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Development and validation of the audio processor satisfaction questionnaire (APSQ) for hearing implant users

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ABSTRACT

Objective: The satisfaction experienced with using an audio processor is very important to hearing implant system users. Currently there are no measures that can be used to assess user satisfaction with an audio processor. This study aims to develop and validate a specific and standardised questionnaire that focuses on user satisfaction with their audio processor.

Design: A preliminary version of the questionnaire was initially developed by experts in the field. Following validation of these results, the final version of the Audio Processor Satisfaction Questionnaire (APSQ) was developed consisting of 15 items. Item analyses and questionnaire validation measurements were assessed.

Study sample: Sixty-nine subjects were recruited and asked to complete the APSQ twice within 2–4 weeks.

Results: Subjects reported a high user satisfaction with the questionnaire and with their audio processor. The questionnaire had good reliability and results for test-retest reliability were high and significant across all items and across subscale analyses.

Conclusion: Item analyses and reliability analyses show that the questionnaire is a valid and reliable tool to assess user satisfaction across different audio processors and hearing implant systems. The APSQ is a quick and easy tool to measure user satisfaction with their audio processor.

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Hearing implant; audio processor; satisfaction; cochlear implant

Introduction

The provision of a hearing device, such as a cochlear implant, middle ear implant, or bone conduction implant, is a successful and effective treatment option for individuals with different types of hearing loss. Receiving a hearing implant (HI) can provide these individuals with a range of benefits that include improved sound perception and localisation, speech understanding, and communication abilities (Kiefer et al. 2005; Skarzynski et al. 2006; Looi et al. 2008; Chen et al. 2013; Li, Soli, and Zheng 2017; Hempel, Simon, and Müller 2018).

It is important for HI manufacturers to be aware of the user's needs and how to satisfy these needs. Various speech perception tests and outcome measurement tools are available to evaluate the objective benefits obtained from using a cochlear implant or other implanted hearing devices (Hochmair-Desoyer et al. 1997; Luetje et al. 2002). However, only a few instruments are available to measure user satisfaction. Previous questionnaires have been developed to evaluate the subjective quality of hearing of HI users, such as the Speech, Spatial and Qualities of Hearing Scale (SSQ) (Gatehouse and Noble 2004), the Hearing Implant Sound Quality Index (HISQUI19) (Amann and Anderson 2014), or the LittleEARS Auditory questionnaire (Weichbold et al. 2005; Coninx et al. 2009). Within the HI community, the ability to obtain information regarding user satisfaction of external devices, and in particular on the use of audio processors, is important. Unlike in the hearing aid field, HI users only have a small and limited range of audio processors to choose from. While there are always new audio processors being developed, HI users will

continue to only have access to audio processors that are produced by a specific manufacturer compatible with their specific hearing system (i.e. cochlear implant, middle ear implant, or bone conduction implant). This is different to hearing aid users who typically have access to a wide range of products and devices from various manufacturers.

The audio processor deserves special attention since it is an essential part of everyday life for a HI user. While most audio processors that are available can provide the user with different features and benefits (e.g. noise reduction algorithms, microphone directionality, behind-the-ear vs single-unit processors), it nonetheless remains important for manufacturers to be aware of the needs and wants of the HI user. Until now, satisfaction measures for HI audio processors have only been designed for specific products (Anderson et al. 2003, 2004; Mertens et al. 2015; Briaire et al. 2016), such as the RONDO device-specific questionnaire (Dazert et al. 2017), but not across different HI audio processors and hearing systems (e.g. audio processors for cochlear implants, middle ear implants, or bone conduction devices) or across different product generations. Within the hearing aid community, standardised user satisfaction questionnaires exist (Cox and Alexander 2001; Saunders, Chisolm, and Abrams 2005). However, there is an increasing need for a specific and standardised questionnaire that concentrates on HI user satisfaction with external components which, to the best of our knowledge, does not currently exist in the literature.

Therefore, this study aims to validate the German language version of the Audio Processor Satisfaction Questionnaire (APSQ; German title: Audioprozessor-Zufriedenheitsfragebogen)

Table 1. A description of each of the items in the questionnaire, grouped according to subscale/content (please note that this is an English translation of the original German language version).

