Practice guidance

Fitting of combination hearing aids for subjects with tinnitus

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General foreword

This document presents Practice Guidance by the British Society of Audiology (BSA). This Practice Guidance represents, to the best knowledge of the BSA, the evidence-base and consensus on good practice, given the stated methodology and scope of the document and at the time of publication.

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Comments on this document are welcomed and should be sent to:

British Society of Audiology
Blackburn House,
Redhouse Road
Seafield,
Bathgate
EH47 7AQ
Tel: +44 (0)118 9660622

bsa@thebsa.org.uk
www.thebsa.org.uk

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Authors

Produced by: The BSA Tinnitus & Hyperacusis Special Interest Group and the Professional Guidance Group

Key Authors:

Magdalena Sereda
NIHR Nottingham Biomedical Research Centre, University of Nottingham
Declarations of interests: MS is a researcher in tinnitus and hyperacusis at the NIHR Nottingham Biomedical Research Centre, University of Nottingham. She is funded by the British Tinnitus Association Head of Research fellowship. She has been chief investigator on tinnitus research funded by the NIHR, the British Society of Audiology, and the British Tinnitus Association.

Derek Hoare
NIHR Nottingham Biomedical Research Centre, University of Nottingham
Declarations of interests: DJH is a researcher in tinnitus and hyperacusis at the NIHR Nottingham Biomedical Research Centre, University of Nottingham. He has been chief investigator on tinnitus research funded by the NIHR, the British Society of Audiology, the British Tinnitus Association, and Action on Hearing Loss. He is a past Chair of the British Tinnitus Association's Professional Advisor's Committee.

Julie Brady
Nottingham University Hospitals NHS Trust
Declaration of interests: None declared.

Tony Kay
Aintree University Hospital NHS Foundation Trust, Liverpool
Declaration of interests: TK is an Audiologist and Head of Audiology Services at Aintree University Hospital NHS Foundation Trust. He has assessed and treated tinnitus and hyperacusis subjects in both the NHS and private sector. He is a past member of the British Tinnitus Association's Professional Advisor's Committee.

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1. Contents

2. Introduction

The purpose of this document is to provide practice guidance and recommendations for fitting of combination hearing aids (combined amplification and sound generation) for subjects with tinnitus.

The term 'shall' is used in this document to refer to essential practice, and 'should' is used to refer to desirable practice.

Unless stated otherwise, the guidance described here represents the status of the current evidence base, taking into account other factors that influence desirable practice, as interpreted by the Professional Guidance Group of the BSA in consultation with its stakeholders (see Appendix A). The document was developed in accordance with the BSA Procedure for Processing Documents (2016).

It is implied throughout this document that the subject (patient/client/customer) should be involved in shared decision-making when undertaking audiological intervention, receiving subsequent information and understanding how it will impact on the personalisation of care. Individual preferences should be taken into account and the role of the clinician is to enable a person to make a meaningful and informed choice (BSA, 2016). Audiological interventions bring a variety of information for both the clinician and the subject that can be used for counselling and decision-making regarding technology and anticipated outcomes.

2.1 Background

Combination hearing aids provide amplification and sound generation within one device. Current combination aids offer the same amplification features as conventional hearing aids, as well as a number of different noise options (Henry et al., 2004; Hoare et al. 2013; Hoare et al. 2014). Broadband noise (such as white, pink, red or brown) is a standard option on most devices. Additional options available on some devices include modulating or filtering broadband noise, noise shaped according to subjects' audiogram, noise centred either at or away from the tinnitus frequency, or nature sounds (e.g. ocean sound).

Combination aids are used as a part of many different management programmes (Tinnitus Retraining Therapy, Tinnitus Masking, Zen Therapy, and Progressive Tinnitus Management) and outside of those. There is a rich literature describing the principles of various management programmes, with many having strict criteria regarding candidacy, fitting and use of combination hearing aids (Tutaj et al., 2018). Marked variability was observed in candidacy and fitting of combination aids between different management programmes and different studies; however it is not clear whether any of these approaches yield superior results.

Work conducted specifically to support the development of this practice guidance included a service evaluation, and a users' survey and focus group.

