonic XL Personal Sound Amplifier	0.70	−1.34	−1.24	−0.52	−0.80
6	Mini Ear Amplifying Aid FK-162	0.26	−0.90	−0.65	−0.80	−0.70
7	Beurer-HA 20	0.11	−1.34	−1.41	−0.86	−1.16
8	GPFATTRY-In the Ear Hearing Amplifier	−1.37	−1.51	−1.27	0.09	−1.35
9	AXON Hearing Aid rechargeable	−3.11	−0.07	−1.58	−0.57	−1.77
10	Digital Hearing Amplifier VHP-202 S	0.30	−1.03	−0.82	−0.43	−0.66
11	Rechargeable Ear Hearing Amplifier ZDB-100 A	−2.97	−0.05	−1.08	−0.35	−1.48
13	Micro Plus ITE Hearing Amplifier	−0.18	0.27	−0.04	−0.61	−0.19
14	Beurer-HA 50	−0.52	−0.78	0.05	−0.14	−0.46
15	ITE voice amplifier ZDC-901 A	−0.50	−0.31	0.26	0.04	−0.17
16	Digital Hearing Amplifier VHP-221 T	−0.04	−0.69	−0.27	0.09	−0.30
17	BTE Amplifier V-185	0.07	−0.77	0.16	−0.88	−0.47
18	Digital Personal Audio Amplifier C-125	0.28	0.91	0.94	−0.27	0.62
19	FIIL-In Ear Mini	0.06	1.32	1.03	0.17	0.86
20	IQ Buds	0.71	1.88	1.46	−0.48	1.19
21	BLJ-BS05R Mini RIC	0.44	0.78	1.03	1.19	1.15
22	VA-3000	0.66	0.46	−0.52	−0.82	−0.07
23	RPSA05 Symphonix	0.30	0.30	0.49	0.33	0.47
24	FIIL-G2090 Hearing Amplifier	0.78	0.27	0.93	2.53	1.50
25	821 Receiver In The Canal Hearing Amplifier	0.47	0.39	0.60	1.42	0.96
26	CS50+ Personal Sound Amplifier	0.54	1.23	1.52	−0.73	0.85
27	Companion Hearing Aid	0.64	1.75	1.54	−0.46	1.15
28	Super Mini VHP-902	0.78	0.40	−0.69	1.81	0.76

Note. DTC devices are listed in order from least to most expensive. THD = total harmonic distortion, rms = root-mean-square, NHS= National Health Service.

overamplification, more than half the DTC devices did not have these features. It should be noted that the aforementioned implications of high maximum OSPL90 and HFA FOG may not be experienced by all DTC users. This is because: (a) it is less likely for the potential users to set their volume control, which nearly all DTC devices have, at full gain and (b) studies presenting both reported and logged data suggest that hearing devices are used more in quiet than noisy situations (Gaffney, 2008; Timmer, Hickson, & Launer, 2017).

The OSPL90 peak frequency might not be significant for adjustable hearing aids because the frequency response shape can be fine-tuned, but this is not the case for the majority of the DTC devices, because frequency specific adjustment is not possible. Nearly half of the DTC devices used in this study had their OSPL90 peak frequency below or at 1.4 kHz. Therefore, they could not adequately amplify high-frequency sounds for sloping high-frequency hearing loss because the peak OSPL90 is in a frequency range where the hearing loss does not require such output levels. Thus, the users of these devices would either overamplify the low frequencies to meet their high-frequency needs or underamplify the high frequencies to keep the low-frequency sounds at a manageable level.

The measured EIN varied considerably between devices. However, the current standard approach to quantifying hearing aids' internal noise might be inaccurate, especially with nonlinear devices. This is because the

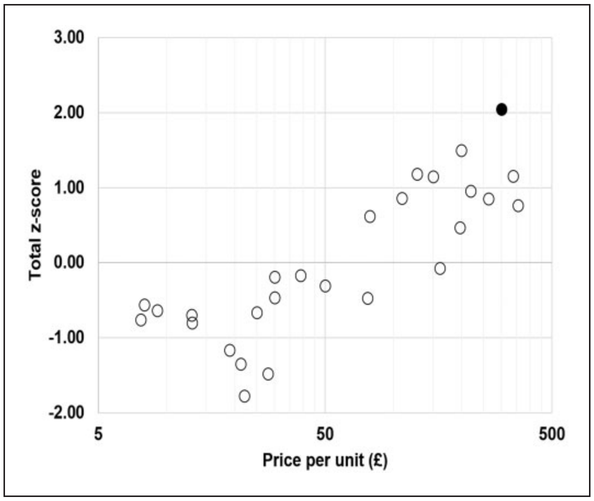

Figure 8. Total standardized z scores as a function of device price. Negative scores = below the average, positive scores = above the average. ITE = in the ear; BTE = behind the ear; RIC = receiver-in-the-canal.

calculation of EIN assumes the hearing aid gain is the same when the noise is measured at the output (with no input signal) as when the gain of the hearing aid is measured (Lewis, Goodman, & Bentler, 2010). Thus, such a comparison between devices might not be meaningful.