Item no.	Item description
	Comfort
3	My processor is skin friendly (no sweating, redness, itching, etc.).
6	My audio processor is comfortable to wear (no uncomfortable pressure, no feeling that the processor is heavy or bulky).
9	I can comfortably wear glasses and my audio processor at the same time.
12	I can comfortably wear head-wear (e.g. hat, helmet) and my audio processor at the same time.
15	My audio processor stays in the same position all day.
	Social life
1	I feel safer and more confident when I wear my audio processor.
4	My audio processor allows me to have a physically active lifestyle.
7	Wearing the audio processor helps me live a more independent life.
10	My audio processor makes it easier for me to enjoy cultural activities (e.g. theatre, cinema).
13	My audio processor makes it easier for me to enjoy social activities (e.g. joining conversations, meeting new people, going out).
	Usability
2	It is easy to put the audio processor back on its proper place on my head.
5	It is easy to change the batteries of my audio processor.
8	It is easy to switch the processor ON and OFF.
11	My audio processor functions properly (does not switch off for no reason).
14	My audio processor is easy to take care of (e.g. to clean, to dry).

as a specific and standardised tool to measure an individual HI user's satisfaction with their external audio processor. The APSQ should be applicable to all HI users, independent of the model or generation of their audio processor. The APSQ aims to evaluate how comfortable the audio processor is to wear every day, how well it works in their everyday life, and how easy or difficult it is to use. Such information would be invaluable to HI device manufacturers, and would provide clinicians, researchers, and other HI users with information regarding the use of different audio processors.

Methods

Development and validation of the questionnaire

Item generation

The APSQ was developed as a paper-based questionnaire to measure user satisfaction with their audio processor with the aim of being used in research studies or in clinical practice. An expert group, consisting of an audiologist and speech therapist, a psychologist, and a bio-statistician, was involved in the development of the questionnaire in association with a clinical engineer with expert knowledge in hearing implants and a health technology expert. The following standards were formulated for item development: (i) the questionnaire should contain items regarding subjective satisfaction with using an audio processor in everyday life, such as ease of use or comfort; (ii) the items should be phrased in a similar way; and (iii) responses to the items should be consistent. The expert group reviewed the literature, compiled a list of items, many of which were obtained from established questionnaires such as the SSQ (Gatehouse and Noble 2004) or the HISQUI19 (Amann and Anderson 2014), conducted face validity on these items, and determined which items should be considered for inclusion. These items were then distributed to two HI users to be reviewed. A total of 21 items were retained, forming the preliminary version of the APSQ.

Preliminary questionnaire

The preliminary version of the APSQ was developed in the German language and was based on 21 items and a 5-point Likert scale. This questionnaire was distributed at the study centre in Hannover, Germany to subjects fluent in the German

language that were there for a routine appointment. The questionnaire was distributed to 60 subjects (28 male, 32 female) with a mean age of 53.2 years (range: 13–89 years). Subjects were asked to complete the questionnaire twice within 4 weeks (i.e. one questionnaire was completed on that day and one 2–4 weeks later at home). Fifty-three of the 60 subjects completed both questionnaires within the given timeframe.

Preliminary validation analyses showed that the questionnaire had an acceptable reliability (Cronbach's alpha = 0.750). The results of the test-retest reliability analyses for the total score and the subscale scores were satisfactory ($r = 0.586$ to $r = 0.849$; $p < 0.001$). Exploratory factor analysis (EFA) with varimax rotation method (extraction method: principal component analysis) was used to check the underlying factor structure of the items. The suitability of the items for factor analysis was confirmed by the results of the Kaiser-Meyer-Olkin (KMO) test, with a value of 0.59, and the Bartlett's test of sphericity ($c^2 = 362$; $df = 153$; $p < 0.001$) as measures of sampling adequacy. Six factors (i.e. components) that explained 67.3% of the total variance were extracted: one factor loaded on the 'comfort' subscale (items 1, 13, 16, 17, 21); two factors loaded on the 'social life' subscale (items 3, 11, 15, 19, 20); and one factor loaded onto another subscale (items 4, 12).

The final questionnaire

For the final version of the APSQ, the questionnaire was reduced to 15 items (an English translation of these items is available in Table 1). Some of the original items were removed because they contained similar content to other items (and so were combined) or they could not be assigned to a specific subscale (and so were either rewritten or removed). While some items did not reach a satisfactory validation level based on the item analyses, they were retained because they contained important information. The items were classified according to their content into three subscales: (i) comfort, (ii) social life, and (iii) usability. Each subscale contained five items. The subscale scores and the total score were obtained by calculating the average scores provided on each item.