The service evaluation involved a UK wide survey of clinical practice (Sereda et al., 2017) and the Delphi survey of UK hearing professionals (Sereda et al., 2018a, b). The survey highlighted variable clinical practices when fitting combination hearing aids for subjects with tinnitus, including recommended levels of sound/noise, timing of fitting amplification and activating sound, and recommended daily use of the devices and different programmes. The Delphi survey established clinical consensus among a panel of 32 UK hearing professionals, on 319 statements covering: (i) candidacy, (ii) fitting procedures, (iii) safety, (iv) recommended use, (v) streaming options, (vi) information provided, and (v) assessments.

The users' survey indicated, that in the UK at least, the decision to offer combination aids lies in the hands of hearing professional (Sereda et al., 2018c). Survey respondents had variable expectations towards combination hearing aids, mainly masking or a reduction of tinnitus. A focus group discussion revealed that a reduction in tinnitus loudness is very important to subjects. It also highlighted that the terminology and language used by clinicians would set certain expectations, however the understanding of certain terms might be very different for subjects and clinicians. Subjects tend to adapt the terminology used by clinicians but it is important to understand what a subject means by specific terms they use and if the understanding of those terms is the same for subject and clinician.

Although the main expectation towards combination aids seemed to be the reduction in tinnitus loudness, users' survey respondents reported a range of other benefits including distraction from tinnitus or a reduction of distraction by tinnitus, improvement in hearing and/or communication, control over tinnitus, replacing tinnitus with more bearable sound, helping the process of habituation, reduction in discomfort, reduction of annoyance from tinnitus, reduction of anxiety, better sleep, and reduced awareness of tinnitus.

The user focus group explored the relative importance of addressing hearing difficulties versus addressing the tinnitus problem. Improvement in hearing and communication seemed as important to users as addressing their tinnitus problem. Participants agreed that they would like devices to be optimised for both hearing loss and tinnitus and would not like to compromise on quality of amplification to address their tinnitus problem.

2.2 Candidacy for a combination hearing aid

The first step is to assess the individual's candidacy for combination hearing aids. A consideration to offer combination aids might be triggered by:

- subject request,
- need for sound enrichment/additional sounds,
- lack of benefit from amplification alone,
- subject spends a lot of time in quiet environments,
- subject reports ambient noise is beneficial for their tinnitus,
- subject does not want to use amplification all the time,
- subject wants a practical way of helping their tinnitus.

Combination aids are appropriate for a wide range of hearing losses. This includes subjects who do not perceive hearing difficulties. They can be offered to subjects who have sound tolerance

problems/hyperacusis as well as tinnitus. Combination hearing aids should be considered for subjects who report troublesome/bothersome/intrusive tinnitus.

Discussion of severity/impact of tinnitus should be part of the history taking. Tinnitus guidelines recommend the use of at least one standardised questionnaire to establish the degree to which a subject experiences tinnitus as bothersome (BSA, 2019a; Cima, 2018). Two questionnaires that are recommended by the BSA Practice Guidance are the Tinnitus Handicap Inventory (THI) and the Tinnitus Functional Index (TFI) (Newman et al., 1996; Meikle et al., 2012).

Combination aids can be used for tinnitus patients regardless of the tinnitus sound they perceive. The sound/noise from the device is not required to match the tinnitus sound. Tinnitus pitch matching and tinnitus masking/minimum masking level measurement are not necessary to inform the decision to offer combination aids.

Combination aids should not be recommended to subjects where expected level of sound/noise would have to be excessively loud such that they impede speech perception or if the subject cannot hear the sound/noise from the device (see also section 4.4). Combination hearing aids should be offered regardless of concurrent treatment with cognitive behavioural therapy or counselling. Poor speech discrimination or pulsatile tinnitus also do not contraindicate offering combination hearing aids.

3. Assessment

3.1 Identifying the main problem

Most subjects present with comorbid tinnitus and hearing loss, which should be fully assessed by completing an in depth history. Hearing loss should be assessed by pure-tone audiometry (PTA) including 3 kHz and 6 kHz following BSA recommended procedures (BSA, 2018a). It is important to establish the ways in which, and how much, tinnitus and hearing loss are impacting the subject and address both if needed.

A standardised questionnaire (THI or TFI) should be used to establish the degree to which a subject experiences tinnitus as bothersome.