Almost 70% of the DTC devices had a harmonic distortion of ⩾2% in at least one frequency. This level of distortion can potentially degrade the perceived sound quality. Indeed, distortion of greater than 1% was found to have a detrimental effect on sound quality (Tan & Moore, 2008).

The upper boundary of the frequency bandwidth for half of the DTC devices, especially the low-cost ones, was <5 kHz. This boundary might limit the potential benefits for wearers of these devices as there is evidence of the importance of high-frequency signals in speech perception in both quiet and noisy environments, use of spatial cues to segregate target speech from competing sounds, as well as self-monitoring of speech (Best, Carlile, Jin, & van Schaik, 2005; Glyde, Buchholz, Dillon, Cameron, & Hickson, 2013; Levy, Freed, Nilsson, Moore, & Puria, 2015; Stelmachowicz, Lewis, Choi, & Brenda, 2007).

Matching to the Prescribed Target

More than half of the DTC devices had an rms difference from the prescription target for an input level of 65 dB SPL of more than 10 dB, which may limit their acceptability for those with mild and moderate sloping hearing loss. A low rms deviation has been reported to lead to higher self-reported benefit (Abrams, Chisolm, McManus, & McArdle, 2012). Baumfield and Dillon (2001) also found that a mean absolute deviation of 6 dB from the prescribed target was enough to degrade the self-reported benefit.

Recent BSA (2018) guidelines recommend that the deviation from the target gain should be within ±5 dB at spot frequencies. In this study, only three DTC devices, plus the NHS hearing aid, had an rms error of ⩽5 dB at the prescribed insertion gain target frequencies for an input level of 65 dB SPL for a mild and moderate hearing loss. Interestingly, the low deviation from the prescribed gain targets for these three devices can be attributed to the smartphone customizer feature, which was available only on these devices.

The ability of the DTC devices to match the maximum output targets was poorer than the match-to-gain targets, with only two devices capable of meeting the BSA tolerance. The majority of the DTC devices had irregular frequency response shapes, meaning that they exceeded the target at some frequencies and undershot it at others. A close inspection of the deviation revealed that, when the volume control was set to FOG, 88% of devices exceeded the maximum output target by >5 dB in at least one frequency. In addition, 96% of the devices undershot the maximum output target by >5 dB at other frequencies. This is problematic, as satisfaction surveys have shown many hearing aid users complain of perceiving loud sounds as uncomfortably loud (Kochkin, 2010). A maximum output that is considerably lower than the target is another issue, especially for individuals with sensorineural hearing loss. This is because they have a narrow dynamic range of hearing; a maximum output that is below the prescribed target will reduce the range even further.

The ability of the DTC device to match the prescribed target slopes had not previously been explored. This study revealed that, in the two higher octaves (1 to 2 kHz and 2 to 4 kHz), for the majority of the devices, the gain did not increase with frequency as much as required by the prescription. In many cases, the gain actually reduced as the frequency increased. The number of devices capable of being within ±5 dB/octave of the target slope decreased as frequency rose. The BSA recommends the slope be within ±5 dB in each octave band; in this study, only two DTC devices, and the NHS hearing aid, were within the BSA tolerance for the three octave bands. These two DTC devices had a smartphone application customizer.

The limited number of DTC devices matching the target slope is relatively consistent with the findings of Munro, Puri, Bird, and Smith (2016) who reported only 63% of conventional hearing aids fitted with ear molds met the NAL-NL1 65 dB SPL target slope. The larger the deviation from the target slope, the higher the possibility that the perceived naturalness of both speech and music would be degraded. The opportunity to adjust the gain–frequency response was very limited for the majority of the devices, often limited to, at best, a high-cut or low-cut programs.

Physical Appearance Rating

The third aim of this study was to investigate patients' perspectives on the appearance of DTC devices, compared with the NHS's hearing aid, and their willingness-to-wear them. Limited information has been published about the cosmetic appearance of DTC devices. In this study, the appearance of the NHS hearing aid (thin-tube-delivery BTE) outranked nearly all of the DTC devices. The less visible the device, the higher the cosmetic rating; the thin-tube BTE, together with the unobtrusive receiver-in-the-canal styles, was comparable in aesthetic appearance rating to the NHS hearing aid used in this study.