The 5-point Likert scale was transformed into a visual analogue scale (VAS) between 0 and 10 to better differentiate users' satisfaction with their audio processor. A score of 0 corresponded to a response of 'does not agree at all' and 10 as 'fully agrees'. If an item did not apply to the subject, then the subject could tick the 'not applicable' option or leave the scale blank.

Table 2. Details on the hearing systems and audio processors used, along with the device usage times, per ear.

	Left ear (n)	Right ear (n)
Normal hearing	4	2
Hearing loss	64	66
Hearing system		
Hearing aid	16	10
Cochlear implant	36	41
EAS system	4	5
Middle ear implant	6	6
Bone conduction implant	1	1
No hearing aid system	5	5
Audio processor		
SONNET	21	25
OPUS 2	16	15
OPUS & RONDO	1	2
Amadé	2	3
SAMBA	5	3
RONDO	1	4
DUET 2	1	–
AP 404	–	1
No audio processor	21	15
Device usage time		
0–3 h	2	0
3–6 h	0	0
6–9 h	3	3
9–12 h	6	10
>12 h	42	41
Missing	15	14

EAS: electric acoustic stimulation.

Subjects

To be included in the main study, subjects had to be 18 years of age or older, implanted with a MED-EL hearing system (MED-EL GmbH, Innsbruck, Austria), have at least 3 months' experience with their current audio processor, be able to complete a self-administered questionnaire, and be fluent in the German language. Adult HI users that met the inclusion criteria were recruited at the study centre. If the HI user agreed to take part, then they received the questionnaire after their routine appointment.

A total of 69 subjects were recruited (31 male, 38 female), with a mean age of 58.96 years (range: 18–87 years). Further information on the hearing systems and audio processors used, along with daily usage times, are shown in Table 2. Over 60% of subjects used their audio processor for more than 12 h per day. This clinical investigation was conducted according to the principles of ISO14155:2011 and the Declaration of Helsinki. The clinical investigation was reviewed and approved by the Ethics Committee at the Hannover Medical School (No. 2692-2015 and No. 3490-2017). Signed and dated informed consent forms were obtained from subjects prior to the study. During this study, the subjects received two paper copies of the APSQ (written in the German language), one to be completed immediately and a second copy to be completed at home after 2–4 weeks. Subjects were asked to complete the questionnaire twice to allow for the repeatability and consistency of the questionnaire to be tested over time. The first copy questionnaire was completed by the subject immediately after enrolment and was returned before the user left the study centre. The subject was then given a second copy of the questionnaire along with a prepaid envelope that could be used to post the questionnaire back to the study centre.

Statistical analysis

IBM SPSS Statistics (IBM, Armonik, New York) was used for all analyses. A *p*-value of less than 0.05 was considered statistically significant. The Kolmogorow-Smirnov test and a graphical

examination were performed to check the data distribution. The items of the APSQ were statistically analysed within the classical test theory model to evaluate the psychometric characteristics of the remaining items (Crocker and Algina 1986; Rust and Golombok 2000). Missing data were treated as 'missing values'. The maximum number of incomplete answers for the validation analyses was set at three items per subject; if this number was exceeded, then the subject was excluded.

Item analysis

Item discrimination and item homogeneity were examined in order to confirm the selected items for the final version of the questionnaire.

The discrimination index indicated the correlation of an item with the total score. A high correlation suggested that the item had a considerable impact on the total score and clearly differentiated between subjects who were 'satisfied' (i.e. high score) versus subjects who were 'not satisfied' (i.e. low score) with a particular item. In terms of discrimination index, 0.40 or higher corresponded to very good items; 0.30–0.39 were reasonably good but could possibly be improved; 0.20–0.29 were marginal items and needed to be revised; and items below 0.19 were considered poor and needed to be majorly revised or removed (Ebel and Frisbie 1986). Item homogeneity reflected the extent to which the individual items correlated with the total score. The more single items that correlated with the total score and the lower the variability of these correlations, the higher the item homogeneity (Adkins 1960).