Other questionnaires may be used which assess the relative importance of addressing hearing difficulties versus addressing tinnitus problems such as the Sound Therapy Option Profile (STOP, Newman & Sandridge, 2006) or the Tinnitus and Hearing Survey (THS, Henry et al., 2015). The STOP asks subjects about both how much tinnitus affects their overall quality of life and how important it is for them to hear better (Newman & Sandridge, 2006). The THS is a tool which rapidly differentiates hearing problems from tinnitus problems and assists subjects and clinicians in determining (collaboratively) whether intervention for tinnitus is appropriate.

3.2 Expectation setting

It is important to establish the subject's expectations of combination hearing aid use. These may include but are not restricted to the device masking their tinnitus, improving hearing and/or listening abilities, reducing tinnitus/making it less noticeable, providing distraction from tinnitus, helping with sleep,

helping with concentration, changing how they feel, or just generally improving quality of life, or relieving physical symptoms. Some subjects will have no immediate expectation of their devices, whilst others may believe the device will 'cure' their tinnitus.

4. Selecting the device

The choice of the device depends on individual subject's amplification needs, subject preferences, availability and ease of use of the features that might be of benefit to the subject (such as volume control, certain sound options, modifications to the sound/noise etc.).

4.1 Bilateral vs unilateral fitting

Bilateral combination hearing aids should be fitted if the subject:

- has bilateral hearing loss and tinnitus (unilateral, bilateral, or central),
- chooses to have two devices.

In these cases bilateral aids should be fitted even if tinnitus is more bothersome in one ear. When bilateral devices are fitted for bilateral tinnitus and unilateral hearing loss, amplification should only be activated in the ear with hearing loss.

The same contraindications as for fitting bilateral hearing aids would prevent fitting of bilateral combination aids. Those include actively discharging ear, anatomical defects, single-sided deafness, severe otalgia and marked otitis externa. Unilateral combination hearing aids can also be fitted for subjects who choose to have one device only. When fitting one combination aid for a subject with bilateral hearing loss, it should be fitted to the ear with tinnitus.

4.2 Choice of earmould/insert

When fitting combination hearing aids the choice of earmould/insert fitting should depend on subject's hearing loss in line with manufacturers' recommendations and safety of use but kept as open as hearing loss permits. Consideration should be given to the use of occluding earmoulds or domes where required to match targets. If the resulting occlusion negatively affects the tinnitus percept the clinician should consider sacrificing a degree of fitting accuracy in favour of a more open fitting.

5. Fitting

The protocol used for fitting combination hearing aids should be flexible to allow for individual subject's preferences. Subject's preferences play an important role in several aspects of fitting combination aids including fitting laterality, programme options, choice of sound/noise, recommended use, and adjustments to sound/noise. Time required for fitting appointment may vary depending on the offered programmes/settings but 60 minutes should be sufficient for bilateral fitting.

5.1 Software and verification

Manufacturer's software is used for the fitting of combination aids. Real ear measurement (REM) should be used to verify the fitting of amplification according to the BSA guidance (BSA, 2018b). Using signals of

80dB SPL and above is not recommended as they can increase tinnitus intensity. If considering Uncomfortable Loudness Levels refer to BSA recommended procedure (BSA, 2019b). Caution should be taken when running feedback measurements and if the patient reports any discomfort this should be abandoned and feedback eliminated in another way e.g. gain reduction.

5.2 Selecting programmes

Programme options offered on combination hearing aids should be agreed with the subject. One or several programmes can be recommended to the subject depending on the circumstances. Being a first time combination aid user is not a contraindication to recommending more than one programme.
One programme (combined programme: amplification and sound/noise) on combination hearing aids should be recommended if:

- the subject prefers to have one programme only,
- the subject does not have sufficient cognitive ability to manage multiple programmes,
- the subject does not have sufficient manual dexterity to manage multiple programmes (however in such cases the use of remote control may be discussed if subject is willing to purchase themselves).

More than one programme should be offered:

- if the emotional reaction to tinnitus changes day by day,
- if the subject feels that their main difficulties are hearing related during the day but in the evening they struggle with tinnitus,
- if tinnitus varies from day to day,
- if the subject wants to trial more than one programme for hearing needs,
- if the subject requires sound generation only programme for a night time,
- if the subject has hearing loss and hearing related difficulties,
- for intermittent tinnitus,
- if the subject's lifestyle requires it,
- if the subject cannot decide between sounds.

When fitting combination hearing aids with more than one programme, subjects should be offered amplification only, as well as combined amplification and sound/noise generation programme. Amplification should be discussed and amplification programmes fitted first before any sound/noise options are activated. Amplification and sound/noise can be activated at the same or separate appointments. The order of the programmes should be discussed and agreed with the subject and chosen according to what would be the most usable for the subject.