Although previous studies have shown conventional in the ear (ITE) models have the lowest visibility rating, and are therefore preferred, among hearing aid styles (Johnson et al., 2005), our findings revealed DTC devices with the ITE style were rated among the least cosmetically appealing. This can be attributed, in part, to the fact that conventional ITE hearing aids are molded to individual wearers' ears and are thus less obtrusive than the noncustomised style that DTC devices necessarily adopt. Also, in the past decade, BTE hearing aids have become smaller and their tubes thinner, decreasing their visibility relative to ITE devices.

While wearing Bluetooth headsets (e.g., Apple AirPods) has become common, Bluetooth headset DTC hearing devices received low aesthetic ratings, which could be a result of their obtrusiveness, as they were twice the size of conventional hearing aids. It is worth noting that photographing the hearing devices from different angles (i.e., 135° from the front) might alter the rating.

This study has shown a strong correlation between physical appearance rating and a person's willingness-to-wear DTC devices, which suggests that the stigma of wearing a hearing aid will continue to be a psychosocial barrier to hearing aid uptake. This trend is not surprising because, as noted earlier, the size and visibility of hearing aids can impact the wearer's preference, satisfaction, and even their intent to purchase a hearing aid (Kochkin, 1994; McCormack & Fortnum, 2013).

In term of the participants' preferred method of obtaining a hearing aid, the results revealed a substantial proportion of respondents preferred the standard approach over purchasing a DTC device online or from retailers. Although the majority of the study's sample were recruited from the University of Manchester research volunteer database, the study's findings are consistent with those of Plotnick and Dybala's (2017), who found 93% of 809 respondents in the United States believed that standard care is absolutely important or very important. In short, these findings suggest that people, at least in the United Kingdom, are mostly not yet ready to purchase a DTC device online or from retailers.

Overall Quality

Although the NHS hearing aid used in our study was first released in 2008 (over a decade ago), the overall quality scores of this aid outweighed all the DTC devices assessed. The low-priced DTC devices (⩽£50) in this study received low overall quality scores. Interestingly, low-priced devices had also received the most negative Amazon feedback reviews with reference to the sound quality as analysed by Manchaiah and Amlani (2018). The z scores of the electroacoustic measurements, and the matching to NAL-NL2 65 dB SPL targets, were similar between the NHS hearing aid and the three DTC devices with smartphone customizers. However, the z scores of the physical appearance ratings markedly lowered the total z scores for these DTC devices. The total z scores for the majority of the devices were reduced dramatically as they were regarded as aesthetically unappealing. It should be noted that some DTC devices contained advanced features (i.e., noise reduction algorithms and streaming capability), and these were not included in the overall quality measurements. Such features can potentially improve the overall quality score of the devices.

Other Considerations—Occlusion

We observed that more than 70% of the devices had a method of coupling to the ear that would mostly or completely occlude the ear canal, with the point of occlusion often being close to the canal entrance. It is well known that such occlusion typically causes a large increase in low-frequency sound level inside the ear canal when the aid wearer talks (Dillon, 2012). This increase is known as the *occlusion effect* and often causes the aid wearer's own voice to have an unacceptable sound quality (Dillon, Birtles, & Lovegrove, 1999). It has been the cause of many complaints by hearing aid wearers with mild loss, who often have normal or near-normal low-frequency hearing. Avoiding this effect has led to the widespread use and acceptance of open-fit hearing aids. The occlusion effect should be just as big a problem for DTC devices that fully occlude the ear canal. We carried out an informal experiment in which five people with normal hearing rated the quality of their own voice while wearing each device, and as expected, devices which physically blocked the ear canal attracted poor ratings. We consider that avoiding the occlusion effect would be an important design feature for DTC devices that are intended to be worn for appreciable amounts of time where the device wearer is likely to engage in conversation. Future research examining the acceptability of DTC devices, particular for people with mild hearing loss, should quantify the extent to which occlusion hinders device acceptability.

Conclusions

Although previous studies have reported electroacoustic performance, this study is novel in that it examined (a) the ability of the DTC devices to match the prescribed gain *and* slope targets and (b) cosmetic appearance ratings and willingness-to-wear the DTC devices, using a very large sample of DTC devices. Nearly all of the DTC devices had aesthetically unappealing designs and inflexible adjustments, making it difficult to match widely accepted targets and potentially making sounds uncomfortably loud for people with mild or moderate sloping hearing loss. Devices with smartphone customizers performed better in terms of electroacoustics and match-to-target gain and slope; however, two of these devices might produce uncomfortably loud sounds and all of them were rated as aesthetically unappealing. The challenge for manufacturers is to develop low-cost products with cosmetic appeal and appropriate electroacoustic characteristics.

Authors' Note

Preliminary results were presented at the *34th World Congress of Audiology*, Cape Town, South Africa, in October of 2018 and the Ear and Technology study day, London, UK, in February 2019.

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Supplemental material

Supplemental material is available for this article online.

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