Scale analysis

Reliability

The scale's internal consistency was tested using Cronbach's alpha. Guttman split-half-coefficient was calculated to estimate the full test reliability of the questionnaire based on split-half measures, whereby the data was split into odd and even numbered items. Typically, a score of 0.7 or above is considered an acceptable level for internal consistency. A value of $\alpha = 0.96$ indicates very high internal consistency (Cronbach 1951; Nunnally 1978). Test reliability as an indication of the consistency and repeatability of the questionnaire across time was checked with the reliability coefficient (KR20). Test reliability shows how likely it is that a subject would obtain the same score when he/she takes the test again. According to Kelley (Kelley 1939), a coefficient between 0.80 and 0.90 is very good, and 0.90 or above is excellent, whereas a coefficient of 0.50 or below has questionable reliability.

Construct validity

EFA with a rotated quartimax factor solution (extraction method: principal component analysis) was used to check the underlying factor structure of the items (Bortz 2005). To test the suitability of the items for factor analysis, the KMO test (Kaiser, Rice, and Little Jiffy 1974) and the Bartlett test of sphericity were performed as measures of sampling adequacy. Factor loadings with absolute values greater than 0.40 were considered significant and assigned to the appropriate factor.

Additional factors

Additional analyses were completed to investigate the impact of different variables on user satisfaction as depicted by the total

Table 3. Results from the item discrimination test.

Subscale	Item no.	Corrected item – total correlation	Discrimination
Comfort	3	0.254	Marginal
	6	0.669	Very good
	9	0.431	Very good
	12	0.691	Very good
	15	0.639	Very good
Social life	1	0.337	Reasonably good
	4	0.527	Very good
	7	0.529	Very good
	10	0.523	Very good
	13	0.393	Reasonably good
Usability	2	0.710	Very good
	5	0.514	Very good
	8	0.263	Marginal
	11	0.655	Very good
	14	0.517	Very good

score. Pearson correlation was conducted to test the relationship between age at implantation and user satisfaction. The influence of sex on audio processor satisfaction was examined by applying the Mann-Whitney *U* test. Univariate analysis of variance was used to examine the effect of the type of audio processor, time since implantation, hearing system usage time, and type of hearing system on user satisfaction.

Results

Item analysis

Nine out of the 15 items had missing data between 1.5% ($n=1$) and 8.8% ($n=6$) (i.e. the items were either not answered or answered as 'not applicable'). One male subject was excluded from final analyses due to having more than three missing item responses on his questionnaire. With the exceptions of items 1, 2, 4, 11, and 14, a broad range of the VAS was used by the subjects to express their satisfaction with the items in the questionnaire. The mean score for the 'comfort' subscale was 8.0 (± 1.62), 8.2 (± 1.31) for the 'social life' subscale, and 9.0 (± 0.84) for the 'usability' subscale. Overall, the mean scores per item ranged between 7.1 and 9.2 (standard deviation = ± 1.86) with a tendency towards a ceiling effect. No floor effects were detected.

Eleven of the items were rated as 'very good' in terms of item discrimination. Only items 3 and 8 had item-total correlations lower than 0.3 (Table 3). All items correlated significantly with the total score (Pearson correlation: $p < 0.001$ to $p = 0.005$), showing good item homogeneity (Table 4).

Scale analysis

Reliability

The questionnaire reached a good reliability with high internal consistency (Cronbach's $\alpha = 0.84$; Guttman's split-half coefficient = 0.86). The result of the test-retest reliability analyses was high and significant ($r = 0.817$; $p < 0.001$), confirming repeatability and consistency of the measure across time. For the test-retest reliability analyses, the data collected from 43 subjects (consisting of two questionnaires per subject) were analysed. 17 subjects completed the second questionnaire outside of the defined time frame of 2–4 weeks and 8 subjects did not return the second questionnaire and, as such, these 25 subjects were excluded from the reliability analyses. Based on visual inspection and statistical analysis of the data collected from those who completed and returned both questionnaires within the given timeframe and

Table 4. Pearson correlation results measuring item homogeneity.