Amplification and sound/noise should be activated at the same appointment if:

- the subject is extremely distressed,
- the subject requests it,
- the subject spends a lot of time in quiet environments,
- the subject had previous experience with hearing aids/sound generators,

- the subject has a very bothersome/distressing/intrusive tinnitus.

Amplification should be fitted first (and sound activated at a later appointment) if:

- hearing loss is the main complaint (over tinnitus),
- the subject is already coping well with tinnitus/only mildly distressed,
- the subject requests that option.

If fitting amplification and activating sound(s) at later appointment, there is no specific recommendation for the minimum time between those appointments, and should be based on subject readiness for further management.

5.3 Advice regarding use of different programmes

The duration of using the devices and using different programmes should be driven by subject choice/preference. Subjects should be encouraged to use programmes with amplification for the benefit of their hearing, and so that they acclimatise to using amplification.

Data logging should be explained to the patient and the potential of that feature to be used in further discussions regarding the choice of programmes available on the devices. Patients should be asked for consent for clinician to use that feature.

Sound/noise only programmes should be used when the subject chooses to. The use of sound/noise programme does not have to be limited to quiet situations or night time. Subjects with hearing loss can use sound/noise only programmes. Amplification only programmes should be used if a subject requires it.

Amplification only should be used:

- in situations where subjects experience hearing difficulty,
- in challenging listening situations when hearing is priority.

However, the presence of ambient/background noise does not always require use of an amplification only programme and sound/noise programmes can be used in those situations as well if a subject prefers to. Environmental steering can also be used in those situations (see section 5.5.2).

Sound/noise programmes should be used:

- if amplification alone is not sufficient to reduce perception of tinnitus,
- in quiet environments where amplification alone is not sufficient,
- when tinnitus is troublesome/bothersome,
- when tinnitus is more/quite noticeable, or intrusive,
- when the subject is concentrating/studying,
- in situations where tinnitus is loud,
- when it helps subjects to hear better.

5.4 Selecting type(s) of sound/noise

The choice of sound/noise should be based on subject preferences and a choice of sound options available on the combination aid should be presented to the subject to choose from. Low level white noise should not be the default sound of choice.

The choice of sound(s) should be based on how they affect the subject's awareness of tinnitus as well as the subject's comfort and acceptability of the sound/noise. Further modifications to the sound/noise should be offered if subject prefers it. Those can include amplitude modulation (where volume fluctuations are applied to the broadband sound), or frequency shaping (such as low- or high-frequency cut off or noise shaped to the individual audiogram).

5.5 Level of sound/noise

Validation of sound/noise generator output should be based on subject's feedback. Sound/noise should be set at blending/mixing point (where the sound/noise starts to blend with tinnitus), just below the level of tinnitus, or at a level that is comfortable for the subject but does not cover/mask tinnitus. Noise should not be set to mask or completely cover the tinnitus, even to achieve initial relief if subject is very distressed. When adjusting level of sound/noise start with a low level and increase gradually.

The noise should be:

- audible to the subject,
- set so it is not intrusive to everyday hearing,
- set according to subject preference.

5.5.1 Noise/sound – safety

Maximum recommended safe wearing time of the combination aid programmes with sound/noise activated depends on the level of sound/noise. Safe listening level is not necessarily the one that is set to the same level as subject's perceived tinnitus. In general, the wearing time will decrease as the level of sound/noise is increased above 80 dB(A). See Table 1 for the maximum safe exposure time for different sound/noise levels according to BS EN 50332-3 standard (BS EN 50332-3:2017).

Total dB(A)	Wearing time/hours per day
<81	Full day
82	16
85	8
88	4
90	3

Table 1. Recommended wearing time per day based on BS EN 50332-3 standard.

When using volume control the max dB(A) level shall be calculated as the default level plus the range of the volume control. Sound pressure levels in dB(A) are derived from SPL in dB applying the A-weighting, where weighting is added to the measured SPL depending on the frequency (BS EN 61672-1:2013). dB SPL to dB(A) conversion tables are available online, e.g. www.engineeringtoolbox.com.

Coupler measurements or REMs may be used to review sound/noise level in the ear. The manufacturer's specifications provide max SPL output of the device. Those could inform safe wearing time recommendations to the subject.