Subscale	Item no.	<i>r</i>	<i>p</i> -Value
Comfort	3	0.344	0.004
	6	0.756	<0.001
	9	0.589	<0.001
	12	0.779	<0.001
	15	0.746	<0.001
Social life	1	0.344	0.005
	4	0.606	<0.001
	7	0.655	<0.001
	10	0.687	<0.001
	13	0.560	<0.001
Usability	2	0.729	<0.001
	5	0.503	<0.001
	8	0.343	0.004
	11	0.502	<0.001
	14	0.502	<0.001

those who did not, no bias regarding a certain subscale of subjects was detected (Univariate ANOVA: dependent variable = age, $F(1; 66) = 0.156$, $p = 0.694$; Univariate ANOVA: dependent variable = total score, $F(1; 66) = 1.485$, $p = 0.227$; Pearson Chi-Square test: gender \times respondents (two groups), $p = 0.318$).

Construct validity

The suitability of the items for EFA was provided by the KMO test and the Bartlett test of sphericity. The KMO test reached a value of 0.76, which is considered 'acceptable' according to Kaiser & Rice (Kaiser, Rice, and Little Jiffy 1974). The result of the Bartlett test of sphericity ($\chi^2 = 376.642$, $df = 105$, $p < 0.001$) indicated a significant correlation between the items. The items loaded mainly onto two factors (i.e. components/factors) and explained 61.4% of the total variance. All five items of the 'comfort' subscale loaded onto component 1, four items from the 'social life' subscale loaded onto component 2, and four items from 'usability' subscale also loaded onto component 1. Item 8 of the 'usability' subscale loaded onto a third component (Table 5).

Additional factors

No significant correlation was found between the subject's age and user satisfaction ($r = 0.098$; $p = 0.426$). Sex also did not have a significant effect on the results according to the Mann-Whitney *U*-test ($p = 0.549$). Results from ANOVA analyses showed no significant effect for type of audio processor on user satisfaction (left ear: $F(6; 40) = 0.386$, $p = 0.884$; right ear: $F(6; 46) = 0.311$, $p = 0.928$). No significant effect of time since implantation on user satisfaction was found (left ear: $F(1; 45) = 0.508$, $p = 0.480$; right ear: $F(1; 51) = 0.308$, $p = 0.581$). Additionally, hearing system usage time had no significant influence on user satisfaction (left ear: $F(3; 49) = 0.204$, $p = 0.893$; right ear: $F(2; 51) = 0.507$, $p = 0.605$). And the type of audio processor did not have a significant effect on the results (left ear: $F(6; 40) = 0.386$, $p = 0.884$; right ear: $F(6; 46) = 0.311$, $p = 0.928$). The type of hearing system also did not have a significant effect on the results (left ear: $F(5; 62) = 0.761$, $p = 0.581$; right ear: $F(5; 62) = 0.675$, $p = 0.644$). In summary, no significant relationships were found between any additional variables and the total score.

Table 5. Results from the exploratory factor analysis (EFA) with a rotated quartimax factor solution (extraction method: principal component analysis).

Subscale	Item no.	Factor loadings		
		C 1	C 2	C 3
Comfort	3	0.551		
	6	0.871		
	9	0.598		
	12	0.574		
	15	0.852		
Social life	1		0.727	
	4	0.557		
	7		0.719	
	10		0.810	
Usability	13		0.843	
	2	0.747		
	5	0.711		
	8			0.798
	11	0.820		
	14	0.632		

C: components (i.e. factors).

Adverse events

No adverse events or adverse device events were reported.

Discussion

The audio processor is a key component for a HI user, with different audio processors available on the market that can provide different features and benefits such MRI compatibility (Srinivasan et al. 2019), adaptive/directional microphone technology (Wimmer, Caversaccio, and Kompis 2015; Honeder et al. 2018), or single-unit devices (Mertens et al. 2015; Dazert et al. 2017). It is, therefore, important for manufacturers to be aware of how an audio processor is perceived by its user. Previous studies have been conducted and reported in the literature that use non-validated questionnaires and surveys to measure user satisfaction with a specific audio processor (Anderson et al. 2003, 2004; Mertens et al. 2015; Briaire et al. 2016; Dazert et al. 2017), but to the best of our knowledge, no questionnaires or surveys exist that can be used across different HI audio processors or hearing systems. Therefore, the goal of this study was to provide manufacturers, clinicians, and researchers with a validated and standardised user-friendly questionnaire, based on established psychometric standards, that could be used to quantify HI users' self-perceived satisfaction with their audio processor in everyday situations. Similar to previously validated questionnaires in the hearing implant field (such as the SSQ (Gatehouse and Noble 2004) or HISQUI19 (Amann and Anderson 2014)), the APSQ offers the ability to analyse the total score or to separate the scores into three subscales (i.e. comfort, social life, and usability).

The subjects recruited for this study used a variety of hearing systems and audio processors, covering a large range of MED-EL products including cochlear implants, electric acoustic stimulation systems, middle ear implants, and bone conduction implants. Importantly, over 60% of the subjects recruited in this study used their audio processors for more than 12h per day (Table 2). As such, they should have good experience with using their audio processor in terms of usage time (i.e. quantity) and with using it in different listening situations (i.e. quality). Therefore, these subjects were considered as a reliable group of individuals to be included in this study.

The data gathered in this study show a high level of user satisfaction with their audio processors, with high values obtained in total scores and in scores across each of the three subscales

which are in correlation with results obtained from previous studies showing that HI users are typically satisfied with their audio processor (Anderson et al. 2003, 2004; Dazert et al. 2017). A greater variety in subject responses was observed with the VAS in comparison to the 5-point Likert scale that was used in the preliminary version, although a tendency towards a ceiling effect was observed with the VAS. However, the main aim of developing this questionnaire was to determine whether or not user satisfaction with an audio processor can be depicted and not to compare user satisfaction across two different audio processors or with the same audio processor over time.

In terms of item discrimination, 11 out of 15 of the items had very good item discrimination (Ebel and Frisbie 1986). Two items (No. 1 and No. 13) had reasonably good discrimination and two items (No. 3 and No. 8) had marginal item discrimination. Nonetheless, these items represent important aspects of a HI user's everyday life and can provide valuable information to the manufacturer in terms of usability, safety, and technical development. All items showed a significant homogeneity confirming that they are measuring the same underlying construct (i.e. user satisfaction) (Adkins 1960).

The internal consistency of the APSQ, tested using Cronbach's alpha and the Guttman split-half-coefficient, showed good reliability and high internal consistency. Furthermore, 43 datasets were analysed for test-retest reliability, and results were found to be highly significant indicating that the questionnaire measures in a consistent manner (Kelley 1939; Cronbach 1951; Nunnally 1978). Therefore, the APSQ is a valid and reliable questionnaire capable of measuring HI users' self-perceived satisfaction with their external audio processors. The ease of administration and scoring with this questionnaire suggests that the APSQ is a useful instrument for evaluating the comfort and usability of audio processors, as well as their role in the user's social life. As such, we aim to translate the APSQ into different languages so that it can be used by HI users worldwide.

Limitations and future research

It is important to note that limitations exist within this study and in the use of the resultant questionnaire. The APSQ aims to simply determine whether or not a HI user is satisfied with their audio processor. The results obtained from this APSQ have a tendency towards a ceiling effect, and as such, cannot be used to measure user satisfaction over time or between devices. The intention of the APSQ is not to discriminate between groups, whereby a ceiling effect would be undesirable, but rather this questionnaire intends to simply be used as a tool to measure whether or not a user is satisfied with their audio processor (and not how satisfied they are with it in relation to another device/user/point in time). Another limitation is that this study only included HI users with at least 3 months experience with their audio processor. This inclusion criterion was chosen because users with less than 3 months experience might not be correctly fitted yet and may not be familiar enough with their audio processor to evaluate it accurately. And finally, the items generated for this questionnaire were obtained from previous questionnaires (such as the SSQ (Gatehouse and Noble 2004) or HISQUI19 (Amann and Anderson 2014)) that cover the key aspects of user satisfaction, however, it is possible that other elements of user satisfaction have not been included in this questionnaire.

Additionally, this paper reports the validation of the German language version of the APSQ. Future research will involve

revalidation of the APSQ in English and other languages. More research is required to further establish the clinical utility of the survey and to evaluate its responsiveness to intervention. We also hope to conduct further research with the APSQ across a more diverse population of HI users.

Conclusion

Results from the item and reliability analyses suggest that the APSQ is a valid and reliable tool to assess user satisfaction with their audio processor across a range of different hearing implant system users. The APSQ can be divided into three subscales that represent different aspects of user satisfaction which could be used to guide the development of future audio processors. Consisting of only 15 items, the APSQ is straightforward, does not require a lot of time to complete, and can easily be added into clinical practice or research studies.

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Disclosure statement

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