5.5.2 Volume control for the sound/noise

The volume control can adjust the level of sound/noise on the combination aid. The manual volume control can be set by the audiology professional to allow only control for the generated sound/noise (not for amplification).

Offering different programmes set for subject's comfort and effect on perception of tinnitus does not replace the volume control function. Volume control for the sound/noise generator should be offered to all subjects who have sufficient dexterity.

In particular volume control should be offered:

- if subject chooses to have one,
- to subjects whose tinnitus fluctuates a lot during the day,
- to subjects who want to have control over their device,
- to subjects whose sensitivity to noise fluctuates,
- to subjects who find it difficult to find the correct volume in the clinic,
- if subject's tinnitus fluctuates and the mixing point was set on a good day,
- for previous sound generator users who had that option available on their previous devices.

Subjects with both tinnitus and hyperacusis should always be offered volume control for the sound/noise.

Combination hearing aids might have an environmental steering option which automatically reduces the level of sound/noise when background noise is present and increases the level when background noise is low. Environmental steering can be offered if the subject prefers automatic volume changes depending on the level of background noise, rather than adjusting the level of noise manually or switching to a different programme.

5.6 Wireless streaming and accessories

Subjects should be made aware of additional options and accessories available for their devices, where they can be sourced and additional costs that may be incurred.

Manufacturers' mobile applications, tinnitus mobile applications, Bluetooth streaming through external devices and streaming from external sources (TV, iPad, Phone, iPhone) should be recommended to subjects as wireless streaming options. Whether to use those options or not should be a subject's choice. Wireless streaming might be useful if a subject already has sounds that they use and benefit from and they would like to access them though the combination aid.

5.7 Fitting combination hearing aids for pulsatile tinnitus

For subjects with pulsatile tinnitus combination hearing aids should be set in a similar way as for subjects with non-pulsatile tinnitus. Modulated or steady-state sound can be used for those subjects, depending on subject preferences.

6. Subject education

6.1 Essential topics to discuss when fitting combination hearing aids

In addition to general tinnitus education, discussion around combination aids should include managing expectations and explanation that combination aids are not a cure for tinnitus but can be an effective management option. The rationale for using combination aids for tinnitus management should be explained alongside relevant research and supplemented with examples of positive outcomes achieved in the past. At the same time limitations of the device should be discussed. Subjects should be made aware that their tinnitus loudness can change temporarily (get quieter or louder) when the devices are removed.

The choice of sound/noise available on the devices and different programmes and what they are used for should be explained (please see sections 2.6.3 and 2.7.2). When setting the noise level at a mixing/blending point (please see section 2.6.4) that concept should be explained to the subject and the rationale for using sound/noise at this level should be given. The importance of not setting the noise above the level of the tinnitus should be highlighted.

Correct use of the devices including duration of use and use of different programmes should be discussed (see section 2.7.2 for more information). Any adjustments that the subject can make should be explained (see section 2.6.4: Volume control).

Subjects should be given the manufacturer's user guide for their devices and any additional user information suggested by the manufacturer (e.g. resources available for download on the websites, links to more information online).

7. Follow-up and measuring outcome

7.1 Follow-up

All combination aid subjects should be offered a follow up appointment. Where possible, subjects should be reviewed 6-12 weeks post fitting. A tinnitus individual management plan should be reviewed

at that appointment (BSA, 2019a). Benefits of combination aids for subject's hearing and tinnitus should be reviewed. Subject feedback on the success of management shall be reviewed and any concerns or problems with management discussed. Acceptability and effectiveness of sound/noise on the device should be discussed and adjustments to the sound/noise made if needed. Data logging should be used to determine the actual use of programmes. This will facilitate discussion and any decision to deactivate programmes that are underused.

7.2 Measuring outcome

For assessing effectiveness of combination aids it is essential to measure the following outcomes:

- impact of tinnitus,
- quality of life,
- general distress,
- impact of hearing loss,
- hyperacusis,
- depression,
- anxiety,
- self-reported effectiveness,
- usage.

The TFI (Meikle et al., 2012) is recommended for measuring outcome of tinnitus treatment (BSA, 2019). Secondary outcomes may include measures of generalised depression and anxiety measured using a validated measure such as the Hospital Anxiety and Depression Scale (HADS, Zigmond & Snaith, 1983).

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Appendix A. Authors and acknowledgments

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